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

FORM 10-K

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

For the year ended December 31, 2018

OR

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

For the transition period from to

Commission File Number 001-37372

Collegium Pharmaceutical, Inc.
(Exact name of registrant as specified in its charter)

Virginia (State or other jurisdiction of incorporation or organization)	**03-0416362** (I.R.S. Employer Identification Number)
100 Technology Center Drive Stoughton, MA (Address of principal executive offices)	**02072** (Zip Code)

(781) 713-3699
(Registrant's telephone number, including area code)

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	The NASDAQ Global Select Market

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, 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 ☐ (Do not check if smaller reporting company)	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 checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of June 30, 2018, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $725 million, based on the closing price of the registrant's common stock on The NASDAQ Global Select Market on June 30, 2018 of $23.83 per share. Shares of the registrant's common stock held by each officer and director and each person known to the registrant to own 10% or more of the outstanding common stock of the registrant have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not a determination for other purposes.

As of January 31, 2019, there were 33,305,011 shares of the registrant's common stock, par value, $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2019 Annual Meeting of Shareholders (the "Proxy Statement"), to be filed within 120 days of the registrant's year ended December 31, 2018, are incorporated by reference in Part II and Part III of this Report on Form 10-K. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K

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Forward-Looking Information

This Annual Report on Form 10-K, or this Form 10-K, includes forward-looking statements. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other important factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our ability to commercialize and grow sales of our products;
- our ability to effectively commercialize in-licensed products and manage our relationships with licensors, including our ability to satisfy our royalty payment obligations in connection with such products;
- our ability to obtain and maintain regulatory approval of our products and any product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product;
- the size of the markets for our products and any product candidates, and our ability to service those markets;
- the success of competing products that are or become available;
- our ability to obtain and maintain reimbursement and third-party payor contracts for our products;
- the costs of commercialization activities, including marketing, sales and distribution;
- the rate and degree of market acceptance of our products;
- changing market conditions for our products;
- the outcome of any patent infringement, opioid-related or other litigation that may be brought by or against us, including litigation with Purdue Pharma, L.P. and Teva Pharmaceuticals USA, Inc.;
- the performance of our third-party suppliers and manufacturers;
- our ability to secure adequate supplies of active pharmaceutical ingredient for each of our products and to manufacture adequate quantities of commercially salable inventory;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain funding for our operations and business development;
- regulatory developments in the United States;
- our expectations regarding our ability to obtain and maintain sufficient intellectual property protection for our products and any product candidates;
- our ability to operate our business without infringing the intellectual property rights of others;
- our ability to comply with stringent government regulations relating to the manufacturing and marketing of pharmaceutical products, including U.S. Drug Enforcement Agency, or DEA, compliance;
- the loss of key commercial, scientific or management personnel;
- our customer concentration, which may adversely affect our financial condition and results of operations;
- the accuracy of our estimates regarding expenses, revenue, capital requirements and need for additional financing; and
- the other risks, uncertainties and factors discussed under the heading “Risk Factors” in this Form 10-K.

In some cases, you can identify these statements by terms such as “aim,” “anticipate,” “believe,” “estimate,” “expect,” “forecast,” “intend,” “outlook,” “plan,” “potential,” “project,” “projection,” “seek,” “may,” “could,” “would,” “should,” “can,” “can have,” “likely,” the negatives thereof and other words and terms of similar meaning. These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Form 10-K and are subject to risks and uncertainties. We discuss many of these risks in greater detail under the heading “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Any forward-looking statements that we make in this Form 10-K speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Form 10-K or to reflect the occurrence of unanticipated events. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

We obtained the industry, market and competitive position data in this Form 10-K from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties. We believe this data is accurate in all material respects as of the date of this Form 10-K. In addition, projections, assumptions and estimates of the future performance of the industry in which we operate and our future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors."

PART I

Item 1. Business

Overview

We are a specialty pharmaceutical company committed to being the leader in responsible pain management. Our first product, Xtampza ER, is an abuse-deterrent, extended-release, oral formulation of oxycodone. In April 2016, the U.S. Food and Drug Administration, or FDA, approved our New Drug Application, or NDA, for Xtampza ER for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. In June 2016, we announced the commercial launch of Xtampza ER.

Our product portfolio also includes Nucynta ER and Nucynta IR, or the Nucynta Products. In December 2017, we entered into a Commercialization Agreement with Assertio Therapeutics, Inc. (formerly known as Depomed), or Assertio, pursuant to which we acquired the right to commercialize the Nucynta Products in the United States and began marketing the Nucynta Products in February 2018. Nucynta ER is an extended-release, or ER, formulation of tapentadol that is indicated for the management of pain severe enough to require daily, around the clock, long term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy in adults, and for which alternate treatment options are inadequate. Nucynta IR is an immediate-release formulation of tapentadol that is indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults.

For the fiscal year ended December 31, 2018, we generated $280.4 million in net revenues, comprised of $69.4 million from sales of Xtampza ER and $211.0 million from sales of the Nucynta Products.

We are headquartered in Stoughton, Massachusetts and our common stock trades on the NASDAQ Global Select Market, or NASDAQ, under the trading symbol "COLL."

Pain, Pain Management and Opioid Abuse in the United States

Acute and Chronic Pain

Pain can be classified along many different variables, including severity, duration and etiology. There are two broad categories of pain based on duration: acute pain, or pain that is self-limited and generally requires treatment for no more than up to a few weeks, and chronic pain, or pain that lasts beyond the healing of an injury or that persists longer than 3-6 months. Chronic pain affects between 50-100 million U.S. adults annually, with as many as 19.6 million of those adults experiencing high impact chronic pain, defined as pain that interferes with daily life or work activities. Acute pain is even more prevalent and can occur after an injury, burn, or trauma or after surgery. Moreover, acute pain and chronic pain are closely related: nearly all cases of chronic pain begin as acute pain.

Chronic pain leads to over $560 billion in healthcare and productivity costs each year according to the Institute of Medicine. Patients with chronic pain make an estimated ten more physician visits per year than those without chronic pain and see more doctors. In addition, studies suggest that healthcare costs for people suffering from chronic pain are higher, and often substantially higher, than for those without chronic pain.

The Role of Prescription Opioids in the Treatment of Pain

Prescription opioids continue to serve as important tools in the treatment of acute and chronic pain where alternative treatments have been inadequate. Prescription opioids are available in immediate-release formulations as well as in

extended-release formulations, which incorporate a time-release mechanism designed to deliver steady amounts of opioid, typically over 12 to 24 hours. Extended-release opioids are designed to offer more convenient dosing with a longer period of consistent blood levels of the active drug as compared to immediate-release formulations.

In 2018, there were approximately 189 million prescriptions for opioids written in the United States, representing a 12 % decline from 2017 levels and including approximately 4.3 million prescriptions for branded extended-release opioids, approximately 16 million prescriptions for generic extended-release opioids, and greater than 168 million prescriptions for immediate-release opioids.

Increasingly, practitioners and regulators are focusing on multidisciplinary, multimodal approaches to pain management, including opioid and nonopioid medications, physical and psychotherapy, and exercise. Recognizing the role that opioid therapy continues to play in effective pain management, these groups are advocating for best practices that support appropriate opioid prescribing practices that may minimize risk of addiction and other adverse events to patients.

Prescription Opioid Abuse is an Epidemic in the United States

Prescription opioids of all kinds, including both immediate-release and extended-release formulations, are subject to manipulation, misuse, and abuse. Abuse-deterrent technologies, including the DETERx platform that is incorporated in Xtampza ER, have emerged to reduce the risk of abuse of prescription opioids, but these technologies do not eliminate the possibility of misuse and abuse.

Extended-release opioids, with their large payload of active pharmaceutical ingredient, may be especially attractive to potential abusers, who tamper with these formulations to overcome the extended-release mechanism and achieve the euphoria that results from rapid increases in the blood concentration of the active pharmaceutical ingredient, a potentially fatal activity known as dose dumping.

The U.S. Centers for Disease Control and Prevention, or CDC, described abuse of prescription drugs in the United States as a vast and deadly epidemic. According to a 2018 CDC report, there were a record-high 63,632 drug overdose deaths in the United States in 2017, representing a rate of 19.8 per 100,000 persons. Prescription and/or illicit opioids were involved in 42,249, or 66.4%, of these drug overdose deaths, with over 17,000 of these fatalities attributed to prescription opioids alone. Although the most recent data available suggests that overdose fatalities in the United States are now declining from their peak in 2017, the CDC reports that there were still 46,151 drug overdose deaths relating to prescription and/or illicit opioids during the twelve months ended May 2018.

The opioid epidemic has, in addition to its death toll, imposed significant burdens on the U.S. healthcare system. In 2015, an estimated 78,840 hospitalizations occurred for opioid-related poisonings in the U.S. In addition, 2015 saw an estimated 140,077 emergency department visits for opioid-related poisonings in the U.S. A nonprofit group that studies the health economy recently estimated that the opioid epidemic has cost the U.S. more than a trillion dollars since 2001, based on CDC mortality data through June of 2017. The greatest financial cost of the epidemic, according to the report, is in lost earnings and productivity losses to employers.

Despite the reduction in opioid prescriptions and the heightened awareness of the risks associated with opioid use, abuse of prescription opioids, including extended-release formulations, continues to be a major public health issue. In 2016, an estimated 11,824,000, or 4.4% of persons aged 12 and older, reported opioid misuse in the prior year. In response to issues surrounding abuse of prescription opioids, pharmaceutical companies have developed novel, abuse-deterrent formulation strategies. Abuse-deterrent formulations target the known or expected routes of abuse, such as crushing in order to snort or dissolving in order to inject, for the specific opioid drug substance. The FDA has encouraged the development of prescription opioids with abuse-deterrent formulations to help combat the opioid crisis, and expanding access to abuse deterrent formulations is part of the FDA's comprehensive Opioids Action Plan.

Legislative and Regulatory Actions

In response to widespread prescription opioid abuse, the U.S. government and a number of state legislatures have enacted legislation and regulations intended to fight the opioid epidemic. The number and scope of legislative and regulatory actions, particularly in the last three years, emphasize the severity of the opioid epidemic and its impact on our society. The FDA has stated that addressing prescription drug abuse is a priority and has reaffirmed that the development of abuse-deterrent opioids is a key part of that strategy.

Recent actions to address the opioid abuse epidemic include:

- *FDA guidance*: In April 2015, the FDA adopted final guidance regarding studies and clinical trials that should be conducted to demonstrate that a given formulation has abuse-deterrent properties, how those studies and clinical trials will be evaluated, and what product labeling claims may be approved based on the results of those studies and clinical trials. The guidance describes four categories of abuse-deterrence studies and clinical trials: Categories 1, 2 and 3 consist of pre-marketing studies and clinical trials designed to evaluate a product candidate's potentially abuse-deterrent properties under controlled conditions, while Category 4, post-marketing clinical trials and studies, assesses the real-world impact of abuse-deterrent formulations. The final guidance also provides examples of product label claims that may be made based on the results of the corresponding studies and clinical trials.

- *FDA Opioids Action Plan:* In February 2016, the FDA released an action plan to address the opioid abuse epidemic and reassess the FDA's approach to opioid medications. The FDA's plan is part of a broader initiative led by the U.S. Department of Health and Human Services, or HHS, to address opioid-related overdose, death and dependence. As part of the HHS initiative:

    - *CDC Prescribing Guidelines*: In March 2016, the CDC released a new Guideline for Prescribing Opioids for Chronic Pain intended to assist primary care providers treating adults for chronic pain in outpatient settings. The guideline provides recommendations to improve communications between doctors and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy.

    - *Enhanced Warnings and Safety Labeling*: In March 2016, the FDA announced required enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose, and death. Subsequently, there have been several class-wide labeling changes, including the addition of boxed warnings relating to serious risks of using certain opioids medications along with benzodiazepines and other central nervous system depressants, including alcohol (Decembers 2016); and additional information relating to the new class-wide REMS (Septembers 2018).

- *Passage of the Comprehensive Addiction and Recovery Act (CARA and CARA 2.0):* In 2016, the Comprehensive Addiction and Recovery Act, or CARA, was enacted to address the national epidemics of prescription opioid abuse and heroin use. Consistent with the initiatives of HHS, this legislation sought to, among other things, expand the availability of naloxone for law enforcement and other first responders; form an interagency task force to develop best practices for pain management with opioid medications; and provide resources to improve state monitoring of controlled substances, including opioids. In 2018, CARA 2.0 was introduced as follow-up legislation to limit initial prescriptions for opioids to 3 days, while exempting initial prescriptions for chronic care, cancer care, hospice or end of life care, and palliative care. CARA 2.0 also increased civil and criminal penalties for opioid manufacturers that fail to report suspicious orders for opioids or fail to maintain effective controls against diversion of opioids.

- *Passage of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)*: In November 2018, the SUPPORT Act was enacted as a comprehensive legislative response to the continuing opioid epidemic. It includes a number of measures directed towards regulation and improvement of treatment for substance use-disorder and increased coverage by CMS of medically-assisted treatment options. In addition, the SUPPORT Act requires HHS to report to Congress on existing barriers to access to abuse-deterrent opioid formulations by Medicare Part C and D beneficiaries.

The Collegium Portfolio

Our mission is to be the leader in responsible pain management. We have leveraged our research and development efforts as well as licensing relationships with third parties, to develop a portfolio of meaningfully differentiated products for use in the treatment of moderate to severe pain.

Xtampza ER

In April 2016, the FDA approved our NDA for Xtampza ER (extended-release oxycodone) for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The approved labeling for Xtampza ER includes human abuse potential studies, as well as data supporting the administration of the product as a sprinkle or administered through feeding tubes. In June 2016, we launched Xtampza ER in the United States. Xtampza ER is formulated using our novel abuse-deterrent technology platform, DETERx, which provides extended-release delivery, while also providing barriers to common methods of abuse and misuse (e.g., crushing, chewing, heating and injecting). This technology combines an active opioid ingredient with a fatty acid and waxes to form microspheres that are filled into a capsule – these wax-based microspheres are designed to resist particle size reduction and dose dumping when subjected to physical and chemical manipulation. Xtampza ER's label indicates a dosing regimen of one capsule every 12 hours and it must be taken with food.

Xtampza ER, OxyContin OP from Purdue, and the authorized generic version of OxyContin (which is identical to the branded version) are the only extended-release oxycodone products marketed in the United States as of January 2019. In 2018, the extended-release oxycodone (OER) market generated approximately $1.8 billion in U.S. sales and there were approximately 3.4 million prescriptions written. OxyContin is the largest selling extended-release oxycodone (and largest-selling branded extended-release opioid) in the United States by dollars and prescription volume, with approximately $1.5 billion in U.S. sales and approximately 2.6 million prescriptions written in 2018. Relative to 2017, dollars generated by sales for OxyContin and its authorized generic forms written in the United States in 2018 declined 19 %, with a 21% decline prescription volume. In 2018, there were approximately 327,000 prescriptions of Xtampza ER written.

Xtampza ER and OxyContin OP (along with its authorized generic) feature the same active pharmaceutical ingredient and feature abuse-deterrent technologies – though the abuse deterrent technologies are designed differently. In November 2017, we announced FDA approval of a Supplemental New Drug Application, or sNDA, for Xtampza ER to include comparative oral pharmacokinetic data from a clinical study evaluating the effect of physical manipulation by crushing Xtampza ER compared with OxyContin OP and a control (oxycodone hydrochloride immediate-release). In the study, Xtampza ER maintained its extended-release pharmacokinetic profile when crushed, while OxyContin OP showed a rapid release of oxycodone when crushed with common household tools; crushed OxyContin OP was bioequivalent to crushed oxycodone IR. The sNDA also added results from an oral human abuse potential study and an oral abuse deterrent claim to the label, making Xtampza ER the only single-agent extended-release oxycodone with oral, intranasal, and intravenous abuse-deterrent labeling.

We believe Xtampza ER represents an abuse-deterrent extended-release oxycodone formulation and is well-positioned to capture a significant share of extended-release oxycodone market.

Nucynta ER and Nucynta IR

In December 2017, we entered into the Nucynta Commercialization Agreement, pursuant to which Assertio agreed to grant us a sublicense of certain of its intellectual property related to the Nucynta Products for commercialization of such products in the United States. On January 9, 2018, we amended the Nucynta Commercialization Agreement and consummated the transactions contemplated thereby.

Pursuant to the Nucynta Commercialization Agreement, we assumed all commercialization responsibilities, including sales and marketing, for the Nucynta Products, while Assertio continues to control manufacturing of the Nucynta Products. We began shipping and recognizing product sales on the Nucynta Products on January 9, 2018 and we began commercial promotion of the Nucynta Products in February 2018. The Nucynta Commercialization Agreement initially required us to pay guaranteed minimum royalty of $135.0 million per year through December 2021, as well as a variable royalty based on annual net sales over $233.0 million. On November 8, 2018, we announced an amendment to certain terms of the Nucynta Commercialization Agreement, which adjusted the royalty structure such that beginning on January 1, 2019 and thereafter, we are obligated to make royalty payments to Assertio conditional upon net sales, and the $135.0 million guaranteed minimum annual royalties were eliminated after 2018.

Nucynta ER is an extended-release formulation of tapentadol that is indicated for the management of pain severe enough to require daily, around-the-clock, long term opioid treatment, and for which alternate treatment options are inadequate. Nucynta ER is also the only extended-release opioid approved by the FDA for management of the

neuropathic pain associated with diabetic peripheral neuropathy. Nucynta IR is an immediate-release formulation of tapentadol that is indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults. Nucynta ER and Nucynta IR are the only tapentadol-based products marketed in the US and the drug substance is patent-protected.

Nucynta ER's label includes data from separate clinical trials that demonstrate its efficacy in improving pain intensity for patients suffering from chronic low back pain and neuropathic pain associated with diabetic peripheral neuropathy. Nucynta IR's label includes data from a clinical trial that demonstrates its efficacy in improving pain intensity for post-surgical acute pain.

Manufacturing of Our Products

Overview

Xtampza ER is manufactured using a proprietary process. This process is reproducible, scalable and cost-efficient, and we believe that the microsphere formulation — and the related manufacturing process — is unique in the extended-release opioid market. To date, we have produced Xtampza ER at a contract manufacturing organization, Patheon, a subsidiary of Thermo Fisher Scientific, Inc. Our microsphere production is currently conducted in an area of the manufacturing plant that is shared with other clients. We are in the process of building out a dedicated manufacturing suite within the same Patheon site. Patheon has an established record of manufacturing products approved in the United States, including products containing controlled substances. We own all of the intellectual property, including know-how and specialized manufacturing equipment, necessary to be able to replicate the manufacturing equipment currently located at Patheon's facility at an alternative location (and with an alternative vendor) if necessary.

Pursuant to our Nucynta Commercialization Agreement, Assertio is responsible for manufacturing and delivering to us the Nucynta Products for commercialization in the United States. As part of our partnership with Assertio, we participate in a Joint Manufacturing Steering Committee with our counterparts at Assertio, through which we take part in decisions regarding the commercial manufacturing of the Nucynta Products.

Drug Substances

The active pharmaceutical ingredient used in Xtampza ER, oxycodone base, is an odorless white crystalline powder. We currently procure this active pharmaceutical ingredient pursuant to a supply agreement with a single U.S.-based manufacturer. We are aware of other suppliers who we would expect to be able to satisfy our commercial orders.

The active pharmaceutical ingredient used in the Nucynta Products is tapentadol, which is supplied to Assertio, the manufacturer of the Nucynta Products, by a single U.S.-based manufacturer.

Oxycodone base and tapentadol are classified as narcotic controlled substances under U.S. federal law. Accordingly, Xtampza ER and the Nucynta Products are classified by the DEA as Schedule II controlled substances, meaning that they have a high potential for abuse and dependence among drugs that are recognized as having an accepted medical use. Consequently, the manufacturing, shipping, dispensing and storing of our products are subject to a high degree of regulation, as described in more detail under the caption "— Governmental Regulation — DEA and Opioid Regulation."

Marketing and Commercialization

We commercialize Xtampza ER and the Nucynta Products in the United States with a dedicated field sales force, consisting of approximately 150 sales representatives and managers, to call on the approximately 10,700 physicians who write approximately 60% of the branded extended-release opioid prescriptions in the United States, with a primary focus on pain specialists. In addition, we employ medical science liaisons, or MSLs, to respond to clinician inquiries about Xtampza ER and the Nucynta Products. We also employ a market-access team to support our formulary approval and payor contracting.

We have developed positioning and messaging campaigns, a publication strategy, initiatives with payor organizations, and distribution and national accounts strategies. Our marketing strategy focuses on increasing awareness of the differentiated features of Xtampza ER and the Nucynta Products.

We primarily sell our products to wholesalers, retail drug store chains, supermarket chains, mass merchandisers, distributors, mail order accounts, hospitals and government agencies. Our wholesalers and distributors purchase products from us and, in turn, supply products to retail drug store chains, independent pharmacies and managed health care organizations. Customers in the managed health care market include health maintenance organizations, nursing homes, hospitals, clinics, pharmacy benefit management companies and mail order customers. Three of our customers comprised 10% or more of our revenue during the year ended December 31, 2018. These customers comprised 36%, 31% and 27% of revenue, respectively.

Intellectual Property

The protection of patents, designs, trademarks and other proprietary rights that we own or license are critical to our success and competitive position. Xtampza ER is protected by fourteen issued patents in the United States (seven of which claim compositions of matter, three of which claim both compositions of matter and methods of use, and two that claim methods of use), one granted and two pending applications in the European Patent Office, two issued patents in Canada, and one issued patent in each of Japan and Australia. Finally, we have six patent applications pending in the United States, one pending patent application in each of Canada and Japan, and one pending PCT application. Our issued U.S. patents are projected to expire in 2023, 2025, 2030, and 2036 and our pending patent applications in the United States, if issued, would be projected to expire in 2023, and 2025. In addition, we use a unique and proprietary process to manufacture our products that requires significant know-how, which we currently protect as trade secrets.

We have concluded that some of our technology is best protected as proprietary know-how, rather than through obtaining patents. Except for the licenses and sublicenses contained in our Nucynta Commercialization Agreement, pursuant to which we commercialize the Nucynta Products in the United States, the District of Columbia, and Puerto Rico, our technology and products are not in-licensed from any third party, and we own all of the rights to Xtampza ER. We believe we have freedom to operate in the United States and other countries, but there can be no assurance that other companies, known and unknown, will not attempt to assert their intellectual property against us.

We also rely on trademarks and trade designs to develop and maintain our competitive position. We have received trademark registration for Collegium Pharmaceutical, Inc., DETERx, and Xtampza ER in the United States, and license the right to use trademarks associated with the Nucynta Products.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how that is not patentable, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we generally require our employees, consultants and advisors to enter into confidentiality agreements prohibiting the disclosure of confidential information and, in some cases, requiring disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. Additionally, these confidentiality agreements require that our employees, consultants and advisors do not bring to us, or use without proper authorization, any third party’s proprietary technology.

Competition

Our industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face competition and potential competition from a number of sources, including pharmaceutical and biotechnology companies, generic drug companies, drug delivery companies and academic and research institutions. Most of the existing and potential competitors have significantly more financial and other resources than we do.

Xtampza ER

Currently, the only extended-release opioid drugs on the market that have an abuse-deterrent product label, in addition to Xtampza ER, are OxyContin OP and Hysingla®, both from Purdue, Embeda from Pfizer, and MorphaBond ER from Daiichi Sankyo. Hysingla is a once a day hydrocodone product. Embeda is a combination of morphine and naltrexone, an opioid antagonist that contains a boxed warning on its product label stating that “the capsules are not to be crushed, dissolved, or chewed due to the risk of rapid release and absorption of a potentially fatal dose of morphine.” MorphaBond ER is a twice daily morphine product formulated with a hard tablet and gelling polymers.

In addition, there are four other extended-release opioids that have been approved with abuse deterrent product labeling Targiniq from Purdue, Arymo from Egalet, Vantrela ER from Teva, and Troxyca ER from Pfizer, none of which are currently on the market. In 2018, the NDAs for Vantrela ER and Troxyca ER were withdrawn by the FDA at the request of the sponsors. Targiniq is a combination of oxycodone and naloxone, an opioid antagonist. Vantrela ER is a twice daily hydrocodone product. Troxyca ER is a combination of oxycodone and naltrexone, an opioid antagonist. A number of other large and small companies are developing abuse deterrent drugs for pain. Many other companies have products indicated for the treatment of moderate to severe, around-the-clock, long-term pain for which alternative treatments are not available, but these products do not have abuse-deterrent claims in their labels, including Pernix and Mallinckrodt, as well as several generic companies.

We believe the key competitive factors that will affect the commercial success of Xtampza ER include the degree of abuse deterrence, bioavailability, therapeutic efficacy, and convenience of dosing and distribution, as well as their safety, cost and tolerability profiles. Xtampza ER may also face competition from commercially available generic and branded extended-release and long-acting opioid drugs other than oxycodone, including fentanyl, hydromorphone, oxymorphone and methadone, as well as opioids that are currently in clinical development, including a generic version of Xtampza ER for which Teva recently submitted an Abbreviated New Drug Application, or ANDA, to the FDA and which is the subject of patent infringement litigation filed by us in February 2018.

Xtampza ER competes against all extended-release opioids, including Purdue's OxyContin OP and its authorized generics. Although no generic oxycodone extended-release products are currently commercially available, it is possible that generic forms of OxyContin OP could become available, in which case Xtampza ER would compete with any such generic oxycodone extended-release products.

Additionally, we are aware of companies with oxycodone product candidates in late-stage development, including Intellipharmaceutics, Nektar Therapeutics and Pain Therapeutics. If these products are successfully developed, approved for marketing and become commercially available, they could represent significant competition for Xtampza ER. It is also possible that a company that has developed an abuse-deterrent technology could initiate an abuse-deterrent oxycodone program at any time.

The Nucynta Products

Nucynta ER competes against other long-acting opioid medications, including: OxyContin; Butrans; Belbuca; and Embeda.

Nucynta IR competes primarily against short-acting opioids used for the management of moderate to severe acute pain in adults. There are numerous such medicines, including: generic hydrocodone acetaminophen; generic oxycodone; generic oxycodone acetaminophen; and generic tramadol.

Government Regulation

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or the FD&C Act, and other federal and state statutes and regulations govern the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, withdrawal of the product from the market, injunctions, fines, civil penalties, and criminal prosecution. Failure to meet FDA requirements for approval would also result in a medication not being approved for marketing.

The process of developing a pharmaceutical product and obtaining FDA approval to market the medication in the United States typically involves:

- completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA's good laboratory practices, or GLP, regulation;

- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin in the United States;
- approval by an independent institutional review board, or IRB, at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with current good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication for which FDA approval is sought;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is manufactured to assess compliance with the FDA's cGMP regulations;
- submission to the FDA of an NDA;
- satisfactory completion of a potential review by an FDA advisory committee, if applicable; and
- FDA review and approval of the NDA.

Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, stability and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLPs. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or subjects under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations, including GCP, an international standard meant to protect the rights, safety and wellbeing of subjects and to define the roles of clinical trial sponsors, administrators, and monitors; and (ii) under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and any effectiveness criteria to be evaluated. Each protocol involving testing on U.S. subjects and subsequent protocol amendments must be submitted to the FDA as part of the IND.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap or be combined.

- Phase 1: The drug is initially introduced into healthy human subjects or patients, and is tested to assess safety, dose tolerance, absorption, metabolism, PK, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness.
- Phase 2: The drug is typically tested in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common AEs and safety risks. Multiple Phase 2 trials may be conducted by the sponsor to obtain information prior to beginning larger and more extensive Phase 3 clinical trials.
- Phase 3: If a drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of subjects, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the clinical trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would

be practically or ethically impossible. Sponsors of clinical trials generally must register and report key parameters of certain clinical trials at the NIH-maintained website ClinicalTrials.gov.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. Pursuant to agreements reached during reauthorization of the Prescription Drug User Fee Act, or PDUFA, the FDA has a goal of acting on most original NDAs within six months or ten months of the application submission or filing date (the FDA conducts a preliminary review of all NDAs within the first 60 days after submission before accepting them for filing), depending on the nature of the drug. The FDA has a number of programs intended to help expedite testing, review, and approval of drug candidates that meet the applicable eligibility criteria. The FDA may refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee — typically a panel that includes clinicians and other experts — for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

If the FDA's evaluations of the NDA and of the sponsor's manufacturing facilities are favorable, the FDA will issue an approval letter, and the sponsor may begin marketing the drug for the approved indications, subject to any post-approval requirements, described further below. If the FDA determines it cannot approve the NDA in its current form, it will issue a complete response letter indicating that the application will not be approved in its current form. The complete response letter usually describes the specific deficiencies that the FDA identified in the application and may require additional clinical or other data or impose other conditions that must be met in order to obtain approval of the NDA. Addressing the deficiencies noted by the FDA could be impractical, and it is possible that the sponsor could withdraw its application or approval may not be obtained or may be costly and may result in significant delays prior to approval.

Where a sponsor wishes to expand the originally approved prescribing information, such as adding a new indication, it must submit and obtain approval of an sNDA. Changes to an indication generally require additional clinical studies, which can be time-consuming and require the expenditure of substantial additional resources. Under PDUFA, the target timeframe for the review of an sNDA to add a new clinical indication is six or ten months from the receipt date, depending on whether or not the sNDA has priority review. As with an NDA, if the FDA determines that it cannot approve an sNDA in its current form, it will issue a complete response letter as discussed above.

REMS

The FDA has the authority to require a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of the approval of an NDA or after approval to ensure that the benefits of a drug outweigh its risks. If the FDA determines a REMS is necessary for a new drug, the drug sponsor must submit a proposed REMS plan as part of its NDA prior to approval. The FDA may also impose a REMS requirement on a drug already on the market if the FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug's benefits continue to outweigh its risks. A REMS can include medication guides, communication plans for healthcare professionals, and Elements To Assure Safe Use, or ETASU. In addition, the REMS must include a timetable to periodically assess the strategy, at a minimum, at 18 months, three years, and seven years after the REMS approval. The requirement for a REMS can materially affect the potential market and profitability of a drug.

In July 2012, the FDA approved a class-wide REMS for extended-release and long-acting opioid products. Extended-release formulations of oxycodone, morphine, hydrocodone and hydromorphone, for example, are required to have a REMS. Manufacturers subject to this class-wide REMS must work together to implement the REMS as part of a single shared system to reduce the burden of the REMS on the healthcare system. The central component of the extended-release/long acting opioid REMS program is an education program for prescribers and patients. Specifically, the REMS includes a Medication Guide available for distribution to patients who are dispensed the drug, as well as a number of ETASU. These ETASU include training for healthcare professionals who prescribe the drug; information provided to prescribers that they can use to educate patients in the safe use, storage, and disposal of opioids; and information provided to prescribers of the existence of the REMS and the need to successfully complete the necessary training. Prescriber training required as part of the REMS is conducted by accredited, independent continuing education providers, without cost to healthcare professionals, under unrestricted grants funded by the opioid analgesic manufacturers. Moreover, REMS assessments must be submitted on an annual basis to assess the extent to which the ETASU are meeting the goals of the REMS and whether the goals or elements should be modified.

In September 2018, and pursuant to its Opioids Action Plan, the FDA approved the final class-wide REMS, which includes several measures to facilitate communication of the risks associated with opioid pain medications to patients and health care professionals and, for the first time, applies to immediate-release and extended-release/long-acting opioid analgesics intended for use in an outpatient setting. The new REMS requires that training be made available to health care providers who are involved in the management of patients with pain (including nurses and pharmacists), and not only to prescribers, and requires that the education cover broader information about appropriate pain management, including alternatives to opioids for the treatment of pain. In connection with the new REMS, the FDA also approved new product labeling containing information about the health care provider education available through the new REMS.

Advertising and Promotion

The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, guidance and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and efficacy that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs for "off-label" uses — that is, uses not approved by the FDA and therefore not described in the drug's labeling — because the FDA does not regulate the practice of medicine. However, FDA regulations impose stringent restrictions on manufacturers' communications regarding off-label uses. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the U.S. Department of Justice, or the Office of the Inspector General of the HHS, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to drug listing and registration, recordkeeping, periodic reporting, product sampling and distribution, adverse event reporting and advertising, marketing and promotion restrictions.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require, in addition to REMS discussed above, post-market testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration subjects entities to periodic announced or unannounced inspections by the FDA or these state agencies, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Regulatory authorities may withdraw product approvals, request product recalls, or take other punitive action if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

The FDA may require post-approval studies and clinical trials if the FDA finds that scientific data, including information regarding related drugs, deem it appropriate. The purpose of such studies would be to assess a known serious risk or signals of serious risk related to the drug or to identify an unexpected serious risk when available data indicate the potential for a serious risk. The FDA may also require a labeling change if it becomes aware of new safety information that it believes should be included in the labeling of a drug.

The Hatch-Waxman Amendments

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an ANDA. An ANDA provides for marketing of a drug product that has the same active pharmaceutical

ingredient in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or efficacy of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to make certain certifications to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than make certifications concerning a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired. For further detail regarding our litigation with Teva regarding the ANDA filed by Teva relating to Xtampza ER, refer to "Item 3. Legal Proceedings".

Exclusivity

Upon NDA approval of a new chemical entity, or NCE, which is a drug that contains no active moiety that has been approved by FDA in any other NDA, that drug receives five years of marketing exclusivity during which FDA cannot receive any ANDA seeking approval of a generic version of that drug or any Section 505(b)(2) NDA, discussed in more detail below, that relies on the FDA's findings regarding that drug. A sponsor may obtain a three-year period of exclusivity for a change to an approved drug, such as the addition of a new indication to the labeling or a new formulation, if the supplement includes reports of new clinical trials (other than bioavailability clinical trials) essential to the approval of the supplement.

An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period.

Section 505(b)(2) NDAs

Generally, drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on data not developed by the applicant, such as the FDA's findings of safety and efficacy in the approval of a similar product or published literature in support of its application.

Section 505(b)(2) NDAs may 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 clinical trials not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. The FDA may then approve the new product candidate for all, or some, of the 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.

To the extent that the Section 505(b)(2) applicant is relying on the FDA's findings of safety and effectiveness for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus approval of a Section 505(b)(2) NDA 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 NCE, 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 Section 505(b)(2) applicant. In the interim period, the FDA may grant tentative approval. Tentative approval indicates that the FDA has determined that the applicant meets the standards for approval as of the date that the tentative approval is granted. Final regulatory approval can only be granted if the FDA is assured that there is no new information that would affect final regulatory/ approval. As with traditional NDAs, a Section 505(b)(2) NDA may be eligible for three-year marketing exclusivity, assuming the NDA includes reports of new clinical trials (other than bioavailability clinical trials) essential to the approval of the NDA. For further detail regarding our litigation with Purdue regarding our Section 505(b)(2) NDA for Xtampza ER , refer to "Item 3. Legal Proceedings".

DEA and Opioid Regulation

Our products are regulated as "controlled substances" as defined in the Controlled Substances Act, or CSA, which establishes registration, security, recordkeeping, reporting, storage, distribution, importation, exportation and other requirements administered by the DEA.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances.

Xtampza ER is listed by the DEA as a Schedule II controlled substance under the CSA. The Nucynta Products are also listed by the DEA as Schedule II controlled substances under the CSA. Consequently, the manufacturing, shipping, storing, selling and using of our products is subject to a high degree of regulation. Schedule II drugs are subject to the strictest requirements for registration, security, recordkeeping and reporting. Also, distribution and dispensing of these drugs are highly regulated. For example, all Schedule II drug prescriptions must be signed by a physician, presented to a pharmacist and may not be refilled without a new prescription.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized.

In addition, a DEA quota system, which was amended in 2018 to require sponsors to strengthen controls over diversion of controlled substances, controls and limits the availability and production of controlled substances in Schedule I or II. In November 2017, the DEA reduced the amount of almost every Schedule II opiate and opioid medication that may be manufactured in the U.S. in calendar year 2018 by 20%. For 2019, the DEA proposed decreased manufacturing quotas for the six most frequently misused opioids, including oxycodone, by an average of 10% as compared to the 2018 quotas.

Distributions of any Schedule I or II controlled substance must also be accompanied by special order forms, with copies provided to the DEA. Because Xtampza ER and the Nucynta Products are regulated as a Schedule II controlled substances, they are subject to the DEA's production and procurement quota scheme. The DEA establishes annually an aggregate quota for how much active opioid ingredients, such as oxycodone and tapentadol, may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. The limited aggregate amount of opioids that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. We and our contract manufacturers must receive an annual quota from the DEA in order to produce or procure any Schedule I or Schedule II substance, including oxycodone base for use in manufacturing Xtampza ER. In addition, Assertio and its contract manufacturers must receive an annual quota from the DEA in order to produce or procure tapentadol for use in manufacturing the Nucynta Products. The DEA may adjust aggregate production quotas

and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments.

The DEA also requires drug manufacturers to design and implement a system that identifies suspicious orders of controlled substances, such as those of unusual size, those that deviate substantially from a normal pattern and those of unusual frequency, prior to completion of the sale. A compliant suspicious order monitoring, or SOM, system includes well-defined due diligence, “know your customer” efforts and order monitoring.

To enforce these requirements, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in administrative, civil or criminal enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate administrative proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

Individual states also independently regulate controlled substances. We and our contract manufacturers are subject to state regulation on distribution of these products.

Two new federal laws address the national epidemics of prescription opioid abuse and illicit opioid use. First, passed in 2016, CARA expands the availability of naloxone for law enforcement and other first responders, forms an interagency task force to develop best practices for pain management with opioid medications and provides resources to improve state monitoring of opioids. The SUPPORT Act, which was signed into law in November 2018, includes a number of measures directed towards regulation and improvement of treatment for substance use-disorder and increased coverage by CMS of medically-assisted treatment options. In addition, the SUPPORT Act requires HHS to report to Congress on existing barriers to access to abuse-deterrent opioid formulations by Medicare Part C and D beneficiaries.

Healthcare Fraud and Abuse Laws and Compliance Requirements

We are subject to federal, state and local laws targeting fraud and abuse in the healthcare industry, violations of which can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs. These laws are potentially applicable to us as both a manufacturer and a supplier of products and they also apply to hospitals, physicians and other potential purchasers of our products. The applicable federal fraud abuse laws apply to products or services reimbursed by federal healthcare programs. Some states, however, have applicable fraud and abuse laws that apply more broadly to include products or services reimbursed by private payors.

The federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Remuneration is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, coupons, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. Under the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b, a person or entity need not have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim, including items or services resulting from a violation of 42 U.S.C. § 1320a-7b, constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes fines against any person who is determined to have presented or caused to be presented claims to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. The federal Anti-Kickback Statute and implementing regulations provide for certain exceptions for “safe harbors” for certain discounting, rebating or personal services arrangements, among other things. However, the lack of uniform court interpretation of the Anti-Kickback Statute makes compliance with the law difficult. Violations of the federal Anti-Kickback Statute can result in significant criminal fines, exclusion from participation in Medicare and Medicaid and follow-on civil litigation, among other things, for both entities and individuals.

Other federal healthcare fraud-related laws also provide criminal liability for violations. The Criminal Healthcare Fraud statute, 18 U.S.C. § 1347 prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit

program, including private third-party payers. Federal criminal law at 18 U.S.C. § 1001, among other sections, prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

The civil False Claims Act and similar state laws impose liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act and similar state laws allow a private individual to bring civil actions on behalf of the federal or state government and to share in any monetary recovery. The Federal Physician Payments Sunshine Act and similar state laws impose reporting requirements for various types of payments to physicians and teaching hospitals. Failure to comply with required reporting requirements under these laws could subject manufacturers and others to substantial civil money penalties. In addition, government entities and private litigants have asserted claims under state consumer protection statutes against pharmaceutical and medical device companies for alleged false or misleading statements in connection with the marketing, promotion and/or sale of pharmaceutical and medical device products, including state investigations and litigation by certain government entities regarding the Company's marketing of opioid products.

Third-Party Payor Coverage and Reimbursement

The commercial success of Xtampza ER and the Nucynta Products will depend, in part, upon the availability of coverage and adequate reimbursement from third-party payors at the federal, state and private levels. Third-party payors include governmental programs such as Medicare or Medicaid, private insurance plans and managed care plans. These third-party payors may deny coverage or reimbursement for a product or therapy in whole or in part if they determine that the product or therapy was not medically appropriate or necessary. Also, third-party payors have attempted to control costs by limiting coverage through the use of formularies and other cost-containment mechanisms and the amount of reimbursement for particular procedures or drug treatments. In addition, some third-party payors also require preapproval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who prescribe such therapies.

The cost of pharmaceuticals and devices continues to generate substantial governmental and third-party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations and business could be adversely affected by current and future third-party payor policies as well as healthcare legislative reforms.

While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, these requirements or any announcement or adoption of such proposals could have a material adverse effect on our ability to obtain adequate prices for Xtampza ER, the Nucynta Products and any other products we may seek to commercialize, and to operate profitably.

Healthcare Reform

In the United States, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs. The Medicare Modernization Act imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for our products. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow

Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from Medicare Part D may result in a similar reduction in payments from non-governmental payors.

In March 2010, the Affordable Care Act was enacted, which significantly changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the Affordable Care Act of importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to 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;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a licensure framework for follow-on biologic products;
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending that began on January 1, 2011.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and, due to the Bipartisan Budget Act of 2015, will remain in effect through 2025 unless additional action is taken by Congress. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and, accordingly, our financial operations.

In December 2017, the Tax Cuts and Jobs Act, or the TCJA, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate, beginning in 2019. The Joint Committee on Taxation estimates that the repeal will result in over 13 million Americans losing their health insurance coverage over the next ten years, and is likely to lead to increases in insurance premiums. It is uncertain how or whether this legislation may affect our customers and, accordingly, our financial operations.

Other Regulatory Requirements

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA and other regulatory authorities have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us.

Employees

As of December 31, 2018, we had a total of 266 full-time employees. None of our employees are represented by a labor organization or under any collective-bargaining arrangements. We consider our employee relations to be good.

Executive Officers of the Company

The following table lists the positions, names and ages of our executive officers as of February 27, 2019:

Name	Age	Position(s)
Executive Officers:		
Joseph Ciaffoni	47	Director, President and Chief Executive Officer
Alison Fleming	44	Executive Vice President and Chief Technology Officer
Paul Brannelly	46	Executive Vice President and Chief Financial Officer
Scott Dreyer	46	Executive Vice President and Chief Commercial Officer
Shirley Kuhlmann	35	Executive Vice President and General Counsel

Executive Officers

Joseph Ciaffoni, Director, President and Chief Executive Officer. Mr. Ciaffoni has served as our President and Chief Executive Officer since July 2018, and prior to that, served as our Executive Vice President and Chief Operating Officer since May 2017. Prior to joining us, Mr. Ciaffoni served as President, U.S. Branded Pharmaceuticals of Endo International plc, a specialty pharmaceutical company, from August 2016 to December 2016. Before that, from April 2012 to August 2016, Mr. Ciaffoni held various positions of increasing responsibility at Biogen Idec, including Senior Vice President, Global Specialty Medicines Group, Senior Vice President, U.S. Commercial and Vice President, U.S. Neurology Field Operations and Marketing. Prior to joining Biogen Idec, Mr. Ciaffoni was Executive Vice President and Chief Operating Officer of Shionogi Inc. and President of Shionogi Pharmaceuticals from July 2008 to October 2010. Mr. Ciaffoni also previously served as Vice President, Sales for Schering-Plough (now Merck) from May 2004 to June 2008, where he was responsible for the cholesterol franchise, and has held several commercial leadership roles at Sanofi-Synthelabo (now Sanofi) from January 2002 to April 2004 and Novartis from January 1994 to December 2001. Mr. Ciaffoni received a B.A. in Communications in 1993 and an M.B.A. in 2000, both from Rutgers, The State University of New Jersey.

Alison Fleming, Ph.D., Chief Technology Officer. Dr. Fleming has served as our Executive Vice President and Chief Technology Officer since January 2017. Prior to being our Chief Technology Officer, Dr. Fleming led our development team as our Vice President, Product Development since October 2002. Prior to joining us, Dr. Fleming's academic research focused on implantable drug delivery systems for cancer therapy. Dr. Fleming is an inventor on several U.S. patents and pending patent applications, and has authored numerous scientific publications and poster presentations in the field of novel drug delivery systems and abuse-deterrent opioid formulations. Dr. Fleming graduated from the University of Massachusetts, Amherst in 1997 with a B.S. in Chemical Engineering and received a Ph.D. in Chemical and Biomolecular Engineering from Cornell University in 2002.

Paul Brannelly, Executive Vice President and Chief Financial Officer. Mr. Brannelly has served as our Executive Vice President and Chief Financial Officer since February 2015. Prior to joining us, Mr. Brannelly served as Senior Vice President, Finance and Administration, and Treasurer of Karyopharm Therapeutics Inc., a biopharmaceutical company, from June 2013 to August 2014. From August 2014 to November 2014, Mr. Brannelly served as a consultant to Karyopharm. Prior to joining Karyopharm, Mr. Brannelly served as Vice President, Finance, Treasurer and Secretary at Verastem, Inc. from August 2010 to May 2013. From January 2010 to September 2011, Mr. Brannelly held the position of Chief Financial Officer at the Longwood Fund, a venture capital firm aimed at investing in, managing and building healthcare companies, where he set up the financial and operational infrastructure following the closing of its first fund and eventually served as Chief Financial Officer of its two startup companies, Verastem and OvaScience, Inc. From November 2005 to September 2009, he served as Vice President, Finance at Sirtris Pharmaceuticals, Inc., a biopharmaceutical company which GlaxoSmithKline plc purchased for $720 million in 2008. Mr. Brannelly started his biopharmaceutical career at Dyax Corporation from September 1999 to May 2002, and subsequently moved on to positions of increasing responsibility at CombinatoRx Inc. from May 2002 to November 2005, including as Vice President, Finance and Treasurer, where he led the initial public offering process. Mr. Brannelly graduated from the University of Massachusetts at Amherst with a B.B.A. in Accounting in 1995.

Scott Dreyer, Executive Vice President and Chief Commercial Officer. Mr. Dreyer has served as our Executive Vice President and Chief Commercial Officer since August 2018, and joined us in January 2018 as Senior Vice President, Sales, Marketing and Training. Prior to joining us, Mr. Dreyer served as the Senior Vice President, Sales, Marketing and Commercial Operations at The Medicines Company, a biopharmaceutical company, from September 2016 to December 2017; Vice President and Chief Marketing Officer – US at Biogen from June 2014 to September 2016; and Vice President, Business Development at Publicis Touchpoint Solutions, a healthcare commercialization company, from October 2013 to June 2014. Mr. Dreyer began his career in the pharmaceutical industry at Merck & Co., where he held roles of increasing responsibility from 1994 to 2013, including Vice President of Hospital and Oncology Sales from 2011 to 2012, and Vice President of Primary Care Sales from 2012 until 2013. Mr. Dreyer holds a B.S. in Biology from Messiah College in 1994.

Shirley Kuhlmann, Executive Vice President and General Counsel. Ms. Kuhlmann has served as our Executive Vice President and General Counsel since March 2018. Prior to joining us, Ms. Kuhlmann was a corporate and securities attorney at Pepper Hamilton LLP from September 2007 until March 2018. At Pepper Hamilton, where she was made a partner effective January 2017, Ms. Kuhlmann advised private and public companies on a range of commercial and transactional matters, including financings, corporate governance and disclosure matters, and mergers and acquisitions and other business combination transactions. Ms. Kuhlmann holds a B.A. in Economics/Political Science from Columbia University in 2004 and a J.D. from Emory University School of Law in 2007.

Our Corporate Information

Our predecessor was incorporated in Delaware in April 2002 under the name Collegium Pharmaceuticals, Inc. and in October 2003, our predecessor changed its name to Collegium Pharmaceutical, Inc. In July 2014, we reincorporated in the Commonwealth of Virginia pursuant to a merger whereby Collegium Pharmaceutical, Inc., a Delaware corporation, merged with and into Collegium Pharmaceutical, Inc., a Virginia corporation, with the Virginia corporation surviving the merger.

Available Information

We maintain a website at www.collegiumpharma.com. We make available, free of charge on our website, our Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, as soon as reasonably practicable after we electronically file those reports with, or furnish them to, the Securities and Exchange Commission, or the SEC. We also make available, free of charge on our website, the reports filed with the SEC by our officers, directors and 10% shareholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. The SEC also maintains a website, at www.sec.gov, that contains reports, proxy and information statements and other information regarding us, and other issuers that file electronically. The information contained on, or that can be accessed through, our website is not a part of or incorporated by reference in this Form 10-K.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as all other information included in this Form 10-K, including our financial statements, the notes thereto and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations." If any of the following risks actually occurs, our business, financial condition, operating results, prospects and ability to accomplish our strategic objectives could be materially harmed. As a result, the trading price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market price of our common stock.

Risks Related to Our Financial Position and Capital Needs

Although we currently generate revenue from the sale of products, we may never become profitable. Our ability to generate sufficient revenue to become profitable is dependent upon our ability to successfully commercialize our products and any products and product candidates that we may develop or acquire in the future on a timely basis, and to address all regulatory requirements applicable to the development and commercialization of our products and any product candidates. Our failure to do so successfully could impair our growth strategy and plans and could have a material adverse effect on our business, financial position, and operating results.

We began the commercial sale of our first product, Xtampza ER, in June 2016 and assumed responsibility for the sales and marketing of the Nucynta Products in January 2018. Our ability to generate sufficient revenue to become profitable depends upon our ability to successfully commercialize our products and any other products and product candidates that we may develop, in-license or acquire in the future. Our ability to generate revenue from our current or future products and any product candidates depends on a number of factors, including our ability to:

- successfully commercialize our products;
- successfully satisfy FDA post-marketing requirements for our products, including studies and clinical trials that have been required for other extended-release/long acting opioid analgesics and individual studies and clinical trials of our products;
- set a commercially viable price for our products;
- manufacture commercial quantities of our products at acceptable cost levels;
- grow and sustain a commercial organization capable of sales, marketing and distribution for the products we sell in the markets in which we have retained or acquired commercialization rights;
- obtain coverage and adequate reimbursement from third parties, including government payors;
- complete and submit regulatory submissions to the FDA; and
- comply with existing and changing laws and regulations that apply to the pharmaceutical industry, including opioid manufacturers.

In addition, because of the numerous risks and uncertainties associated with product development and commercialization, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability.

Even though we are generating revenues from the sale of our products currently, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

If we require additional capital to fund our operations and we fail to obtain necessary financing, we may be unable to complete the commercialization of our products or the development and commercialization of our future product candidates.

Our operations have consumed substantial amounts of cash. We believe that our cash and cash equivalents at December 31, 2018 together with expected cash inflows from the commercialization of our products, will enable us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future. However, certain economic or strategic factors may require us to seek additional cash through private or public debt or equity offerings.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts, when required or on acceptable terms, we also could be required to:

- significantly delay, scale back or discontinue the development and/or the commercialization of our products or our future product candidates or one or more of our other research and development initiatives;
- seek collaborators for our products and/or one or more of our future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms our rights to technologies, products or future product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly curtail operations.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the generation of sufficient levels of revenue from the sale of our products;
- the cost of growing and maintaining sales, marketing and distribution capabilities for our products and any other products we may acquire or develop;
- the outcome, timing and cost of regulatory approvals by the FDA, including the potential for the FDA to require that we perform more studies than, or evaluate clinical endpoints other than those that we currently expect;
- the timing and costs associated with manufacturing (1) our products, for commercial sale and clinical trials, and (2) our future product candidates for preclinical studies, clinical trials and, if approved, for commercial sale;
- the cost of litigation relating to our products or future product candidates, including our patent infringement litigation with each of Purdue and Teva, and ongoing litigation related to opioid marketing and distribution practices, which may be expensive to defend;
- the cost of implementing additional infrastructure and internal systems and hiring additional employees as our organization grows;
- our need to expand our regulatory and compliance functions; and
- the effect of competing technological and market developments.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our products or technologies.

We may seek additional capital through a combination of private and public equity offerings, debt financings, receivables or royalty financings, strategic collaborations and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing shareholders' ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing shareholders. Debt, receivables and royalty financings may be coupled with an equity component, such as warrants to purchase stock, which could also result in dilution of our existing shareholders' ownership. The incurrence of additional indebtedness could result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur further debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could have a material adverse effect on our ability to conduct our business and may result in additional liens being placed on our assets and intellectual property. If we were to default on any of our indebtedness, we could lose such assets and intellectual property. If we raise additional funds through strategic collaborations and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our products, technologies or revenue streams or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our commercialization or product development efforts or grant rights to develop and market our technologies that we would otherwise prefer to develop and market ourselves.

We have a limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Our predecessor was originally incorporated in Delaware in April 2002 under the name Collegium Pharmaceuticals, Inc. and in October 2003, our predecessor changed its name to Collegium Pharmaceutical, Inc. In July 2014, we reincorporated in the Commonwealth of Virginia pursuant to a merger whereby Collegium Pharmaceutical, Inc., a Delaware corporation, merged with and into Collegium Pharmaceutical, Inc., a Virginia corporation, with the Virginia corporation surviving the merger. From 2002 until 2010, our operations focused primarily on marketing proprietary therapies to the wound care and dermatology industry through our former subsidiary, Onset Therapeutics, LLC, which was spun off and became a part of PreCision Dermatology, Inc. in 2010. Since 2010, our operations have focused primarily on developing the DETERx technology platform and identifying and developing product candidates that utilize the DETERx technology, including our first product, Xtampza ER. We are currently in the early years of operating as a commercial stage company, and although we have expanded our product portfolio, we have a limited track record of successful commercialization of these products. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2018, we had a federal net operating loss, or NOL, carryforward of approximately $324.5 million and state NOL carryovers of approximately $285.2 million, which are available to offset future taxable income. The U.S. federal NOL carryforwards begin to expire in 2022, and the state NOL carryforwards begin to expire in 2030. We also had U.S. federal tax credits of approximately $3.6 million, and state tax credits of approximately $885,000. These tax attributes are generally subject to a limited carryover/carryback period and are also subject to the annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended (Code), or Section 382.

The federal R&D credit generally has a twenty-year carryover term, and our state R&D credit is generally available for a fifteen-year carryover.

Under Section 382, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income may be limited. We may experience ownership changes in the future as a result of shifts in our stock ownership some of which are outside our control. We have not completed a current study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations,

which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

As of December 31, 2018, and December 31, 2017, we have provided a full valuation allowance for deferred tax assets including NOL and tax credit carryovers.

Risks Related to our Products

If we are unable to successfully commercialize Xtampza ER or the Nucynta Products, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

To date, we have invested substantial resources in the development of Xtampza ER, which has been approved by the FDA. In February 2018, we began marketing the Nucynta Products. Our business and future success are substantially dependent on our ability to successfully and timely commercialize these products. We may never be able to successfully commercialize our products.

Our ability to successfully commercialize Xtampza ER will depend on many factors, including but not limited to:

- our ability to successfully satisfy FDA post-marketing requirements, including studies and clinical trials that have been required for other extended-release/long acting opioid analgesics and individual studies of Xtampza ER and its components;
- our ability to manufacture commercial quantities of Xtampza ER at reasonable cost and with sufficient speed to meet commercial demand;
- our ability to continue to build and retain a sales and marketing organization to market Xtampza ER;
- our success in educating physicians, patients and caregivers about the benefits, administration, use and coverage of Xtampza ER;
- the perceived availability and advantages, relative cost, relative safety and relative efficacy of other abuse-deterrent products and treatments with similar indications;
- our ability to successfully defend any challenges to our intellectual property or suits asserting patent infringement relating to Xtampza ER;
- the availability of coverage and adequate reimbursement for Xtampza ER;
- a continued acceptable safety profile of Xtampza ER; and
- our ability to comply with applicable legal and regulatory requirements.

Our ability to successfully commercialize the Nucynta Products will depend on many factors including, but not limited to, our ability to:

- develop and execute our sales and marketing strategies for the Nucynta Products;
- obtain and maintain adequate coverage, reimbursement and pricing from managed care, government and other third-party payers;

- maintain and manage the necessary sales, marketing, supply chain, managed markets and other capabilities and infrastructure that are required to successfully integrate and commercialize the Nucynta Products;
- successfully defend any challenges to intellectual property or suits asserting patent infringement relating to the Nucynta Products;
- obtain adequate supply of Nucynta ER and Nucynta IR; and
- comply with applicable legal and regulatory requirements.

The success of our efforts to commercialize the Nucynta Products may also depend on additional factors, including the outcome of a pending appellate decision in litigation between Assertio and ANDA filers who are seeking to market a generic version of the Nucynta Products in the United States.

Many of these matters are beyond our control and are subject to other risks described elsewhere in this "Risk Factors" section. Accordingly, we cannot assure you that we will be able to successfully commercialize or generate sufficient revenue from our products. If we cannot do so, or are significantly delayed in doing so, our business will be materially harmed.

Despite receiving approval by the FDA, additional data may emerge that could change the FDA's position on the product labeling of Xtampza ER and our ability to successfully market Xtampza ER may be adversely affected.

The FDA can change the product labeling for Xtampza ER at any time. If the product label for Xtampza ER is modified in the future so as to exclude the flexible dose administration options, or the FDA requires us to have additional boxed warning language similar to competitor product labeling stating that "crushing, dissolving or chewing can cause rapid release and absorption of a potentially fatal dose of the active drug," it will limit our ability to differentiate Xtampza ER from other abuse-deterrent opioid formulations on the basis of flexible dosing options, and we may not be able to market Xtampza ER for use by patients with dysphagia who have pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. As a result, this may have an adverse effect on our business and our prospects for future growth.

Xtampza ER was approved with label language describing abuse-deterrent properties of the formulation with respect to the nasal and IV routes of abuse, consistent with Guidance for Industry, "Abuse-Deterrent Opioids- Evaluation and Labeling". In November 2017, the FDA approved an sNDA for Xtampza ER to include comparative oral pharmacokinetic data from a clinical study evaluating the effect of physical manipulation by crushing Xtampza ER compared with OxyContin OP and a control (oxycodone hydrochloride immediate-release), results from an oral human abuse potential study and the addition of an oral abuse deterrent claim. Per FDA guidance, data that emerges from post-marketing studies or other sources could prompt the FDA to withdraw or amend its approval of the product labeling describing the abuse deterrent properties of the formulation, which withdrawal or amendment could adversely impact our ability to successfully commercialize Xtampza ER.

Xtampza ER and the Nucynta Products are subject to mandatory REMS programs, which could increase the cost, burden and liability associated with the commercialization of these products.

The FDA has approved REMS for extended-release and long acting, or LA, opioid drugs formulated with the active pharmaceutical ingredients fentanyl, hydromorphone, methadone, morphine, oxycodone, oxymorphone, and others as part of a federal initiative to address prescription drug abuse and misuse, or the ER/LA opioid REMS. In September 2018, the FDA announced that immediate-release, or IR, opioid drugs will be subject to the same REMS as ER/LA opioids (now called the Opioid Analgesic REMS). One of the primary goals of the REMS is to ensure that the benefits of these drugs continue to outweigh the risks.

The REMS introduces new safety measures designed to reduce risks and improve the safe use of opioids, while continuing to provide access to these medications for patients in pain. The REMS applies to more than 20 companies that manufacture opioid analgesics. Under the REMS, companies are required to make education programs available to prescribers based on the FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the

Treatment and Monitoring of Patients with Pain. It is expected that companies will meet this obligation by providing educational grants to continuing education providers, who will develop and deliver the training. The REMS also requires companies to distribute FDA-approved educational materials to prescribers and patients on the safe use of these drugs. The companies must perform periodic assessments of the implementation of the REMS and the success of the program in meeting its goals. The FDA will review these assessments and may require additional elements to achieve the goals of the program. At present, a physician does not have to complete the training offered under REMS as a prerequisite for ability to prescribe opioids; however, the FDA is considering circumstances where it would require some type of mandatory training as a precondition. Congress has also considered legislation that would require prescribers to have continuing medical education on best practices in prescribing opioids. These requirements, if enacted, could impact the number of prescriptions written by physicians for our products.

If the FDA determines that a REMS is necessary during review of an application, the drug sponsor must agree to the REMS plan at the time of approval. Xtampza ER and the Nucynta Products have been subject to the REMS requirement since their approval. REMS includes a Medication Guide that is dispensed with each prescription, physician training based on FDA-identified learning objectives, audits to ensure that the FDA's learning objectives are addressed in the physician trainings, letters to prescribing physicians, professional organizations and state licensing entities alerting each to the REMS, and the establishment of a call center to provide more information about the REMS. We anticipate that our future product candidates will also be subject to these REMS requirements. There may be increased cost, administrative burden and potential liability associated with the marketing and sale of these types of product candidates subject to the REMS requirements, which could reduce the commercial benefits to us from the sale of these product candidates.

If we fail to comply with our obligations in the Nucynta Commercialization Agreement or otherwise experience disruptions to our business relationship with Assertio, we could lose license rights that are important to our business.

The Nucynta Commercialization Agreement imposes various diligence, milestone, royalty and other obligations on us. If we fail to comply with the obligations under the Nucynta Commercialization Agreement, Assertio may have the right to terminate the license, in which event we would not be able to market the Nucynta Products.

In addition, Assertio may terminate the Nucynta Commercialization Agreement under certain circumstances, regardless of whether we are compliant with the terms of such agreement. If annual net sales of the Nucynta Products are less than $180.0 million in any 12-month period through January 1, 2022, or if they are less than $170.0 million in any 12-month period commencing on January 1, 2022, then Assertio will have the right to terminate the Nucynta Commercialization Agreement without penalty.

Although Xtampza ER has been approved with abuse deterrent labeling, the FDA could require changes to such labeling or we could fail to promote such abuse deterrent claims in compliance with FDA regulations.

Xtampza ER was developed in compliance with the FDA's April 2015 guidance regarding opioid abuse deterrence and has received FDA-approved product labeling that describes its abuse deterrent features, which allows us to promote those features and differentiate Xtampza ER from other opioid products containing the same active pharmaceutical ingredients. Because the FDA closely regulates promotional materials and other promotional activities, even though the FDA approved product labeling that includes a description of the abuse deterrent characteristics of Xtampza ER, the FDA may object to our marketing claims and product advertising campaigns. This could lead to the issuance of warning letters or untitled letters, suspension or withdrawal of our products from the market, recalls, fines, disgorgement of money, operating restrictions, injunctions, and civil or criminal prosecution. Any of these consequences would harm the commercial success of Xtampza ER. In addition, the April 2015 final FDA guidance on abuse-deterrent opioids is not binding law and may be superseded or modified at any time. Also, if the FDA determines that our post-marketing data do not demonstrate that the abuse-deterrent properties result in reduction of abuse, or demonstrate a shift to routes of abuse that present a greater risk, the FDA may find that product labeling revisions are needed, and potentially require the removal of our abuse-deterrence claims, which would have a material adverse effect on our ability to successfully commercialize Xtampza ER.

Failure to comply with ongoing governmental regulations for marketing any product, including Xtampza ER and the Nucynta Products, could delay or inhibit our ability to generate revenues from their sale and could also expose us to claims or other sanctions.

Advertising and promotion of any product that has obtained approval in the United States, including Xtampza ER and the Nucynta Products, is heavily scrutinized by, among others, the FDA, the Department of Justice, or the DOJ, the Office of Inspector General of HHS, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or other government agencies.

In the United States, engaging in off-label promotion of our products, can also subject us to false claims litigation under federal and state statutes, and other litigation and/or investigation, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which we promote or distribute our drug products. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth in recent years, leading to several substantial civil and criminal settlements based on certain sales practices promoting off-label drug uses. This increased focus and scrutiny has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from the Medicare, Medicaid and other federal and state healthcare programs.

If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our products, we could become subject to significant liability, which could materially adversely affect our business and financial condition.

In addition, later discovery of previously unknown problems with a product, manufacturer or facility, or our failure to update regulatory files, may result in restrictions, including withdrawal of the product from the market. The failure to obtain or maintain requisite governmental approvals, or FDA required product withdrawals or warnings arising from identification of serious and unanticipated adverse side effects, could delay or preclude us from further developing, marketing or realizing the full commercial potential of our products.

Risks Related to Intellectual Property

Unfavorable outcomes in intellectual property litigation could result in costly litigation and potentially limit our ability to commercialize our products.

Our commercial success depends upon our ability to commercialize products without infringing the intellectual property rights of others. Our current or future products, or any uses of them, may now or in the future infringe third-party patents or other intellectual property rights. This is due in part to the considerable uncertainty within the pharmaceutical industry about the validity, scope and enforceability of many issued patents in the United States and, to date, there is no consistency regarding the breadth of claims allowed in pharmaceutical patents. We cannot currently determine the ultimate scope and validity of patents which may be granted to third parties in the future or which patents might be asserted to be infringed by the manufacture, use and sale of our products. In part as a result of this uncertainty, there has been, and we expect that there will continue to be, significant litigation in the pharmaceutical industry regarding patents and other intellectual property rights.

Third parties may assert infringement claims against us, or other parties we have agreed to indemnify, based on existing patents or patents that may be granted in the future. We are aware of third-party patents and patent applications related to oxycodone formulations, including those listed in the FDA's Orange Book for oxycodone products. Because of the delay between filing and publication of patent applications, and because applications can take several years to issue, there may

be currently pending third-party patent applications that are unknown to us, which may later result in issued patents. Because of the uncertainty inherent in intellectual property litigation, we could lose, even if the case against us was weak or flawed.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing or commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our products or force us to cease some of our business operations.

In connection with any NDA that we file under Section 505(b)(2), we are required to notify the patent holder of the reference listed drug that we identify in our NDA, that we have certified to the FDA that any patents listed for the listed drug in the FDA's Orange Book publication are invalid, unenforceable or will not be infringed by the manufacture, use or sale of our drug. If the patent holder files a patent infringement lawsuit against us within 45 days of its receipt of notice of our certification, the FDA is automatically prevented from approving our Section 505(b)(2) NDA until the earliest of 30 months after the lawsuit is filed, expiration of the patents, settlement of the lawsuit and a court decision in the infringement case that is favorable to us. Accordingly, we may invest significant time and expense in the development of our products only to be subject to significant delay and patent litigation before our products may be commercialized.

If we are found by the court to have infringed a valid patent claim, we could be prevented from using the patented technology or be required to pay the patent holder for the right to license the patented technology. If we decide to pursue a license to use one or more of these patents, we may not be able to obtain a license on commercially reasonable terms, if at all, or the license we obtain may require us to pay substantial royalties or grant cross licenses to our patent rights. For example, if the relevant patent is owned by a competitor, such as Purdue, that competitor may choose not to license patent rights to us. If we decide to develop alternative technology, we may not be able to do so in a timely or cost-effective manner, if at all.

Even if we are found not to infringe or patent claims are found invalid or unenforceable, defending any such infringement claim would be expensive and time consuming, and could delay the commercialization of our products and distract management from their normal responsibilities.

Competitors may sue us as a way of delaying the introduction of our products. Any litigation, including any interference or derivation proceedings to determine priority of inventions, oppositions or other post-grant review proceedings to patents in the United States, or litigation against our collaborators may be costly and time consuming and could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. We expect that litigation may be necessary in some instances to determine the validity and scope of our proprietary rights. Litigation may be necessary in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products Ultimately, the outcome of such litigation, including our pending litigation with Purdue, could compromise the validity and scope of our patents or other proprietary rights or hinder our ability to manufacture and market our products.

If we are unable to obtain or maintain intellectual property rights for our technologies, products or any future product candidates which we may develop, we may lose valuable assets or be unable to compete effectively in our market.

We depend on our ability to protect our proprietary technology. We rely on patent and trademark laws, unpatented trade secrets and know-how, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability to obtain and maintain patent protection in the United States with respect to our proprietary technology and products.

The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights in the United States. The rights already granted under any of our currently issued patents and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking.

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 inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.

Given the amount of time required for the development, testing and regulatory review of product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products identical, similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected.

With respect to patent rights, our patent applications may not issue into patents, and any issued patents may not provide protection against competitive technologies, may be held invalid or unenforceable if challenged or may be interpreted in a manner that does not adequately protect our technology or future product candidates. Even if our patent applications issue into patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. The examination process may require us to narrow the claims in our patents, which may limit the scope of patent protection that may be obtained. Our competitors may design around or otherwise circumvent patents issued to us or licensed by us.

The scope of patent protection in the United States is highly uncertain, and changes in U.S. patent law have increased that uncertainty and could diminish the value of patents in general, thereby impairing our ability to protect our products or future product candidates.

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. Changes in either the patent laws or interpretation of the patent laws in the United States may diminish the value of our patents or narrow the scope of our patent protection.

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States typically are not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights, in the United States, are highly uncertain.

Patent reform legislation could increase the uncertainties and costs associated with the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith America Invents Act, or the Leahy-Smith Act, which was signed into law on September 16, 2011, made significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted and litigated. Many of the substantive changes to patent law associated with the Leahy-Smith Act and, in particular, the “first to file” provisions described below, became effective in 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Pursuant to the Leahy-Smith Act, the United States transitioned to a “first to file” system in which the first inventor to file a patent application will be entitled to the patent. In addition, third parties are allowed to submit prior art before the issuance of a patent by the U.S. Patent and Trademark Office, or USPTO, and may become involved in opposition, derivation, reexamination, or inter partes review challenging our patent rights or the patent rights of others. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including novelty, nonobviousness and enablement. It is possible that prior art of which both we and the patent examiner were unaware during prosecution exists, which could render our patents invalid. Moreover, there may exist prior art of which we were

or are aware, and which we did not or do not consider relevant to our patents, but which could nevertheless be determined to render our patents invalid. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could have a material adverse effect on our competitive position with respect to third parties.

Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or license from third parties may be challenged in the courts or patent offices in the United States. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents, or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our patented technology, trademarks and other intellectual property rights is expensive, difficult and, may in some cases not be possible. In some cases, it may be difficult or impossible to detect third party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

We may be forced to litigate to enforce or defend our intellectual property, which could be expensive, time consuming and unsuccessful, and result in the loss of valuable assets.

We may be forced to litigate to enforce or defend our intellectual property rights against infringement and unauthorized use by competitors, and to protect our trade secrets. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights. In so doing, we may place our intellectual property at risk of being invalidated, rendered unenforceable or limited or narrowed in scope.

Further, this can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can.

Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. In addition, an adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. 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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

We may not be responsible for or have control over the prosecution or enforceability of our licensed technology and have to rely on the licensor to enforce or defend our intellectual property.

In some cases, patent prosecution of our licenses is controlled solely by the licensor, like in certain circumstances under the Nucynta Commercialization Agreement. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;

- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we license prevent or impair our ability to maintain such licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected products.

We may be subject to claims by third parties of ownership of what we regard as our own intellectual property or obligations to make compensatory payments to employees or others.

While it is our policy to require our employees 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 or obtaining such an agreement with each party who, in fact, develops intellectual property that we regard as our own. In addition, they may breach the assignment agreements or such agreements may not be self-executing, and 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 defending against such claims, litigation could result in substantial costs and be a distraction to management.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and products, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our 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, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. Despite these efforts, any of these parties may breach the agreements 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 in the United States may be less willing or unwilling to protect trade secrets. 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 competitor, or those to whom they communicate with, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed or independently developed, our competitive position would be harmed.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including potential competitors. These employees typically executed proprietary rights, non-disclosure and non-competition agreements in connection with their previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs, damage our reputation and be a distraction to management.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, 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.

The USPTO requires compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents are required to be paid to the USPTO in several stages over the lifetime of the patents. 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, but are not limited to, 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 fail to maintain the patents and patent applications covering our products, our competitive position would be adversely affected.

Risks Related to the Commercialization of Our Products

If we are unable to successfully develop and utilize our own sales and marketing capabilities or enter into strategic alliances with marketing collaborators, we may not be successful in commercializing our products and may be unable to generate sufficient product revenue.

Our commercial organization continues to grow and evolve, and in light of its short history and limited track record, we cannot guarantee that we will be successful in marketing our products that may be approved for marketing. In addition, we compete with other pharmaceutical and biotechnology companies with extensive and well-funded sales and marketing operations to recruit, hire, train and retain sales and marketing personnel. If we are unable to continue to grow and maintain adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. Factors that may inhibit our efforts to commercialize our products in the United States include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to reach adequate numbers of physicians who may prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating and maintaining an independent sales and marketing organization.

If we are not successful in recruiting and retaining sales and marketing personnel or in building a sales and marketing infrastructure or if we do not successfully enter into appropriate strategic alliances with marketing collaborators, agreements with contract sales organizations or collaboration arrangements, we will have difficulty commercializing our products. To the extent we commercialize our products by entering into agreements with third-party collaborators, we may have limited or no control over the sales, marketing and distribution activities of these third parties, in which case our future revenues would depend heavily on the success of the efforts of these third parties.

If physicians, patients, healthcare payors and the medical community do not accept and use our products, we will not achieve sufficient product revenues and our business will suffer.

Physicians, patients, healthcare payors and the medical community may not accept and use our products. Acceptance and use of our products will depend on a number of factors including:

- the timing of market introduction of our products as well as the availability of competitive products;
- approved indications, warnings and precautions language that may be less desirable than anticipated;

- perceptions by members of the healthcare community, including physicians, about the safety and efficacy of our products;
- perceptions by members of the healthcare community, including physicians, about the relevance and efficacy of our abuse deterrent technology;
- the pricing and cost-effectiveness of our products relative to competing products;
- the potential and perceived advantages of our products over alternative treatments;
- the convenience and ease of administration to patients of our products;
- actual and perceived availability of coverage and reimbursement for our products from government or other third-party payors;
- any negative publicity related to our or our competitors' products;
- the prevalence and severity of adverse side effects, including limitations or warnings contained in a product's FDA approved product labeling;
- FDA's and HHS's policy initiatives, including their plans and goals to reduce the overall rate of misuse and abuse of opioid drugs;
- our ability to implement a REMS; and
- effectiveness of marketing and distribution efforts by us and any licensees and distributors.

If our products fail to achieve an adequate level of acceptance by physicians, healthcare payors, patients or the medical community, we will not be able to generate sufficient revenue to become or remain profitable. Since we expect to rely on sales generated by Xtampza ER and the Nucynta Products for substantially all of our revenues for the foreseeable future, the failure of Xtampza ER or the Nucynta Products to find market acceptance would harm our business prospects.

Our products contain and our future product candidates may contain controlled substances, the manufacture, use, sale, importation, exportation and distribution of which are subject to regulation by state and federal law enforcement and other regulatory agencies.

Our products contain and our future product candidates may contain, controlled substances that are subject to state and federal laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Xtampza ER's active ingredient, oxycodone, and the Nucynta Products' active ingredient, tapentadol, are both classified as Schedule II controlled substances under the CSA and regulations of the DEA. A number of states also independently regulate these drugs, including oxycodone and tapentadol, as controlled substances.

We and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state and federal law enforcement and regulatory agencies and comply with state and federal laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

Furthermore, the amount of Schedule II substances that can be obtained for clinical trials and commercial distribution is limited by the CSA and DEA regulations. In July 2018, the DEA published final guidelines strengthening the process for setting controls over diversion of controlled substances and making other improvements in the quota management regulatory system. For 2019, the DEA has proposed decreased manufacturing quotas for the six most frequently misused opioids, including oxycodone, by an average of 10% as compared to the 2018 quotas. We may not be able to obtain

sufficient quantities of these controlled substances in order to complete our clinical trials or meet commercial demand. If commercial demand for Xtampza ER, or any of our other approved products, increases and we cannot meet such demand in a timely fashion because of our limited supply of its active pharmaceutical ingredient (in the case of Xtampza ER, oxycodone) then physicians may perceive such product as unavailable and may be less likely to prescribe it in the future.

In addition, controlled substances are also subject to regulations governing manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, recordkeeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of our products that include controlled substances. The DEA and some states conduct periodic inspections of registered establishments that handle controlled substances.

Failure to obtain and maintain required registrations or to comply with any applicable regulations could delay or preclude us from developing and commercializing our products that contain controlled substances and subject us to enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In some circumstances, violations could lead to criminal proceedings. Because of their restrictive nature, these regulations could limit commercialization of our products containing controlled substances.

Recently enacted and future legislation may increase the difficulty and cost for us to commercialize our products and may reduce the prices we are able to obtain for our products.

In the United States, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system generally, and the manufacturing, distribution, and marketing of opioids in particular, that could prevent or delay marketing approval of future product candidates, restrict or regulate post-approval activities or affect our ability to profitably sell our products for which we obtain marketing approval.

Laws 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 health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms may continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure 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 of our products 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.

On February 27, 2018, a bipartisan group of senators introduced Senate Bill 2456 (S.2456). S.2456 is characterized as "CARA 2.0," in reference to the Comprehensive Addiction and Recovery Act of 2016. CARA 2.0 would limit initial prescriptions for opioids to three days, while exempting initial prescriptions for chronic care, cancer care, hospice or end of life care, and palliative care. CARA 2.0 would also increase civil and criminal penalties for opioid manufacturers that fail to report suspicious orders for opioids or fail to maintain effective controls against diversion of opioids. The bill would increase civil fines from $10,000 to $100,000, and if a manufacturer fails to maintain effective controls or report suspicious orders with knowledge or willful disregard, the bill would double criminal penalties from $250,000 to $500,000. If this bill were signed into law, it could adversely affect our ability to successfully commercialize our products. In addition, in 2017 several states, including Indiana, Louisiana, and Utah, enacted laws that further limit or restrict opioid prescriptions.

In October 2018, President Trump signed the Substance Use Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act. Among other things, this legislation provides funding for research and development of non-addictive painkillers that could potentially compete with our products. It also clarifies FDA's authority to require that certain opioids be dispensed in packaging that limits their abuse potential, makes changes to Medicare and Medicaid in an effort to limit over-prescription of opioid painkillers, and increases penalties against manufacturers and distributors related to the over-prescription of opioids, including the failure to report

suspicious orders and keep accurate records. The ultimate effect of this legislation is currently not known, but could potentially have a material adverse effect on our business.

In addition, state pharmacy laws may permit pharmacists to substitute generic products for branded products if the products are therapeutic equivalents, or may permit pharmacists and pharmacy benefit managers to seek prescriber authorization to substitute generics in place of our products, which could significantly diminish demand for them and significantly impact our ability to successfully commercialize our products and generate revenues.

Our products may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could have a material adverse effect on our business. Such pricing regulations may address the rebates that manufacturers offer to pharmaceutical benefit managers, or the discounts that manufacturers provide others within the pharmaceutical distribution chain.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products can vary widely. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Pricing limitations may hinder our ability to recoup our investment in our products.

Our ability to commercialize any product successfully will also depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with discounts and rebates from list prices and are challenging the prices charged for medical products. We have agreed to provide such discounts and rebates to certain third-party payors. We expect increasing pressure to offer larger discounts and rebates. Additionally, a greater number of third-party payors may seek discounts and rebates in order to offer or maintain access for our products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be and whether it will be satisfactory.

In January 2019, as part of its cost containment efforts for government-reimbursed prescription medications, HHS released a proposed rule that (1) eliminates AKS safe harbor protection for rebates paid to prescription benefit managers; (2) creates a new safe harbor for discounts provided to beneficiaries at the point of sale; and (3) creates a new safe harbor for administrative fees paid by manufacturers to prescription benefit managers. The goal of the proposed safe harbor changes is to eliminate rebates from manufacturers to prescription benefit managers and replace them with point-of-sale discounts to beneficiaries. The proposed new rule only applies to Medicare, Medicare Advantage and Medicaid plans, not to private commercial insurance plans. The proposed regulation faces opposition from pharmacy benefit managers and others who do not believe it will have its intended effect of reducing overall costs to government beneficiaries. We cannot be sure whether the proposed rule will be adopted either in its current form or in an amended form, and do not know what impact the uncertainty will have on our agreements and relationships with pharmacy benefit managers and other pertinent parties. If the rule is finalized, we will likely be required to alter our agreements with these parties to come into compliance with the new rule, and it is uncertain what financial impact these alterations will have on our list prices, discounts, and reimbursement levels for our products

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable reimbursement rates from both

government-funded and private payors for our products could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Social issues around the abuse of opioids, including law enforcement concerns over diversion of opioids and regulatory efforts to combat abuse, could decrease the potential market for our products.

Media stories regarding prescription drug abuse and the diversion of opioids and other controlled substances are commonplace. Law enforcement and regulatory agencies may apply policies and guidelines that seek to limit the availability or use of opioids. Such efforts may inhibit our ability to commercialize our products.

Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of oxycodone or other opioid drugs; the limitations of abuse-resistant formulations; the ability of drug abusers to discover previously unknown ways to abuse opioid drugs, including Xtampza ER and the Nucynta Products; public inquiries and investigations into prescription drug abuse; litigation; or regulatory activity regarding sales, marketing, distribution or storage of opioid drugs could have a material adverse effect on our reputation. Such negative publicity could reduce the potential size of the market for our products and decrease the revenues we are able to generate from their sale. Similarly, to the extent opioid abuse becomes less prevalent or less urgent of a public health issue, regulators and third party payers may not be willing to pay a premium for abuse-deterrent formulations of opioid.

Many state legislatures have enacted legislation intended to reduce opioid abuse, for example by establishing prescription drug monitoring programs and mandating prescriber education. The SUPPORT Act allows for sharing of this type of data across state lines. Efforts by the FDA and other regulatory and legislative bodies to combat abuse of opioids may negatively impact the market for our products. In February 2016, the FDA released an action plan to address the opioid abuse epidemic and reassess the FDA's approach to opioid medications. The plan identifies the FDA's focus on implementing policies to reverse the opioid abuse epidemic, while maintaining access to effective treatments. The actions set forth in the FDA's plan include strengthening post marketing study requirements to evaluate the benefit of long-term opioid use, changing the REMS requirements to provide additional funding for physician education courses, releasing a draft guidance setting forth approval standards for generic-abuse deterrent opioid formulations, and seeking input from the FDA's Science Board to broaden the understanding of the public risks of opioid abuse. The FDA's Science Board met to address these issues on March 1, 2016. In November 2017, FDA issued a final guidance addressing approval standards for generic abuse-deterrent opioid formulations, which included recommendations about the types of studies that companies should conduct to demonstrate that the generic drug is no less abuse-deterrent than its brand-name counterpart. The FDA's plan is part of a broader initiative led by the HHS to address opioid-related overdose, death and dependence. The HHS initiative's focus is on improving physician's use of opioids through education and resources to address opioid over-prescribing, increasing use and development of improved delivery systems for naloxone, which can reverse overdose from both prescription opioids and heroin, to reduce overdose-related deaths, and expanding the use of Medication-Assisted Treatment, which couples counseling and behavioral therapies with medication to address substance abuse. As part of this initiative, the CDC has launched a state grant program to offer state health departments resources to assist with abuse prevention efforts, including efforts to track opioid prescribing through state-run electronic databases. In March 2016, as part of the HHS initiative, the CDC released a Guideline for Prescribing Opioids for Chronic Pain. The guideline is intended to assist primary care providers treating adults for chronic pain in outpatient settings. The guideline provides recommendations to improve communications between doctors and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy. The guideline states that no treatment recommendations about the use of abuse-deterrent opioids can be made at this time. The SUPPORT Act, described above, also addresses opioid-related abuse by, among other things, seeking to increase access to and reimbursement for addiction treatment, advancing new initiatives to promote education and awareness of appropriate pain treatment among health care providers and improving coordination among federal agencies in relation to border checks.

The FDA continues to evaluate extended-release and abuse-deterrent opioids in the post-market setting. In March 2017, the FDA's Advisory Committee met to discuss OPANA ER (oxymorphone hydrochloride) extended-release tablets. A majority of the Advisory Committee voted that the benefits do not outweigh the risks of OPANA ER. Upon the FDA's subsequent request in June 2017, OPANA ER was removed from the market. Also, in July 2017, the FDA held a public workshop to discuss available data and methods to assess the impact of opioid formulations with abuse-deterrent properties on misuse, abuse, addiction, overdose, and death in the post-market context. The FDA will continue to

scrutinize the impact of abuse-deterrent opioids and in the future could impose further restrictions to products currently on the market, which may include changing labeling, imposing additional prescribing restrictions, or seeking a product's removal from the market.

Recently, CVS Pharmacy announced it would only fill first-time opioid prescriptions for acute pain for a seven day supply. In July 2017, the Pharmaceutical Care Management Association, a trade association representing pharmacy benefit managers, wrote a letter to the commissioner of the FDA in which it expressed support for, among other things, the CDC guidelines and a seven-day limit on the supply of opioids for acute pain. In addition, states, including the Commonwealths of Massachusetts and Virginia and the States of New York, Ohio, Arizona, Maine, New Hampshire, Vermont, Rhode Island, Colorado, Wisconsin, Alabama, South Carolina, Washington and New Jersey, have either recently enacted, intend to enact, or have pending legislation or regulations designed to, among other things, limit the duration and quantity of initial prescriptions of immediate-release forms of opiates and mandate the use by prescribers of prescription drug databases and mandate prescriber education. Also, at the state and local level, a number of states and cities have brought separate lawsuits against various pharmaceutical companies marketing and selling opioid pain medications, alleging misleading or otherwise improper promotion of opioid drugs to physicians and consumers. In addition, the attorneys general from several states have announced the launch of a joint investigation into the marketing and sales practices of drug companies that market opioid pain medications. We are currently subject to such lawsuits and investigations, as discussed under the heading "Legal Proceedings" in this Form 10-K. Many of these changes and others could cause us to expend additional resources in developing and commercializing our products to meet additional requirements. Advancements in development and approval of generic abuse-deterrent opioids could also compete with and potentially impact physician use of our products and cause our products to be less commercially successful.

If the FDA or other applicable regulatory authorities approve generic products with abuse deterrent claims that compete with our products could reduce our sales.

Once an NDA, including a Section 505(b)(2) application, is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an ANDA. The FD&C Act, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active pharmaceutical ingredients, dosage form, strength, route of administration, and conditions of use, or product labeling, as our product and that the generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our product. These generic equivalents would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product. Accordingly, competition from generic equivalents to our products would substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our products. In November 2017, FDA issued a final guidance to assist industry in the development of generic versions of approved opioids with abuse-deterrent formulations, including recommendations about the types of studies that companies should conduct to demonstrate that the generic drug is no less abuse-deterrent than its brand-name counterpart. In July 2018, the FDA posted three revised product-specific guidances related to generic abuse-deterrent opioid formulations, which recommend specific in vivo studies and in vitro study considerations for abuse deterrence evaluations. These guidances are part of FDA's wider focus on assisting developers of generic abuse-deterrent formulations navigate the regulatory path to market more quickly. Earlier market entry of generic abuse-deterrent formulations could have a material adverse effect on our business.

Guidelines and recommendations published by various organizations can reduce the use of our products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the healthcare and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our products.

Risks Related to Our Dependence on Third Parties

If the third-party manufacturer of Xtampza ER fails to devote sufficient time and resources to Xtampza ER, or its performance is substandard, and/or we encounter challenges in completing our dedicated facility at our third-party manufacturer's site, our costs may be higher than expected and could have a material adverse effect on our business. Our commercialization partner also relies on sole suppliers to manufacture the Nucynta Products, which presents a similar risk.

We do not own any manufacturing facilities and have limited experience in drug development and commercial manufacturing. We currently have no plans to build our own clinical or commercial scale manufacturing facility. We lack the resources and expertise to manufacture and test, on a commercial scale, the technical performance of Xtampza ER. We currently rely, and expect to continue to rely, on a limited number of experienced personnel and contract manufacturers for our products, as well as other vendors to formulate, test, supply, store and distribute our products and we control only certain aspects of their activities. In 2016, we began the buildout of a dedicated facility for a portion of the Xtampza ER manufacturing process, at a site operated by our contract manufacturing organization, Patheon. This dedicated facility has required significant capital expenditures and, when operational, is likely to result in significantly increased fixed costs. This dedicated facility requires the maintenance of additional regulatory approvals and entails other costs, all of which we will need to absorb. We cannot guarantee that we will be able to successfully leverage the dedicated facility in a timely or profitable manner, or within the budget that we currently project. If the demand for Xtampza ER and any future related products never meets our expectations and forecasts, or if we do not produce the output we plan, we may not be able to realize the return on investment we anticipated, which would have a negative impact on our financial condition and results of operations.

Although we have identified alternate sources for these services, it would be time-consuming, and require us to incur additional cost, to qualify these sources.

Our reliance on a limited number of vendors and, in particular, Patheon N.V., as our single manufacturer for Xtampza ER, exposes us to the following risks, any of which could delay commercialization of our products, result in higher costs, or deprive us of potential product revenues:

- Our contract manufacturer, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial demand (even after accounting for the increased capacity to be provided by the dedicated facility), may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, may be affected by natural disasters that interrupt or prevent manufacturing of our products, may experience shortages of qualified personnel to adequately staff production operations, may experience shortages of raw materials and may have difficulties finding replacement parts or equipment.

- Our contract manufacturer could default on their agreement with us to meet our requirements for commercial supplies of Xtampza ER and/or deliver the dedicated facility according to the currently agreed timeline.

- The use of alternate manufacturers may be difficult because the number of potential manufacturers that have the necessary governmental licenses to produce narcotic products is limited. Additionally, the FDA and the DEA must approve any alternative manufacturer of Xtampza ER, before we may use the alternative manufacturer to produce commercial supplies.

- It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all. Our contract manufacturer and vendors may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products.

- If our contract manufacturer were to terminate our arrangement or fail to meet our commercial manufacturing demands, we may be forced to delay our development and commercial programs.

Failure to obtain the necessary active pharmaceutical ingredients, excipients or components necessary to manufacture Xtampza ER could adversely affect our ability to commercialize the product, which could in turn adversely affect our

results of operations and financial condition. Certain components of Xtampza ER are naturally derived products, for which we rely on sole suppliers. The inability of any of our raw material suppliers to provide components that meet our specifications and requirements could adversely impact our ability to manufacture our product.

Our reliance on third parties reduces our control over our development and commercialization activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. The FDA and other regulatory authorities require that Xtampza ER to be manufactured according to cGMP. Any failure by our third-party manufacturer to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of products in a timely manner, could lead to a shortage of commercial product. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for products previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, imposing civil penalties or pursuing criminal prosecution.

Our commercialization partner for the Nucynta Products, Assertio, currently relies on a single supplier to manufacture each of the Nucynta Products. Any stock out, or failure to obtain sufficient supplies of each of the Nucynta Products, or the necessary active pharmaceutical ingredients, excipients or components necessary to manufacture each of the Nucynta Products, could adversely affect our ability to commercialize the Nucynta Products, which could in turn adversely affect our results of operations and financial condition. Assertio experienced delays in the manufacture, packaging and delivery of certain dosage strengths of Nucynta ER in the third and fourth quarters of 2017 and the first quarter of 2018 following Hurricanes Irma and Maria in Puerto Rico. We and our commercialization partner may continue to experience further outages in the future.

Because we currently rely on a sole supplier to manufacture the active pharmaceutical ingredient of our products, any production problems with our supplier could have a material adverse effect on us.

We presently depend upon a single supplier for the active pharmaceutical ingredient for Xtampza ER (oxycodone base) and the Nucynta Products (tapentadol) and we contract, either directly or indirectly, through Assertio with this supplier, as necessary, for commercial supply of our products. Although we have identified an alternate source for oxycodone base for Xtampza ER, it would be time-consuming and costly to qualify this source. Since we and, in the case of tapentadol, Assertio, currently obtain active pharmaceutical ingredients from this manufacturer on a purchase-order basis, either we, Assertio, and/or our supplier may terminate the arrangements, without cause, at any time without notice. If our supplier were to terminate an arrangement for an active pharmaceutical ingredient, or fail to meet our supply needs, we might incur substantial costs and be forced to delay our development or commercialization programs. Any such delay could have a material adverse effect on our business.

Manufacturing issues may arise that could increase product and regulatory approval costs, delay commercialization or limit commercial supply.

As we scale up manufacturing of our products and conduct required stability testing, we may encounter product, packaging, equipment and process-related issues that may require refinement or resolution in order to proceed with our planned clinical trials, obtain regulatory approval for commercial marketing and build commercial supplies. In the future, we may identify impurities, which could result in increased scrutiny by regulatory authorities, delays in our clinical programs and regulatory approval, increases in our operating expenses, failure to obtain or maintain approval or limitations in our commercial supply.

We depend on wholesale pharmaceutical distributors for retail distribution of our products; if we lose any of our significant wholesale pharmaceutical distributors, that loss may materially adversely affect our financial condition and results of operations.

A significant percentage of our product shipments are to a limited number of independent wholesale pharmaceutical distributors. Three of our wholesale pharmaceutical distributors represented 36%, 31% and 27% of our product shipments for the year ended December 31, 2018. The loss by us of any of these wholesale pharmaceutical distributors' accounts, or a material reduction in their purchases, could have a material adverse effect on our business, results of

operations, financial condition and prospects. The significance of each wholesale pharmaceutical distributor account to our business adversely impacts our ability to negotiate favorable commercial terms with each such distributor, and as a result, we may be forced to accept terms that adversely impact our results of operations.

In addition, these wholesale customers comprise a significant part of the distribution network for pharmaceutical products in the United States. This distribution network has undergone, and may continue to undergo, significant consolidation marked by mergers and acquisitions. As a result, a small number of large wholesale distributors control a significant share of the market. Consolidation of drug wholesalers has increased, and may continue to increase, competitive and pricing pressures on pharmaceutical products. We cannot guarantee that we can manage these pricing pressures or that wholesaler purchases will not fluctuate unexpectedly from period to period.

Our products could be subject to post-marketing requirements, which requirements may, in some cases, not be capable of timely or satisfactory completion without participation in consortia over which we have limited control.

Our products are subject to a comprehensive regulatory scheme, including post-marketing requirements, or PMRs, to conduct epidemiological studies and clinical trials. We intend to fulfill our PMRs by virtue of our participation in the Opioid PMR Consortium, or OPC. Although we retain discretion in how to discharge such PMRs, the scale and scope of the studies required by the FDA make it cost prohibitive to discharge these requirements other than by joining the OPC that was formed to conduct them. We are a member of OPC and engage in decision-making as a member of that organization, but do not have a majority. If the OPC fails to conduct sufficiently rigorous studies or is unable to achieve the patient enrollment or other requirements established by the FDA, we may be unable to satisfy our PMRs and the FDA may choose to withdraw or otherwise restrict its approval of our products. Such withdrawal or restriction would have an adverse impact on our business and financial condition.

In the future, we may depend on collaborations with third parties for the development and commercialization of our products. If those collaborations are not successful, we may not be able to capitalize on the market potential of these products.

We may not be successful in establishing development and commercialization collaborations which could adversely affect, and potentially prohibit, our ability to develop or commercialize our products. These collaborations, including the Nucynta Commercialization Agreement, pose the following risks to us:

- Collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations.
- Collaborators may not pursue development and commercialization of our product or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities.
- Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon our product, repeat or conduct new clinical trials or require a new formulation of our product for clinical testing.
- Collaborators may fail to obtain necessary regulatory approval, conduct clinical trials inappropriately, or may obtain unfavorable results in their clinical trials, which may have an adverse effect on the development or commercialization of our product.
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.
- A collaborator with marketing and distribution rights to our products may not commit sufficient resources to the marketing and distribution of such products.

- Collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.

- Disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or that result in costly litigation or arbitration that diverts management attention and resources.

- We may lose certain valuable rights under circumstances specified in our collaborations.

- Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable products.

- Collaboration agreements may not lead to development or commercialization of products in the most efficient manner or at all. If a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

- Our ability to successfully commercialize products pursuant to collaboration agreements may be adversely affected by disputes or delays arising from supply and/or manufacturing agreements between such collaborators and third parties—agreements to which we may not be a party.

We may rely on collaborators to market and commercialize our products, who may fail to effectively commercialize our products.

We may utilize strategic collaborators or contract sales forces, where appropriate, to assist in the commercialization of our products. We currently possess limited resources and may not be successful in establishing collaborations or co-promotion arrangements on acceptable terms, if at all. We also face competition in our search for collaborators and co-promoters. If we enter into strategic collaborations or similar arrangements, we will rely on third parties for financial resources and for development, commercialization, sales and marketing and regulatory expertise. Our collaborators, if any, may fail to develop or effectively commercialize our products because they cannot obtain the necessary regulatory approvals, they lack adequate financial or other resources or they decide to focus on other initiatives. Any failure of our third-party collaborators to successfully market and commercialize our products would diminish our revenues.

We rely on third parties to conduct our non-clinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if they terminate their agreement with us, we may not be able to maintain regulatory approval for our products and our business could suffer a material adverse effect.

We have relied upon and plan to continue to rely upon contract research organizations, or CROs, to monitor and manage data for our ongoing non-clinical and clinical programs. We rely on these parties for execution of our non-clinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and clinical trials are conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with federal regulations and current GCP, which are international standards meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, advisors and monitors, enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and foreign regulatory authorities in the form of International Conference on Harmonization, or ICH, guidelines for all of our products. Regulatory authorities enforce these GCP through periodic inspections of trial sponsors, principal investigators and trial sites. In addition, we and our CROs are required to comply with special regulations regarding the enrollment of recreational drug abusers in clinical trials. If we or any of our CROs fail to comply with applicable GCP and other regulations, including as a result of any recent changes in such regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. While

we have agreements governing activities of our CROs, we have limited influence over their actual performance. Failure to comply with applicable regulations in the conduct of the clinical trials for our products may require us to repeat preclinical studies and clinical trials, which would have an adverse impact on our commercial efforts.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for our products. As a result, the commercial prospects for our products would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus, and there is a limited number of CROs that are equipped and willing to manage clinical trials that involve recreational drug abusers. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the patients participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. Identifying, qualifying and managing performance of third-party service providers can be difficult, time-consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. If any of our relationships with our CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines.

Our internal capacity to perform these functions is limited. Outsourcing these functions involves risks that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our ability to advance our products through clinical trials will be compromised. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Risks Related to Our Business and Strategy

We have been and may be the subject of litigation matters, including government investigations, for which we may be unable to obtain or maintain insurance adequate to cover potential liabilities.

Our business exposes us to significant potential risk from litigation matters, including government investigations and lawsuits alleging violations of various federal and state laws in connection with the marketing and sale of opioids. For example, we, along with other manufacturers of prescription opioid medications, are or have been the subject of lawsuits brought by counties and localities in Arkansas, Massachusetts, Pennsylvania and Kentucky, in addition to a health system and various member hospitals, regarding the sales and marketing of opioid medications. In addition to direct expenditures for defense, settlement and damages, there is a possibility of adverse publicity, loss of revenues and disruption of business as a result of such litigation matters. The resolution of these lawsuits may require lengthy and costly negotiations, and we may incur substantial defense costs in addition to any settlement or other liabilities or restrictions that we may accept in order to resolve such matters. Further, we may be unable to obtain or maintain insurance on acceptable terms or with adequate coverage against potential liabilities or other losses incurred in connection with certain litigation matters. The cost, effort and management attention required to resolve these lawsuits may adversely affect our financial condition and ability to conduct our business.

We face substantial competition from other biotechnology and pharmaceutical companies, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The biopharmaceutical industry is intensely competitive and subject to rapid and significant technological change. In addition, the competition in the pain and opioid market is intense. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions.

We face and will continue to face competition from other companies in the pharmaceutical and medical device industries. Our products compete with currently marketed oral opioids, transdermal opioids, local anesthetic patches, stimulants and implantable and external infusion pumps that can be used for infusion of opioids and local anesthetics. Products of these types are marketed by Actavis, BioDelivery Sciences, Endo, Mallinckrodt, Pfizer, Purdue, Teva, and others. Some of these current and potential future competitors may be addressing the same therapeutic areas or indications as we are. Many of our current and potential future competitors have significantly greater research and development capabilities than we do, have substantially more marketing, manufacturing, financial, technical, human and managerial resources than we do, and have more institutional experience than we do. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that allow them to develop and commercialize their products before us and limit our ability to develop or commercialize our products. Our competitors may also develop drugs that are safer, more effective, more widely used and less costly than ours, and they may also be more successful than us in manufacturing and marketing their products.

Furthermore, if the FDA approves a competitor's 505(b)(2) application for a drug candidate before our application for a similar drug candidate and grants the competitor a period of exclusivity, the FDA may take the position that it cannot approve our NDA for a similar drug candidate.

In addition, competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these products may have an entirely different approach or means of accomplishing similar therapeutic effects than our products. Our competitors may develop products that are safer, more effective or less costly than our products and, therefore, present a serious competitive threat to our product offerings.

The widespread acceptance of currently available therapies with which our products compete may limit market acceptance of our products. Oral medications, transdermal drug delivery systems, such as drug patches, injectable products and implantable drug delivery devices are currently available treatments for chronic pain, are widely accepted in the medical community and have a long history of use. These treatments will compete with our products and the established use of these competitive products may limit the potential for our products to receive widespread acceptance.

The use of legal and regulatory strategies by competitors with innovator products may increase our costs associated with the introduction or marketing of our products, or significantly reduce the profit potential of our products.

Companies with innovator drugs often pursue strategies that may serve to prevent or delay competition from alternatives to their innovator products. These strategies include, but are not limited to:

- seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate a product's bioequivalence or "sameness" to the related innovator product;
- filing suits for patent infringement that automatically delay FDA approval of products seeking approval based on the Section 505(b)(2) pathway;
- obtaining extensions of market exclusivity by conducting clinical trials of innovator drugs in pediatric populations or by other methods;

- persuading the FDA to withdraw the approval of innovator drugs for which the patents are about to expire, thus allowing the innovator company to develop and launch new patented products serving as substitutes for the withdrawn products;

- seeking to obtain new patents on drugs for which patent protection is about to expire; and

- initiating legislative and administrative efforts in various states to limit the substitution of innovator products by pharmacies.

These strategies could delay, reduce or eliminate our entry into the market and our ability to generate revenues from our products.

Our future success depends on our ability to retain our key personnel.

We are highly dependent upon the services of our key personnel, including our President and Chief Executive Officer, Joseph Ciaffoni, our Chief Technology Officer, Alison Fleming, PhD, our Chief Financial Officer, Paul Brannelly, our Chief Commercial Officer, Scott Dreyer, and our General Counsel, Shirley Kuhlmann. Each employee is employed by us at will and is permitted to terminate his or her employment with us at any time pursuant to the terms of his or her employment agreement. We do not maintain “key person” insurance for any of our executives or other employees. The loss of the services of Mr. Ciaffoni, Dr. Fleming, Mr. Brannelly, Mr. Dreyer or Ms. Kuhlmann could impede the achievement of our development and commercialization objectives.

If we are unable to attract and retain highly qualified employees, we may not be able to grow effectively.

Our future growth and success depend on our ability to recruit, retain, manage and motivate our scientific, clinical, manufacturing and commercial employees. The loss of any member of our senior management team or the inability to hire or retain experienced management personnel could compromise our ability to execute our business plan and harm our operating results. Because of the specialized nature of our business, we rely heavily on our ability to attract and retain qualified personnel. The competition for qualified personnel in the pharmaceutical field is intense, and as a result, we may be unable to continue to attract and retain qualified personnel necessary to execute business or to recruit suitable replacement personnel.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

We have experienced a period of rapid growth. Our management, personnel and systems may not be adequate to support this and future growth. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Future growth would impose significant added responsibilities on members of management, including:

- managing the commercialization of any FDA-approved products;

- overseeing clinical trials effectively;

- identifying, recruiting, maintaining, motivating and integrating additional employees, including any sales and marketing personnel engaged in connection with the commercialization of any approved product;

- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;

- improving our managerial, development, operational and financial systems and procedures; and

- developing our compliance infrastructure and processes to ensure compliance with regulations applicable to

public companies.

As our operations expand, we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future financial performance and our ability to commercialize our products and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

We may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies, which could have a material adverse effect on our operating results, dilute our shareholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets, including preclinical, clinical or commercial stage products or businesses, in-licensing or out-licensing of products or technologies, or other strategic alliances and collaborations, to expand our existing technologies and operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any such transaction, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. We have limited experience with acquiring other companies, products or product candidates, and limited experience with licensing and forming strategic alliances and collaborations. We may not find suitable acquisition candidates, and if we make an acquisition, we may not integrate the acquisition successfully into our existing business and we may incur additional debt or assume unknown or contingent liabilities in connection therewith. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business. We may not be able to find suitable strategic alliances or collaborators or identify other investment opportunities, and we may experience losses related to any such investments.

To finance any acquisitions, licenses or collaborations, we may incur significant transaction expenses and we may choose to issue debt or shares of our common or preferred stock as consideration. Any such issuance of shares would dilute the ownership of our shareholders. If the price of our common stock is low or volatile, we may not be able to acquire, license, or otherwise obtain rights to other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Commercial sales of our products and clinical trials of our products and any future product candidates may expose us to expensive product liability claims, and we may not be able to maintain product liability insurance on reasonable terms or at all.

We currently carry product liability insurance. Product liability claims may be brought against us by patients, healthcare providers, others using, administering or selling our products or patients enrolled in our clinical trials. If we cannot successfully defend ourselves against claims that our products caused injuries, we could incur substantial liabilities. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any products;
- injury to our reputation and significant negative media attention;
- significant costs to defend the related litigation;
- substantial monetary awards to patients;
- loss of revenue;

- diversion of management and scientific resources from our business operations;
- termination of clinical trial sites or entire trial programs;
- withdrawal of clinical trial participants;
- the inability to commercialize our products; and
- an increase in product liability insurance premiums or an inability to maintain product liability insurance coverage.

Our inability to maintain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our products. Any agreements we may enter into in the future with collaborators in connection with the development or commercialization of our products may entitle us to indemnification against product liability losses, but such indemnification may not be available or adequate should any claim arise. In addition, many of our agreements require us to indemnify third parties and these indemnification obligations may exceed the coverage under our product liability insurance policy.

Our products may be associated with undesirable adverse reactions or have other properties that could result in significant negative consequences.

Undesirable adverse reactions associated with our products could cause us, our IRBs, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in a restrictive product label or the delay, denial or withdrawal of regulatory approval by the FDA. For example, even though Xtampza ER was generally well tolerated by patients in our clinical trials, in some cases there were adverse reactions, one of which was a serious adverse event, moderate in severity, of gastroesophageal reflux.

If we or others identify undesirable adverse events associated with our products, a number of potentially significant negative consequences could result, including:

- we may be forced to suspend marketing of the product;
- regulatory authorities may withdraw their approvals of the product or impose restrictions on its distribution;
- regulatory authorities may require additional warnings or contradictions in the product label that could diminish the usage or otherwise limit the commercial success of the product;
- we may be required to conduct additional post-marketing studies;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our products.

Our employees, independent contractors, principal investigators, CROs, CMOs, wholesalers, distributors, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, CMOs, wholesalers, distributors, consultants and vendors may engage in fraudulent conduct or other illegal activity. Misconduct

by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates:

- FDA, DEA or similar regulations of foreign regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities;
- manufacturing standards;
- federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by foreign regulatory authorities; or
- laws that require the reporting of financial information or data accurately.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Ethics, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business and results of operations, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could have a material adverse effect on our ability to operate our business and our results of operations.

Our relationships with customers and payors are subject to applicable anti-kickback, fraud and abuse, transparency, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings.

Healthcare providers, physicians and payors play a primary role in the recommendation and prescription of our products. Our arrangements with payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products and any product candidates for which we may obtain marketing approval. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations may affect our ability to operate and expose us to areas of risk, including:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal False Claims Act, which imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute

constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute to defraud any healthcare benefit program or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- federal laws requiring drug manufacturers to report annually information related to certain payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership or investment interests held by physicians and their immediate family members, including under the federal Open Payments program, commonly known as the Sunshine Act, as well as other state laws regulating marketing activities and requiring manufacturers to report marketing expenditures, payments and other transfers of value to physicians and other healthcare providers;

- federal government price reporting laws, which require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed drugs. Participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, potential liability for the failure to report such prices in an accurate and timely manner, and potentially limit our ability to offer certain marketplace discounts; and

- state equivalents of each of the above laws, including state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers; state laws which require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restricting payments that may be made to healthcare providers; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

While we do not submit claims and our customers will make the ultimate decision on how to submit claims, we may provide reimbursement guidance and support regarding our products to our customers and patients. If a government authority were to conclude that we provided improper advice to our customers and/or encouraged the submission of false claims for reimbursement, we could face action by government authorities. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Nonetheless, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur significant costs.

In connection with our research and development activities and our manufacture of materials and products, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture,

storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our research and development involves the use, generation and disposal of hazardous materials, including chemicals, solvents, agents and biohazardous materials. Although we believe that our safety procedures for storing, handling and disposing of such materials comply with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We currently contract with third parties to dispose of these substances that we generate, and we rely on these third parties to properly dispose of these substances in compliance with applicable laws and regulations. We cannot eliminate the risk of contamination or injury from these materials. If these third parties do not properly dispose of these substances in compliance with applicable laws and regulations, we may be subject to legal action by governmental agencies or private parties for improper disposal of these substances. The costs of defending such actions and the potential liability resulting from such actions are often very large. In the event we are subject to such legal action or we otherwise fail to comply with applicable laws and regulations governing the use, generation and disposal of hazardous materials and chemicals, we could be held liable for any damages that result, and any such liability could exceed our resources.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, this insurance may not provide adequate coverage against potential liabilities. We maintain insurance for environmental liability or toxic tort claims, but we may not continue to maintain such insurance in the future, and such insurance, to the extent maintained, may not be adequate to cover liabilities that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Our business and operations would suffer in the event of computer system failures, accidents or security breaches.

Despite the implementation of security measures, our internal computer systems, and those of our CROs, contract manufacturing organization and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks and other malfeasance, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our commercial and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our commercialization and drug development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further commercialization of our products could be delayed.

Risks Related to Our Common Stock

The price of our common stock may be volatile and you may lose all or part of your investment.

The market price of our common stock is highly volatile and may be subject to wide fluctuations in response to numerous factors, some of which are beyond our control. In addition to the factors discussed in these Risk Factors, these factors include:

- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate;

- the outcome of any patent infringement or other litigation that may be brought by or against us, including the ongoing Purdue and Teva litigation matters;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- results of clinical trials of our products or those of our competitors;
- regulatory or legal developments in the United States;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our products or clinical development programs;
- actual or anticipated variations in our quarterly operating results;
- the number and characteristics of our efforts to in-license or acquire additional products;
- introduction of new products or services by us or our competitors;
- failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other shareholders;
- changes in accounting practices;
- significant lawsuits, including patent or shareholder litigation;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions;
- publication of research reports about us, our competitors or our industry, or positive or negative recommendations or withdrawal of research coverage by securities or industry analysts; and

- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks stated above could have a material adverse effect on the market price of our common stock.

As we operate in the pharmaceutical and biotechnology industry, we are especially vulnerable to these factors to the extent that they affect our industry or our products. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

Actual or potential sales of our common stock by our directors or employees, including our executive officers, pursuant to pre-arranged stock trading plans or otherwise could cause our stock price to fall or prevent it from increasing for numerous reasons, and actual or potential sales by such persons could be viewed negatively by investors.

In accordance with the guidelines specified under Rule 10b5-1 of the Exchange Act and our policies regarding stock transactions, our directors and employees, including our executive officers, could adopt stock trading plans pursuant to which they may sell shares of our common stock from time to time in the future. Generally, sales under such plans by our executive officers and directors require public filings. Actual or potential sales of our common stock by such persons could cause our common stock to fall or prevent it from increasing for numerous reasons. For example, a substantial number of shares of our common stock becoming available (or being perceived to become available) for sale in the public market could cause the market price of our common stock to fall or prevent it from increasing. Also, actual or potential sales by such persons could be viewed negatively by investors.

Future issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our shareholders and could cause our stock price to fall.

Significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. These future issuances of common stock or common stock-related securities, together with the exercise of outstanding options and any additional shares issued in connection with acquisitions, if any, may result in material dilution to our investors. Such sales may also result in material dilution to our existing shareholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

Our principal shareholders and management own a significant portion of our stock and have the ability to exert significant control over matters subject to shareholder approval.

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own a significant portion of our voting stock, including shares subject to outstanding options. As a result, if these shareholders were to choose to act together, they would be able to significantly influence the outcome of all matters requiring shareholder approval, including the election of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest. The interests of this group of shareholders may not always coincide with your interests or the interests of other shareholders and they may act in a manner that advances their best interests and not necessarily those of other shareholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock. Such concentration of ownership control may:

- delay, defer or prevent a change in control;

- entrench our management and/or the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving us that other shareholders may desire.

We are subject to anti-takeover provisions in our amended and restated articles of incorporation and amended and restated bylaws and under Virginia law that could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our shareholders.

Certain provisions of Virginia law, the state in which we are incorporated, and our amended and restated articles of incorporation and amended and restated bylaws could hamper a third party's acquisition of us, or discourage a third party from attempting to acquire control of us. These provisions include:

- a provision allowing our board of directors to set the terms of and issue preferred stock with rights senior to those of the common stock without any vote or action by the holders of our common stock. The issuance of preferred stock could adversely affect the rights and powers, including voting rights, of the holders of common stock;
- advance written notice procedures and notice requirements with respect to shareholder proposals and shareholder nomination of candidates for election as directors;
- a provision that only the board of directors, the chairman of the board of directors or the president may call a special meeting of the shareholders;
- the application of Virginia law prohibiting us from entering into certain transactions with the beneficial owner of more than 10 percent of our outstanding voting stock for a period of three years after such person first reached that level of stock ownership, unless certain conditions are met;
- a provision dividing our board of directors into three classes, each serving three-year terms;
- the requirement that the authorized number of our directors be changed only by resolution of our board of directors;
- a provision that our board of directors shall fill any vacancies on our board of directors, including vacancies resulting from a board of directors' resolution to increase the number of directors;
- limitations on the manner in which shareholders can remove directors from the board of directors;
- the lack of cumulative voting in the election of directors; and
- the prohibition on shareholders acting by less-than-unanimous written consent.

These provisions also could limit the price that certain investors might be willing to pay in the future for shares of our common stock. In addition, these provisions make it more difficult for our shareholders to remove our board of directors or management or elect new directors to our board of directors.

We may fail to qualify for continued listing on The NASDAQ Global Select Market which could make it more difficult for investors to sell their shares.

Our common stock is listed on The NASDAQ Global Select Market (NASDAQ). As a NASDAQ listed company, we are required to satisfy the continued listing requirements of NASDAQ for inclusion in the Global Select Market to maintain such listing, including, among other things, the maintenance of a minimum closing bid price of $1.00 per share and shareholders' equity of at least $10.0 million. There can be no assurance that we will be able to maintain compliance

with the continued listing requirements or that our common stock will not be delisted from NASDAQ in the future. If our common stock is delisted by NASDAQ, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity with respect to our securities;
- a determination that our shares are a "penny stock," which will require brokers trading in our shares to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our shares;
- a limited amount of news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

As of December 31, 2018, we are no longer an "emerging growth company" and, as a result, are required to comply with increased disclosure and governance requirements.

As the market value of our common stock held by non-affiliates was greater than $700 million as of the last business day of the most recent second quarter, we ceased to be an "emerging growth company" as defined in the JOBS Act as of December 31, 2018. As a large accelerated filer, we are subject to certain requirements that apply to other public companies but did not previously apply to us. These requirements include:

- the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
- the requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Exchange Act; and
- the "say on pay" provisions (requiring a non-binding stockholder vote to approve compensation of certain executive officers) and the "say on golden parachute" provisions (requiring a non-binding stockholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Act and some of the disclosure requirements of the Dodd-Frank Act relating to compensation of our chief executive officer.

Therefore, this Annual Report is subject to Section 404(b) of the Sarbanes-Oxley Act, which requires that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting. Compliance with Section 404 is expensive and time consuming for management and could result in the detection of internal control deficiencies of which we are currently unaware. The loss of "emerging growth company" status and compliance with the additional requirements substantially increases our legal and financial compliance costs and make some activities more time consuming and costly.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting. We are required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment must include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting.

During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its reviews, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations reflect the reality that judgments can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

The exercise of options and warrants and other issuances of shares of common stock or securities convertible into or exercisable for shares of common stock will dilute your ownership interests and may adversely affect the future market price of our common stock.

Sales of our common stock in the public market, either by us or by our current shareholders, or the perception that these sales could occur, could cause a decline in the market price of our securities. All of the shares of our common stock held by those of our current shareholders may be immediately eligible for resale in the open market either in compliance with an exemption under Rule 144 promulgated under the Securities Act, or pursuant to an effective resale registration statement that we have previously filed with the SEC. Such sales, along with any other market transactions, could adversely affect the market price of our common stock.

As of December 31, 2018, there were outstanding options to purchase an aggregate of 3,585,856 shares of our common stock at a weighted average exercise price of $16.20 per share, of which options to purchase 1,608,346 shares of our common stock were then exercisable. In addition, as of December 31, 2018, the Company had an outstanding warrant

with Assertio to purchase 1,041,667 shares of our common stock at an exercise price of $19.20 per share. The exercise of options and warrants at prices below the market price of our common stock could adversely affect the price of shares of our common stock. Additional dilution may result from the issuance of shares of our common stock in connection with collaborations or manufacturing arrangements or in connection with other financing efforts.

Any issuance of our common stock that is not made solely to then-existing shareholders proportionate to their interests, such as in the case of a stock dividend or stock split, will result in dilution to each shareholder by reducing his, her or its percentage ownership of the total outstanding shares. Moreover, if we issue options or warrants to purchase our common stock in the future and those options or warrants are exercised you may experience further dilution. Holders of shares of our common stock have no preemptive rights that entitle them to purchase their pro rata share of any offering of shares of any class or series.

We have broad discretion in the use of our cash and cash equivalents, and, despite our efforts, we may use them in a manner that does not increase the value of our shareholders' investment.

We have broad discretion in the use of our cash and cash equivalents, and investors must rely on the judgment of our management regarding the use of our cash and cash equivalents. Our management may not use cash and cash equivalents in ways that ultimately increase the value of our common stock. Our failure to use our cash and cash equivalents effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the commercialization of our products. We may invest our cash and cash equivalents in short-term or long-term, investment-grade, interest-bearing securities. These investments may not yield favorable returns. If we do not invest or apply our cash and cash equivalents in ways that enhance shareholder value, we may fail to achieve expected financial results, which could cause the price of our common stock to decline.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be our shareholders' sole source of gain.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our capital stock will be our shareholders' sole source of gain for the foreseeable future.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our corporate headquarters are located in Stoughton, Massachusetts, where we lease 50,678 square feet of office space under a lease agreement that was executed in March 2018. We took possession of the space in August 2018 when tenant improvements were substantially complete, and the lease will continue for a term of approximately 10 years after an initial four-month free rent period. The lease term may be extended for two additional five-year terms at our election.

Our former corporate headquarters are located in Canton, Massachusetts, where we continue to lease 9,660 square feet of office space under a lease agreement that was amended in October 2018. The lease term terminates in August 2020 and may be extended for an additional five years at our election.

We believe that our existing facilities are adequate for our current and expected future needs. We may seek to negotiate new leases or evaluate additional or alternate space for our operations. We believe that appropriate alternative space is readily available on commercially reasonable terms.

Item 3. Legal Proceedings

Xtampza ER Litigation

We filed the NDA for Xtampza ER as a 505(b)(2) application, which allows us to reference data from an approved drug listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book), in this case OxyContin OP. The 505(b)(2) process requires that we certify to the FDA and notify Purdue, as the holder of the NDA and any other Orange Book-listed patent owners, that we do not infringe any of the patents listed for OxyContin OP in the Orange Book, or that the patents are invalid. We made such certification and provided such notice on February 11, 2015 and such certification documented why Xtampza ER does not infringe any of the 11 Orange Book listed patents for OxyContin OP, five of which have been invalidated in court proceedings. Under the Hatch-Waxman Act of 1984, Purdue had the option to sue us for infringement and receive a stay of up to 30 months before the FDA could issue a final approval for Xtampza ER, unless the stay was earlier terminated.

Purdue exercised its option and elected to sue us for infringement in the District of Delaware on March 24, 2015 asserting infringement of three of Purdue's Orange Book-listed patents (Patent Nos. 7,674,799, 7,674,800, and 7,683,072) and a non-Orange Book-listed patent (Patent No. 8,652,497), and accordingly, received a 30-month stay of FDA approval.

The Delaware court transferred the case to the District of Massachusetts. After we filed a partial motion for judgment on the pleadings relating to the Orange Book-listed patents, the District Court of Massachusetts ordered judgment in our favor on those three patents, and dismissed the claims asserting infringement of those patents with prejudice. Upon dismissal of those claims, the 30-month stay of FDA approval was lifted. As a result, we were able to obtain final approval for Xtampza ER and launch the product commercially.

In November 2015, Purdue filed a follow-on suit asserting infringement of another patent, Patent No. 9,073,933. In June 2016, Purdue filed another follow-on suit asserting infringement of another non-Orange Book listed patent, Patent No. 9,155,717. In April 2017, Purdue filed another follow-on suit asserting infringement of another patent, Patent No. 9,522,919, which was late-listed in the Orange Book and therefore could not trigger any stay of FDA approval. Then, in September 2017, Purdue filed another follow-on suit asserting infringement of another non-Orange Book listed patent, Patent No. 9,693,961 or the '961 patent.

On March 13, 2018, we filed a Petition for Post-Grant Review, or PGR, of the ′961 patent with the Patent Trial and Appeal Board, or PTAB. The PGR argues that the ′961 patent is invalid for lack of a written description, for lack of enablement, for indefiniteness, and as being anticipated by prior art. Purdue filed its Patent Owner Preliminary Response on July 10, 2018. The PTAB entered an order to institute post-grant review of all claims of the ′961 patent on October 4, 2018, upon a finding that it is more likely than not that the claims of the ′961 patent are unpatentable. The PTAB has scheduled oral argument on the proceedings for July 10, 2019 and, absent special circumstances, will issue a decision on the patentability of the ′961 patent by no later than October 4, 2019.

In October 2017, and in response to the filing of our sNDA seeking to update the drug abuse and dependence section of the Xtampza ER label, Purdue filed another suit asserting infringement of the ′933 and ′919 patent. We filed a motion to dismiss that action, and the Court granted our motion on January 16, 2018.

The current suits have been consolidated by the District of Massachusetts, where Purdue asserted infringement of five patents: the ′497 patent, the ′933 patent, the ′717 patent, the ′919 patent, and the ′961 patent. The Court issued an order on September 28, 2018 in which it granted in part a motion for summary judgment filed by us and in which the Court ruled that the ′497 and ′717 patents are not infringed by us. As a result, only the ′933, the ′919, and the ′961 patents remain in dispute. On October 16, 2018, we filed a motion to stay proceedings in the district court on the '961 patent pending the PGR. None of these suits are associated with any stay of FDA approval for Xtampza ER. Purdue has made a demand for monetary relief but has not quantified its alleged damages. Purdue has also requested a judgment of infringement, an adjustment of the effective date of FDA approval, and an injunction on the sale of our products accused of infringement. We have denied all claims and seek a judgment that the patents are invalid and/or not infringed by us; We are also seeking a judgment that the case is exceptional, with an award to us of our fees for defending the case.

The parties are in the early stages of fact discovery. Written discovery has commenced with depositions expected to commence during the first half of 2019. A claim construction hearing was held on June 1, 2017. On November 21, 2017, the Court issued its claim construction ruling, construing certain claims of the ′933, ′497, and ′717 patents. No trial date has been scheduled.

We plan to continue, defending this case vigorously. At this stage, we are unable to evaluate the likelihood of an

unfavorable outcome or estimate the amount or range of potential loss, if any.

Nucynta Litigation

On February 7, 2018, Purdue filed a patent infringement suit against us in the District of Delaware. Specifically, Purdue argues that our sale of immediate release and extended release Nucynta infringes U.S. Patent Nos. 9,861,583, 9,867,784, and 9,872,836. Purdue has made a demand for monetary relief in its complaint but has not quantified its alleged damages.

On December 6, 2018, we filed an Amended Answer asserting an affirmative defense for patent exhaustion. On December 10, 2018, the Court granted the parties' stipulation for resolution of our defense of patent exhaustion and stayed the action, with the exception of briefing on and resolution of the Company's Motion for Judgment on the Pleadings and any discovery related to that Motion. On December 12, 2018, the Company filed a Rule 12(c) Motion for Judgment on the Pleadings, arguing that the Purdue's claims were barred by the doctrine of patent exhaustion. Purdue filed its response on January 11, 2019 and we filed a reply on January 25, 2019. That Motion is currently under advisement, and, if successful, would result in a dismissal of this suit.

We plan to defend this case vigorously. At this stage, we are unable to evaluate the likelihood of an unfavorable outcome or estimate the amount or range of potential loss, if any.

Teva Litigation

We have fourteen patents listed in the FDA *Orange Book* as covering our abuse-deterrent product and methods of using it to treat patients: Patents Nos. 7,399,488; 7,771,707; 8,449,909; 8,557,291; 8,758,813; 8,840,928; 9,044,398; 9,248,195; 9,592,200; 9,682,075; 9,737,530, 9,763,883; 9,968,598; 10,004,729, or the Orange Book Patents.

Teva Pharmaceuticals USA, Inc., or Teva, filed a Notice Letter of Patent Certification against twelve of the fourteen listed Orange Book Patents (the '598 and '729 patents were listed among the Orange Book Patents after receipt of Teva's Notice Letter), alleging that they were invalid and/or not infringed by the proposed oxycodone products that are the subject of Teva's Abbreviated New Drug Application, ANDA. On February 22, 2018—within the 45-day period that gives us a 30-month stay on FDA approval of Teva's ANDA while the parties have an opportunity to litigate—we sued Teva in the District of Delaware on eleven of the Orange Book Patents. Teva responded to our complaint on May 14, 2018, alleging that the Orange Book Patents are invalid and are not infringed by Teva's proposed ANDA products and asserting counterclaims of non-infringement and invalidity of the Orange Book Patents. We answered Teva's counterclaims on June 4, 2018. According to the Scheduling Order for this case, fact discovery will close on July 30, 2019 and expert discovery will close on January 31, 2020.

Opioid Litigation

On March 19, 2018, a lawsuit was filed by multiple local governments in the Circuit Court of Crittenden County, Arkansas, against us and other pharmaceutical manufacturers and distributors alleging a variety of claims related to opioid marketing and distribution practices. On January 29, 2019, we were dismissed from this litigation without prejudice.

On March 21, 2018, we, along with other pharmaceutical manufacturers and distributors, were named in a class-action lawsuit filed in the Eastern District of Kentucky by a family practice clinic, on behalf of other similarly-situated healthcare providers. The action alleges violations of the Racketeer Influenced and Corrupt Organizations Act relating to opioid marketing and distribution practices. On April 14, 2018, the lawsuit was conditionally transferred by the Judicial Panel on Multi-District Litigation to the federal Prescription Opiate Multi District Litigation, or MDL, in the Southern District of Ohio. On April 10, 2018, the conditional transfer was finalized and the lawsuit was docketed in the MDL on April 11, 2018. On May 4, 2018, we, along with other pharmaceutical manufacturers and distributors, were named in two lawsuits filed in the MDL by the Fiscal Court of Bourbon County, Kentucky and the Fiscal Court of Owen County, Kentucky, relating to opioid marketing and distribution practices. On June 11 and 12, 2018, we were named in four lawsuits filed in the MDL by a health system and various member hospitals. On September 26, 2018, we were named in two lawsuits filed in the MDL by the Fiscal Court of Lee County, Kentucky and the Fiscal Court of Wolfe County, Kentucky. The lawsuits allege violations of the RICO Act, fraud, public nuisance, negligence, and violations of state consumer protections laws. The lawsuits all seek, generally, penalties and/or injunctive relief. The MDL lawsuits in

which we have been named are not designated representative cases in the MDL and, therefore, are effectively currently stayed.

On May 29, 2018, a lawsuit was filed by Bucks County, Pennsylvania against us and other pharmaceutical manufacturers and on June 12, 2018, a lawsuit was filed by Clinton County, Pennsylvania, against us and other pharmaceutical manufacturers and distributors. On June 6, 2018, a lawsuit was filed by Mercer County, Pennsylvania, against us and other pharmaceutical manufacturers and distributors. These lawsuits allege claims related to opioid marketing and distribution, including negligence, fraud, unjust enrichment, public nuisance, and violations of state consumer protections laws. These cases have been consolidated for discovery purposes in the Delaware County Court of Common Pleas as part of a consolidated proceeding of similar lawsuits brought by numerous Pennsylvania counties against other pharmaceutical manufacturers and distributors.

On July 30, 2018, a lawsuit was filed by the City of Worcester, Massachusetts against us and other pharmaceutical manufacturers and distributors. The action alleges a variety of claims related to opioid marketing and distribution practices including public nuisance, common law fraud, negligent misrepresentation, negligence, violations of Mass Gen. Laws ch. 93A, *Section 11*, unjust enrichment and civil conspiracy. In February 2019, the City of Worcester case was transferred to the Business Litigation Session of the Superior Court. Additional lawsuits brought by cities and towns in Massachusetts were filed in December 2018 and February 2019; City of Salem, City of Framingham, Town of Lynnfield, City of Springfield, City of Haverhill, City of Gloucester, Town of Canton, Town of Wakefield; and City of Chicopee. The plaintiffs in these lawsuits are seeking to transfer and consolidate each of the additional lawsuits for possible coordination before the Business Litigation Session. The same plaintiffs' law firm has indicated it intends to file more complaints against us and other pharmaceutical manufacturers and distributors on behalf of additional Massachusetts municipalities.

We dispute the allegations in these lawsuits and intend to vigorously defend these actions. At this stage, we are unable to evaluate the likelihood of an unfavorable outcome or estimate the amount or range of potential loss, if any.

Opioid-Related Requests and Subpoenas

We, like a number of other pharmaceutical companies, have received subpoenas or civil investigative demands related to opioid sales and marketing. We have received such subpoenas or civil investigative demands from the Offices of the Attorney General of each of Washington, New Hampshire, and Massachusetts. We are currently cooperating with the each of the foregoing states in their respective investigations.

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 is publicly traded on the NASDAQ Global Select Market under the symbol "COLL" since May 7, 2015. Prior to May 7, 2015, there was no public trading market for our common stock. The following table sets forth, for

the periods indicated, the high and low sales prices for our common stock as reported on NASDAQ:

Year Ended December 31, 2018	High	Low
First quarter	$ 29.90	$ 17.17
Second quarter	$ 28.91	$ 20.81
Third quarter	$ 24.44	$ 14.00
Fourth quarter	$ 19.83	$ 13.70

Year Ended December 31, 2017	High	Low
First quarter	$ 17.60	$ 9.88
Second quarter	$ 13.20	$ 7.37
Third quarter	$ 13.47	$ 9.03
Fourth quarter	$ 20.92	$ 9.01

Holders

As of January 31, 2019, there were 34 holders of record of our common stock. The number of holders of record does not include beneficial owners whose shares are held by nominees in street name.

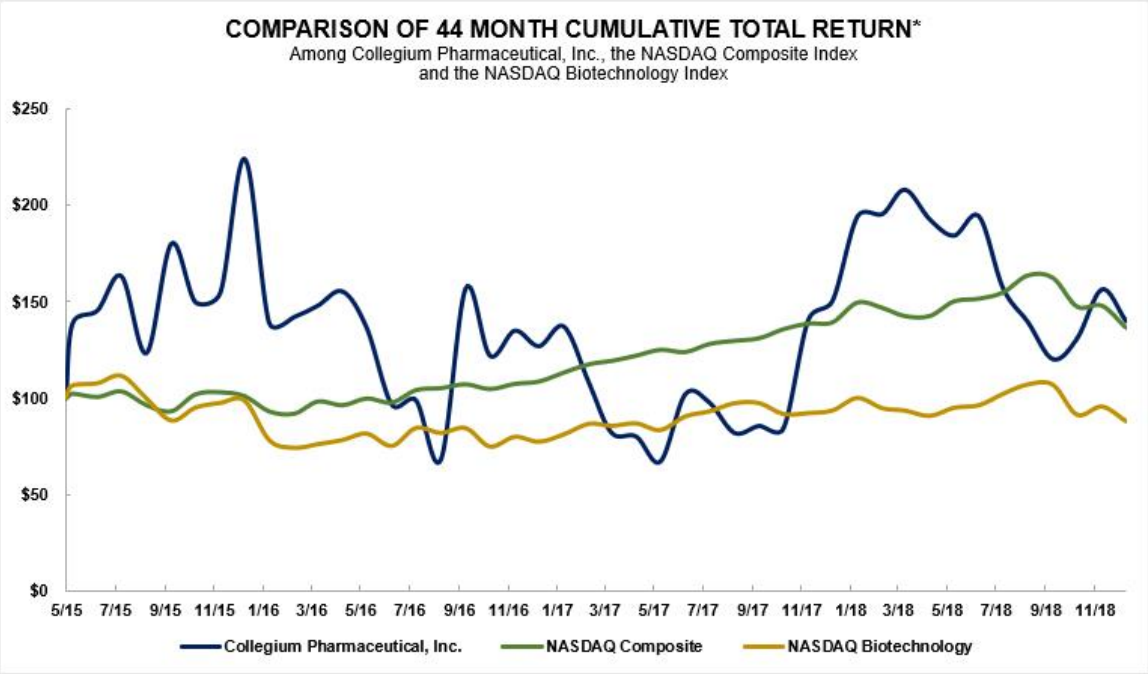
Dividends

We have never declared or paid cash dividends on our common stock, and we do not expect to pay any cash dividends on our common stock in the foreseeable future.

Stock Performance Graph

The following graph shows a comparison from May 7, 2015, the date on which our common stock first began trading on the NASDAQ Global Select Market, of the total cumulative shareholder return on an assumed investment of $100.00 in cash in our common stock as compared to the same investment in the NASDAQ Composite Index and the NASDAQ Biotechnology Index, all through December 31, 2018. Such returns are based on historical results and are not intended to

suggest future performance. Data for the NASDAQ Composite Index and NASDAQ Biotechnology Index assume reinvestment of dividends, however no dividends have been declared on our common stock to date.



$100 investment in stock or index		May 7, 2015	December 31, 2017	December 31, 2018
Collegium Pharmaceutical, Inc. (COLL)	$	100.00	$ 150.20	$ 139.71
NASDAQ Composite Index (IXIC)	$	100.00	$ 139.59	$ 136.74
NASDAQ Biotechnology Index (NBI)	$	100.00	$ 93.20	$ 87.61

The performance graph and related information shall not be deemed to be “soliciting material” or to be “filed” with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act, except to the extent that we specifically incorporate it by reference into such filing.

Recent Sales of Unregistered Securities

There were no unregistered sales of equity securities during the period covered by this Form 10-K, except as disclosed on our Form 8-K filed on November 8, 2018.

ATM Sales Agreement

In March 2017, we commenced an “at-the-market” offering of our common stock and entered into a Controlled Equity Offering Sales Agreement (the “ATM Sales Agreement”) with Cantor Fitzgerald, as agent, pursuant to which we may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $60.0 million. No shares were sold pursuant to the ATM Sales during the year ended December 31, 2018. During the year ended December 31, 2017, we sold an aggregate of 3,126,998 shares of common stock under the ATM Sales Agreement at an average gross sales price of $11.36 per share, generating net proceeds of $34.3 million after deduction of underwriting discounts and commissions and expenses payable by us. The proceeds from the sales were used to fund the continued commercialization of Xtampza ER, research, working capital, business development and for other general corporate purposes.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

The following table sets forth purchases of our common stock for the three months ended December 31, 2018:

Period	(a) Total number of shares purchased [1]	(b) Average Price Paid per Share	(c) Total number of shares purchased as part of publicly announced plans or programs	(d) Maximum number of shares that may yet be purchased under the plans or programs
October 1, 2018 through October 31, 2018	-	$ -	-	-
November 1, 2018 through November 30, 2018	4,683	$ 19.19		
December 1, 2018 through December 31, 2018	-	$ -	-	-
Total	**4,683**	**$ 19.19**	-	-

(1) All of the shares were transferred to us from employees in satisfaction of minimum tax withholding obligations associated with the vesting of restricted stock units during the period.

Item 6. Selected Financial Data

You should read the following selected financial data together with our consolidated financial statements and the related notes appearing elsewhere in this Form 10-K and "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this Form 10-K. The selected historical financial information in this section is not intended to replace our financial statements and the related notes thereto. Our historical results are not necessarily indicative of results to be expected in any period in the future.

	Years ended December 31,				
	2018	2017	2016	2015	2014
	(in thousands, except share and per share amounts)				
Statement of Operations Data:					
Product revenues, net	$ 280,413	$ 28,476	$ 1,711	$ —	$ —
Costs and expenses					
Cost of product revenues	165,677	2,595	213	—	—
Research and development	8,661	8,572	14,948	7,975	14,959
Selling, general and administrative	126,760	92,756	80,632	18,932	2,706
Total costs and expenses	301,098	103,923	95,793	26,907	17,665
Loss from operations	(20,685)	(75,447)	(94,082)	(26,907)	(17,665)
Interest expense	(20,130)	—	(94)	(439)	(252)
Interest income	1,687	582	—	—	—
Other income	—	—	—	91	—
Net loss	$ (39,128)	$ (74,865)	$ (94,176)	$ (27,255)	$ (17,917)
Basic and diluted net loss per common share[1]:	$ (1.19)	$ (2.47)	$ (3.88)	$ (1.48)	$ (22.72)
Weighted-average shares used to compute loss per common share[1]:	32,953,808	30,265,262	24,262,945	13,542,282	933,997

(1) See Note 2 to our consolidated financial statements included elsewhere in this Form 10-K for an explanation of the method used to calculate net loss per common share attributable to common shareholders, including the method used to calculate the number of shares used in the computation of the per share amount.

	As of December 31,				
	2018	2017	2016	2015	2014
Balance Sheet Data:					
Cash and cash equivalents	$ 146,633	$ 118,697	$ 153,225	$ 95,697	$ 1,634
Working capital[1]	48,386	101,996	132,979	88,451	(5,921)
Total assets	291,245	135,568	162,017	97,718	5,090
Other long-term liabilities	10,534	—	1,513	4,214	6,914
Total shareholders' equity (deficit)	91,585	104,080	134,908	85,072	(89,348)

(1) Working capital is calculated as current assets minus current liabilities.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Form 10-K. The following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of many factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this Form 10-K, including those set forth under "Forward-looking Statements" and "Risk Factors", as revised and supplemented by those risks described from time to time in other reports which we file with the SEC.

Overview

We are a specialty pharmaceutical company committed to being the leader in responsible pain management. Our first product, Xtampza ER, is an abuse-deterrent, extended-release, oral formulation of oxycodone. In April 2016, the FDA, approved our NDA for Xtampza ER for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. In June 2016, we announced the commercial launch of Xtampza ER.

Our product portfolio also includes the Nucynta Products. In December 2017, we entered into the Commercialization Agreement with Assertio, pursuant to which we acquired the right to commercialize the Nucynta Products in the United States. Nucynta ER is an extended-release formulation of tapentadol that is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy in adults, and for which alternate treatment options are inadequate. Nucynta IR is an immediate-release formulation of tapentadol that is indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults.

We closed the transactions contemplated by the Nucynta Commercialization Agreement, as amended, on January 9, 2018, and we began marketing and commercially selling the Nucynta Products in February 2018.

For the fiscal year ended December 31, 2018, we generated $280.4 million in net revenues, comprised of $69.4 million from sales of Xtampza ER and $211.0 million from sales of the Nucynta Products.

Outlook

We expect to continue to incur significant commercialization expenses related to marketing, manufacturing, distribution, selling and reimbursement activities. We are promoting Xtampza ER to approximately 10,700 physicians who write approximately 60% of the branded extended-release oral opioid prescriptions in the United States with a sales team of approximately 150 sales representatives and managers.

We began shipping and recognizing product sales on the Nucynta Products on January 9, 2018, and we began commercial promotion of the Nucynta Products in February 2018. We are promoting the Nucynta Products to the same physicians to whom we promote Xtampza ER, leveraging our existing sales organization. We will pay a royalty to Assertio on all revenues from the sale of Nucynta Products based on certain net sales thresholds and paid a royalty of $132.0 million in 2018.

We have never been profitable and have incurred net losses in each year since inception. We incurred net losses of $39.1 million, $74.9 million and $94.2 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of $337.2 million. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations. We expect to continue to incur net losses in the near future as we continue to commercialize our products. Our net losses may fluctuate significantly from quarter to quarter and year to year.

We believe that our cash and cash equivalents at December 31, 2018, together with expected cash inflows from the commercialization of our products, will enable us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future.

Financial Operations Overview

Product Revenues

Product revenue through the year ended December 31, 2018 has been generated from product sales of Xtampza ER and the Nucynta Products. In accordance with Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers*, product sales are recorded net of a provision for estimated chargebacks, rebates, sales incentives and allowance, distribution service fees, and returns upon delivery of products to customers.

Cost of Product Revenues

Cost of product revenues include amortization of the Nucynta Intangible Asset, royalty expense, the cost of active pharmaceutical ingredient, or API, the cost of producing finished goods that correspond with revenue for the reporting period, as well as certain period costs related to freight, packaging, stability and quality testing. Please refer to Note 4, *License Agreements*, and Note 9, *Intangible Assets*, for further detail around the Nucynta Intangible Asset and royalty expense.

Research and Development Expenses

Research and development expenses consist of development costs associated with our products, product platform technology and development of our product candidates. These costs are expensed as incurred and include:

- compensation and employee-related costs, including stock-based compensation;
- costs associated with conducting our preclinical, clinical and regulatory activities, including fees paid to third-party professional consultants and service providers;
- costs incurred under clinical trial agreements;
- costs for laboratory supplies;
- costs to acquire, develop and manufacture preclinical study and clinical trial materials; and
- facilities, depreciation and other expenses including allocated expenses for rent and maintenance of facilities.

We cannot determine with certainty the timing of initiation, the duration or the completion costs of future preclinical studies and clinical trials. At this time, due to the inherently unpredictable nature of preclinical and clinical development, we are unable to estimate with any certainty the costs we will incur and the timelines required for our products. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. In addition, we cannot forecast which products may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Our research and development has been focused primarily on developing our DETERx platform technology and Xtampza ER. Accordingly, historically we have not tracked research and development costs by project. In addition, we use our employee and infrastructure resources across multiple research and development projects.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation and travel expenses for our employees in executive, finance, sales and marketing and administrative functions. Other selling, general and administrative expenses include facility-related costs and professional fees for directors, accounting and legal services, and expenses associated with obtaining and maintaining patents. As we continue to invest in the commercialization of our products, we expect our selling, general and administrative expenses to be substantial for the foreseeable future.

Interest Expense

Interest expense consists primarily of non-cash interest costs related to our Nucynta Commercialization Agreement and cash interest costs from Loan and Security Agreement with Silicon Valley Bank (“SVB”).

Interest Income

Interest income consists of interest earned on our cash and cash equivalents.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. Estimates include revenue recognition, including the estimates of product returns, units prescribed, discounts and allowances related to commercial sales of our products, estimates utilized in the valuation of inventory, estimates of useful lives with respect to intangible assets, accounting for stock-based compensation, contingencies, intangible assets and tax valuation reserves. We base our estimates and assumptions on historical experience when available and on various factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2, *Summary of Significant Accounting Policies*, to our consolidated financial statements appearing elsewhere in this on Form 10-K, we believe the following accounting policies to be most critical to the significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

Our accounting policy for revenue recognition will have a substantial impact on reported results and relies on certain estimates. Estimates are based on historical experience, current conditions and various other assumptions that we believe are reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity and the amounts of revenues and expenses. Actual results may differ from these estimates under different assumptions or conditions.

Product Revenue

Our only source of revenue to date has been generated by sales of our products, which are primarily sold to distributors ("customers"), which in turn sell the product to pharmacies for the treatment of patients ("end users"). For the year ended December 31, 2018, in accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), revenue for product sales is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. This generally occurs upon delivery; when estimated provisions for chargebacks, rebates, sales incentives and allowances, distribution service fees, and returns are reasonably determinable. Therefore, product sales are recorded upon delivery net of estimated chargebacks, rebates, sales incentives and allowances, distribution service fees, as well as estimated product returns.

Prior to the adoption of ASC 606 on January 1, 2018, we recognized revenue in accordance with ASC Topic 605, *Revenue Recognition* ("legacy GAAP"), or when there was persuasive evidence of an arrangement; when title and risk of loss had passed to the customer; when estimated provisions for chargebacks, rebates, sales incentives and allowances, distribution service fees, and returns were reasonably determinable; and when collectability was reasonably assured. The satisfaction of these criteria generally occurred upon delivery of products to customers, or the sell-in method of revenue recognition under legacy GAAP. We began recognizing revenue on the sell-in method in the third quarter of 2017. The adoption of Topic 606 did not have a material impact on our consolidated financial position, results of operations, equity or cash flows for the year ended December 31, 2018. Prior to the third quarter of 2017, we recognized revenue when products were dispensed to end users, or the sell-through method of revenue recognition under legacy GAAP, as we did not have sufficient experience with product sales to estimate returns at the time product was sold to customers. In the third quarter of 2017, we transitioned to the sell-in method of revenue recognition and recorded a cumulative one-time $4.4 million increase to revenues.

Sales Deductions

Sales deductions consist primarily of managed care rebates; government rebates; co-pay program incentives; sales incentives and allowances; provisions for product returns; distribution service fees; prompt pay discounts; and chargebacks. These deductions are recorded as reductions to revenue in the same period as the related sales are recognized. Reserves are based on estimates of the amounts earned or to be claimed on the related sales. Estimates are based on our historical experience of existing or similar programs, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. As a result, we estimate the accruals and related reserves required for amounts payable under these programs.

If actual results vary, we may need to adjust these estimates, which could have an effect on earnings in the period of the adjustment.

Intangible Assets

We record the fair value of finite-lived intangible assets as of the transaction date. Intangible assets are then amortized over their estimated useful lives using either the straight-line method, or if reliably determinable, based on the pattern in which the economic benefit of the asset is expected to be utilized. We test intangible assets for potential impairment whenever triggering events or circumstances present an indication of impairment. If the sum of expected undiscounted future cash flows of the intangible assets is less than the carrying amount of such assets, the intangible assets would be written down to the estimated fair value, calculated based on the present value of expected future cash flows.

As of December 31, 2018, our only intangible asset was related to the Nucynta Commercialization Agreement (the "Nucynta Intangible Asset").

Results of Operations

Comparison of the Years Ended December 31, 2018, 2017 and 2016

The following table summarizes the results of our operations for the years ended December 31, 2018, 2017 and 2016:

	Years ended December 31,		
	2018	2017	2016
	(in thousands)		
Product revenues, net	$ 280,413	$ 28,476	$ 1,711
Cost of product revenues	165,677	2,595	213
Research and development	8,661	8,572	14,948
Selling, general and administrative	126,760	92,756	80,632
Interest expense	(20,130)	—	(94)
Interest income	1,687	582	—
Net loss	$ (39,128)	$ (74,865)	$ (94,176)

Comparison of the Years Ended December 31, 2018 and 2017

Product revenues, net were $280.4 million for the year ended December 31, 2018, compared to $28.5 million for the year ended December 31, 2017. The $251.9 million increase was primarily related to sales of the Nucynta Products pursuant to the Nucynta Commercialization Agreement consummated in January 2018. For the year ended December 31, 2018, the Nucynta Products product revenues, net were $211.0 million. In addition, Xtampza ER product revenues, net were $69.4 million for the year ended December 31, 2018, which represents a $40.9 million increase compared to the year ended December 31, 2017. The increase in Xtampza ER product revenues, net was primarily due to an increase in sales volume due to increasing demand.

Cost of product revenues was $165.7 million for the year ended December 31, 2018, compared to $2.6 million for the

year ended December 31, 2017. The $163.1 million increase was primarily related to $109.8 million of amortization expenses associated with the intangible asset related to the Nucynta Commercialization Agreement. The remaining increase was primarily related to volume of product sales in the year ended December 31, 2018.

Research and development expenses were $8.7 million for the year ended December 31, 2018, compared to $8.6 million for the year ended December 31, 2017. The $89,000 increase was primarily related to an increase in salaries, wages and benefits of $1.0 million, primarily due to increases in employee headcount and stock-based compensation expense. This was partially offset by a $670,000 decrease in development manufacturing expenses following the termination of the Onsolis License and Development Agreement in 2017.

Selling, general and administrative expenses were $126.8 million for the year ended December 31, 2018, compared to $92.8 million for the year ended December 31, 2017. The $34.0 million increase was primarily related to:

- an increase in salaries, wages and benefits of $14.0 million, primarily due to increases in employee headcount, including an increase in stock-based compensation expense of $5.3 million;
- an increase in sales and marketing costs of $10.8 million, primarily related to the Nucynta Products and continued support of Xtampza ER;
- an increase in PDUFA related expenses of $2.7 million, primarily due to the acquisition of the Nucynta Products;
- an increase in audit, legal, and other professional fees of $3.2 million;
- an increase in regulatory costs, including consulting and subscriptions, of $2.1 million, primarily due to the acquisition of the Nucynta Products;
- an increase in consulting fees of $1.6 million;
- an increase in insurance expense of $1.7 million, primarily due to an increase in product liability insurance; offset by
- a decrease of $1.8 million due to the impairment charge relating to the termination of the Onsolis License and Development Agreement with BDSI in 2017.

Interest expense was $20.1 million for the year ended December 31, 2018. This includes $19.3 million of non-cash interest expense associated with the minimum royalty payments related to the Nucynta Commercialization Agreement, which was entered into during the year ended December 31, 2018, and interest expense on our term loan of $849,000.

Interest income was $1.7 million for the year ended December 31, 2018, compared to $582,000 for the year ended December 31, 2017. The increase was primarily due to higher interest rates on money market funds.

Comparison of the Years Ended December 31, 2017 and 2016

Product revenues, net were $28.5 million for the year ended December 31, 2017, compared to $1.7 million for the year ended December 31, 2016. The $26.8 million increase was primarily related to an $18.6 million increase in sold-through units of Xtampza ER, as well as a $3.8 million increase as a result of changing to the sell-in method during the year ended December 31, 2017. In addition, a $4.4 million increase to revenues was recorded in the third quarter of 2017 to recognize revenue from shipments from prior periods as a result of changing to the sell-in method in the third quarter of 2017.

Cost of product revenues was $2.6 million for the year ended December 31, 2017, compared to $213,000 for the year ended December 31, 2016. The $2.4 million increase was primarily related to increased sales in the year ended December 31, 2017.

Research and development expenses were $8.6 million for the year ended December 31, 2017, compared to $14.9 million for the year ended December 31, 2016. The $6.3 million decrease was primarily related to:

- a decrease in clinical trial costs of $4.0 million due to the completion of certain clinical trials in 2016;
- a decrease in research-related regulatory costs of $2.1 million following the commercial launch of Xtampza ER in 2016;
- a decrease in Xtampza ER manufacturing costs of $1.9 million reflecting that, prior to April 2016, we expensed manufacturing costs associated with Xtampza ER as research and development expense; offset by
- an increase in non-clinical trial costs of $932,000 relating to studies required to be conducted following FDA approval of Xtampza ER; and
- an increase in salaries, wages and benefits of $678,000 primarily due to an increase in research and

development, including an increase in incentive compensation and stock-based compensation expense.

Selling, general and administrative expenses were $92.8 million for the year ended December 31, 2017, compared to $80.6 million for the year ended December 31, 2016. The $12.2 million increase was primarily related to:

- an increase in salaries, wages and benefits of $15.8 million primarily due to an increase from 234 to 250 employees, including the addition of a sales force of approximately 150 employees in the second quarter of 2016, and stock-based compensation expense;
- an increase in legal fees of $2.1 million, primarily due to costs related to litigation;
- an increase of $1.8 million due to the impairment charge relating to the termination of the Onsolis License and Development Agreement with BDSI; offset by
- a decrease in PMR and other regulatory costs associated with FDA approval of Xtampza ER of $3.9 million, primarily due to higher one-time costs incurred upon the commercial launch of Xtampza ER in 2016;
- a decrease in commercial, sales and marketing costs of $2.9 million, primarily due to higher costs incurred upon the commercial launch of Xtampza ER in 2016; and
- a decrease in distribution and manufacturing costs of $667,000.

Liquidity and Capital Resources

Sources of liquidity

We have incurred net losses and negative cash flows from operations since inception. Historically, we have funded our operations primarily through the private placements of our preferred stock and convertible notes, public offerings of common stock, and commercial bank debt. As of December 31, 2018, we had $146.6 million in cash and cash equivalents.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of December 31, 2018 together with expected cash inflows from the commercialization of our products, will enable us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future.

Equity Financing

In January 2016, we issued and sold in a public offering an aggregate of 2,750,000 shares of our common stock at $20.00 per share. We received proceeds from this public offering of approximately $51.2 million, after deduction of underwriting discounts and commissions and expenses payable by us.

In October 2016, we issued and sold in a public offering an aggregate of 5,750,000 shares of our common stock at $16.00 per share, including 750,000 shares of common stock upon the exercise by the underwriters of their option to purchase additional shares at the public offering price. We received net proceeds from this public offering of approximately $86.2 million, after deduction of underwriting discounts and commissions and estimated expenses payable by us.

In March 2017, we commenced an “at-the-market” offering of our common stock and entered into the ATM Sales Agreement with Cantor Fitzgerald, as agent, pursuant to which we may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $60.0 million. No shares were sold pursuant to the ATM Sales Agreement during the year ended December 31, 2018. During the year ended December 31, 2017, we sold an aggregate of 3,126,998 shares of common stock under the ATM Sales Agreement at an average gross sales price of $11.36 per share, generating net proceeds of $34.3 million after deduction of underwriting discounts and commissions and expenses payable by us.

Silicon Valley Bank Term Loan Facility

Since August 2012, we have maintained a term loan facility with Silicon Valley Bank, or SVB, which was amended in connection with, and as a condition to, consummation of the transactions contemplated by the Nucynta Commercialization Agreement. Under the amended term loan, or the New Term Loan, we now have a term loan facility in an amount of $11.5 million, which replaces our previously existing term loan facility. The proceeds of the New Term Loan were used to finance certain payment obligations under the Nucynta Commercialization Agreement and to repay

the balance of the previously existing term loan. The New Term Loan also provided SVB's consent with respect to the Nucynta Commercialization Agreement.

The New Term Loan bears interest at a rate per annum of 0.75% above the prime rate (as defined in the agreement governing the New Term Loan). We will repay the New Term Loan in equal consecutive monthly installments of principal plus monthly payments of accrued interest, commencing in July 2019, provided that, if we achieve EBITDA (as defined in the agreement governing the New Term Loan) in excess of $2.5 million for two consecutive calendar quarters prior to June 2019, such payments will commence in January 2020. All outstanding principal and accrued and unpaid interest under the New Term Loan, and all other outstanding obligations with respect to the New Term Loan, are due and payable in full in December 2022. We may prepay the New Term Loan, in full but not in part, with a prepayment fee of (i) 3.0% of the outstanding principal balance prior to January 2019, (ii) 2.0% of the outstanding principal balance following January 2019 and prior to January 2020 and (iii) 1.0% of the outstanding principal balance following January 2020, plus, in each case, a final payment fee of $719,000. Under the New Term Loan, we will be required to maintain a liquidity ratio of at least 2.0 to 1.0. Any amounts outstanding during the continuance of any event of default under the New Term Loan will bear additional interest at the per annum rate of 5.0%.

In November 2018, we entered into an amended and restated Loan and Security Agreement with SVB, that supersedes our original loan agreement and subsequent amendments with SVB. The amended and restated Loan and Security Agreement updated the loan documentation between us and SVB, and modified the minimum liquidity ratio to be at least 1.5 to 1.0, along with other non-material changes. The amended and restated Loan and Security Agreement did not modify our borrowings, interest rates, or repayment terms.

Cash flows

	Years ended December 31,		
	2018	**2017**	**2016**
Net cash provided by (used in) operating activities	$ 169,390	$ (67,018)	$ (75,053)
Net cash used in investing activities	(24,354)	(990)	(2,977)
Net cash (used in) provided by financing activities	(117,197)	33,480	135,558

Operating activities. Cash provided by operating activities was $169.4 million in the year ended December 31, 2018, compared to cash used by operating activities of $67.0 million in the year ended December 31, 2017. The $236.4 million increase in cash provided by operating activities was primarily due to the non-cash adjustments related to the Nucynta Commercialization Agreement. While payments made for guaranteed minimum royalties are classified as financing activities, the amortization from the Nucynta Intangible Asset of $109.8 million and the non-cash interest expense related to the guaranteed minimum royalties of $19.3 million are classified as adjustments to cash provided by operating activities. In addition, cash provided by operating activities increased due to a benefit from changes in the working capital accounts and due to a benefit from the change in net loss. The benefit from the change in the working capital accounts was primarily driven by a benefit from accrued rebates, returns and discounts of $106.6 million, partially offset by the change in accounts receivable $68.2 million. These changes are directly related to the significant increase in product revenues in 2018, as the provisions for rebates, returns and discounts are recognized in the same period in which product is delivered to wholesalers, while payment for rebates, returns and discounts is generally based on prescriptions and actual returned product.

Cash used in operating activities was $67.0 million in the year ended December 31, 2017 and $75.1 million in the year ended December 31, 2016. The $8.1 million decrease in cash used in operating activities was primarily due to the change in net loss, partially offset by changes in the working capital accounts, including significant changes in accounts receivable and accrued rebates, returns and discounts in the year ended December 31, 2017, and non-cash operating activities such as stock-based compensation expense, non-cash impairment charges and depreciation and amortization.

Investing activities. Cash used in investing activities was $24.4 million in the year ended December 31, 2018 and $1.0 million in the year ended December 31, 2017. The increase in cash used in investing activities was primarily due to a payment of $18.9 million to Assertio upon closing of the Nucynta Commercialization Agreement and $5.5 million paid for purchases of property, plant, and equipment for our corporate headquarters and dedicated production suite at our contract manufacturing organization.

Cash used in investing activities was $1.0 million in the year ended December 31, 2017 and $3.0 million in the year ended December 31, 2016. The decrease in cash used in investing activities was primarily due to a one-time upfront fee paid to BDSI for the Onsolis License and Development Agreement in the year ended December 31, 2016.

Financing activities. Cash used in financing activities was $117.2 million for the year ended December 31, 2018, compared to cash provided by financing activities of $33.5 million in the year ended December 31, 2017. The increase in cash used by financing activities was primarily due to an increase in cash used in the repayment of minimum royalty payments associated with the Nucynta Commercialization Agreement for the Nucynta Products of $132.0 million, offset by proceeds received from our term loan of $10.0 million, and proceeds received from the exercise of stock options of $4.3 million. The remaining change is primarily due to higher payments made for employee restricted stock tax withholdings.

Cash provided by financing activities was $33.5 million for the year ended December 31, 2017, compared to cash provided by financing activities of $135.6 million for the year ended December 31, 2016. The decrease in cash provided by financing activities was primarily due to the net proceeds of $34.3 million from the issuance of common stock in 2017, compared to net proceeds of $137.3 million from the issuance of common stock in 2016.

Funding requirements

We believe that our cash and cash equivalents at December 31, 2018, together with expected cash inflows from the commercialization of our products, will enable us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future. However, we are subject to all the risks common to the commercialization and development of new pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

Certain economic or strategic considerations may cause us to seek additional cash through private or public debt or equity offerings. Such funds may not be available when needed, or, we may not be able to obtain funding on favorable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing shareholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Our forecast that our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. The amount and timing of future funding requirements, both near- and long-term, will depend on many factors, including:

- the generation of reasonable levels of revenue from the products sales;
- the cost of growing and maintaining sales, marketing and distribution capabilities for our products;
- the timing and costs associated with manufacturing our products, for commercial sale and clinical trials
- the cost of patent infringement litigation, including our litigation with each of Purdue and Teva, relating to Xtampza ER and the Nucynta Products, which may be expensive to defend;
- the cost of litigation related to opioid marketing and distribution practices;
- our need to expand our regulatory and compliance functions; and
- the effect of competing technological and market developments.

If we cannot capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2018 that will affect our future liquidity:

	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
			(in thousands)		
Operating lease obligations [1]	$ 14,657	$ 1,032	$ 2,566	$ 2,636	$ 8,423
Debt	11,500	1,642	6,572	3,286	—
Purchase obligations [2]	6,000	3,000	3,000	—	—
Total	$ 32,157	$ 5,674	$ 12,138	$ 5,922	$ 8,423

[1] Operating lease obligations represent future minimum lease payments under our non-cancelable operating lease in effect as of December 31, 2018, reflecting remaining lease payments for space at our current headquarters in Stoughton, Massachusetts, and former headquarters in Canton, Massachusetts.

[2] Purchase obligations represent the minimum purchase obligations of up to $3.0 million per year with our contract manufacturer as of December 31, 2018. The disclosed amounts represent the maximum amount that could be payable under the minimum purchase obligations.

We also have employment agreements with executive officers that would require us to make severance payments to them if we terminate their employment without cause or the executives resign for good cause. These payments are contingent upon the occurrence of various future events, and the amounts payable under these provisions depend upon the level of compensation at the time of termination of employment, are therefore not calculable at this time, and, as a result, we have not included any such amounts in the table above.

Nucynta Commercialization Agreement

As more fully described in Note 4, *License Agreements*, and Note 9, *Intangible Assets*, to the consolidated financial statements in January 2018, we closed the Nucynta Commercialization Agreement with Assertio, which initially required us to make annual minimum royalty payments of $537,000, which consisted of scheduled payments of $132,000 in 2018, $135,000 in 2019, $135,000 in 2020, and $135,000 in 2021. The guaranteed minimum royalty payments were a contractual obligation incurred at the closing of the transaction and were included as a component of the accumulated cost of the acquired intangible asset. As a result, we included the present value of the guaranteed minimum royalty payments as a component of the Nucynta Intangible Asset recognized upon closing and recorded a corresponding asset acquisition obligation of $482.3 million.

In November 2018, we entered into an amendment to the Commercialization Agreement to adjust the royalty structure, as well as other changes more fully described in Note 4, *License Agreements*, and Note 9, *Intangible Assets*, to the consolidated financial statements. The amendment eliminated the guaranteed minimum royalty payments in years 2019, 2020, and 2021, and instead added a conditional obligation to make royalty payments based on net sales for years 2019, 2020, and 2021. As such, we remeasured the guaranteed minimum royalty obligation as of the amendment date. This remeasurement resulted in a $369.6 million decrease to the asset acquisition obligation and a corresponding reduction to the Nucynta Intangible Asset.

In the year ended December 31, 2018, we paid $132.0 million of guaranteed minimum royalty payments owed for 2018 and classified such payments as financing outflows in our statement of cash flows. Cost of product revenues recognized in the year ended December 31, 2018 included $109.8 million of amortization expense related to the Nucynta Intangible Asset. In addition, in the year ended December 31, 2018, we recognized $19.3 million of non-cash interest expense related to the guaranteed minimum royalty payments.

In future periods, we expect to classify royalties paid under the Commercialization Agreement as operating outflows as such payments are conditional upon net sales. We also expect to recognize such royalties as a component of costs of product revenues in our statement of operations, in addition to ongoing amortization expense related to the Nucynta Intangible Asset. We expect amortization expense for the Nucynta Intangible Asset for the years ended December 31, 2019, 2020, and 2021 to be $14.8 million, $14.8 million, and $14.8 million, respectively.

Non-GAAP Financial Measures

To supplement our financial results presented on a U.S. generally accepted accounting principles, or GAAP, basis, we have included information about non-GAAP adjusted loss. We internally use non-GAAP adjusted loss to understand, manage and evaluate the Company as we believe it represents the performance of our core business. Because this non-GAAP measure is an important internal measure for the Company, we believe that the presentation of the non-GAAP financial measure provides analysts, investors and lenders insight into management's view and assessment of the Company's ongoing operating performance. In addition, we believe that the presentation of this non-GAAP financial measure, when viewed with our results under GAAP and the accompanying reconciliation, provides supplementary information that may be useful to analysts, investors, lenders, and other third parties in assessing the Company's performance and results from period to period. We report this non-GAAP measure in order to portray the results of our major operations – commercializing innovative, differentiated products for people suffering from pain – prior to considering certain income statement elements. This non-GAAP financial measure should be considered in addition to, and not a substitute for, or superior to, net income or other financial measures calculated in accordance with GAAP. Non-GAAP adjusted loss is not based on any standardized methodology prescribed by GAAP and represents GAAP net loss adjusted to exclude stock-based compensation expense, amortization expense for the Nucynta intangible asset, non-cash interest expense recognized on the Nucynta minimum royalty payments, and minimum royalty payments due and payable in connection with the Nucynta Commercialization Agreement. Any non-GAAP financial measures used by us may be calculated differently from, and therefore may not be comparable to, a non-GAAP measure used by other companies.

	Three Months Ended December 31,		Years ended December 31,	
	2018	2017	2018	2017
GAAP net income (loss)	$ 9,086	$ (17,403)	$ (39,128)	$ (74,865)
Non-GAAP adjustments:				
Stock-based compensation expense	3,598	2,078	13,778	7,945
Nucynta related amortization expense (1)	15,494	-	109,834	-
Nucynta non-cash interest expense (2)	2,169	-	19,281	-
Nucynta minimum royalty payment due (3)	(33,750)	-	(132,000)	-
Total non-GAAP adjustments	$ (12,489)	$ 2,078	$ 10,893	$ 7,945
Non-GAAP adjusted loss	$ (3,403)	$ (15,325)	$ (28,235)	$ (66,920)

	First Quarter 2018	Second Quarter 2018	Third Quarter 2018	Fourth Quarter 2018
GAAP net income (loss)	$ (18,652)	$ (13,060)	$ (16,502)	$ 9,086
Non-GAAP adjustments:				
Stock-based compensation expense	2,728	3,526	3,926	3,598
Nucynta related amortization expense (1)	29,526	32,407	32,407	15,494
Nucynta non-cash interest expense (2)	5,528	5,943	5,641	2,169
Nucynta minimum royalty payment due (3)	(30,750)	(33,750)	(33,750)	(33,750)
Total non-GAAP adjustments	$ 7,032	$ 8,126	$ 8,224	$ (12,489)
Non-GAAP adjusted loss	$ (11,620)	$ (4,934)	$ (8,278)	$ (3,403)

(1) Represents amortization expense of the Nucynta intangible asset.
(2) Represents non-cash interest expense recognized related to the Nucynta minimum royalty payments.
(3) Represents minimum royalty payment due and payable in connection with the Nucynta Commercialization Agreement.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements during the periods presented, as defined under SEC rules.

Item 7A. Quantitative and Qualitative Disclosures about Market Risks

We are exposed to market risk related to changes in interest rates. As of December 31, 2018, we had cash and cash equivalents consisting of cash and money market funds of $146.6 million. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our money market funds are short-term highly liquid investments. Due to the short-term duration and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio.

Item 8. Consolidated Financial Statements and Supplementary Data

Our consolidated financial statements, together with the reports of our independent registered public accounting firms, begin on page F-1 of this Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure
None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of the Chief Executive Officer and the Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this report. The term “disclosure controls and procedures” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed 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 within the time periods specified in the SEC’s rules and forms. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2018.

Management’s Report on Internal Control Over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

(1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company’s assets that could have a material effect on the consolidated financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Also, projections of any evaluation of effectiveness of internal control over financial reporting 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 or procedures may deteriorate. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce,

though not eliminate, this risk.

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rules 13a 15(f) and 15d 15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting. Management has used the framework set forth in the report entitled “Internal Control—Integrated Framework (2013)” published by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) to evaluate the effectiveness of our internal control over financial reporting. Based on its evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2018, the end of our most recent fiscal year.

Changes in Internal Control Over Financial Reporting

As required by Rule 13a-15(d) of the Exchange Act, our management, including our Chief Executive Officer and our Chief Financial Officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer did not identify any change in our internal control over financial reporting during the fiscal quarter ended December 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Collegium Pharmaceutical, Inc.

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Collegium Pharmaceutical, Inc. and subsidiaries (the "Company") as of December 31, 2018, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2018, of the Company and our report dated February 27, 2019, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the 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 the policies or procedures may deteriorate.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
February 27, 2019

Item 9B. Other Information

Not applicable.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

Other than the information regarding our executive officers provided in Part I of this report under the heading "Business—Executive Officers of the Registrant," the information required to be furnished pursuant to this item is incorporated herein by reference to our definitive proxy statement for the 2019 Annual Meeting of the Shareholders.

Our board of directors has adopted a Code of Ethics applicable to all of our employees, executive officers and directors. The Code of Ethics is available on our website at www.collegiumpharma.com. Our board of directors is responsible for overseeing compliance with the Code of Ethics, and our board of directors or an appropriate committee thereof must approve any waivers of the Code of Ethics for employees, executive officers or directors. Disclosure regarding any amendments to the Code of Ethics, or any waivers of its requirements, will be made on our website.

Item 11. Executive Compensation

The information required by this Item 11 is incorporated herein by reference from our definitive proxy statement for the 2019 Annual Meeting of Shareholders.

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

The information required by this Item 12 is incorporated herein by reference from our definitive proxy statement for the 2019 Annual Meeting of Shareholders.

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

The information required by this Item 13 is incorporated herein by reference from our definitive proxy statement for the 2019 Annual Meeting of Shareholders.

Item 14. Principal Accountant Fees and Services

The information required by this Item 14 is incorporated herein by reference from our definitive proxy statement for the 2019 Annual Meeting of Shareholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules

Consolidated Financial Statements

See Part II, Item 8 for the Consolidated Financial Statements required to be included in this Form 10-K.

Consolidated Financial Statement Schedules

All financial statement schedules are omitted because they are not applicable or the required information is included in the consolidated financial statements or notes thereto.

Exhibits

Exhibit Number	Exhibit Description
2.1†	Agreement and Plan of Merger, dated July 10, 2014, by and between Collegium Pharmaceutical, Inc., a Delaware corporation, and Collegium Pharmaceutical, Inc., a Virginia corporation.(1)
3.1†	Second Amended and Restated Articles of Incorporation of Collegium Pharmaceutical, Inc.(2)
3.2†	Amended and Restated Bylaws of Collegium Pharmaceutical, Inc.(8)
4.1†	Warrant to Purchase Stock, dated November 8, 2018, issued by Collegium Pharmaceutical, Inc. to Assertio Therapeutics, Inc.(16)
10.1†	Office Lease Agreement, dated August 28, 2012, by and between 780 Dedham Street Holdings, LLC and Collegium Pharmaceutical, Inc.(1)
10.2†	First Amendment to Lease, dated March 24, 2015, by and between Park at 95, LLC (as successor in interest to 780 Dedham Street Holdings, LLC) and Collegium Pharmaceutical, Inc.(1)
10.3†	Office Lease agreement by and between Campanelli-Trigate 100 TCD Stoughton, LLC, and Collegium Pharmaceutical, Inc as of March 23, 2018.(12)
10.4†	Second Amendment, dated October 19, 2018, to Lease by and between Park at 95, LLC and Collegium Pharmaceutical, Inc.(15)
10.5†	Loan and Security Agreement, dated August 28, 2012, by and between Silicon Valley Bank and Collegium Pharmaceutical, Inc.(1)
10.6†	First Amendment to Loan and Security Agreement, dated January 31, 2014, by and between Silicon Valley Bank and Collegium Pharmaceutical, Inc.(1)
10.7†	Assumption and Second Amendment to Loan and Security Agreement, dated August 12, 2014, by and between Silicon Valley Bank and Collegium Pharmaceutical, Inc.(1)
10.8†	Third Amendment to Loan and Security Agreement, dated September 25, 2014, by and between Silicon Valley Bank and Collegium Pharmaceutical, Inc.(1)
10.9†	Fourth Amendment to Loan and Security Agreement, dated October 31, 2014, by and between Silicon Valley Bank and Collegium Pharmaceutical, Inc.(1)
10.10†	Sixth Amendment to Loan and Security Agreement, dated January 9, 2018, by and between Collegium Pharmaceutical, Inc. and Silicon Valley Bank.(9)
10.11†	Seventh Amendment to Loan and Security Agreement, dated March 30, 2018, by and between Silicon Valley Bank and Collegium Pharmaceutical, Inc.(12)
10.12†	Amended and Restated Loan and Security Agreement, dated November 1, 2018, by and between Silicon Valley Bank and Collegium Pharmaceutical, Inc.(15)
10.13†	Subordination Agreement, dated November 14, 2014, by and among Collegium Pharmaceutical, Inc., Silicon Valley Bank and the creditors named therein.(1)
10.14†	Subordination Agreement, dated December 2, 2014, by and among Collegium Pharmaceutical, Inc., Silicon Valley Bank and the creditors named therein.(1)
10.15†	Form of Confidentiality and Inventions Agreement.(1)
10.16+†	Offer Letter, dated January 29, 2015, by and between Collegium Pharmaceutical, Inc. and Garen Bohlin.(1)
10.17†	Series D Convertible Preferred Stock Purchase Agreement, dated March 6, 2015, by and among Collegium Pharmaceutical, Inc. and the purchasers thereto.(1)
10.18+†	2015 Employee Stock Purchase Plan.(3)
10.19+†	Performance Bonus Plan.(4)
10.20(a)+†	Amended and Restated 2014 Stock Incentive Plan.(3)
10.20(b)+†	Form of Incentive Stock Option Agreement under the Amended and Restated 2014 Stock Incentive Plan.(3)
10.20(c)+†	Form of Non-Qualified Stock Option Agreement under the Amended and Restated 2014 Stock Incentive Plan.(3)
10.20(d)+†	Form of Restricted Stock Award Agreement under the Amended and Restated 2014 Stock Incentive Plan.(3)
10.21+†	Restricted Stock Award Agreement, dated April 2, 2015, by and between Collegium Pharmaceutical, Inc. and Michael T. Heffernan.(4)
10.22†	Form of Indemnification Agreement.(4)

10.23+†	Employment Agreement, dated August 4, 2015, by and between Michael Heffernan and Collegium Pharmaceutical, Inc.(5)
10.24+†	Employment Agreement, dated August 4, 2015, by and between Paul Brannelly and Collegium Pharmaceutical, Inc.(5)
10.25+†	Employment Agreement, dated May 31, 2017, by and between Collegium Pharmaceutical, Inc. and Joseph Ciaffoni.(10)
10.26+†	Employment Agreement, effective as of March 16, 2018, by and between Shirley Kuhlmann and Collegium Pharmaceutical, Inc. (12)
10.27+†	Letter Agreement dated June 4, 2018, by and between Collegium Pharmaceutical, Inc. and Michael T. Heffernan.(13)
10.28+†	Amendment to Employment Agreement, dated June 4, 2018, by and between Collegium Pharmaceutical, Inc. and Joseph Ciaffoni.(13)
10.29+†	Employment Agreement, dated July 10, 2018, by and between Collegium Pharmaceutical, Inc. and Scott Dreyer.(14)
10.30*†	License and Development Agreement, dated as of May 11, 2016, by and between Collegium Pharmaceutical, Inc. and BioDelivery Systems International, Inc.(7)
10.31*†	Commercialization Agreement, by and among, Assertio, Inc., Collegium Pharmaceutical, Inc. and Collegium NF, LLC, dated as of December 4, 2017.(11)
10.32†	Amendment dated January 9, 2018 to Commercialization Agreement by and among Assertio, Inc. and Collegium Pharmaceutical, Inc. and Collegium NF, LLC.(11)
10.33†	Amendment No. 2 to Commercialization Agreement, dated August 29, 2018, by and among Collegium Pharmaceutical, Inc., Collegium NF, LLC, and Assertio Therapeutics, Inc.(15)
10.34†	Amendment No. 3 to Commercialization Agreement, dated November 8, 2018, by and among Collegium Pharmaceutical, Inc., Collegium NF, LLC, and Assertio Therapeutics, Inc.(16)
21.1	Subsidiaries of Collegium Pharmaceutical, Inc.
23.1	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.
31.1	Certifying Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certifying Statement of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifying Statement of the Chief Executive Officer pursuant to Section 1350 of Title 18 of the United States Code.
32.2	Certifying Statement of the Chief Financial Officer pursuant to Section 1350 of Title 18 of the United States Code.
101	The following financial information from this Annual Report on Form 10-K for the year ended December 31, 2018, formatted in XBRL: (i) Consolidated Balance Sheets as of December 31, 2018, 2017, (ii) Consolidated Statements of Operations for the years ended December 31, 2018, 2017 and 2016, (iii) Consolidated Statements of Shareholders' Equity for the Years Ended December 31, 2018, 2017 and 2016, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017 and 2016, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text.

†Previously filed.

+Indicates management contract or compensatory plan.

* Subject to confidential treatment request.

(1)Previously filed as an exhibit to the registrant’s Registration Statement on Form S-1 (File No. 333-203208) filed with the Commission on April 2, 2015.

(2)Previously filed as an exhibit to the registrant’s Current Report on Form 8-K filed with the Commission on May 12, 2015.

(3)Previously filed as an exhibit to the registrant’s Registration Statement on Form S-8 (File No. 333-207744) filed with the Commission on November 2, 2015.

(4)Previously filed as an exhibit to the registrant's Registration Statement on Form S-1/A (File No. 333-203208) filed with the Commission on April 27, 2015.

(5)Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the Commission on August 10, 2015.

(6)Previously filed as an exhibit to the registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015 filed with the Commission on August 12, 2015.

(7)Previously filed as an exhibit to the registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2016 filed with the Commission on August 11, 2016.

(8)Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the Commission on December 1, 2017.

(9)Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the Commission on January 10, 2018.

(10)Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the Commission on May 31, 2017.

(11)Previously filed as an exhibit to the registrant's Annual Report on Form 10-K filed with the Commission on March 7, 2018.

(12)Previously filed as an exhibit to the registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2018 filed with the Commission on May 9, 2018.

(13) Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the Commission on June 4, 2018.

(14)Previously filed as an exhibit to the registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2018 filed with the Commission on August 8, 2018.

(15)Previously filed as an exhibit to the registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2018 filed with the Commission on November 8, 2018.

(16)Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the Commission on November 8, 2018.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

COLLEGIUM PHARMACEUTICAL, INC.

By: /s/ Joseph Ciaffoni.
Joseph Ciaffoni
Chief Executive Officer

Signature	Title	Date
/s/ Joseph Ciaffoni Joseph Ciaffoni	President and Chief Executive Officer (Principal Executive Officer) and Director	February 27, 2019
/s/ Paul Brannelly Paul Brannelly	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 27, 2019
/s/ Michael T. Heffernan, R.Ph. Michael T. Heffernan, R.Ph.	Chairman of the Board	February 27, 2019
/s/ Garen G. Bohlin Garen G. Bohlin	Director	February 27, 2019
/s/ John A. Fallon, M.D. John A. Fallon, M.D.	Director	February 27, 2019
/s/ John G. Freund, M.D. John G. Freund, M.D.	Director	February 27, 2019
/s/ David Hirsch, M.D., Ph.D. David Hirsch, M.D., Ph.D.	Director	February 27, 2019
/s/ Gwen Melincoff Gwen Melincoff	Director	February 27, 2019
/s/ Gino Santini Gino Santini	Director	February 27, 2019

/s/ Theodore R. Schroeder Theodore R. Schroeder	Director	February 27, 2019

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed by the following persons in the capacities and on the dates indicated

COLLEGIUM PHARMACEUTICAL, INC.
Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Collegium Pharmaceutical, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Collegium Pharmaceutical, Inc. and subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, shareholders' equity, and cash flows, for each of the three years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 27, 2019, expressed an unqualified opinion on the Company's internal control over financial reporting.

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 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. 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/ Deloitte & Touche LLP

Boston, Massachusetts
February 27, 2019

We have served as the Company's auditor since 2016.

COLLEGIUM PHARMACEUTICAL, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2018	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 146,633	$ 118,697
Accounts receivable	77,946	9,969
Inventory	7,817	1,813
Prepaid expenses and other current assets	5,116	3,005
Total current assets	237,512	133,484
Property and equipment, net	9,274	1,826
Intangible assets, net	44,255	—
Restricted cash	—	97
Other long-term assets	204	161
Total assets	$ 291,245	$ 135,568
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 12,150	$ 5,684
Accrued expenses	30,551	8,541
Accrued rebates, returns and discounts	144,783	15,784
Current portion of term loan payable	1,642	1,479
Total current liabilities	189,126	31,488
Other long-term liabilities	676	—
Term loan payable, long-term	9,858	—
Total liabilities	199,660	31,488
Commitments and contingencies (see Note 11)		
Shareholders’ equity:		
Preferred stock, $0.001 par value; authorized shares - 5,000,000 at December 31, 2018 and December 31, 2017; issued and outstanding shares - none at December 31, 2018 and December 31, 2017	—	—
Common stock, $0.001 par value; authorized shares - 100,000,000 at December 31, 2018 and December 31, 2017; issued and outstanding shares - 33,265,629 at December 31, 2018 and 32,770,678 at December 31, 2017	33	33
Additional paid-in capital	428,729	402,096
Accumulated deficit	(337,177)	(298,049)
Total shareholders’ equity	91,585	104,080
Total liabilities and shareholders’ equity	$ 291,245	$ 135,568

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

COLLEGIUM PHARMACEUTICAL, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)

	Years ended December 31,		
	2018	**2017**	**2016**
Product revenues, net	$ 280,413	$ 28,476	$ 1,711
Costs and expenses			
Cost of product revenues	165,677	2,595	213
Research and development	8,661	8,572	14,948
Selling, general and administrative	126,760	92,756	80,632
Total costs and expenses	301,098	103,923	95,793
Loss from operations	(20,685)	(75,447)	(94,082)
Interest expense	(20,130)	—	(94)
Interest income	1,687	582	—
Net loss	$ (39,128)	$ (74,865)	$ (94,176)
Loss per share - basic and diluted	$ (1.19)	$ (2.47)	$ (3.88)
Weighted-average shares - basic and diluted	32,953,808	30,265,262	24,262,945

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

COLLEGIUM PHARMACEUTICAL, INC.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(In thousands, except share data)

	Common Stock		Additional Paid- In Capital	Treasury Stock, at cost	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Balance at December 31, 2015	20,739,351	$ 21	$ 214,062	$ (3)	$ (129,008)	$ 85,072
Exercise of common stock options	81,831	—	443	—	—	443
Issuance for employee stock purchase plan	42,918	—	442	—	—	442
Public offerings of common stock, net of issuance costs of $845	8,500,000	8	137,332	—	—	137,340
Retirement of treasury stock	—	—	(3)	3	—	—
Stock-based compensation	—	—	5,787	—	—	5,787
Net loss	—	—	—	—	(94,176)	(94,176)
Balance at December 31, 2016	29,364,100	29	358,063	—	(223,184)	134,908
Exercise of common stock options	158,801	1	735	—	—	736
Issuance for employee stock purchase plan	110,841	—	1,141	—	—	1,141
Vesting of restricted stock units ("RSUs")	14,757	—	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs	(4,819)	—	(68)	—	—	(68)
Public offerings of common stock, net of issuance costs of $1,253	3,126,998	3	34,280	—	—	34,283
Stock-based compensation	—	—	7,945	—	—	7,945
Net loss	—	—	—	—	(74,865)	(74,865)
Balance at December 31, 2017	32,770,678	33	402,096	—	(298,049)	104,080
Exercise of common stock options	349,777	—	4,255	—	—	4,255
Issuance for employee stock purchase plan	86,929	—	1,117	—	—	1,117
Vesting of RSUs	85,119	—	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs	(26,874)	—	(560)	—	—	(560)
Stock-based compensation	—	—	13,778	—	—	13,778
Issuance of warrant	—	—	8,043	—	—	8,043
Net loss	—	—	—	—	(39,128)	(39,128)
Balance at December 31, 2018	33,265,629	$ 33	$ 428,729	$ —	$ (337,177)	$ 91,585

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

COLLEGIUM PHARMACEUTICAL, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years ended December 31,		
	2018	**2017**	**2016**
Operating activities			
Net loss	$ (39,128)	$ (74,865)	$ (94,176)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Amortization expense for Nucynta asset acquisition	109,834	—	—
Depreciation and amortization, excluding Nucynta asset acquisition	1,074	594	655
Non-cash impairment charges	—	1,845	—
Lease incentive obligation	—	(34)	(34)
Stock-based compensation expense	13,778	7,945	5,787
Non-cash interest expense	19,281	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(68,231)	(7,840)	(2,129)
Inventories	219	(497)	(1,316)
Prepaid expenses and other assets	(166)	(1,057)	(923)
Accounts payable	6,465	(3,422)	5,569
Accrued expenses	18,995	(527)	6,570
Accrued rebates, returns and discounts	106,593	15,784	—
Deferred revenue	—	(4,944)	4,944
Other long-term liabilities	676	—	—
Net cash provided by (used in) operating activities	169,390	(67,018)	(75,053)
Investing activities			
Upfront cash paid for Nucynta asset acquisition	(18,877)	—	—
Upfront cash paid for Onsolis asset acquisition	—	—	(2,500)
Purchases of property and equipment	(5,477)	(990)	(477)
Net cash used in investing activities	(24,354)	(990)	(2,977)
Financing activities			
Proceeds from issuances of common stock from public offerings, net of issuance costs of $30, $1,198 and $845, respectively	(30)	34,338	137,340
Proceeds from issuances of common stock from employee stock purchase plans	1,117	1,141	442
Repayment of asset acquisition obligations	(132,000)	—	—
Proceeds from term loan amendment	10,021	—	—
Repayment of term loan	—	(2,667)	(2,667)
Proceeds from the exercise of stock options	4,255	736	443
Payments made for employee restricted stock tax withholdings	(560)	(68)	—
Net cash (used in) provided by financing activities	(117,197)	33,480	135,558
Net increase (decrease) in cash, cash equivalents and restricted cash	27,839	(34,528)	57,528
Cash, cash equivalents and restricted cash at beginning of period	118,794	153,322	95,794
Cash, and cash equivalents and restricted cash at end of period	$ 146,633	$ 118,794	$ 153,322
Supplemental disclosure of cash flow information			
Cash paid for offering costs	$ 30	$ 1,228	$ —
Cash paid for interest	$ 582	$ 139	$ 284
Supplemental disclosure of non-cash activities			
Acquisition of property and equipment in accrued expenses	$ 3,261	$ 216	$ 81
Liabilities assumed from Nucynta asset acquisition included in accrued rebates, returns and discounts	$ 22,406	$ —	$ —
Liabilities assumed from Nucynta asset acquisition included as a reduction to accounts receivable	$ 254	$ —	$ —
Warrant issued in connection with Nucynta asset acquisition	$ 8,043	$ —	$ —

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

COLLEGIUM PHARMACEUTICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except share and per share data)

1. NATURE OF BUSINESS

Organization

Collegium Pharmaceutical, Inc. (the "Company") was incorporated in Delaware in April 2002 and then reincorporated in Virginia in July 2014. The Company has its principal operations in Stoughton, Massachusetts. The Company is a specialty pharmaceutical company committed to being the leader in responsible pain management. The Company's first product, Xtampza ER® is an abuse-deterrent, extended-release, oral formulation of oxycodone. In April 2016, the U.S. Food and Drug Administration ("FDA") approved the Company's new drug application ("NDA") filing for Xtampza ER for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. In June 2016, the Company announced the commercial launch of Xtampza ER.

The Company's product portfolio also includes Nucynta ER and Nucynta IR,(the "Nucynta Products"). In December 2017, the Company entered into a Commercialization Agreement with Assertio Therapeutics, Inc. (formerly known as Depomed) ("Assertio"), pursuant to which the Company acquired the right to commercialize the Nucynta Products in the United States and began marketing the Nucynta Products in February 2018. Nucynta ER is an extended-release formulation of tapentadol that is indicated for the management of pain severe enough to require daily, around-the-clock, long term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy in adults, and for which alternate treatment options are inadequate. Nucynta IR is an immediate-release formulation of tapentadol that is indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults.

The Company's operations are subject to certain risks and uncertainties. The principal risks include inability to successfully commercialize products, changing market conditions for products and development of competing products, changing regulatory environment and reimbursement landscape, litigation related to opioid marketing and distribution practices, manufacture of adequate commercial inventory, inability to secure adequate supplies of active pharmaceutical ingredients for each of our products, key personnel retention and protection of intellectual property, patent infringement litigation and the availability of additional capital financing on terms acceptable to the Company.

Public Offerings of Common Stock

In January 2016, the Company issued and sold in a public offering an aggregate of 2,750,000 shares of its common stock at $20.00 per share. The Company received net proceeds from this public offering of approximately $51,174, after deduction of underwriting discounts and commissions and expenses payable by the Company.

In October 2016, the Company issued and sold in a public offering an aggregate of 5,750,000 shares of its common stock at $16.00 per share. The Company received net proceeds from this public offering of approximately $86,166, after deduction of underwriting discounts and commissions and expenses payable by the Company.

Controlled Equity Offering Sales Agreement

In March 2017, the Company entered into a Controlled Equity Offering Sales Agreement (the "ATM Sales Agreement"), with Cantor Fitzgerald & Co., as sales agent ("Cantor Fitzgerald"), pursuant to which the Company may issue and sell, from time to time, through Cantor Fitzgerald, shares of the Company's common stock, up to an aggregate offering price of $60,000 (the "ATM Shares").

Under the ATM Sales Agreement, Cantor Fitzgerald may sell the ATM Shares by methods deemed to be an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the “Securities Act”), including sales made directly on The NASDAQ Global Select Market, on any other existing trading market for the ATM Shares or to or through a market maker. In addition, under the ATM Sales Agreement, Cantor Fitzgerald may sell the ATM Shares by any other method permitted by law, including in privately negotiated transactions.

The Company is not obligated to make any sales of the ATM Shares under the ATM Sales Agreement. The Company or Cantor Fitzgerald may suspend or terminate the offering of ATM Shares upon notice to the other party and subject to other conditions. The Company will pay Cantor Fitzgerald a commission of up to 3.0% of the gross proceeds from the sale of the ATM Shares pursuant to the ATM Sales Agreement and has agreed to provide Cantor Fitzgerald with customary indemnification and contribution rights.

No shares were sold pursuant to the ATM Sales during the year ended December 31, 2018. During the year ended December 31, 2017, the Company sold an aggregate of 3,126,998 ATM Shares under the ATM Sales Agreement at an average gross sales price of $11.36 per share generating net proceeds of $34,283 after deduction of underwriting discounts and commissions and expenses payable by the Company.

Basis of Accounting

The consolidated financial statements include the accounts of Collegium Pharmaceutical, Inc. as well as the accounts of its subsidiaries Collegium Securities Corp. (a Massachusetts corporation), incorporated in December 2015, and Collegium NF LLC (a Delaware limited liability company), incorporated in December 2017, both wholly owned subsidiaries requiring consolidation. The consolidated financial statements are prepared in conformity with generally accepted accounting principles in the United States of America (“GAAP”). All intercompany balances and transactions have been eliminated in consolidation.

Liquidity

The Company has experienced net losses since its inception, and as of December 31, 2018, had an accumulated deficit of $337,177. The Company expects to continue to incur net losses in the near future. A successful transition to profitable operations is dependent upon achieving a level of revenues adequate to support the Company’s cost structure.

The Company believes that its cash and cash equivalents at December 31, 2018 together with expected cash inflows from the commercialization of its products, will enable the Company to fund its operating expenses, debt service and capital expenditure requirements under its current business plan for the foreseeable future.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of consolidated financial statements in accordance with GAAP requires the Company to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues, costs and expenses and the disclosure of contingent assets and liabilities in the Company’s consolidated financial statements and accompanying notes. The most significant estimates in the Company’s consolidated financial statements relate to revenue recognition, including the estimates of product returns, units prescribed, discounts and allowances related to commercial sales of products, estimates of useful lives with respect to intangible assets, accounting for stock based compensation, contingencies, impairment of intangible assets and tax valuation reserves. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. The Company’s actual results may differ from these estimates under different assumptions or conditions.

Fair Value Measurements

Disclosures of fair value information about financial instruments are required, whether or not recognized in the balance sheet, for financial instruments with respect to which it is practicable to estimate that value. Fair value measurements and disclosures describe the fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value, as follows:

Level 1 inputs: Quoted prices (unadjusted) in active markets for identical assets or liabilities
Level 2 inputs: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly
Level 3 inputs: Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability

Transfers are calculated on values as of the transfer date. There were no transfers between Levels 1, 2 and 3 during the years ended December 31, 2018 and 2017.

The following tables present the Company's financial instruments carried at fair value using the lowest level input applicable to each financial instrument at December 31, 2018 and 2017.

December 31, 2018	Total	Quoted Prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Money market funds, included in cash equivalents	$ 92,914	$ 92,914	$ —	$ —
December 31, 2017				
Money market funds, included in cash equivalents	$ 81,225	$ 81,225	$ —	$ —

During the year ended December 31, 2018, the Company issued a warrant to purchase 1,041,667 shares of common stock of the Company to Assertio. The Company used a Black-Scholes option pricing model to determine the fair value of the warrant as of the date of issuance. This model requires Level 1 and Level 2 inputs on the valuation date, including the risk-free interest rate, the expected volatility of the Company's common stock, the remaining contractual term of the warrant and the expected dividend yield. The minimum royalty liability associated with the guaranteed future minimum royalty payments and the fair value of the warrant instrument were included as a component of the intangible asset acquired in connection with the Commercialization Agreement, which is further described in Note 9.

As of December 31, 2018, and December 31, 2017, the carrying amounts of the Company's other assets and liabilities approximated their estimated fair values.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to significant concentration of credit risk, consist primarily of cash and cash equivalents and accounts receivable. The Company maintains its cash deposits primarily with one reputable and nationally recognized financial institution. In addition, as of December 31, 2018, the Company's cash equivalents were invested in money market funds. The Company has not experienced any material losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the financial institutions in which those deposits are held.

Three customers comprised 10% or more of the Company's accounts receivable balance as of December 31, 2018. These customers comprised 54%, 26% and 16% of the accounts receivable balance, respectively. The same three customers comprised 10% or more of the Company's revenue during the year ended December 31, 2018. These customers

comprised 36%, 31% and 27% of revenue, respectively. To date, the Company has not experienced any losses with respect to the collection of its accounts receivable and believes that its entire accounts receivable balances is collectible as of December 31, 2018. The Company has no financial instruments with off-balance sheet risk of loss.

Cash and Cash Equivalents

Cash and cash equivalents include cash in readily available checking and savings accounts and money market funds. The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents.

The Company's cash equivalents, which consist of money market funds, are measured at fair value on a recurring basis. As of December 31, 2018 and 2017, the carrying amount of cash equivalents was $92,914 and $81,225, respectively, which approximates fair value and was determined based upon Level 1 inputs. Money market funds are valued using quoted market prices with no valuation adjustments applied. Accordingly, these securities are categorized as Level 1.

Inventory

Inventories are stated at the lower of cost or net realizable value. Inventory costs consist of costs related to the manufacturing of the Company's products, which are primarily the costs of contract manufacturing. The Company determines the cost of its inventories on a specific identification basis, and removes amounts from inventories on a first-in, first-out basis. If the Company identifies excess, obsolete or unsalable items, inventories are written down to their realizable value in the period in which the impairment is identified. These adjustments are recorded based upon various factors, including the level of product manufactured by the Company, the level of product in the distribution channel, current and projected demand and the expected shelf-life of the inventory components. As of December 31, 2018, cumulative estimates of excess inventory recorded as a component of cost of product revenues were immaterial.

The Company outsources the manufacturing of Xtampza ER to a sole contract manufacturer that produces the finished product. In addition, the Company currently relies on a sole supplier for the active pharmaceutical ingredient in Xtampza ER. The Company's Nucynta Commercialization Agreement partner also relies on a sole supplier to produce the finished products. Accordingly, the Company has concentration risk associated with its commercial manufacturing of Xtampza ER and the Nucynta Products.

Prior to the approval of Xtampza ER by the FDA in April 2016, the Company recorded all costs incurred related to the manufacturing of Xtampza ER as research and development expense. Subsequent to approval, the Company began capitalizing these costs as inventory as they are incurred.

The Company has capitalized $7,817 of inventory as of December 31, 2018. The Company expects sales of the capitalized units to occur during the next twelve months.

Property and Equipment

Property and equipment, including leasehold improvements, are recorded at cost. Maintenance and repair costs are expensed as incurred. Costs which materially improve or extend the lives of existing assets are capitalized. Property and equipment are depreciated when placed into service using the straight-line method based on their estimated useful lives as follows:

Asset Category	Estimated Useful Life
Machinery and equipment	5 years
Computers and office equipment	3 - 5 years
Furniture and fixtures	7 years
Leasehold improvements	Lesser of remaining lease term and estimated useful life

Costs for capital assets not yet placed into service have been capitalized as construction-in-progress, and will be depreciated in accordance with the above guidelines once placed into service.

Upon retirement or sale, the cost of assets disposed and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is recorded in the statements of operations. The Company disposed of fully depreciated assets of $905 during the year ended December 31, 2018. During the years ended December 31, 2017 and 2016 disposals were immaterial. The Company did not have any material gains or losses from the retirement, sale or disposal of property and equipment during the years ended December 31, 2018, 2017, or 2016.

Intangible Assets

The Company records the fair value of finite-lived intangible assets as of the transaction date. Intangible assets are then amortized over their estimated useful lives using either the straight-line method, or if reliably determinable, based on the pattern in which the economic benefit of the asset is expected to be utilized. The Company tests intangible assets for potential impairment whenever triggering events or circumstances present an indication of impairment. If the sum of expected undiscounted future cash flows of the intangible assets is less than the carrying amount of such assets, the intangible assets would be written down to the estimated fair value, calculated based on the present value of expected future cash flows.

Restricted Cash

Restricted cash is reported as non-current unless the restrictions are expected to be released in the next twelve months. The Company had no restricted cash as of December 31, 2018. As of December 31, 2017, the Company had restricted cash of $97, which represents cash held in a depository account at a financial institution to collateralize a conditional stand by letter of credit for the Company’s former headquarters.

Revenue Recognition

See Note 3 for further detail.

Research and Development Costs

Research and development costs are charged to expense as incurred and consist of costs incurred to further the Company’s research and development activities, including salaries and employee related costs, costs associated with conducting preclinical and clinical activities, including fees paid to third-party professional consultants and service providers, costs incurred under preclinical and clinical trial agreements, costs for laboratory supplies, costs to acquire, develop and manufacture preclinical study and clinical trial materials, facilities, depreciation and other expenses including allocated expenses for rent and maintenance of facilities.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as selling, general and administrative expense as incurred since the recoverability of such expenditures is uncertain.

Advertising and Product Promotion Costs

Advertising and product promotion costs are included in selling, general and administrative expenses and were $17,497, $11,019, and $16,328 in the years ended December 31, 2018, 2017, and 2016 respectively. Advertising and product promotion costs are expensed as incurred.

Stock-Based Compensation

The Company accounts for grants of stock options, restricted stock awards and restricted stock units to employees, including members of the board of directors, based on their grant date fair value and recognizes compensation expense over their vesting period. The Company estimates the fair value of stock options as of the date of grant using the

Black-Scholes option pricing model and restricted stock awards and restricted stock units based on the fair value of the underlying common stock as determined by management.

Income Taxes

The Company accounts for income taxes under the liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the years in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies and the absence of carryback available from results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future, in excess of its net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (i) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (ii) for those tax positions that meet the more likely than not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company will recognize interest and penalties related to uncertain tax positions within income tax expense. Any accrued interest and penalties will be included within the related tax liability. As of December 31, 2018 and December 31, 2017, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company’s statements of operations.

Net Loss per Common Share

Basic net loss per common share is calculated by dividing the net loss attributable to common shareholders by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common shareholders by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period, as determined in accordance with the treasury stock accounting method. For purposes of the diluted net loss per share calculation, stock options, warrants and unvested restricted stock units are considered potentially dilutive securities. Because the Company has reported a net loss for the years ended December 31, 2018, 2017 and 2016, diluted net loss per common share is the same as basic net loss per common share for those periods.

Recently Adopted Accounting Pronouncements

New accounting pronouncements are issued periodically by the Financial Accounting Standards Board (“FASB”) and are adopted by the Company as of the specified effective dates.

In May 2014, the FASB issued Accounting Standards Update, or ASU, 2014-09, *Revenue from Contracts with Customers* (“ASC Topic 606”), which amends the guidance for accounting for revenue from contracts with customers. This ASU supersedes the revenue recognition requirements in ASC Topic 605, *Revenue Recognition*, and creates a new ASC Topic 606, *Revenue from Contracts with Customers*. In 2015, 2016 and 2017, the FASB issued additional ASUs related to ASC Topic 606, including ASUs 2015-14, 2016-08, 2016-10, 2016-12, 2016-20, 2017-13, 2017-14, that delayed the effective date of and clarified various aspects of the new guidance, including principal versus agent considerations, identifying performance obligations, and licensing. The Company adopted ASC Topic 606, on January 1, 2018 using the modified retrospective method for all contracts not completed as of the date of adoption. The adoption of ASC Topic 606 did not have an impact on the Company’s consolidated financial position, results of operations, equity or

cash flows as of the adoption date for the year ended December 31, 2018. Refer to Note 3 for the required disclosures and a discussion of the Company's policies related to revenue recognition.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, and in November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*. The purpose of ASU 2016-15 is to reduce the diversity in presentation and classification of the following items within the Statement of Cash Flows: debt prepayments, settlement of zero coupon debt instruments, contingent consideration payments, insurance proceeds, securitization transactions and distributions from equity method investees. The update also addresses classification of transactions that have characteristics of more than one class of cash flows. ASU 2016-18 requires the Statement of Cash Flows to explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the Statement of Cash Flows. The Company adopted these new standards on January 1, 2018 using the retrospective transition method as required with respect to each period presented. The adoption of these standards did not have an impact on the Company’s consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which supersedes the lease accounting requirements in ASC Topic 840 with ASC Topic 842 and significantly impacts lessee accounting and disclosures. First, this guidance requires lessees to identify arrangements that should be accounted for as leases. Under ASU 2016-02, for lease arrangements exceeding a 12-month term, a right-of-use asset and lease obligation is recorded by the lessee for all leases, whether operating or financing, while the income statement will reflect lease expense for operating leases and interest expense for financing leases. The balance sheet amount recorded for existing leases at the date of adoption of ASU 2016-02 must be calculated using the applicable incremental borrowing rate at the date of adoption. Leases with a term of 12 months or less will be accounted for in a manner similar to ASC Topic 840 for operating leases. This guidance is effective for fiscal years beginning after December 15, 2018. Early adoption is permitted. In July 2018, the FASB issued ASU 2018-10, *Leases (Topic 842), Codification Improvements* and *ASU 2018-11, Leases (Topic 842), Targeted Improvements*, to correct unintended application of guidance and provide additional transition guidance.

The Company adopted ASU 2016-02 on January 1, 2019 under the modified retrospective method by initially applying the new standard at the adoption date and recognizing a cumulative-effect adjustment to the opening balance of retained earnings. This adoption method did not impact comparative prior periods presented. The Company utilized of the transition package of practical expedients permitted within the new standard, which, among other things, allowed the Company to carryforward the historical lease classification. The Company anticipates the adoption of ASU 2016-02 will result in a right-to-use asset and corresponding lease liability of $9,500 to $11,500 on its balance sheet primarily related to the operating lease agreements for its corporate headquarters. In addition, the Company has implemented new accounting policies, processes and controls that will be used to identify and account for leases going forward.

3. REVENUE FROM CONTRACTS WITH CUSTOMERS

The Company’s revenue to date is from sales of the Company’s products, which are primarily sold to distributors (“customers”), which in turn sell the product to pharmacies for the treatment of patients (“end users”).

Revenue Recognition

In accordance with ASC Topic 606, *Revenue from Contracts with Customers* (“ASC Topic 606”), the Company recognizes revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the

contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Adoption of ASC Topic 606, Revenue from Contracts with Customers

The Company adopted ASC Topic 606 on January 1, 2018 using the modified retrospective method. Under this method, prior periods were not retrospectively adjusted and, as a result, the reported results for 2018 reflect the application of ASC Topic 606 guidance while the reported results for 2017 were prepared under the guidance of ASC Topic 605, *Revenue Recognition* (“legacy GAAP”).

Immediately prior to the adoption date of January 1, 2018, the Company recognized revenue in accordance with legacy GAAP, or when there was persuasive evidence of an arrangement; when title and risk of loss had passed to the customer; when estimated provisions for chargebacks, rebates, sales incentives and allowances, distribution service fees, and returns were reasonably determinable; and when collectability was reasonably assured. The satisfaction of these criteria generally occurred upon delivery of products to customers, or the sell-in method of revenue recognition under legacy GAAP. The Company began recognizing revenue on the sell-in method in the third quarter of 2017. Prior to the third quarter of 2017, the Company recognized revenue when products were dispensed to end users, or the sell-through method of revenue recognition under legacy GAAP, as the Company did not have sufficient experience with product sales to estimate returns at the time product was sold to customers.

As a result of the considerations discussed above, the Company concluded that, as of the adoption date, it would record revenue net of a provision for estimated chargebacks, rebates, sales incentives and allowances, distribution service fees, and returns upon delivery of products to customers under either the sell-in method of revenue recognition under legacy GAAP or under ASC Topic 606 as of the adoption date. Therefore, the adoption of ASC Topic 606 did not have a material impact on the Company’s consolidated financial position, results of operations, equity or cash flows as of January 1, 2018. In the third quarter of 2017, the Company transitioned to the sell-in method of revenue recognition and the Company recorded a cumulative one-time $4,377 increase to revenues during the three months ended September 30, 2017. Therefore, the adoption of Topic 606 would not have had a material impact on the Company’s consolidated financial position, results of operations, equity or cash flows as of December 31, 2018.

Performance Obligations

The Company determined that performance obligations are satisfied and revenue is recognized when a customer takes control of the Company’s product, which occurs at a point in time. This generally occurs upon delivery of the products to customers, at which point the Company recognizes revenue and records accounts receivable, which represents the Company’s only contract asset. Payment is typically received 30 to 90 days after satisfaction of the Company’s performance obligations and generally does not have an effect on contract asset and contract liability balances. Under the practical expedients permitted by the rules of the adoption, the Company will expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the assets is one year or less.

Transaction Price and Variable Consideration

Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer (“transaction price”). The transaction price for product sales includes variable consideration related to chargebacks, rebates, sales incentives and allowances, distribution service fees, and returns. The Company will estimate the amount of variable consideration that should be included in the transaction price under the expected value method. These estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as the Company’s historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment

patterns. These provisions reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained and is included in net sales only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. In general, performance obligations do not include any estimated amounts of variable consideration that are constrained. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

The following table summarizes activity in each of the Company's product revenue provision and allowance categories for the year ended December 31, 2018:

	Rebates and Incentives (1)	Product Returns (2)	Trade Allowances and Chargebacks (3)
Balance at December 31, 2017	$ 12,647	$ 3,137	$ 2,256
Provision related to current period sales	243,158	17,326	68,189
Liabilities assumed from asset acquisition (4)	22,406	—	254
Changes in estimate related to prior period sales	(32)	—	—
Credits/payments made	(148,861)	(4,998)	(55,858)
Balance at December 31, 2018	$ 129,318	$ 15,465	$ 14,841

(1) Rebates and incentives includes managed care rebates, government rebates, co-pay program incentives, and sales incentives and allowances. Provisions for rebates and discounts are deducted from gross revenues at the time revenues are recognized and are included in accrued rebates, returns and discounts in the Company's Condensed Consolidated Balance Sheets.

(2) Provisions for product returns are deducted from gross revenues at the time revenues are recognized and are included in accrued rebates, returns and discounts in the Company's Condensed Consolidated Balance Sheets.

(3) Trade allowances and chargebacks include fees for distribution service fees, prompt pay discounts, and chargebacks. Trade allowances and chargebacks are deducted from gross revenue at the time revenues are recognized and are recorded as a reduction to accounts receivable in the Company's Condensed Consolidated Balance Sheets.

(4) The Company recorded a liability of $22,660 related to sales of Nucynta Products that occurred prior to the closing date of January 9, 2018, for which the Company is liable under the terms of the Nucynta Commercialization Agreement. This assumed liability, representing $22,406 of assumed rebates and incentives and $254 of assumed trade allowances and chargebacks, was recorded as a component of the intangible asset acquired.

As of December 31, 2018, the Company did not have any transaction price allocated to remaining performance obligations and any costs to obtain contracts with customers, including pre-contract costs and set up costs, were immaterial.

Disaggregation of Revenue

Product revenues, net consisted of the following:

	Year ended December 31,		
	2018	2017	2016
Xtampza ER	$ 69,383	$ 28,476	$ 1,711
Nucynta Products	211,030	—	—
Total product revenues, net	$ 280,413	$ 28,476	$ 1,711

4. LICENSE AGREEMENTS

The Company periodically enters into license and development agreements to develop and commercialize its products.

The Company's license and development agreements are as follows:

Nucynta Commercialization Agreement

On January 9, 2018 (the "Closing Date"), the Company consummated the transactions contemplated by the Nucynta Commercialization Agreement, pursuant to which Assertio agreed to grant a sublicense of certain of its intellectual property related to the Nucynta Products for commercialization in the United States. The Company began selling the Nucynta Products on January 9, 2018 and began commercial promotion of the Nucynta Products in February 2018. Pursuant to the Nucynta Commercialization Agreement, the Company paid a one-time, non-refundable license fee of $10,000 to Assertio at the closing of the Nucynta Commercialization Agreement, 6,223 for transferred inventory and $1,987 as reimbursement for prepaid expenses. The Company also assumed the existing liabilities of the Nucynta Products, including $22,660 related to sales of Nucynta Products that occurred prior to the closing date of January 9, 2018. The Nucynta Commercialization Agreement initially required the Company to pay guaranteed minimum royalty of $135,000 per year through December 2021, payable in quarterly payments of $33,750, prorated in 2018 for the Closing Date, as well as a variable royalty based on annual net sales over $233,000. Beginning January 2022 and for each year of the Nucynta Commercialization Agreement term thereafter, the Company was required to pay a variable royalty on annual net sales of the Nucynta Products, but without a guaranteed minimum.

Effective August 2018, the Company entered into a Second Amendment to the Nucynta Commercialization Agreement to clarify the mechanism for transferring title of products to be sold by the Company pursuant to the agreement and various related matters. The Second Amendment did not have an impact on the Company's financial statements.

Effective November 2018, the Company entered into the Third Amendment to the Nucynta Commercialization Agreement to adjust the royalty structure and termination clauses. Pursuant to the amended Nucynta Commercialization Agreement, the $135,000 guaranteed minimum annual royalties are eliminated, and the Company is no longer required to secure its royalty payment obligations with a standby letter of credit. Beginning on January 1, 2019 and thereafter, the Company will be conditionally obligated to make royalty payments to Assertio conditional upon net sales and based on the following royalty structure for the period between January 1, 2019 and December 31, 2021:

(i) 65% of annual net sales of the Nucynta Products up to $180,000, plus
(ii) 14% of annual net sales of the Nucynta Products between $180,000 and $200,000, plus
(iii) 58% of annual net sales of the Nucynta Products between $210,000 and $233,000, plus
(iv) 20% of annual net sales of the Nucynta Products between $233,000 and $258,000, plus
(v) 15% of annual net sales of the Nucynta Products in excess of $258,000.

The Amendment does not modify the royalties payable on sales of the Nucynta Products on and after January 1, 2022, which will remain as contemplated by the Nucynta Commercialization Agreement as in effect on January 9, 2018, based on the following royalty structure:

(i) 58% of annual net sales of the Nucynta Products up to $233,000, plus
(ii) 25% of annual net sales of the Nucynta Products between $233,000 and $258,000, plus
(iii) 17.5% of annual net sales of the Nucynta Products in excess of $258,000.

In addition, prior to January 1, 2022, if the annual net sales of the Nucynta Products are in the range of $180,000 to $243,000, the Company will be required to pay a supplemental royalty to Assertio, for ultimate payment to Grünenthal GmbH, not to exceed a maximum of 4.9% of net sales of the Nucynta Products. If annual net sales of Products are less than $180,000 in any 12-month period through January 1, 2022, or if they are less than $170,000 in any 12-month period commencing on January 1, 2022, then Assertio will have the right to terminate the Nucynta Commercialization Agreement without penalty. The Amendment further provides that the Company does not have a right to terminate the Nucynta Commercialization Agreement prior to December 31, 2021. The Company will be required to pay a $5,000 termination fee to Assertio in connection with any termination by the Company with an effective date between December 31, 2021 and December 31, 2022. In connection with execution of the Third Amendment, the Company issued a warrant to purchase 1,041,667 shares of common stock of the Company (the "Warrant") at an exercise price of $19.20 per share. The Warrant will expire in November 2022 and includes customary adjustments for changes in the

Company's capitalization.

The assets acquired, liabilities assumed, and equity interests issued by the Company in connection with the Nucynta Commercialization Agreement are further described in Note 9.

Commercialization Agreement for Onsolis

In May 2016, the Company entered into an agreement with BioDelivery Sciences International, Inc. ("BDSI") to license the rights to develop, manufacture, and commercialize Onsolis® (fentanyl buccal soluble film), or Onsolis, in the United States. Onsolis is a Transmucosal Immediate-Release Fentanyl ("TIRF") film indicated for the management of breakthrough pain in certain cancer patients. During the term of the License Agreement, milestone payments in the aggregate amount of $21,000 could become payable by the Company subject to the satisfaction of certain commercialization, intellectual property, and net sales milestones, including $4,000 upon the first commercial sale of the product in the United States. Finally, the Company was required to pay royalties in the upper teens based on annual net sales of the product in the United States.

During the year ended December 31, 2016, the Company made an upfront payment of $2,500 and recorded the payment as a component of intangible assets (the "Onsolis Intangible Asset"). No milestones were achieved, nor did any royalties become payable, under the License Agreement. On December 8, 2017, the Company, after a review of its product portfolio, provided written notice to BDSI of termination of the License and Development Agreement. The termination was effective pursuant to the terms of such agreement on March 8, 2018. Upon such termination of the License Agreement, the Company's rights to develop and commercialize Onsolis reverted to BDSI. As a result of this notice of termination, the Company determined that the carrying amount of the intangible asset was not recoverable and recognized an impairment loss of $1,845 during the year ended December 31, 2017. As of the years ended December 31, 2018 and 2017, the Onsolis net intangible asset is zero.

5. NET LOSS PER COMMON SHARE

For the years ended December 31, 2018, 2017 and 2016, the securities discussed below were anti-dilutive due to the net losses in those periods and, therefore, the number of shares used to compute basic and diluted earnings per share are the same for of those periods.

The following table presents the computations of basic and dilutive net loss per share:

	Years ended December 31,		
	2018	2017	2016
Loss attributable to common shareholders — basic and diluted	$ (39,128)	$ (74,865)	$ (94,176)
Weighted-average number of common shares used in net loss per share - basic and diluted	32,953,808	30,265,262	24,262,945
Loss per share - basic and diluted	$ (1.19)	$ (2.47)	$ (3.88)

The following potentially dilutive securities outstanding have been excluded from the computations of diluted weighted-average shares outstanding because such securities have an antidilutive impact due to losses reported (in common stock equivalent shares):

	Years ended December 31,		
	2018	2017	2016
Outstanding stock options	3,585,856	3,037,690	2,326,801
Warrants	1,041,667	2,445	2,445
Unvested restricted stock (1)	3,018	31,943	82,512
Restricted stock units	514,603	218,872	41,741

(1) - Includes shares of unvested restricted stock remaining from the early exercise of stock options.

6. INVENTORY

Inventory consisted of the following:

	As of December 31, 2018	As of December 31, 2017
Raw materials	$ 496	$ 616
Work in process	671	322
Finished goods	6,650	875
Total inventory	$ 7,817	$ 1,813

During the years ended December 31, 2018 and 2017, the aggregate charges to date related to excess inventory were immaterial. These expenses were recorded as a component of cost of product revenues.

7. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	As of December 31, 2018	2017
Prepaid regulatory fees	$ 3,035	$ 1,434
Other prepaid expenses	655	279
Prepaid insurance	340	310
Prepaid development costs	78	526
Other current assets	1,008	456
Prepaid expenses and other current assets	$ 5,116	$ 3,005

8. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	As of December 31, 2018	2017
Machinery and equipment	$ 1,613	$ 1,447
Computers and office equipment	1,277	702
Leasehold improvements	567	700
Furniture and fixtures	1,111	117
Construction-in-process	6,543	528
Total property and equipment	11,111	3,494
Less: accumulated deprecation	(1,837)	(1,668)
Property and equipment, net	$ 9,274	$ 1,826

Depreciation expense related to property and equipment amounted to $1,074, $336 and $258 for the years ended December 31, 2018, 2017 and 2016, respectively. The Company disposed of fully depreciated assets of $905 during the year ended December 31, 2018. During the years ended December 31, 2017 and 2016 disposals were immaterial.

9. INTANGIBLE ASSETS

As of December 31, 2018, the Company's only intangible asset is related to the Nucynta Commercialization Agreement.

Nucynta Intangible Asset

The Company determined the Nucynta Commercialization Agreement should be accounted for as an asset acquisition in accordance with ASC 805-50 as substantially all of the fair value of the gross assets acquired is concentrated in the sublicense of the Nucynta Products, which is a single identifiable asset. The Company concluded that the fair value estimates of the assets surrendered, liabilities incurred, and equity interests issued were more clearly evident than the fair value of the assets received, and therefore followed a cost accumulation model to determine the consideration transferred in the asset acquisition.

The table below represents the costs accumulated as of December 31, 2018, to acquire the sublicense of the Nucynta Products based on the terms of the Nucynta Commercialization Agreement, as amended:

Acquisition consideration:		
Upfront cash paid	$	18,877
Minimum royalty payment obligation [(1)]		112,719
Rebates, incentives, trade allowances and chargebacks assumed		22,660
Warrant issued		8,043
Total acquisition consideration:	$	162,299

(1) Represents $132,000 of minimum royalty payments owed under the Nucynta Commercialization Agreement discounted for present value adjustments of $19,281.

The Company then allocated the consideration transferred to the individual assets acquired on a relative fair value basis as summarized in the table below:

Assets acquired:		
Nucynta Intangible Asset	$	154,089
Inventory		6,223
Prepaid expenses		1,987
Total consideration allocated to assets acquired:	$	162,299

Under the original terms of the Nucynta Commercialization Agreement, the Company was obligated to make guaranteed annual minimum royalty payments of $537,000 to Assertio, which consisted of scheduled payments of $132,000 in 2018, $135,000 in 2019, $135,000 in 2020, and $135,000 in 2021. Due to the nature of the guaranteed minimum royalty payment obligation and the fact that it was required to be settled in cash, the Company determined that the future minimum royalty payments represented a liability that should be recorded at its fair value as of the closing date. The Company calculated the fair value of the future minimum royalty payments to be $482,300 using a discount rate of 5.7%. The discount rate was determined based on a review of observable market data of similar liabilities. The Company determined the $54,700 discount should be recognized as interest expense in the Statement of Operations using the effective interest method and over the repayment period from January 9, 2018 through December 2021. Prior to the Third Amendment to the Nucynta Commercialization Agreement, the Company recognized interest expense of $19,281 relating to the minimum royalty payments.

A summary of the costs included in the Nucynta Intangible Asset as of the acquisition date of January 9, 2018, is as follows:

Costs included in Nucynta Intangible Asset:		
Upfront cash paid	$	10,000
Transaction costs		667
Minimum royalty payment obligation [(2)]		482,300
Rebates, incentives, trade allowances and chargebacks assumed [(3)]		22,660
Total cost:	$	515,627

(2) Represents $537,000 of minimum royalty payments owed under the Nucynta Commercialization Agreement discounted for present value adjustments of $54,700.

(3) Represents $22,660 of liabilities assumed related to sales of Nucynta Products that occurred prior to the closing date of January 9, 2018, for which the Company is liable under the terms of the Nucynta Commercialization Agreement. This assumed liability, representing $22,406 of assumed rebates and incentives and $254 of assumed trade allowances and chargebacks, was recorded as a component of the intangible asset acquired as part of the Nucynta Commercialization Agreement.

Effective November 8, 2018 (the “Amendment Date”), the Company entered into the Third Amendment to the Nucynta Commercialization Agreement, which eliminated the guaranteed minimum royalty payment obligations for years 2019, 2020 and 2021. As a result, the Company remeasured the remaining contractual obligation as of the Amendment Date and recorded a reduction of the acquired intangible asset and obligation. As of December 31, 2018, the Company had paid all of the $132,000 of minimum royalty payment obligation owed under the Nucynta Commercialization Agreement for 2018.

A summary of the gross carrying amount, accumulated amortization, and net book value of the Nucynta Intangible Asset from the acquisition date through December 31, 2018 is as follows:

	Gross Carrying Value	Accumulated Amortization	Net Book Value
Cost basis as of acquisition date:	$ 515,627	$ -	$ 515,627
Amortization from acquisition date through Amendment Date	-	(107,662)	(107,662)
Adjustment due to the remeasurement of liability as of Amendment Date	(369,581)	-	(369,581)
Additional costs incurred as of Amendment Date[(4)]	8,043	-	8,043
Amortization from Amendment Date through period end	-	(2,172)	(2,172)
Total, as amended:	$ 154,089	$ (109,834)	$ 44,255

(4) Represents fair value of warrant issued in connection with the Amendment to the Nucynta Commercialization Agreement.

Warrant

In November 2018, in connection with the Third Amendment to the Nucynta Commercialization Agreement, the Company issued a warrant to purchase 1,041,667 shares of common stock of the Company at an exercise price of $19.20 per share. The terms of the warrant are fixed, with the exception of customary adjustments for changes in the Company’s capitalization. The warrant may only be settled with the issuance of shares of common stock upon exercise and will expire in November 2022. The Company has recorded the relative fair value of the warrant as a component of equity interest issued by the Company as consideration transferred in the cost accumulation model for the asset acquisition. The Company estimated the fair value of the warrant on the date of issuance to be approximately $8,043 using the Black-Scholes option-pricing model. The Company concluded that the warrant met the definition of an equity instrument and was recorded as a component of additional paid-in capital in the Company’s Consolidated Balance Sheet as of the issuance date.

Amortization

The Company has been amortizing the Nucynta Intangible Asset over its useful life, which is the period over which the asset is expected to contribute directly or indirectly to the future cash flows of the Company. The Company determined that the useful life for the intangible asset was approximately 4.0 years from the closing date of January 9, 2018. The Company will recognize amortization expense as a component of cost of product revenues in the Statement of Operations on a straight-line basis over its useful life as it approximates the period of economic benefits expected to be realized from future cash inflows from sales of the Nucynta Products. Prior to the Third Amendment to the Nucynta Commercialization Agreement, the Company had recognized $107,662 of amortization expense. As the accumulated cost basis of the intangible asset was reduced with the Third Amendment to the Nucynta Commercialization agreement on November 8, 2018, the Company will continue to prospectively amortize the residual net intangible asset on a straight-line basis over the remaining useful life. For the year ended December 31, 2018, the Company recognized amortization expense of $109,834. As of December 31, 2018, the remaining amortization period is approximately 3.0 years and estimated amortization for 2019, 2020 and 2021 is expected to be $14,752, $14,752, and $14,751.

Onsolis Intangible Asset

In May 2016, the Company entered into an agreement with BDSI to license the rights to develop, manufacture, and commercialize Onsolis, in the United States. During the year ended December 31, 2016, the Company made an upfront payment of $2,500 and recorded the payment as a component of intangible assets (the “Onsolis Intangible Asset”). On December 8, 2017, the Company, after a review of its product portfolio, provided written notice to BDSI of termination of the License and Development Agreement. The termination was effective pursuant to the terms of such agreement on March 8, 2018, and the Company’s rights to develop and commercialize Onsolis reverted to BDSI. As a result of this notice of termination, the Company determined that the carrying amount of the intangible asset was not recoverable and that the carrying amount exceeded its fair value. As such, an impairment loss of $1,845 was recognized and included as a component of sales, general and administrative expense during the year ended December 31, 2017 and the net intangible asset is zero as of the years ended December 31, 2018.

Amortization Expense

Amortization expense relating to the Company’s intangible assets for the years ended December 31, 2018, 2017 and 2016 were as follows:

	Years ended December 31,		
	2018	**2017**	**2016**
Nucynta amortization expense included in cost of product revenues	$ 109,834	$ —	$ —
Onsolis amortization expense included in selling, general and administrative expense	—	258	397
Total amortization expense	$ 109,834	$ 258	$ 397

10. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of December 31, 2018	As of December 31, 2017
Accrued cost of product revenues	$ 15,138	$ —
Accrued bonuses	4,286	2,940
Accrued inventory	3,745	—
Accrued sales and marketing	2,193	624
Accrued incentive compensation	1,806	1,790
Accrued payroll and related benefits	1,544	1,382
Accrued audit and legal	480	405
Accrued interest	274	6
Accrued development costs	—	517
Accrued other operating costs	1,085	877
Total accrued expenses	$ 30,551	$ 8,541

11. COMMITMENTS AND CONTINGENCIES

Legal Proceedings

From time to time, the Company may face legal claims or actions in the normal course of business. Except as disclosed below, the Company is not currently a party to any litigation and, accordingly, does not have any amounts recorded for any litigation related matters.

Xtampza ER Litigation

The Company filed the NDA for Xtampza ER as a 505(b)(2) application, which allows the Company to reference data from an approved drug listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book), in this case OxyContin OP. The 505(b)(2) process requires that the Company certifies to the FDA and notify Purdue Pharma, L.P. ("Purdue"), as the holder of the NDA and any other Orange Book-listed patent owners, that the Company does not infringe any of the patents listed for OxyContin OP in the Orange Book, or that the patents are invalid. The Company made such certification and provided such notice on February 11, 2015 and such certification documented why Xtampza ER does not infringe any of the 11 Orange Book listed patents for OxyContin OP, five of which have been invalidated in court proceedings. Under the Hatch-Waxman Act of 1984, Purdue had the option to sue the Company for infringement and receive a stay of up to 30 months before the FDA could issue a final approval for Xtampza ER, unless the stay was earlier terminated.

Purdue exercised its option and elected to sue the Company for infringement in the District of Delaware on March 24, 2015 asserting infringement of three of Purdue's Orange Book-listed patents (Patent Nos. 7,674,799, 7,674,800, and 7,683,072) and a non-Orange Book-listed patent (Patent No. 8,652,497), and accordingly, received a 30-month stay of FDA approval.

The Delaware court transferred the case to the District of Massachusetts. After the Company filed a partial motion for judgment on the pleadings relating to the Orange Book-listed patents, the District Court of Massachusetts ordered judgment in the Company's favor on those three patents, and dismissed the claims asserting infringement of those patents with prejudice. Upon dismissal of those claims, the 30-month stay of FDA approval was lifted. As a result, the Company was able to obtain final approval for Xtampza ER and launch the product commercially.

In November 2015, Purdue filed a follow-on suit asserting infringement of another patent, Patent No. 9,073,933. In June 2016, Purdue filed another follow-on suit asserting infringement of another non-Orange Book listed patent, Patent No.

9,155,717. In April 2017, Purdue filed another follow-on suit asserting infringement of another patent, Patent No. 9,522,919, which was late-listed in the Orange Book and therefore could not trigger any stay of FDA approval. Then, in September 2017, Purdue filed another follow-on suit asserting infringement of another non-Orange Book listed patent, Patent No. 9,693,961.

On March 13, 2018, the Company filed a Petition for Post-Grant Review ("PGR") of the ′961 patent with the Patent Trial and Appeal Board ("PTAB"). The PGR argues that the ′961 patent is invalid for lack of a written description, for lack of enablement, for indefiniteness, and as being anticipated by prior art. Purdue filed its Patent Owner Preliminary Response on July 10, 2018. The PTAB entered an order to institute post-grant review of all claims of the ′961 patent on October 4, 2018, upon a finding that it is more likely than not that the claims of the ′961 patent are unpatentable. Purdue filed its Patent Owner Response on January 30, 2019. The PTAB has scheduled oral argument on the proceedings for July 10, 2019 and, absent special circumstances, will issue a decision on the patentability of the ′961 patent by no later than October 4, 2019.

In October 2017, and in response to the filing of the Company's sNDA seeking to update the drug abuse and dependence section of the Xtampza ER label, Purdue filed another suit asserting infringement of the ′933 and ′919 patent. The Company filed a motion to dismiss that action, and the Court granted its motion on January 16, 2018.

The current suits have been consolidated by the District of Massachusetts, where Purdue asserted infringement of five patents: the ′497 patent, the ′933 patent, the ′717 patent, the ′919 patent, and the ′961 patent. The Court issued an order on September 28, 2018 in which it granted in part a motion for summary judgment filed by the Company, and in which the Court ruled that the ′497 and ′717 patents are not infringed by the Company. As a result, only the ′933, the ′919, and the ′961 patents remain in dispute. On October 16, 2018, the Company filed a motion to stay proceedings in the district court on the '961 patent pending the PGR. None of these suits are associated with any stay of FDA approval for Xtampza ER. Purdue has made a demand for monetary relief but has not quantified its alleged damages. Purdue has also requested a judgment of infringement, an adjustment of the effective date of FDA approval, and an injunction on the sale of the Company's products accused of infringement. The Company has denied all claims and seeks a judgment that the patents are invalid and/or not infringed by the Company; the Company is also seeking a judgment that the case is exceptional, with an award to the Company of its fees for defending the case.

The parties are in the early stages of fact discovery. Written discovery has commenced with depositions expected to commence during the first half of 2019. A claim construction hearing was held on June 1, 2017. On November 21, 2017, the Court issued its claim construction ruling, construing certain claims of the ′933, ′497, and ′717 patents. No trial date has been scheduled.

The Company is, and plans to continue, defending this case vigorously. At this stage, the Company is unable to evaluate the likelihood of an unfavorable outcome or estimate the amount or range of potential loss, if any.

Nucynta Litigation

On February 7, 2018, Purdue filed a patent infringement suit against the Company in the District of Delaware. Specifically, Purdue argues that the Company's sale of immediate release and extended release Nucynta infringes U.S. Patent Nos. 9,861,583, 9,867,784, and 9,872,836. Purdue has made a demand for monetary relief in its complaint but has not quantified its alleged damages.

On December 6, 2018, the Company filed an Amended Answer asserting an affirmative defense for patent exhaustion. On December 10, 2018, the Court granted the parties' stipulation for resolution of the Company's defense of patent exhaustion and stayed the action, with the exception of briefing on and resolution of the Company's Motion for Judgment on the Pleadings and any discovery related to that Motion. On December 12, 2018, the Company filed a Rule 12(c) Motion for Judgment on the Pleadings, arguing that the Purdue's claims were barred by the doctrine of patent exhaustion. Purdue filed its response on January 11, 2019 and the Company filed a reply on January 25, 2019. That Motion is currently under advisement, and, if successful, would result in a dismissal of this suit.

The Company plans to defend this case vigorously. At this stage, the Company is unable to evaluate the likelihood of an

unfavorable outcome or estimate the amount or range of potential loss, if any.

Teva Litigation

The Company has fourteen patents listed in the FDA *Orange Book* as covering the Company's abuse-deterrent product and methods of using it to treat patients: Patents Nos. 7,399,488; 7,771,707; 8,449,909; 8,557,291; 8,758,813; 8,840,928; 9,044,398; 9,248,195; 9,592,200; 9,682,075; 9,737,530, 9,763,883; 9,968,598; 10,004,729 (the "Orange Book Patents").

Teva Pharmaceuticals USA, Inc. ("Teva") filed a Notice Letter of Patent Certification against twelve of the fourteen listed Orange Book Patents (the '598 and '729 patents were listed among the Orange Book Patents after receipt of Teva's Notice Letter), alleging that they were invalid and/or not infringed by the proposed oxycodone products that are the subject of Teva's Abbreviated New Drug Application ("ANDA"). On February 22, 2018—within the 45-day period that gives the Company a 30-month stay on FDA approval of Teva's ANDA while the parties have an opportunity to litigate—the Company sued Teva in the District of Delaware on eleven of the Orange Book Patents. Teva responded to the Company's complaint on May 14, 2018, alleging that the Orange Book Patents are invalid and are not infringed by Teva's proposed ANDA products and asserting counterclaims of non-infringement and invalidity of the Orange Book Patents. The Company answered Teva's counterclaims on June 4, 2018. According to the Scheduling Order, fact discovery will close on July 30, 2019 and expert discovery will close on January 31, 2020.

Opioid Litigation

On March 19, 2018, a lawsuit was filed by multiple local governments in the Circuit Court of Crittenden County, Arkansas, against the Company and other pharmaceutical manufacturers and distributors alleging a variety of claims related to opioid marketing and distribution practices. On January 29, 2019, the Company was dismissed form this litigation without predjudice.

On March 21, 2018, the Company, along with other pharmaceutical manufacturers and distributors, were named in a class-action lawsuit filed in the Eastern District of Kentucky by a family practice clinic, on behalf of other similarly-situated healthcare providers. The action alleges violations of the Racketeer Influenced and Corrupt Organizations Act relating to opioid marketing and distribution practices. On April 14, 2018, the lawsuit was conditionally transferred by the Judicial Panel on Multi-District Litigation to the federal Prescription Opiate Multi District Litigation (the "MDL") in the Southern District of Ohio. On April 10, 2018, the conditional transfer was finalized and the lawsuit was docketed in the MDL on April 11, 2018. On May 4, 2018, the Company, along with other pharmaceutical manufacturers and distributors, were named in two lawsuits filed in the MDL by the Fiscal Court of Bourbon County, Kentucky and the Fiscal Court of Owen County, Kentucky, relating to opioid marketing and distribution practices. On June 11 and 12, 2018, the Company was named in four lawsuits filed in the MDL by a health system and various member hospitals. On September 26, 2018, the Company was named in two lawsuits filed in the MDL by the Fiscal Court of Lee County, Kentucky and the Fiscal Court of Wolfe County, Kentucky. The lawsuits allege violations of the RICO Act, fraud, public nuisance, negligence, and violations of state consumer protections laws. The lawsuits all seek, generally, penalties and/or injunctive relief. The MDL lawsuits in which the Company has been named are not designated representative cases in the MDL and, therefore, are effectively currently stayed.

On May 29, 2018, a lawsuit was filed by Bucks County, Pennsylvania against the Company and other pharmaceutical manufacturers and on June 14, 2018, a lawsuit was filed by Clinton County, Pennsylvania, against the Company and other pharmaceutical manufacturers and distributors. On June 6, 2018, a lawsuit was filed by Mercer County, Pennsylvania, against the Company and other pharmaceutical manufacturers and distributors. These lawsuits allege claims related to opioid marketing and distribution, including negligence, fraud, unjust enrichment, public nuisance, and violations of state consumer protections laws. These cases have been consolidated for discovery purposes in the Delaware County Court of Common Pleas as part of a consolidated proceeding of similar lawsuits brought by numerous Pennsylvania counties against other pharmaceutical manufacturers and distributors.

On July 30, 2018, a lawsuit was filed by the City of Worcester, Massachusetts against the Company and other pharmaceutical manufacturers and distributors. The action alleges a variety of claims related to opioid marketing and

distribution practices including public nuisance, common law fraud, negligent misrepresentation, negligence, violations of Mass Gen. Laws ch. 93A, *Section 11*, unjust enrichment and civil conspiracy. In February 2019, the City of Worcester case was transferred to the Business Litigation Session of the Superior Court. Additional lawsuits brought by cities and towns in Massachusetts were filed in December 2018 and February 2019; City of Salem, City of Framingham, Town of Lynnfield, City of Springfield, City of Haverhill, City of Gloucester, Town of Canton, Town of Wakefield; and City of Chicopee. The plaintiffs in these lawsuits are seeking to transfer and consolidate each of the additional lawsuits for possible coordination before the Business Litigation Session. The same plaintiffs' law firm has indicated it intends to file more complaints against us and other pharmaceutical manufacturers and distributors on behalf of additional Massachusetts municipalities.

The Company disputes the allegations in these lawsuits and intends to vigorously defend these actions. At this stage, the Company is unable to evaluate the likelihood of an unfavorable outcome or estimate the amount or range of potential loss, if any.

Opioid-Related Request and Subpoenas

The Company, like a number of other pharmaceutical companies, has received subpoenas or civil investigative demands related to opioid sales and marketing. The Company has received such subpoenas or civil investigative demands from the Offices of the Attorney General of each of Washington, New Hampshire, and Massachusetts. The Company is currently cooperating with the each of the foregoing states in their respective investigations.

Operating Leases

In March 2018, the Company entered into an operating lease for its new corporate headquarters (the "Stoughton Lease") pursuant to which the Company leases approximately 50,678 of rentable square feet of space, in Stoughton, Massachusetts. The Stoughton Lease commenced in August 2018 when the Company took possession of the space after tenant improvements were substantially complete. After the initial four-month free rent period following possession of the space, the operating lease will continue for a term of 10 years. The Company has the right to extend the term of the Stoughton Lease for two additional five-year terms, provided that written notice is provided to the landlord no later than 12 months prior to the expiration of the then current Stoughton Lease term. The annual base rent is $1,214, or $23.95 per rentable square foot, and will increase annually by 2.5% to 3.1% over the subsequent years. The Company recognizes rent expense on a straight-line basis over the lease term and records rent expense in excess of contractual lease payments as deferred rent liability.

The Company continues to lease 9,660 square feet of office and research space at its former corporate headquarters located in Canton, Massachusetts (the "Canton Lease"). The Canton Lease terminates in August 2020 and may be extended for an additional five years at the Company's election.

Aggregate minimum lease commitments of the Company under its non-cancelable operating leases as of December 31, 2018 are as follows:

2019	$	1,032
2020		1,305
2021		1,261
2022		1,299
2023		1,337
After 2023		8,423
Total minimum lease payments	$	14,657

Rent expense under the operating lease agreements amounted to approximately $817, $194 and $182 for the years ended December 31, 2018, 2017 and 2016, respectively. Deferred rent was approximately $734 as of December 31, 2018. Deferred rent as of December 31, 2017 was immaterial. In addition, as of December 31, 2017, the Company maintained a stand by letter of credit in connection with the Canton Lease of $97, which was classified as restricted cash in the

Consolidated Balance Sheets. As of December 31, 2018, the Company was no longer required to maintain a standby letter of credit for the Canton lease and therefore no longer has a restricted cash balance relating to the Canton Lease.

Amounts provided by the lessor related to tenant improvements are considered inducements to enter into the lease. The Company has recorded these costs in the Consolidated Balance Sheets as leasehold improvements, with the corresponding liabilities as deferred lease incentive and lease note payable. These liabilities are amortized on a straight-line basis over the term of the lease.

12. TERM LOAN PAYABLE

On August 28, 2012, the Company entered into a loan agreement ("Original Term Loan") with Silicon Valley Bank ("SVB") to borrow up to a maximum amount of $1,000. The Original Term Loan bore interest at a rate per annum of 2.25% above the prime rate fixed at the time of advance of the Original Term Loan (5.50%). The Original Term Loan was subsequently amended in 2014 and 2015 to provide for additional borrowings of up to $8,000, adjust the interest rate, extend the loan draw period, and modify loan covenants (as amended, the "Existing Term Loan"). As of December 31, 2017, the future payments under the Existing Term Loan were $1,479.

In connection with, and as a condition to, consummation of the transactions contemplated by the Nucynta Commercialization Agreement, the Company entered into a Consent and Amendment to Loan and Security Agreement (the "Consent and Amendment") with SVB to amend the Existing Term Loan. The Consent and Amendment provided the Company with a new term loan facility in an original principal amount of $11,500, which replaced the Existing Term Loan and the proceeds of which were used by the Company to finance certain payment obligations under the Nucynta Commercialization Agreement and to repay the balance of the Existing Term Loan. The Consent and Amendment also provided SVB's consent with respect to transactions contemplated by the Nucynta Commercialization Agreement.

The Consent and Amendment bears interest at a rate per annum of 0.75% above the prime rate (as defined in the Consent and Amendment). The Company will repay the Consent and Amendment in equal consecutive monthly installments of principal plus monthly payments of accrued interest, commencing in July 2019, provided that, if the Company achieves EBITDA (as defined in the Consent and Amendment) in excess of $2,500 for two (2) consecutive calendar quarters prior to June 2019, such payments will commence in January 2020. All outstanding principal and accrued and unpaid interest under the New Term Loan, and all other outstanding obligations with respect to the New Term Loan, are due and payable in full in December 2022. The Company may prepay the Consent and Amendment, in full but not in part, with a prepayment fee of (i) 3.0% of the outstanding principal balance prior to the first anniversary of the Consent and Amendment, (ii) 2.0% of the outstanding principal balance following the first anniversary of the Consent and Amendment and prior to the second anniversary of the Consent and Amendment and (iii) 1.0% of the outstanding principal balance following the second anniversary of the Consent and Amendment, plus, in each case, a final payment fee of $719. Under the Consent and Amendment, the Company will be required to maintain a liquidity ratio of at least 2.0 to 1.0. Any amounts outstanding during the continuance of any event of default under the New Term Loan will bear additional interest at the per annum rate of 5.0%.

In November 2018, the Company entered into an amended and restated Loan and Security Agreement ("New Term Loan") with SVB, that supersedes the Company's original loan agreement and subsequent amendments with SVB. The New Term Loan amended and restated the loan documentation between the Company and SVB and modified the minimum liquidity ratio to be at least 1.5 to 1.0, along with other non-material changes. The New Term Loan did not modify the Company's borrowings, interest rates, or repayment terms.

As of December 31, 2018, scheduled principle repayments under the Company's term loan are as follows:

2019	$	1,642
2020		3,286
2021		3,286
2022		3,286
Balance	$	11,500

13. EQUITY

Common Stock

As of December 31, 2018 and 2017, the Company had reserved the following shares of common stock for the issuance of shares upon the exercise of stock options and warrants and the issuance of shares under the 2015 Employee Stock Purchase Plan:

	As of December 31,	
	2018	**2017**
Options to purchase common stock	4,710,771	4,153,055
Employee stock purchase plan	788,053	547,276
Warrants	1,041,667	2,445
Total	6,540,491	4,702,776

Warrants

As of December 31, 2018, the warrant issued to Assertio in November 2018 was the Company's only outstanding warrant, which is described in greater detail in Note 9.

14. STOCK-BASED COMPENSATION

Stock Options, Restricted Stock Awards and Restricted Stock Units

In May 2015, the Company adopted the Amended and Restated 2014 Stock Incentive Plan (the "Plan"), under which an aggregate of 2,700,000 shares of common stock were authorized for issuance to employees, officers, directors, consultants and advisors of the Company, plus an annual increase to be added on the first day of each fiscal year until the expiration of the Plan equal to 4% of the total number of outstanding shares of common stock on December 31st of the immediately preceding calendar year (or a lower amount as otherwise determined by the board of directors prior to January 1st). As of December 31, 2018, 1,166,529 shares of common stock were available for issuance pursuant to the Plan. The Plan provides for granting of both Internal Revenue Service qualified incentive stock options ("ISOs") and non-qualified options ("NQs"), restricted stock awards ("RSAs") and restricted stock units ("RSUs"). Stock options generally vest over a four year period of service. The options generally have a ten year contractual life and, upon termination, vested options are generally exercisable between one and three months following the termination date, while unvested options are forfeited immediately.

Stock option activity under the Plan is summarized as follows:

	Shares	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2017	3,037,690	$ 13.00	8.4	$ 16,829
Granted	1,159,280	23.76		
Exercised	(349,777)	12.17		
Cancelled	(261,337)	17.83		
Outstanding at December 31, 2018	3,585,856	$ 16.20	8.0	$ 11,170
Exercisable at December 31, 2018	1,608,346	$ 12.63	7.2	$ 7,690
Vested and expected to vest at December 31, 2018	3,389,023	$ 15.97	7.9	$ 10,882

The total intrinsic value of stock options exercised for the year ended December 31, 2018 was $3,970. As of December 31, 2018, the unrecognized compensation cost related to outstanding options was $19,285, and is expected to be recognized as expense over approximately 2.4 years.

As of December 31, 2018, the weighted-average grant date fair value of vested options was $8.38. The weighted-average grant date fair value of options granted during the year ended December 31, 2018 was $14.51. The weighted-average grant date fair value of options that vested during the year ended December 31, 2018 was $8.11.

Restricted stock awards under the Plan are summarized as follows:

	Shares (1)	Weighted-Average Purchase Price per Share
Unvested at December 31, 2017	10,816	$ 5.73
Granted	—	—
Vested	(10,816)	5.73
Unvested at December 31, 2018	—	$ —

(1) Excludes 3,018 shares of unvested restricted stock remaining from the early exercise of stock options as of December 31, 2018.

The total fair value of restricted stock awards vested during the year ended December 31, 2018, was $62. As of December 31, 2018, there is no unrecognized compensation cost related to restricted stock awards.

Restricted stock units under the Plan are summarized as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2017	218,872	$ 12.64
Granted	403,334	23.41
Vested	(85,119)	13.00
Forfeited	(22,484)	20.84
Outstanding at December 31, 2018	514,603	$ 20.67

As of December 31, 2018, the unrecognized compensation cost related to restricted stock units was $7,987 and is expected to be recognized as expense over approximately 2.4 years.

Employee Stock Purchase Plan

The Company's 2015 Employee Stock Purchase Plan allows employees as designated by the Company's Board of Directors to purchase shares of the Company's common stock. The purchase price is equal to 85% of the lower of the closing price of the Company's common stock on (1) the first day of the purchase period or (2) the last day of the purchase period. The first purchase period commenced in the year ended December 31, 2016. The expense for the years ended December 31, 2018, 2017 and 2016 was $493, $380 and $457, respectively.

Stock-Based Compensation Expense

The Company granted stock options to employees for the years ended December 31, 2018, 2017 and 2016. The Company estimates the fair value of stock options as of the date of grant using the Black-Scholes option pricing model and restricted stock awards and restricted stock units based on the fair value of the award.

Stock-based compensation for all stock options, restricted stock awards, restricted stock units and for the employee stock purchase plan are reported within:

	Years ended December 31,		
	2018	2017	2016
Research and development	$ 1,468	$ 888	$ 638
Selling, general and administrative	12,310	7,057	5,149
Total stock-based compensation expense	$ 13,778	$ 7,945	$ 5,787

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee stock option grants were as follows:

	Year ended December 31,		
	2018	2017	2016
Risk-free interest rate	2.6 %	2.0 %	1.5 %
Volatility	64.8 %	71.0 %	76.3 %
Expected term (years)	6.11	6.01	6.02
Expected dividend yield	— %	— %	— %

Risk-free Interest Rate. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the stock option grants.

Expected Volatility. Due to the Company's limited operating history and lack of company-specific historical or implied volatility, the expected volatility assumption is based on the Company's volatility as well as the historical volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology and pharmaceutical industries. In evaluating similarity, the Company considers factors such as industry, stage of life cycle and size.

Expected Term. The expected term represents the period of time that options are expected to be outstanding. Because the Company does not have historical exercise behavior through December 31, 2018 it determined the expected life assumption using the simplified method, which is an average of the contractual term of the option and its vesting period.

Expected Dividend Yield. The expected dividend yield assumption is based on the fact that the Company has never paid cash dividends and has no present intention to pay cash dividends.

15. INCOME TAXES

For the years ended December 31, 2018, 2017 and 2016, the Company did not record a current or deferred income tax

expense or (benefit) due to current and historical losses incurred by the Company. The Company's losses before income taxes consist solely of losses from domestic operations.

The enactment of the *Tax Cuts and Jobs Act (TCJA)* in December 2017, as further described below, resulted in a remeasurement of the Company's net deferred tax asset due to the reduction in corporate rates from 35% to a 21% flat tax, which is included in the Company's 2017 rate reconciliation. A reconciliation of income tax expense (benefit) computed at the statutory federal income tax rate to income taxes as reflected in the consolidated financial statements is as follows:

	As of December 31,		
	2018	**2017**	**2016**
Federal income tax expense at statutory rate	21.00 %	34.00 %	34.00 %
(Increase) decrease income tax (benefit) resulting from:			
State income tax, net of federal benefit	5.89	3.93	3.43
Permanent differences	(2.51)	(2.49)	(1.45)
U.S. - TCJA	—	(43.32)	—
Research and development credit	0.52	0.53	0.27
Change in valuation allowance	(24.90)	7.35	(36.25)
Effective income tax rate	0.00 %	0.00 %	0.00 %

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets and liabilities are comprised of the following:

	As of December 31,		
	2018	**2017**	**2016**
Deferred tax assets:			
U.S. and state net operating loss carryforwards	$ 82,501	$ 62,715	$ 71,049
Research and development credits	4,364	3,892	3,712
Accruals and other	4,676	3,615	1,541
Depreciation and amortization	269	145	261
Total deferred tax assets	91,810	70,367	76,563
Valuation allowance	(80,290)	(70,367)	(76,563)
Deferred tax assets after valuation allowance	11,520	—	—
Deferred tax liabilities – intangible assets	(11,520)	—	—
Net deferred tax assets	$ —	$ —	$ —

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. As of December 31, 2018, and December 31, 2017, based on the Company's history of operating losses, the Company has concluded that it is not more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of December 31, 2018 and December 31, 2017. The valuation allowance increased $9,923 during the year ended December 31, 2018 due primarily to net operating losses generated during the year. The valuation allowance decreased $6,196 during 2017 primarily due to the enacted change in the corporate income tax rate from the enactment of TCJA signed into law in December 2017.

As of December 31, 2018, 2017, and 2016, the Company had U.S. federal net operating loss carryforwards of $324,533, $249,511, and $190,926, respectively, which may be available to offset future income tax liabilities. TCJA will generally allow losses incurred after 2017 to be carried over indefinitely but will generally limit the NOL deduction to the lesser of the NOL carryover or 80% of a corporation's taxable income (subject to Code Section 382/383). Also, there will be no carryback for losses incurred after 2017. Losses incurred prior to 2018 will generally be deductible to the extent of the lesser of a corporation's NOL carryover or 100% of a corporation's taxable income (subject to Code Section 382/383)

and be available for twenty years from the period the loss was generated.

As of December 31, 2018, 2017, and 2016, the Company also had U.S. state net operating loss carryforwards of $285,181, $205,074, and $145,902, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2038.

As of December 31, 2018, 2017 and 2016, the Company had federal research and development tax credit carryforwards of approximately $3,628, $3,426, and $3,367, respectively, available to reduce future tax liabilities which expire at various dates through 2038. As of December 31, 2018, 2017 and 2016 the Company had state research and development tax credit carryforwards of approximately $885, $589, and $522, respectively, available to reduce future tax liabilities which expire at various dates through 2033.

The TCJA was enacted in December 2017. Among other things, the TCJA reduces the U.S. federal corporate tax rate from 35 percent to 21 percent beginning in 2018. During 2018 the Company finalized its review of the impact of TCJA on the NOL rules and determined its impact on its NOL carryovers. The impact of TCJA to the Company was primarily attributable to the limitation on the deductions associated with executive compensation under Internal Revenue Code Section 162(m). The Company made adjustments during 2018 to its carryovers associated with its analysis of TCJA so that as of December 31, 2018, the Company's NOL carryovers have been adjusted to comply with the impact of TCJA's changes to the tax treatment of executive compensation under Internal Revenue Code Section 162(m). Since a full valuation allowance has been provided against the Company's net deferred tax asset, the impact of adjustments during 2018 to the net deferred tax asset associated with the impact of TCJA does not result in any financial statement impact.

Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50 percent, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed numerous financings as well as its IPO since its inception. The Company has not completed a current study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since its formation. As a result, if the Company earns net taxable income, its ability to use its pre-change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

The Company files income tax returns in the United States and in several states. The federal and state income tax returns are generally subject to tax examinations for the tax years ended December 31, 2015 through December 31, 2018. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities to the extent utilized in a future period. The Company originally recorded an unrecognized tax benefit of $902 (net rate effected unrecognized tax benefit of $235) during 2017 associated with its IRS examination of its 2015 federal income tax return, and accordingly reduced its NOL deferred tax asset during 2017. The Company settled its IRS audit during 2018, which resulted in a total decrease to its NOL carryover of $36. As a result of the IRS settlement, the Company reversed this unrecognized tax benefit and trued-up its NOL carryover during 2018 to reflect the reduction of the $36 to its NOL as required by the IRS settlement. This is included in the tabular rollforward below of gross unrecognized tax benefits. Since a full valuation allowance has been provided against the Company's net operating loss carryover, the true up of the NOL carryover and associated deferred tax asset during 2018 does not result in any financial statement impact.

For all years through December 31, 2018, the Company generated research credits but has not conducted a study to document the qualified activities. This study may result in an adjustment to the Company's research and development credit carryforwards. The Company has reduced its deferred tax asset for its estimate of credits that could be reduced, and that is included in the tabular rollforward of uncertain tax positions. Since a full valuation allowance has been

provided against the Company's research and development credits the reduction in the gross deferred tax asset established for the research and development credit carryforwards does not result in any financial statement impact.

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits (UTB) is as follows:

	As of December 31,	
	2018	2017
Gross UTB Balance at January 1	$ 1,364	$ —
Additions based on tax positions related to the current year	64	57
Additions for tax positions of prior years	—	1,307
Reductions for tax positions of prior years	(24)	—
Settlements	(902)	—
Reductions due to lapse of applicable statute of limitations	—	—
Gross UTB Balance at December 31	502	1,364
Net UTB impacting the effective tax rate at December 31 (included in the change in the valuation allowance in rate reconciliation)	$ 481	$ 680

16. EMPLOYEE BENEFITS

The Company has a retirement savings plan, which is qualified under section 401(k) of the Code, for its employees. The plan allows eligible employees to defer, at the employee's discretion, pretax compensation up to the Internal Revenue Service annual limits. Employees become eligible to participate starting on the first day of employment. The Company is not required to contribute to this plan. Total expense for contributions made by the Company for the years ended December 31, 2018, 2017 and 2016 was $1,208, $969 and $613 respectively.

17. UNAUDITED QUARTERLY OPERATING RESULTS

The following is a summary of unaudited quarterly results of operations for the years ended December 31, 2018 and 2017:

Year ended December 31, 2018	First Quarter	Second Quarter	Third Quarter	Fourth Quarter (2)
Product revenues, net	$ 63,749	$ 73,061	$ 70,176	$ 73,427
Costs and expenses				
Cost of product revenues	43,106	46,838	46,007	29,726
Research and development	2,268	2,237	1,907	2,249
Selling, general and administrative	31,582	31,279	33,448	30,451
Total costs and expenses	76,956	80,354	81,362	62,426
Loss from operations	$ (13,207)	$ (7,293)	$ (11,186)	$ 11,001
Interest expense	(5,700)	(6,158)	(5,868)	(2,404)
Interest income	255	391	552	489
Net loss	$ (18,652)	$ (13,060)	$ (16,502)	$ 9,086
Weighted-average shares - basic	32,903,674	32,967,718	33,012,174	33,250,180
(Loss) earnings per share - basic	$ (0.57)	$ (0.40)	$ (0.50)	$ 0.27
Weighted-average shares - diluted	32,903,674	32,967,718	33,012,174	33,769,765
(Loss) earnings per share - diluted	$ (0.57)	$ (0.40)	$ (0.50)	$ 0.27

Year ended December 31, 2017	First Quarter	Second Quarter	Third Quarter (1)	Fourth Quarter
Product revenues, net	$ 2,172	$ 3,560	$ 11,950	$ 10,794
Costs and expenses				
Cost of product revenues	371	577	553	1,094
Research and development	2,130	2,179	2,069	2,194
Selling, general and administrative	22,847	22,062	22,758	25,089
Total costs and expenses	25,348	24,818	25,380	28,377
Loss from operations	$ (23,176)	$ (21,258)	$ (13,430)	$ (17,583)
Interest income	98	137	167	180
Net loss	$ (23,078)	$ (21,121)	$ (13,263)	$ (17,403)
Weighted-average shares - basic and diluted	29,350,268	29,441,514	29,753,043	32,485,572
Loss per share - basic and diluted	$ (0.79)	$ (0.72)	$ (0.45)	$ (0.54)

(1) - In the third quarter of 2017, the Company recorded a one-time $4,377 increase to revenues as a result of the Company's change to the sell-in method in the third quarter of 2017.
(2) - In the fourth quarter of 2018, the Company executed the Third Amendment to the Nucynta Commercialization Agreement, which eliminated the guaranteed minimum royalty payment obligations after 2018. As a result, the Company remeasured the remaining contractual obligation as of the Amendment Date and reduced the intangible asset. Consequently, amortization expense included within cost of product revenues was $15,494 in the fourth quarter compared to $32,407, $32,407 and $29,526 in the third, second and first quarters, respectively. Similarly, interest expense associated with the minimum royalty payments was $2,169 in the fourth quarter compared to $5,641, $5,943 and $5,528 in the third, second and first quarters, respectively. See Note 9 for further detail.

Exhibit 21.1

Subsidiaries of Collegium Pharmaceutical, Inc.

Subsidiary	Jurisdiction of Incorporation
Collegium Securities Corporation	Massachusetts
Collegium NF, LLC	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-213964 on Form S-3 and Registration Statement Nos. 333-207744, 333-218767 and 333-225498 on Form S-8 of our reports dated February 27, 2019, relating to the consolidated financial statements of Collegium Pharmaceutical, Inc. and subsidiaries (the “Company”), and the effectiveness of the Company's internal control over financial reporting, appearing in this Annual Report on Form 10-K of Collegium Pharmaceutical Inc. for the year ended December 31, 2018.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
February 27, 2019

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joseph Ciaffoni, certify that:

1. I have reviewed this annual report on Form 10-K of Collegium Pharmaceutical, Inc.;

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

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

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

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

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

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

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

5. The registrant's other certifying officer 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.

/s/ JOSEPH CIAFFONI
Joseph Ciaffoni
President and Chief Executive Officer

Dated: February 27, 2019

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Paul Brannelly, certify that:

1. I have reviewed this annual report on Form 10-K of Collegium Pharmaceutical, Inc.;

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

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

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

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

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

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

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

5. The registrant's other certifying officer 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.

Dated: February 27, 2019

/s/ PAUL BRANNELLY
Paul Brannelly
Executive Vice President and 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 Collegium Pharmaceutical, Inc. (the "Company") for the fiscal year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Joseph Ciaffoni, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(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: February 27, 2019

/s/ JOSEPH CIAFFONI
Joseph Ciaffoni
President and Chief Executive Officer

Exhibit 32.2

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

In connection with the annual report on Form 10-K of Collegium Pharmaceutical, Inc. (the "Company") for the fiscal year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Paul Brannelly, Executive Vice President and Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(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: February 27, 2019

/s/ PAUL BRANNELLY
Paul Brannelly
Executive Vice President and Chief Financial Officer