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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, 2016

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)
780 Dedham Street, Suite 800 **Canton, MA** (Address of principal executive offices)	**02021** (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 and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted 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 and post 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, or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☒	Non-accelerated filer ☐ (Do not check if smaller reporting company)	Smaller reporting company ☐

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, 2016, 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 $197 million, based on the closing price of the registrant's common stock on The NASDAQ Global Select Market on June 30, 2016 of $11.85 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 March 1, 2017, there were 29,448,609 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 2017 Annual Meeting of Shareholders (the "Proxy Statement"), to be filed within 120 days of the registrant's year ended December 31, 2016, 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 obtain and maintain regulatory approval of our products and product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product;
- our plans to commercialize our product candidates and grow sales of our products;
- the size and growth potential of the markets for our products and product candidates, and our ability to service those markets;
- the success of competing products that are or become available;
- our ability to obtain reimbursement and third-party payor contracts for our products;
- the costs of commercialization activities, including marketing, sales and distribution;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- the rate and degree of market acceptance of our products and product candidates;
- changing market conditions for our products and product candidates;
- the outcome of any patent infringement or other litigation that may be brought against us, including litigation with Purdue Pharma, L.P.;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- the success, cost and timing of our product development activities, studies and clinical trials;
- our ability to obtain funding for our operations;
- regulatory developments in the United States and foreign countries;
- our expectations regarding our ability to obtain and adequately maintain sufficient intellectual property protection for our products and product candidates;
- our ability to operate our business without infringing the intellectual property rights of others;
- the performance of our third-party suppliers and manufacturers;
- our ability to comply with stringent U.S. and foreign government regulation in the manufacture of pharmaceutical products, including U.S. Drug Enforcement Agency, or DEA, compliance;
- the loss of key scientific or management personnel;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act; and
- the accuracy of our estimates regarding expenses, revenue, capital requirements and need for additional financing.

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 developing and commercializing next-generation abuse-deterrent products that incorporate our patented DETERx platform technology for the treatment of chronic pain and other diseases. Our first product, Xtampza, is an abuse-deterrent, extended-release, oral formulation of oxycodone, a widely prescribed opioid medication. In April 2016, the U.S. Food and Drug Administration, or FDA, approved our new drug application, or NDA, filing for Xtampza 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. Certain human abuse potential studies are included in the approved label, as well as data supporting the administration of the product as a sprinkle or administered through feeding tubes. In June 2016, we announced the commercial launch of Xtampza. In October 2016, we announced the submission of a New Drug Submission to Health Canada seeking marketing approval of Xtampza for the same indication for which we obtained approval from the FDA.

Xtampza has the same active ingredient as OxyContin OP, which is the largest selling abuse-deterrent, extended-release opioid in the United States by dollars, with $2.1 billion in U.S. sales in 2016. We conducted a comprehensive preclinical and clinical program for Xtampza consistent with FDA guidance on abuse-deterrence. These studies and clinical trials demonstrated that chewing, crushing and/or dissolving Xtampza, and then taking it orally or smoking, snorting, or injecting it did not meaningfully change its drug release profile or safety characteristics. By contrast, clinical trials performed by us and others — including head-to-head clinical trials comparing Xtampza with OxyContin OP — have shown that drug abusers can achieve rapid release and absorption of the active ingredient by manipulating OxyContin OP using common household tools and methods commonly available on the Internet. In October 2016, we announced the submission of a Supplemental New Drug Application to the FDA for Xtampza to include comparative oral pharmacokinetic data from a recently completed clinical study evaluating the effect of physical manipulation by crushing Xtampza compared with OxyContin OP and a control (oxycodone hydrochloride immediate-release).

In addition, our preclinical studies and clinical trials have shown that the contents of the Xtampza capsule can be removed from the capsule and sprinkled on food or into a cup, and then directly into the mouth, or administered through feeding tubes, without compromising their drug release profile, safety or abuse-deterrent characteristics. By contrast, OxyContin OP, which is formulated in hard tablets, has a black box warning label stating that crushing, dissolving, or chewing can cause rapid release and absorption of a potentially fatal dose of the active ingredient. We believe that Xtampza can address the pain management needs of the approximately 11 million patients in the United States who suffer from chronic pain and have difficulty swallowing.

In May 2016, we entered into a License and Development Agreement with BioDelivery Science International, Inc. which grants us an exclusive license to make, use, sell, offer for sale, import, develop and commercialize Onsolis in the United States. Onsolis is a Transmucosal Immediate-Release Fentanyl film indicated for the management of breakthrough pain in cancer patients 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. We plan to commercialize Onsolis upon receipt of FDA approval of a Prior Approval Supplement for the manufacturing transfer. Subject to such approval, we expect to launch Onsolis in the first half of 2018.

Since 2010, when we divested our former subsidiary, Onset Therapeutics, LLC, to PreCision Dermatology, Inc., we have devoted substantially all of our resources to the development of our patented DETERx platform technology, the preclinical and clinical advancement of our product candidates, pre-commercialization activities and the creation and protection of related intellectual property. Since 2011, we have not generated any significant revenue from product sales and we continue to incur significant research, development and other expenses related to our ongoing operations. Prior to our initial public offering of common stock, or IPO, in May 2015, we funded our operations primarily through the private placement of preferred stock, convertible notes and commercial bank debt. Since our IPO, we have funded our operations primarily through the proceeds of public offerings and sale of our equity securities.

Background on Chronic Pain and Opioid Abuse

Patients Suffering from Chronic Pain

Chronic pain, typically defined as pain that lasts beyond the healing of an injury or that persists longer than three months, is a worldwide problem with serious health and economic consequences. According to the National Institutes of Health, or NIH, chronic pain represents a public health crisis of epidemic proportions affecting approximately 100 million people in the United States and 20-30% of the population worldwide — more than heart disease, cancer and diabetes combined. Common types of chronic pain include lower back pain, arthritis, headache, and face and jaw pain. The prevalence of chronic pain is expected to rise in the future, as the incidence of associated illnesses such as diabetes, arthritis and cancer increases in the aging population.

Chronic pain leads to over $560 billion in healthcare and productivity costs each year according to the Institute of Medicine. Prescription opioids remain the primary treatment for chronic pain. Chronic pain patients often start treatment with immediate release opioids, but change to extended-release opioids to achieve more convenient dosing with more consistent blood levels of the active drug. Extended-release opioids incorporate a large amount of opioid with a time-release mechanism designed to deliver steady amounts of opioid, typically over 12 to 24 hours.

Annual sales from extended-release and long-acting opioids represent approximately $5.7 billion (24 million prescriptions) of the approximately $14 billion U.S. opioid market in 2016. OxyContin OP generated U.S. sales of $2.1 billion in 2016, which represents approximately a 16% U.S. market share of all extended-release and long-acting opioid prescriptions.

Prescription Opioid Abuse is an Epidemic in the United States

Abusers tamper with extended-release opioid drugs to achieve the euphoria that results from rapid increases in the blood concentration of the active 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 growing and deadly epidemic. Deaths in the United States from prescription opioid overdose have grown from approximately 4,000 in 1999 to approximately 16,000 in 2013.

According to a 2012 study conducted by the CDC, annually there are 144,000 treatment admissions for abuse or misuse of opioids, 560,000 emergency room visits for misuse or abuse of opioids, over 2.5 million individuals who abuse or are dependent on opioids and over 7.3 million non-medical users who use opioids without prescriptions or for non-therapeutic effects. The American Journal of Managed Care estimated in a 2013 report that opioid abuse costs public and private healthcare payors over $72 billion annually in direct healthcare costs, including costs of emergency room visits, rehabilitation and associated health problems.

The FDA has estimated that nearly 35 million Americans have used prescription pain relievers, including opioid-containing drugs, for non-prescription purposes at least once in their lifetime. A 2011 research report from the Substance Abuse and Mental Health Services Administration estimated that between 1999 and 2009 there was a 430% increase in substance-abuse treatment facility admissions resulting from the use of prescription pain relievers. According to a 2011 study by the University of Michigan, one in 12 high school seniors reported non-medical use of Vicodin, a combination of acetaminophen and hydrocodone, and one in 20 high school seniors reported non-medical use of OxyContin.

Drug abusers find currently approved extended-release opioids desirable because of the large amount of drug payload, which they attempt to release quickly into the bloodstream to create euphoria. It is difficult for drug abusers to achieve this rapid release and absorption into the bloodstream by taking multiple intact extended-release opioid tablets or capsules because doing so often causes sleepiness and/or respiratory distress before euphoria is achieved. Instead, abusers attempt to defeat the extended-release properties in order to achieve rapid release of the active ingredient.

Despite the introduction of OxyContin OP in 2010 as the first FDA-approved, abuse-deterrent extended-release opioid formulation, abuse of extended-release opioids, including OxyContin OP, continues to be a major public health issue. OxyContin OP, even with its abuse-deterrent formulation, remains vulnerable to abuse using common household objects, like pill crushers. Third party studies found that abusers of OxyContin OP use various routes of abuse — including snorting, injection and oral abuse — despite its abuse-deterrent features. In a third party study of OxyContin abusers both before and after OxyContin OP was introduced, researchers found that while the non-oral route of administration of abuse of OxyContin OP (i.e., injection, snorting and smoking) decreased after its introduction, oral abuse of OxyContin OP increased from approximately 52% to 75% of OxyContin abusers.

OxyContin OP Tablet + $6.39 Pill Crusher = Abuseable Fine Powder in 16 Seconds

Legislative and Regulatory Actions

In response to widespread prescription opioid abuse, the U.S. government and a number of state legislatures have introduced, and in some cases have enacted, legislation and regulations intended to encourage the development of abuse-deterrent forms of pain medications. The FDA has stated that addressing prescription drug abuse is a priority, and the development of abuse-deterrent opioids is a key part of that strategy.

In 2010, Purdue received approval for a new formulation of OxyContin, named OxyContin OP, designed to make it more difficult to abuse. In April 2013, the FDA approved new product labeling for OxyContin OP, which, for the first time included abuse-deterrent product label claims consistent with the FDA's January 2013 draft abuse-deterrent product label guidance. At the same time, the FDA withdrew the approval of the original, non-abuse-deterrent OxyContin formulation, thus preventing the commercialization of generic versions of the original OxyContin that did

not have abuse-deterrent properties. This decision by the FDA is consistent with its public statement that the development of abuse-deterrent opioid analgesics is a public health priority.

Recent actions to address the opioid abuse epidemic include:

- *STOPP Act:* In July 2012, a bipartisan group of Congressional leaders introduced the STOPP (Stop the Tampering of Prescription Pills) Act. Reintroduced in February 2013, this bill, if approved, would require that non-abuse-deterrent opioids be removed from the market if an abuse-deterrent formulation of that opioid has already been approved for marketing by the FDA. Since being reintroduced in 2013, this bill was referred to the U.S. House of Representatives' Subcommittee on Health and there has been no further action taken. This bill has since been reintroduced in the U.S. House of Representatives and was referred to the Subcommittee on Health in May 2015, with no further action taken since.

- *FDA guidance:* In January 2013, the FDA introduced draft 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 draft guidance described 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 assess the real-world impact of a potentially abuse-deterrent formulation. These requirements were largely adopted in the April 2015 final FDA guidance, which also provides examples of product label claims that may be made based on the results of the corresponding studies and clinical trials.

- *48 state and territorial attorneys general support development of abuse-deterrent opioids:* In March 2013, the National Association of Attorneys General urged the FDA to adopt standards requiring manufacturers and marketers of prescription opioids to develop abuse-deterrent versions of those products. Their letter, signed by 48 state and territorial attorneys general, commended the FDA for expeditiously proposing guidance that establishes clear standards for manufacturers who develop and market abuse-resistant opioid products, while considering incentives for undertaking the research and development necessary to bring such products to market. It also encouraged the FDA to ensure that generic versions of such products are designed with similar abuse-resistant features.

- *FDA mandated product label changes:* On September 10, 2013, the FDA announced its intention to require product label changes to all approved extended-release and long-acting opioids. In particular, the FDA announced its intention to update the indications for these opioids so that they will be indicated only 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. On April 16, 2014, the FDA updated these indications. The FDA also requires post-marketing studies and clinical trials for any such opioids.

- *29 state and territorial attorneys general speak out against the approval of non-abuse-deterrent narcotics:* In December 2013, the attorneys general of 29 states and territories urged the FDA to reconsider its approval of Zohydro™ ER, an extended-release hydrocodone formulation with no abuse-deterrent properties, or alternatively to set a rigorous timeline for reformulation of Zohydro ER in an abuse-deterrent form, with significant limitations on prescriptions of Zohydro ER in the interim. In early 2014, members of Congress from three states introduced a bill to revoke FDA approval of Zohydro ER and prevent the FDA from approving any new opioids that do not have abuse-deterrent features and the governor of Massachusetts signed an executive order (since overturned by a court) that attempted to ban the dispensing of Zohydro ER in Massachusetts.

- *Massachusetts and Maine approved laws to mandate that insurers cover abuse-deterrent opioids:* In August 2014 and June 2015, the governors of Massachusetts and Maine, respectively, signed laws establishing a drug formulary commission charged with identifying drugs with a heightened public health risk due to their potential for abuse and formulations of abuse-deterrent drugs that may be substituted for these drugs that have a heightened public health risk. When a prescriber writes a prescription for an opioid identified as having a heightened public health risk, the pharmacist must dispense an interchangeable abuse-deterrent product from the formulary, if one exists, except when the prescriber indicates "no substitution." The Massachusetts and Maine laws also require insurers to cover abuse-deterrent opioid drugs on a basis not less favorable than corresponding non-abuse-deterrent drugs. Several other states have enacted or are in the process of introducing similar legislation, including Florida, Maryland and West Virginia.

- *FDA held public meeting to discuss abuse-deterrent opioid formulations:* In September 2014, the FDA announced a public meeting to discuss the development, assessment and regulation of opioid medications. In its public notice, the FDA stated that it "looks forward to a future in which all or substantially all opioid medications are less susceptible to abuse than the conventional formulations that dominate the market today." In October 2014, the FDA held the public meeting with key stakeholders to solicit input regarding three primary topics: how to make abuse-deterrent opioid formulations the standard of care, how to best incentivize the pharmaceutical industry to develop next-generation opioid products, and how to ensure that patients have access to affordable abuse-deterrent opioids by implementing guidance for the release of generic abuse-deterrent opioids.

- *Industry group letter to the FDA:* In January 2015, two major trade associations of the drug industry, Biotechnology Industry Organization, or BIO, and Pharmaceutical Research and Manufacturers of America, or PhRMA, sent a letter to the FDA urging the agency to take two actions: decline to approve generic formulations of opioid medications that lack abuse-deterrent properties comparable to those of already-approved branded formulations, and remove from the market any generic, non-abuse-deterrent formulations of opioid medications with abuse-deterrent formulations.

- *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 plan identifies 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 postmarketing 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 Scientific Board to broaden the understanding of the public risks of opioid abuse. The FDA's Scientific Advisory Board met to address these issues on March 1, 2016. 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. 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. In March 2016, as part of the HHS initiative, the CDC released a new 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. Also, 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. The FDA also required safety labeling changes across all prescription opioids related to potentially harmful drug interactions. In August 2016, the FDA announced that it is requiring boxed warnings for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines.

- *U.S. Senate Passed Comprehensive Addiction and Recovery Act:* In March 2016, the U.S. Senate passed the Comprehensive Addiction and Recovery Act to address the national epidemics of prescription opioid abuse and heroin use. Consistent with the initiatives of HHS, this legislation would expand the availability of naloxone, which can counter the effects of opioid overdose, for law enforcement and other first responders. The legislation also calls for HHS to convene an interagency task force to develop best practices for pain management with opioid medications. The legislation would also provide resources to improve state monitoring of controlled substances, including opioids. Other initiatives include resources for treating opioid addiction in incarcerated persons and expanding opioid abuse prevention education and treatment efforts.

- *Passage of 21st Century Cures Act:* In December 2016, the 21st Century Cures Act became law. Among its provisions, the Act provides $1 billion dollars in grants to states for opioid abuse prevention and treatment.

Types of Abuse-Deterrent Technologies

In response to the opioid abuse epidemic, the pharmaceutical industry has created a number of abuse-deterrent products and product candidates, using a variety of technologies. These strategies generally fall under the following categories:

- *Physical/Chemical Barriers:* Physical barriers are formulations designed to prevent chewing, crushing, cutting, grating or grinding for oral or nasal abuse. Physical and chemical barriers can make it difficult to extract the opioid from the formulation for IV abuse using common solvents such as water. For example, OxyContin OP uses a cured, thermoformed polymer to make the tablets harder to crush for oral or nasal abuse. When crushed, the product gels in the presence of small injectable volumes of liquid, making it more difficult to draw into a syringe.

- *Agonist/Antagonist Combinations:* An opioid antagonist can be co-formulated with an active opioid ingredient, or agonist, to interfere with or reduce the euphoria associated with abuse.

  - The antagonist can be physically sequestered in the tablet (e.g., Pfizer's Embeda®). When taken orally as directed, the majority of the encapsulated antagonist is eliminated in the gastrointestinal, or GI, tract and not absorbed into the bloodstream, allowing the active ingredient to work. However, when crushed or dissolved by an abuser or patient, the antagonist is released with the active ingredient and both are absorbed into the bloodstream, with the intent of blunting the euphoric effects of the active ingredient. A problem with this approach is that if the tablet is crushed or dissolved, the antagonist can cause the patient or abuser to experience opioid withdrawal, with potentially serious consequences.

  - Alternatively, the antagonist can be co-formulated in a fixed ratio with the active ingredient (e.g., Purdue's Targiniq™). When taken orally as directed, most of the antagonist is circulated directly to the liver and rendered ineffective, allowing the active ingredient to work. However, when snorted or injected, the antagonist is distributed in the bloodstream before it gets to the liver, with the intent of preventing euphoria. A disadvantage with this approach is that it limits the amount of active ingredient a patient can take, which may make it inadequate to control chronic pain. Further, the presence of the antagonist in the co-formulated drug may precipitate withdrawal, with potentially serious consequences.

  Market research studies performed for us have shown that some physicians prefer not to use an abuse-deterrent formulation with an opioid antagonist because such formulations may be less useful in addressing chronic pain and because their antagonist components may precipitate withdrawal.

- *Prodrug approaches:* A prodrug is a drug administered in an inactive, or less active, form designed to enable more effective delivery. The prodrug is then converted by the body into the active ingredient through a normal, metabolic process. In a prodrug opioid, the active ingredient is designed to be released if the drug is taken orally, but if an abuser or patient takes a large amount of the drug, the prodrug is not broken down or absorbed rapidly enough to create euphoria. If injected or snorted, the prodrug is not broken down and the active ingredient is not released. No opioids using a prodrug approach are currently marketed.

We believe Xtampza represents the best-in-class approach to an abuse-deterrent extended-release opioid formulation.

Xtampza does not incorporate an opioid antagonist, is not a prodrug, and is resistant to abuse through physical or chemical manipulation.

Chronic Pain with Dysphagia

It is estimated that more than 10% of patients with chronic pain, or approximately 11 million patients, have dysphagia, or difficulty in swallowing, because they have cancer, are elderly, have other medical problems or have difficulty swallowing without a known medical cause. The FDA recognized the unmet medical needs of this growing population in issuing draft guidance in December 2013, in which the FDA cited survey data that suggest that as many as 40% of Americans may have difficulties swallowing tablets and capsules and noted that these difficulties can precipitate a number of adverse events and noncompliance with treatment regimens.

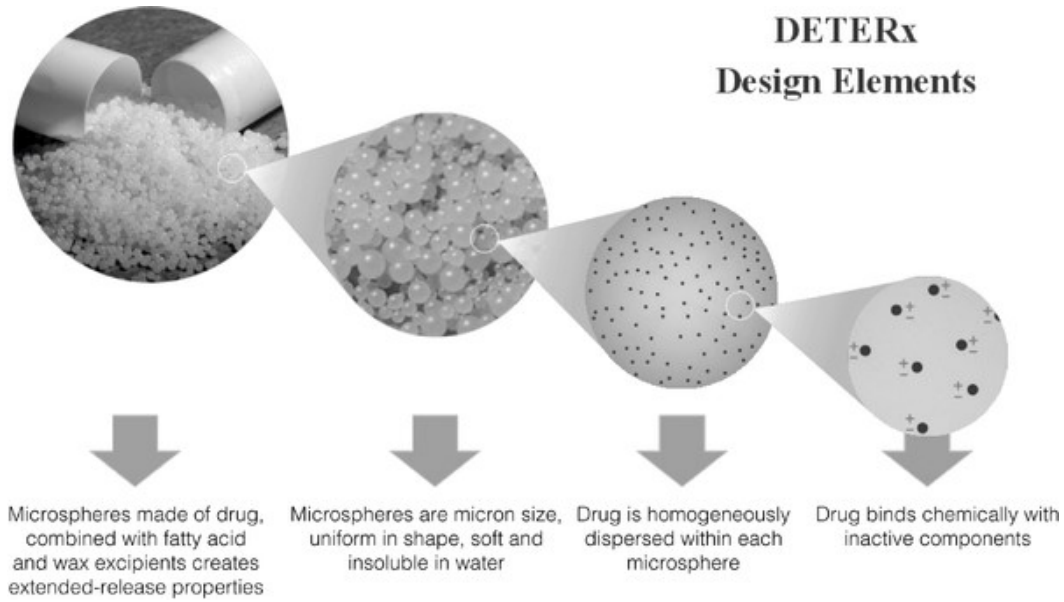
Except for Xtampza, all FDA-approved, orally administered extended-release opioids have a black box warning product label stating that "crushing, dissolving or chewing can cause rapid release and absorption of a potentially fatal dose of the active drug," making them unsuitable or unattractive for patients who suffer from chronic pain with dysphagia, or CPD. OxyContin OP's product label states that "there have been post-marketing reports of difficulty in swallowing OxyContin tablets. These reports included choking, gagging, regurgitation and tablets stuck in the throat… Consider use of an alternative analgesic in patients who have difficulty swallowing." An external marketing study performed for us in 2013 estimated that Xtampza has a peak revenue potential for U.S. patients with CPD in excess of $700 million annually.

Our Solution: The DETERx Platform Technology

Overview

DETERx is a novel, proprietary, patented platform technology that is designed to maintain the extended-release and safety profiles of highly abused drugs in the face of various methods of abuse and tampering, including chewing, crushing and/or dissolving, and then taking them orally or snorting or injecting them. The DETERx formulation consists of wax-based microspheres that are filled into a capsule. The microspheres are spherical micron-sized beads that are prepared by combining the active ingredient (oxycodone, in the case of Xtampza) with inactive ingredients. Each microsphere, whether inside or outside the capsule, is designed to be abuse-deterrent and extended-release. The active ingredient is solubilized and homogenously dispersed in each microsphere.

Xtampza microspheres have a median particle size of approximately 300 microns and are comprised of the active ingredient (oxycodone), a fatty acid, and wax and surfactant excipients which are all Generally Recognized As Safe, or GRAS, by the FDA. The microspheres are formulated through a proprietary melt process in which the active ingredient, as a free base, is combined with fatty acid and wax and surfactant excipients to form a molten solution in which the base is solubilized via an ionic interaction with the fatty acid. The resulting homogenous liquid is spray congealed into small droplets using a proprietary spinning disk manufacturing process. The droplets rapidly congeal into solid wax-based microspheres, which are then filled into capsules. Differing product strengths are achieved by varying the weight of the microspheres loaded into a capsule. When administered orally as directed, the Xtampza formulation is designed to be administered every 12 hours and releases oxycodone over an extended period of time in the GI tract by diffusion from the microspheres into gastrointestinal fluids.



Because of our proprietary DETERx platform technology, each individual microsphere has extended-release and abuse-deterrent properties. The microspheres are designed to be administered in capsule form, sprinkled on food or into a cup then directly in the mouth, or administered into the stomach via a gastric or nasogastric tube without compromising their abuse-deterrent, extended-release profile. These features may make Xtampza uniquely suited to address the needs of patients suffering from CPD.

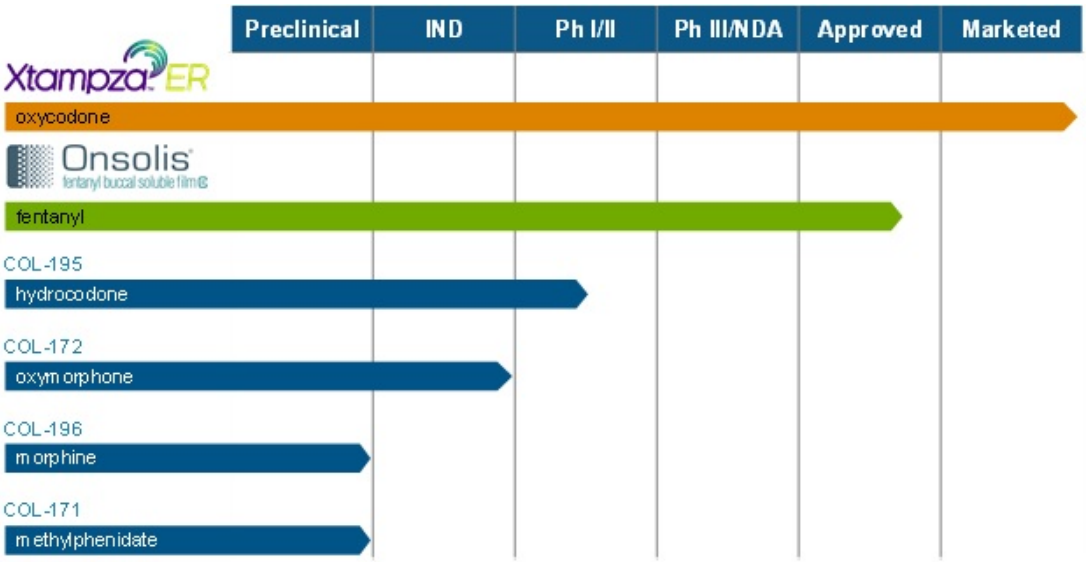
Abuse-Deterrent Features

Abusers often seek to accelerate the absorption of opioids into the bloodstream by crushing them in order to swallow, snort or smoke the drug, or dissolving them in order to inject the drug. The wax-based microspheres produced using the DETERx platform technology have physical and chemical barriers that are intended to reduce the potential for these forms of abuse. We believe that microspheres made using our proprietary technology deter the most common methods of manipulating opioids for abuse because of their features described in the table below.

Abuse-Deterrent Features of DETERx Platform Technology

Method of Abuse	Abuse-Deterrent Feature:	Advantages
Oral	*Particle Size, Matrix Composition and Fusing Effect*	The microspheres are small and soft, so chewing or crushing them to further reduce the particle size does not meaningfully reduce the particle size or increase the surface area. The hydrophobic excipient matrix of each microsphere is composed of soft, fatty, and wax-based inactive ingredients that tend to agglomerate and fuse when crushed.
Injection	*Less Soluble Salt Form*	We created a novel salt form of the active ingredient, which is less soluble in aqueous solutions (such as water) but readily dissolved in fatty excipients, such as those used in our DETERx formulation.
	Matrix Composition	The hydrophobic excipient matrix is designed to trap the active ingredient, making it difficult for abusers to extract the opioid.
	High Melting Point	Melting the waxy composition of the microspheres results in quick solidification when heat is removed, clogging a syringe.
Snorting	*Matrix Composition*	The hydrophobic excipient matrix is designed to trap the active ingredient, preventing the release of the opioid in the nose and causing temporary nasal side effects that make Xtampza undesirable for nasal abuse.

Pipeline



We have applied our DETERx platform technology to Xtampza as well as the product candidates in our pipeline, with the exception of Onsolis. We recently completed formulation development work for our extended-release, abuse-deterrent hydrocodone program. Based upon an assessment of the market opportunity and the potential to differentiate from currently marketed hydrocodone products as well as programs in development, we are prioritizing our abuse deterrent hydrocodone program as our second product in development. We filed an investigational new drug application,

or IND, with the FDA in December 2015 and initiated a clinical trial in the first quarter of 2016. We also have an extended-release, abuse-deterrent oxymorphone program for the treatment of chronic pain for which we have filed an IND. This program has been granted Fast Track status by the FDA. In addition, we have other extended-release, abuse-deterrent product candidates that have completed preliminary preclinical studies, including morphine for pain and methylphenidate for the treatment of attention deficit hyperactivity disorder, or ADHD. All of these product candidates share similar abuse-deterrent qualities as Xtampza and are designed to be suitable for patients with difficulty swallowing. We own all of the rights to Xtampza and our DETERx-based product candidates.

Each of our product candidates is being developed to seek FDA approval in accordance with Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FD&C Act. Section 505(b)(2) permits an applicant to file an NDA that relies, in part, on data not developed by or for the applicant and to which the applicant has not received a right of reference, such as the FDA's findings of safety and efficacy in the approval of a similar drug, or listed drug, or published literature in support of its application.

Xtampza

Overview

Our first FDA-approved product, Xtampza, is an abuse-deterrent, extended-release, oral formulation of oxycodone, a widely prescribed opioid medication. In April 2016, the FDA approved our new NDA filing for Xtampza 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. Certain human abuse potential studies are included in the approved label, as well as data supporting the administration of the product as a sprinkle or administered through feeding tubes. In June 2016, we announced the commercial launch of Xtampza. In October 2016, we announced the submission of a New Drug Submission to Health Canada seeking marketing approval of Xtampza for the same indication for which we obtained approval from the FDA.

Xtampza has the same active ingredient as OxyContin OP, which is the largest selling abuse-deterrent, extended-release opioid in the United States by dollars, with $2.1 billion in U.S. sales in 2016. We conducted a comprehensive preclinical and clinical program for Xtampza consistent with FDA guidance on abuse-deterrence. These studies and clinical trials demonstrated that chewing, crushing and/or dissolving Xtampza, and then taking it orally or smoking, snorting, or injecting it did not meaningfully change its drug release profile or safety characteristics. By contrast, clinical trials performed by us and others — including head-to-head clinical trials comparing Xtampza with OxyContin OP — have shown that drug abusers can achieve rapid release and absorption of the active ingredient by manipulating OxyContin OP using common household tools and methods commonly available on the Internet. In October 2016, we announced the submission of a Supplemental New Drug Application to the FDA for Xtampza to include comparative oral pharmacokinetic data from a recently completed clinical study evaluating the effect of physical manipulation by crushing Xtampza compared with OxyContin OP and a control (oxycodone hydrochloride immediate-release).

In addition, our preclinical studies and clinical trials have shown that the contents of the Xtampza capsule can be removed from the capsule and sprinkled on food or into a cup, and then directly into the mouth, or administered through feeding tubes, without compromising their drug release profile, safety or abuse-deterrent characteristics. By contrast, OxyContin OP, which is formulated in hard tablets, has a black box warning label stating that crushing, dissolving, or chewing can cause rapid release and absorption of a potentially fatal dose of the active ingredient.

Market Opportunity

We believe that Xtampza can capture a significant share of the $5.7 billion U.S. extended-release opioid market, including a portion of the existing $2.1 billion OxyContin OP market. In addition, we believe that Xtampza can become a market leader for treating patients with chronic pain who have difficulty swallowing.

OxyContin OP Extended-Release Market

Purdue launched OxyContin OP in 2010. In April 2013, the FDA determined that Purdue had been successful in demonstrating OxyContin OP's abuse-deterrent characteristics and permitted Purdue to amend its product label to include certain abuse-deterrent claims. Since the launch of OxyContin OP, there has been a reduction in the overall abuse of OxyContin, primarily in the snorted and injected routes of administration.

The FDA also concluded that the benefits of the previously-approved non-abuse-deterrent OxyContin no longer outweighed its risks and removed it from the list of drugs eligible to serve as a reference product for future generic or Section 505(b)(2) approvals. As a result, we believe that all extended-release oxycodone products, including generic products, may be required to have abuse-deterrent claims as part of the FDA approval process.

Despite OxyContin OP's commercial success, it carries with it a well-documented abuse stigma both for physicians who prescribe it and for patients who use it to treat chronic pain. In a market research study conducted for us in 2013, 35% of patients surveyed who were taking OxyContin OP indicated concern that their friends or family have a negative perception of OxyContin OP. Of the 1,021 patients surveyed in the study, 11% of chronic pain patients responded that they have had their opioid medication stolen, most often from their home, and 76% indicated an interest in switching to a pain medication similar to OxyContin OP but that was more abuse-deterrent. A market research study of 30 physicians conducted for us in 2015 concluded that while physicians view OxyContin OP as an effective and valuable option, one third reported prescribing it less often than they would like because of patients' reticence to use OxyContin OP because of its reputation for addiction and abuse.

Further, in a third party study of post-marketing data on misuse and diversion of prescription opioid analgesics, the initial decline in abuse of OxyContin OP by patients who reported abusing the non-abuse-deterrent OxyContin 30 days prior to entering treatment for opioid abuse disorder, plateaued at 25% to 30%, with no further decreases from 2012 to study conclusion in 2014. A sub-population of participants was surveyed to investigate their continued abuse of OxyContin. Among the 88 participants who abused both non-abuse-deterrent OxyContin and OxyContin OP, their continued abuse of OxyContin OP was explained by: (i) a transition from non-oral routes of administration to oral use (approximately 43%); (ii) successful efforts to defeat the abuse-deterrent formulation mechanism leading to a continuation of inhaled or injected use (approximately 34%); and (iii) exclusive use of the oral route independent of formulation type (approximately 23%). Representative comments of participants who continued to abuse OxyContin OP demonstrated that participants were able to identify methods of circumventing the abuse deterrent properties using the internet.

Other Extended-Release Opioids

While OxyContin OP is the largest selling extended-release opioid in the United States by dollars in 2016, there are approximately 20 million additional prescriptions for non-abuse-deterrent extended-release opioids annually in the United States. Many of these opioids include active ingredients, such as morphine, that are commonly perceived as having greater adverse side effects than oxycodone-based formulations. Because of the abuse stigma associated with OxyContin OP and non-abuse-deterrent opioid formulations, we believe that Xtampza offers physicians treating chronic pain an attractive alternative to the existing options. Our market research also demonstrates that payors recognize the prevalence of opioid abuse and its corresponding economic burden. This research indicates that "brand" prices would be acceptable for products that are differentiated. As such, we aim to achieve broad Tier 3 payor coverage on commercial plans and contract with Medicare and Medicaid. In a market research study conducted for us, 83% of disease specialists (such as oncologists and neurologists) and 67% of pain specialists surveyed indicated that they would prescribe Xtampza for patients without dysphagia.

Chronic Pain with Dysphagia

In a market research survey conducted for us, of 1,021 patients with chronic pain, 30% of the patients reported that they have trouble swallowing or do not like to swallow pills, and 65% of the patients did not realize that cutting, crushing or grinding extended-release opioids can change the drug release profile. Most of the currently approved abuse-deterrent opioid drugs do not have an FDA product label that permits the sprinkling of the product on food or into a cup, and then directly in the mouth and administration through feeding tubes for use by patients with CPD, creating an unmet medical need due to the lack of adequate treatment options. Further, in an effort to make them easier to swallow, some patients with CPD — and 47 of the 1,021 patients participating in the survey conducted for us — crush their prescribed extended-release opioids and can inadvertently harm themselves because of the rapid immediate-release of the active ingredient. Because our Xtampza microspheres are designed to be able to be removed from the capsule and still retain their abuse-deterrent and extended-release properties, we believe that Xtampza is an effective pain-management solution for

patients with CPD. An external marketing study performed for us in 2013 estimated that Xtampza has a peak revenue potential for U.S. patients with CPD in excess of $700 million annually.

Onsolis

In May 2016, we licensed the U.S. rights to develop and commercialize Onsolis from BioDelivery Sciences International, Inc. Onsolis is a Transmucosal Immediate-Release Fentanyl (TIRF) film indicated for the management of breakthrough pain in cancer patients 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Onsolis incorporates BioDelivery Sciences' BioErodible MucoAdhesive (BEMA®) technology for rapid and controlled delivery of fentanyl, a Schedule II controlled substance, via buccal (inner cheek) administration.

Onsolis was originally approved by the FDA in 2009 and voluntarily removed from the market in 2011 to address appearance-related issues. A reformulation of Onsolis was approved by the FDA in 2015. We plan to launch Onsolis after the completion of the transfer of manufacturing and submission to the FDA of a Prior Approval Supplement, which requires approval prior to launch. We estimate that approval will occur in the first half of 2018.

Manufacturing

Overview

Xtampza and our product candidates created with our DETERx technology platform are 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 at our contract manufacturing organization, Patheon. The existing Patheon facility has the capacity to support our commercialization of Xtampza during the first several years after commercial launch. We are working with Patheon to build dedicated manufacturing capacity at Patheon's existing facility. Patheon has an established record of manufacturing products approved in the United States, including 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.

Drug Substances

The active ingredient used in Xtampza, oxycodone base, is an odorless white crystalline powder. We currently procure this active ingredient pursuant to a supply agreement with a single U.S.-based manufacturer. If our current supplier is unable to supply oxycodone base in the quantities and at the times we require it, we are aware of other suppliers who we would expect to be able to satisfy our commercial orders.

Oxycodone base is classified as a narcotic controlled substance under U.S. federal law. Xtampza is, and we expect that our product candidates will be, classified by the U.S. Drug Enforcement Administration, or 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, we expect that the manufacturing, shipping, dispensing and storing of our product candidates will be subject to a high degree of regulation, as described in more detail under the caption "— Governmental Regulation — DEA Regulation."

Marketing and Commercialization

We are in the process of commercializing Xtampza in the United States with a direct sales force. We plan to explore out-licensing partnerships for Xtampza in other international markets, such as Canada, Australia and Japan, as well as countries in Latin America and Europe.

The members of our management team who are leading the commercialization of Xtampza have substantial experience in pharmaceutical sales and marketing. We have a dedicated field sales force, consisting of approximately 120 sales professionals, to call on the approximately 10,400 physicians who write approximately 60% of the branded

extended-release oral opioid prescriptions in the United States, with a primary focus on pain specialists. In addition, we deploy a focused sales force of approximately 25 specialty sales representatives to call on institutions where patients require extended-release opioids, such as skilled nursing or hospice facilities and hospitals. In addition, we employ medical sales liaisons, or MSLs, to respond to clinician inquiries about Xtampza. We also employ a market-access team to support our formulary approval and payor contracting.

We are continuing to execute our commercialization strategy with the input of key opinion leaders in the field of pain management, as well as healthcare practitioners. We have developed positioning and messaging campaigns, a publication strategy, initiatives with payor organizations, and distribution and national accounts strategies. Our marketing strategy includes increasing awareness of the differentiated features of Xtampza, the hazards of opioids that are not abuse-deterrent, and increasing awareness of solutions for patients with CPD who require or would benefit from extended-release opioids.

Intellectual Property

We regard the protection of patents, designs, trademarks and other proprietary rights that we own or license as critical to our success and competitive position. Our patent portfolio directed toward Xtampza and our DETERx technology consists of eight issued patents in the United States (five of which claim compositions of matter, one of which claims both compositions of matter and methods of use, and two that claim methods of use), two pending applications in the European Union, 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 and 2025, and our pending patent applications in the United States, if issued, would be projected to expire in 2023, 2025, 2030, and 2036. 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.

Our policy is to patent the technology, inventions and improvements that we consider important to the development of our business, but only in those cases in which we believe that the costs of obtaining patent protection is justified by the commercial potential of the technology, and typically only in those jurisdictions that we believe present significant commercial opportunities to us. We have concluded that some of our technology is best protected as proprietary know-how, rather than through obtaining patents. In some cases, we publish the invention such that it becomes prior art in order for us to secure freedom to operate and to prevent a third party from patenting the invention before us. Our technology and products are not in-licensed from any third party, and we own all of the rights to Xtampza and our product candidates. 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.

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.

Our Strategy

Our goal is to become the leading marketer of abuse-deterrent extended-release opioids and other commonly abused products. Key elements of our strategy to achieve this goal are to:

- *Commercialize Xtampza in the United States ourselves.* We continue to strengthen our commercial organization, including our sales force and commercial manufacturing capacity for U.S. commercialization of Xtampza. Our management team has extensive experience commercializing pharmaceutical products, and we are in the process of establishing sales, marketing and reimbursement functions to commercialize Xtampza in

the United States. We are detailing Xtampza to approximately 10,400 physicians who write approximately 60% of the branded extended-release oral opioid prescriptions in the United States with a sales team of approximately 120 sales representatives. We believe that this physician group also represents a significant portion of the top prescribers of extended-release and long-acting opioids (including drugs formulated with fentanyl and methadone) currently used to treat patients with CPD. In addition, we deploy a separate, focused sales team of approximately 25 specialty sales representatives to detail Xtampza to nursing homes, hospices, and other institutions treating large populations of the elderly and other patients who need chronic pain relief and have difficulty swallowing.

- *Establish Xtampza as the treatment of choice for patients with CPD.* Xtampza has been approved with product labeling for sprinkling Xtampza microspheres on soft foods or into a cup, and then directly into the mouth, or through a gastrostomy or nasogastric feeding tube.

- *Establish strategic collaborations to accelerate and maximize the potential of our products and product candidates worldwide.* We intend to seek strategic collaborations with other pharmaceutical companies to commercialize Xtampza and our product candidates outside the United States and to develop certain of our product candidates that are outside of our core therapeutic focus.

- *Advance other product candidates that incorporate our DETERx platform technology.* We have begun advancing our development program for COL-195, an abuse-deterrent, extended-release hydrocodone for the treatment of chronic pain. We initiated clinical trials for our hydrocodone product candidate in the first quarter of 2016. We also have an IND application on file for COL-172, an abuse-deterrent, extended-release oxymorphone for the treatment of chronic pain, which has been granted Fast Track status by the FDA. In addition, we have COL-171, a proprietary preclinical DETERx extended-release, abuse-deterrent methylphenidate formulation for the treatment of ADHD.

- *Acquire additional products and product candidates.* We may identify and license, co-promote or acquire products or product candidates being developed for pain indications and other complementary products. In May 2016, we entered into a License and Development Agreement with BioDelivery Science International, Inc. which grants us an exclusive license to make, use, sell, offer for sale, import, develop and commercialize Onsolis in the United States. We plan to commercialize Onsolis upon receipt of FDA approval of a Prior Approval Supplement for the manufacturing transfer. Subject to such approval, we expect to launch Onsolis in the first half of 2018.

Our commercialization strategy for Xtampza continues to evolve, and as part of that evolution, we are developing positioning and messaging campaigns, a publication strategy, initiatives with payor organizations, and distribution and national accounts strategies.

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.

Currently, the only opioid drugs on the market for chronic pain relief that have an abuse-deterrent product label are OxyContin OP and Hysingla®, both of which are marketed by Purdue, and Embeda, which is marketed by Pfizer. Hysingla is a once a day hydrocodone product. Embeda is a combination of morphine and naltrexone, an opioid antagonist that can be sprinkled on soft food but 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.”

In addition, there are five other approved extended-release opioids that have abuse-deterrent product labeling, Vantrela ER from Teva, Targiniq from Purdue, Troxyca ER from Pfizer, MorphaBond™ ER from Inspirion Delivery Technologies, LLC and Arymo from Egalet, none of which are currently on the market. Vantrela ER is a twice daily

hydrocodone product. Targiniq is a combination of oxycodone and naloxone, an opioid antagonist. Troxyca ER is a combination of oxycodone and naltrexone, an opioid antagonist. MorphaBond ER is a twice daily morphine product formulated with a hard tablet and gelling polymers. Arymo is an extended-release morphine product formulated as a hard tablet which is expected to be available in the first quarter of 2017. A number of other large and small companies are developing abuse-deterrent drugs for chronic pain. Many other companies have products for the treatment of chronic pain which do not have abuse-deterrent claims in their labels, including Endo Pharmaceuticals, Pernix and Mallinckrodt, as well as several generic companies.

We believe the key competitive factors that will affect the development and commercial success of our products and product candidates include their degree of abuse deterrence, bioavailability, therapeutic efficacy, and convenience of dosing and distribution, as well as their safety, cost and tolerability profiles. Xtampza 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.

Xtampza competes against all extended-release opioids, including Purdue's OxyContin OP for the treatment of patients experiencing pain severe enough to require around-the-clock analgesia. Although no generic oxycodone extended-release products are currently commercially available, and although the FDA has not issued guidance on the regulatory pathway for generic abuse-deterrent products, it is possible that generic forms of OxyContin OP could become available, in which case Xtampza would compete with any such generic oxycodone extended-release products.

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

Government Regulation

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The FD&C Act and other federal and state statutes and regulations, govern, among other things, 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 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.

The IND automatically becomes effective 30 days after receipt by FDA unless, within the 30-day time period, the FDA raises concerns or questions relating to one or more proposed clinical trials and places the clinical trial on hold, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin.

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.

GCP requirements include that all research subjects provide their informed consent in writing for their participation in any clinical trial. An independent IRB for each site proposing to conduct the clinical trial must review and approve the informed consent information as well as the clinical trial protocol before the trial commences at that site, and must monitor the study until completed. The FDA or the IRB may order the temporary or permanent discontinuation of a clinical trial at any time and on various grounds, particularly upon the belief that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial subjects, or impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap or be combined. In 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 usually involves trials 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. If a compound 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. The NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently set at $2,038,100, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees, currently set at $97,750 per product and $512,200 per establishment. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Rather than accept an NDA for filing, then FDA may request additional information. In this event, the NDA must be resubmitted with the additional information and may be subject to payment of additional user fees. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has established certain performance goals for the review of new drug applications. The agency endeavors to review applications for standard review drug products within 10 to 12 months of the acceptance for filing, and aims to review applications for drugs granted priority review, which may apply to drugs that the FDA determines offer major advances in treatment or provide a treatment where no adequate therapy exists, within six to eight months. The review process for both standard and priority review may be extended by FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also 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. In addition, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMP is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter to indicate that the review cycle for an application is complete and that the application is not ready for approval. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA may ultimately decide that an application does not satisfy the regulatory criteria for approval. If, and when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. Changes to certain of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses similar procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

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. In determining whether a REMS is necessary, the FDA must consider the size of the population likely to use the drug, the seriousness of the disease or condition to be treated, the expected benefit of the drug, the duration of treatment, the seriousness of known or potential adverse events, and whether the drug is a new molecular entity. 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. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. 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 February 2009, the FDA informed manufacturers of certain opioid products that it would require a REMS for their opioid drug products. Subsequently, the FDA initiated efforts to develop a new standardized REMS for these opioid medications to ensure their safe use, and in July 2012, 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.

As part of the FDA's Opioid Action Plan, the agency intends to update the extended-release and long-acting opioid REMS after having evaluated existing requirements and considered recommendations from the joint meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee on May 3-4, 2016. The recommendations from that meeting included: extending training to other health care professionals involved in the management of patients with pain; expanding the REMS requirements to include the immediate-release opioid analgesic drug manufacturers; and evaluating the best approach to implementing mandatory prescriber education on pain management.

Advertising and Promotion

The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, standards 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 effectiveness 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.

Fast Track Designation

The FDA has various programs to facilitate the development and expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the Fast Track designation program, the sponsor of a new product candidate may request the FDA to designate the product for a specific indication as a Fast Track product concurrent with or after the submission of the IND for the product candidate. The FDA must determine if the product candidate qualifies for Fast Track designation within 60 days after receipt of the sponsor's request.

In addition to other benefits, such as the ability to have more frequent interactions with the FDA, the FDA may initiate review of sections of a Fast Track product's NDA before the application is complete. The FDA's time period goal for reviewing a Fast Track application does not begin until the last section of the NDA is submitted. In addition, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

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 post-market testing, known as Phase 4 testing, REMS, 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 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. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product

approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered. In addition, other regulatory actions may be taken, including, among other things, warning letters, the seizure of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, refusal to approve pending applications or supplements to approved applications, civil penalties, and criminal prosecution.

As part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. The Prescription Drug Marketing Act, or PDMA, and associated regulations, impose certain recordkeeping and reporting requirements and other limitations on the distribution of drug samples to physicians. The PDMA also requires that state licensing of distributors who distribute prescription drugs meet certain federal guidelines that include minimum standards for storage, handling and record keeping. In addition, the PDMA and a growing majority of states also impose certain drug pedigree requirements on the sale and distribution of prescription drugs. The PDMA sets forth civil and criminal penalties for violations. In 2010, a statutory provision was enacted that required manufacturers and authorized distributors of record to report on an annual basis certain information about prescription drug samples they distributed. The FDA issued a draft compliance policy guide on the reporting requirement. The FDA stated that it would exercise enforcement discretion with regard to companies that have not submitted reports until the FDA finalizes the reporting requirement and/or provides notice that it is revising its exercise of enforcement discretion.

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 abbreviated NDA, or ANDA. An ANDA provides for marketing of a drug product that has the same active 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.

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 drug may obtain a three-year period of exclusivity for a change to the drug, such as the addition of a new indication to the labeling or a new formulation, during which FDA cannot approve an ANDA or any Section 505(b)(2) NDA, 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. If the Section 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and efficacy is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical trials of the new product. The FDA may also require companies to perform additional clinical trials or provide additional materials to support the change from the approved product. 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 new chemical entity, listed in the Orange Book for the referenced product has expired; and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the 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.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, clinical trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to post certain information regarding the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

DEA Regulation

Our first product, Xtampza, is regulated as a "controlled substance" 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 the handling of controlled substances through a closed chain of distribution. This control extends to the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

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. Schedule II drugs are those that meet the following characteristics:

- high potential for abuse;
- currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions;
- abuse may lead to severe psychological or physical dependence; and
- are considered "dangerous."

Xtampza, an abuse-deterrent oral formulation of oxycodone, is listed by the DEA as a Schedule II controlled substance under the CSA. Consequently, the manufacturing, shipping, storing, selling and using of the 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, physically 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.

The DEA typically inspects a facility to review its security measures prior to issuing a registration. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA, for example distribution reports for Schedule I and II controlled substances, Schedule III substances that are narcotics, and other designated substances. Reports must also be made for thefts or losses of any controlled substance, and to obtain authorization to destroy any controlled substance. In addition, special permits and notification requirements apply to imports and exports of narcotic drugs.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. 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 is regulated as a Schedule II controlled substance, it will be subject to the DEA's production and procurement quota scheme. The DEA establishes annually an aggregate quota for how much oxycodone 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. 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.

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 will be subject to state regulation on distribution of these products.

International Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations regarding safety and efficacy and governing, among other things, clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional review periods, and the time may be longer or shorter than that required to obtain FDA approval and, if applicable, DEA classification. The requirements governing, among other things, the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Many foreign countries are also signatories to the internal drug control treaties and have implemented regulations of controlled substances similar to those in the United States. Our products will be subject to such regulation which may impose certain regulatory and reporting requirements and restrict sales of these products in those countries.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

In addition to regulations in Europe and the United States, we will be subject to a variety of foreign regulations governing, among other things, the conduct of clinical trials, pricing and reimbursement and commercial distribution of our products. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Other Healthcare Laws and Compliance Requirements

In the United States, the research, manufacturing, distribution, sale and promotion of drug products and medical devices are subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of HHS (e.g., the Office of Inspector General), the DOJ, state Attorneys General and other state and local government agencies. For example, sales, marketing and scientific/educational grant programs must comply with fraud and abuse laws such as the federal Anti-Kickback Statute, the federal False Claims Act, as amended and similar state laws. In order to participate in the Medicaid program, existing federal law requires pharmaceutical manufacturers to pay rebates to state governments, based on a statutory formula, on covered outpatient drugs reimbursed by the Medicaid program as a condition of having their drugs paid for by Medicaid. Manufacturers are required to report AMP and best price for each of their covered outpatient drugs to the government on a regular basis. Additionally, some state Medicaid programs have imposed a requirement for supplemental rebates over and above the formula set forth in federal law, as a condition for coverage. In addition to the Medicaid Rebate Program, federal law also requires that if a pharmaceutical manufacturer wishes to have its outpatient drugs covered under Medicaid as well as under Medicare Part B, it must sign a “Master Agreement” obligating it to provide a formulaic discount that results in a

federal ceiling price, or maximum price that participating manufacturers may charge for covered drugs sold to the U.S. Departments of Defense (including the TRICARE retail pharmacy program), Veterans Affairs, the Public Health Service and the Coast Guard, and also provide discounts through a drug pricing agreement meeting the requirements of Section 340B of the Public Health Service Act, for outpatient drugs sold to certain specified eligible health care organizations. The formula for determining the discounted purchase price under the 340B drug pricing program is defined by statute and is based on the AMP and rebate amount for a particular product as calculated under the Medicaid Drug Rebate Program, discussed above.

The federal Anti-Kickback Statute prohibits any person from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce or reward 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. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on one hand, and prescribers, purchasers, and formulary managers, on the other. The term "remuneration" is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include the transfer of anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at other than its fair market value. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain business arrangements from prosecution, the exemptions and safe harbors are drawn narrowly and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability in all cases. The reach of the federal Anti-Kickback Statute was broadened by the recently enacted Affordable Care Act, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal 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. Additionally, many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to referral of patients for healthcare items or services reimbursed by any third-party payor, not only the Medicare and Medicaid programs in at least some cases, and do not contain safe harbors.

The federal False Claims Act imposes liability on any person or entity that, 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 allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically. In addition, various states have enacted false claims laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payor and not merely a federal healthcare program. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The False Claims Act has been used to assert liability on the basis of inadequate care, kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper promotion of off-label uses not expressly approved by FDA in a drug's label, and allegations as to misrepresentations with respect to the services rendered. To the extent we participate in government healthcare programs, our future activities relating to the reporting of discount and rebate information and other information affecting federal, state and third party reimbursement of our products, and the sale and marketing of our products and our service arrangements or data purchases, among other activities, may be subject to scrutiny under these laws. We are unable to predict whether we would be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the cost of defending such claims, as well as any sanctions imposed, could adversely affect our financial performance. Also, HIPAA created several new federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute 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.

In addition, we may be subject to, or our marketing activities in the future may be limited by, data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA and its implementing regulations established uniform standards for certain "covered entities," which are healthcare providers, health plans and healthcare clearinghouses, governing the conduct of specified electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included expansion of HIPAA's privacy and security standards through HITECH, which became effective on February 17, 2010. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," which are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

Additionally, under the federal Open Payments program, created under Section 6002 of the Affordable Care Act and its implementing regulations, manufacturers of drugs for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) must report information related to "payments or other transfers of value" made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and manufacturers and applicable group purchasing organizations must report ownership and investment interests held by physicians (as defined above) and their immediate family members. Such reports are to be made to the Centers for Medicare & Medicaid Services, or CMS, by the 90th day following the end of each subsequent year and CMS subsequently is to publish the reported information on a publicly available website.

There are also an increasing number of state "sunshine" laws that require manufacturers to file reports with states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. Several states have enacted legislation requiring pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities and/or register their sales representatives. Such legislation also prohibits pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing and prohibits certain other sales and marketing practices. These laws may affect our future sales, marketing and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private *qui tam* actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are approved and sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Third-Party Payor Coverage and Reimbursement

The commercial success of Xtampza and our product candidates, if approved, 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.

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.

Some third-party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. 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 and our product candidates and to operate profitably.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

Healthcare Reform

In the United States and foreign jurisdictions, 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 for which we receive marketing approval. 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.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by HHS, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness clinical trials are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor’s product could adversely affect the sales of our product candidates. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.
In March 2010, the Affordable Care Act was enacted, which includes measures to significantly change 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 new 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 new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- creation of the Independent Payment Advisory Board, which has authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations (the IPAB has not yet been called upon to act as the annual determinations by the CMS Office of the Actuary have not identified a savings target for implementation in years 2015 or 2016); 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 new 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.

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 has 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.

Research and Development

We incurred research and development expenses of $14.9 million, $8.0 million and $15.0 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Employees

As of December 31, 2016, we had a total of 234 full-time employees. Of these, 28 were engaged in full-time research and development activities. 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 March 1, 2017:

Name	Age	Position(s)
Executive Officers:		
Michael T. Heffernan, R.Ph.	52	Chairman, President and Chief Executive Officer
Paul Brannelly	44	Executive Vice President and Chief Financial Officer
Barry S. Duke	57	Executive Vice President and Chief Commercial Officer
Alison B. Fleming	42	Chief Technology Officer

Executive Officers

Michael T. Heffernan, R.Ph., Chairman, President and Chief Executive Officer. Mr. Heffernan has served as our President and Chief Executive Officer and as a member of our board of directors since October 2003. Mr. Heffernan has over twenty-five years of experience in the pharmaceutical and related healthcare industries. He was previously the Founder, President and Chief Executive Officer of Onset Therapeutics, LLC, a dermatology-focused company that developed and commercialized products for the treatment of skin-related illnesses and was responsible for the spin-off of the business from the Company to create PreCision Dermatology, Inc. which was acquired by Valeant Pharmaceuticals International, Inc. Mr. Heffernan has held prior positions as Co-Founder, President and Chief Executive Officer of Clinical Studies Ltd., a pharmaceutical contract research organization that was sold to PhyMatrix Corp., and as President and Chief Executive Officer of PhyMatrix. Mr. Heffernan started his career at Eli Lilly and Company, where he served in numerous sales and marketing roles. He serves on the board of directors of Keryx Biopharmaceuticals, Inc (NASDAQ: KERX) (July 2016 to present) and Veloxis Pharmaceuticals A/S (CPH: VELO) (March 2015 to present). Mr. Heffernan previously served on the board of directors and as Chairman of Ocata Therapeutics, Inc. (NASDAQ: OCAT), Cornerstone Therapeutics Inc. (now known as Chiesi USA, Inc.) (NASDAQ: CRTX) and numerous privately held companies. Mr. Heffernan graduated from the University of Connecticut with a B.S. in Pharmacy in 1987 and is a Registered Pharmacist.

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. (NASDAQ: KPTI) 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. (NASDAQ: VSTM) 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. (NASDAQ: OVAS). 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, where he managed the S-1 preparation and due diligence process for Sirtris' initial public offering and managed the company's transition to being a public company. 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.

Barry S. Duke, Executive Vice President and Chief Commercial Officer. Mr. Duke has served as our Executive Vice President and Chief Commercial Officer since March 2015. Prior to joining us, Mr. Duke was Vice President of Sales and Marketing — U.S. Biosurgery at Sanofi, Inc. (formerly Genzyme Corporation) from October 2011 to September 2014. From September 2014 to March 2015, Mr. Duke served as a sales and marketing consulting in the biopharmaceutical industry. Mr. Duke joined Sanofi in March 2005 as an area sales director and was promoted to Vice President of Sales — U.S. Biosurgery in November 2007, a position he held until September 2011, when he was promoted to Vice President of Sales and Marketing — U.S. Biosurgery. Prior to Sanofi, Mr. Duke was Senior Director of National Sales at Enzon Pharmaceuticals, Inc. (NASDAQ: ENZN) from November 2002 to March 2005. Prior to Enzon, Mr. Duke was Regional Sales Director at Élan Corporation, plc (now known as Élan Corporation Ltd) from March 2001 to November 2002. Over the course of his career, Mr. Duke has also held various sales positions at The Liposome Company, Inc., Astra USA, Inc., Centocor, Inc. and The Upjohn Company.

Alison B. Fleming, Ph.D., Chief Technology Officer. Dr. Fleming has served as or 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. In 2001, Dr. Fleming was the recipient of the Jorge Heller Journal of Controlled Release Outstanding Paper Award. 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.

Our Corporate Information

Our predecessor was incorporated in Delaware in April 2002 under the name Collegium Pharmaceuticals, Inc. In October 2003, our predecessor changed its name to Collegium Pharmaceutical, Inc. In 2010, our predecessor divested its subsidiary, Onset Therapeutics, LLC to PreCision Dermatology, 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. Since 2010, we have devoted substantially all of our resources to the development of our patented DETERx platform technology, the preclinical and clinical advancement of our product candidates, the commercialization of Xtampza and the creation and protection of related intellectual property.

Available Information

We maintain a website at www.collegiumpharma.com. We make available, free of charge on our website, our annual report on 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 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 Quarterly Report on Form 10-Q, 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

We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future.

We are an early commercial-stage pharmaceutical company. To date, we have focused on developing our first product, Xtampza. Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. Since 2010, when we divested our former subsidiary, Onset Therapeutics, LLC, to PreCision Dermatology, Inc., we have not generated any material revenue from product sales, and we continue to incur significant research, development, commercialization and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since January 1, 2011. For the year ended December 31, 2016, we reported a net loss of $94.2 million, and we had an accumulated deficit of $223.2 million at December 31, 2016.

We expect to continue to incur losses for the foreseeable future as we continue to commercialize Xtampza and continue our development of, and seek regulatory approvals for, our product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on our ability to generate revenues and on the rate of future growth of our expenses. If any of our product candidates fail in clinical trials or does not gain final regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses and expected future losses have had and will continue to have an adverse effect on our shareholders' equity and working capital.

We currently generate no material revenue from the sale of products and may never become profitable.

We began the commercial sale of our first product, Xtampza, in June 2016 and have not generated any material revenue from product sales. Our ability to generate additional revenue and become profitable depends upon our ability to successfully commercialize Xtampza, our existing product candidates, and any other product candidates that we may in-license or acquire in the future. Even if we are able to successfully achieve regulatory approval for these product candidates, we do not know when any of these product candidates will generate revenue for us, if at all. Our ability to generate revenue from our current or future product candidates depends on a number of factors, including our ability to:

- successfully commercialize Xtampza;
- successfully satisfy FDA post-marketing requirements for Xtampza, including studies and clinical trials that have been required for other extended release/long acting opioid analgesics and individual studies and clinical trials of Xtampza;
- set a commercially viable price for our products;
- manufacture commercial quantities of our products at acceptable cost levels;
- develop a commercial organization capable of sales, marketing and distribution for the products we intend to sell ourselves in the markets in which we have retained commercialization rights;

- find suitable distribution collaborators to help us market, sell and distribute our products, if approved, in markets outside the United States;
- obtain coverage and adequate reimbursement from third parties, including government payors;
- successfully complete development activities, including the necessary clinical trials, with respect to our product candidates;
- complete and submit NDAs to the FDA and obtain regulatory approval for indications for which there is a commercial market; and
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities, if we choose to commercialize our product candidates outside the United States.

In addition, because of the numerous risks and uncertainties associated with product development, including that our product candidates may not advance through development or achieve the safety and efficacy (including the efficacy of our abuse-deterrent technology) endpoints of applicable clinical trials, 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. Furthermore, we anticipate incurring significant costs associated with commercializing these products.

Even if we are able to generate revenues from the sale of our products, 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 development and commercialization of our product candidates.

Our operations have consumed substantial amounts of cash. We expect to continue to spend substantial amounts to advance the development of our product candidates and to commercialize Xtampza and any product candidates for which we may receive regulatory approval. We believe that our existing cash and cash equivalents and expected revenue contributions from Xtampza will be sufficient to fund our operations into 2019, including the commercialization of Xtampza, and the continuation of our development of our product candidates. However, we may require additional capital for the further development and commercialization of our product candidates and may also need to raise additional funds sooner in order to continue development of our product candidates.

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 or the commercialization of Xtampza, our product candidates or one or more of our other research and development initiatives;
- seek collaborators for Xtampza and/or one or more of our 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 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 ability to obtain and maintain abuse-deterrent claims in the product labels for our products and product candidates;
- our ability to successfully satisfy the FDA post-marketing requirements of Xtampza, including studies and clinical trials that have been required for other extended release/long acting opioid analgesics and individual studies and clinical trials of Xtampza;
- clinical development plans for our product candidates;
- the outcome, timing and cost of the regulatory approval process by the FDA and foreign regulatory authorities, including the potential for regulatory authorities to require that we perform more studies than those that we currently expect;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, including defending Purdue's remaining patent infringement claims against us;
- the cost and timing of completion of existing or expanded commercial-scale outsourced manufacturing activities;
- the cost of maintaining, and if appropriate, expanding, sales, marketing and distribution capabilities for Xtampza and any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products; and
- the initiation, progress, timing, costs and results of clinical trials for our product candidates and any future product candidates we may in-license.

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

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 beyond our existing indebtedness with Silicon Valley Bank 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 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 Xtampza or our product candidates, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization 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. 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. Although the FDA has approved Xtampza, we have not yet obtained final regulatory approval for any of our product candidates or demonstrated an ability to commercialize a product successfully. 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, 2016, we had a federal net operating loss, or NOL, carryforward of approximately $190.9 million and state net operating loss carryovers of approximately $145.9 million, which are available to offset future taxable income. We also had U.S. federal tax credits of approximately $3.4 million, and state tax credits of approximately $0.5 million, these tax attributes are prior to consideration of annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended, or Section 382. These carryforwards begin to expire in 2022. 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 performed any current analyses under Section 382 and cannot forecast or otherwise rely on deriving benefit from our various federal or state tax attribute carryforwards. 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.

Risks Related to our Products and Product Candidates

Our success depends in large part on the commercial success of our lead product, Xtampza.

To date, we have invested substantial resources in the development of our lead product, Xtampza, which has been approved by the FDA. Our business and future success are substantially dependent on our ability to successfully and timely commercialize this product, which may never occur. We currently generate no material revenues from product sales and we may never be able to commercialize Xtampza, or any product candidates that are approved by the FDA, successfully.

Our ability to successfully commercialize Xtampza 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 and clinical trials of Xtampza;
- the ability to manufacture commercial quantities of Xtampza at reasonable cost and with sufficient speed to meet commercial demand;
- our ability to build a sales and marketing organization to market Xtampza;
- our success in educating physicians, patients and caregivers about the benefits, administration, use and coverage of Xtampza;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of other abuse-deterrent products and treatments for chronic pain and chronic pain with dysphagia;

- our ability to successfully defend any challenges to our intellectual property relating to Xtampza;
- the availability of coverage and adequate reimbursement for Xtampza; and
- a continued acceptable safety profile of Xtampza following approval.

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 revenue from Xtampza. 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, and our ability to successfully market Xtampza may be adversely affected.

It is estimated that the U.S. market includes approximately 11 million patients with chronic pain with dysphagia. Our Xtampza microspheres are designed to be removed from the capsule and sprinkled on food or into a cup, and then directly into the mouth, or in feeding tubes, without compromising their extended-release properties. On April 26, 2016, the FDA granted approval for the Xtampza NDA, including an approved product label. The FDA could change the product labeling. If the product label for Xtampza is modified in the future so as to exclude the flexible dose administration options, including the ability to sprinkle the Xtampza microspheres on food or into a cup, then directly in the mouth, or in feeding tubes, or the FDA requires us to have a boxed warning 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 from other abuse-deterrent opioid formulations on the basis of alternative dosing options, and we may not be able to market Xtampza to patients with chronic pain with dysphagia. As a result, this may have an adverse effect on our business and our prospects for future growth.

If the FDA does not conclude that our product candidates in development are sufficiently bioequivalent, or demonstrate comparable bioavailability to their respective listed drugs, or if the FDA otherwise does not conclude that our product candidates satisfy the requirements for the Section 505(b)(2) approval pathway, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and the FDA may not approve those product candidates.

A key element of our strategy is to seek FDA approval for our product candidates through the Section 505(b)(2) regulatory pathway. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FD&C Act, permits the filing of an NDA that contains full safety and efficacy reports but where at least some of the information required for approval comes from studies not conducted by or for the applicant, such as the FDA's findings of safety and efficacy in the approval of a similar drug, and for which the applicant has not obtained a right of reference and/or published literature. Such reliance is typically predicated on a showing of bioequivalence or comparable bioavailability to an approved drug.

If the FDA does not allow us to pursue the Section 505(b)(2) approval pathway for our product candidates, or if we cannot demonstrate bioequivalence or comparable bioavailability of our product candidates to approved products, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates would increase. Moreover, our inability to pursue the Section 505(b)(2) approval pathway could result in new competitive products reaching the market sooner than our product candidates, which could have a material adverse effect on our competitive position and our business prospects. Even if we are allowed to pursue the Section 505(b)(2) approval pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization on a timely basis, if at all.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its policies and practices with respect to Section 505(b)(2) regulatory approvals, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

Even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the

indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products, including additional preclinical studies and clinical trials.

Our decision to seek approval of our product candidates, including Xtampza, under Section 505(b)(2) increases the risk that a patent infringement suit may be filed against us, which would delay the FDA's final regulatory approval of such product candidates.

In connection with any NDA that we file under Section 505(b)(2), we are required to notify the patent holders of the reference listed drug 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, expiration of the patents, settlement of the lawsuit or 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 product candidates only to be subject to significant delay and expensive and time-consuming patent litigation before our product candidates may be commercialized.

Even if we are found not to infringe any potential plaintiff's patent claims or the claims are found invalid or unenforceable, defending any such infringement claim could be expensive and time-consuming, and could delay the launch of our product candidates and distract management from their normal responsibilities. The Court could decline to hear our summary judgment motion, could decline to act expeditiously to issue a decision or hold a trial, or could decline to find that all of the listed patents are invalid or non-infringed. If we are unsuccessful in our defense of non-infringement and unable to prove invalidity of the listed patents, the court could issue an injunction prohibiting the launch of our product candidates. If we were to receive final regulatory approval by the FDA and launch any of our product candidates, , prior to a full and final determination that the patents are invalid or non-infringed, we could be subject to substantial liability for damages if we do not ultimately prevail on our defenses to a claim of patent infringement.

The regulatory approval processes of the FDA and foreign regulatory authorities are lengthy, time-consuming and unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval varies among jurisdictions and may change during the course of a product candidate's clinical development. Although the FDA has approved Xtampza, it is possible that none of our product candidates or any future product candidates that we may in-license, acquire or develop will ever obtain final regulatory approval from the FDA or any foreign regulatory authority. Moreover, even after any product candidate receives final regulatory approval, the FDA may require, as it has for Xtampza, costly post-marketing requirements. Successful and timely satisfaction of these post-marketing requirements will be necessary for us to maintain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or a foreign regulatory authority, or we may be required to conduct more extensive studies and clinical trials in order to receive such approval, for many reasons, including, but not limited to:

- the FDA and/or foreign regulatory authorities may disagree with or disapprove of the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure to demonstrate that a product candidate is bioequivalent to its listed drug;
- failure of clinical trials to meet criteria required for approval;

- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- deficiencies in the manufacturing processes or failure of third-party manufacturing facilities with whom we contract for clinical and commercial supplies to pass inspection;
- the FDA or foreign regulatory authorities may not approve the manufacturing processes or facilities of third party manufacturers with which we contract for clinical and commercial supplies; or
- insufficient data collected from clinical trials of our product candidates or changes in the approval policies or regulations that render our preclinical and clinical data insufficient to support the submission and filing of an NDA or to obtain regulatory approval.

The lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market our product candidates, which would harm our business, results of operations and prospects significantly.

In addition, even if we obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve, with respect to certain foreign regulatory authorities, the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing requirements, or may approve a product label that does not include the labeling claims necessary or desirable for the successful commercialization of that product. Any of the foregoing scenarios could have a material adverse effect on our business.

The FDA or a foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or cause us to abandon the development program. Even if we obtain regulatory approval, our product candidates may be approved for fewer or more limited indications than we request, such approval may be contingent on the performance of costly post-marketing requirements, or we may not be allowed to include the labeling claims necessary or desirable for the successful commercialization of such product candidate.

In order to market and sell our products outside the United States, we will likely need to obtain separate marketing approvals and comply with numerous and varied regulatory requirements and regimes, which can involve additional testing, may take substantially longer than the FDA approval process, and still generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. FDA approval does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by the FDA or regulatory authorities in other countries or jurisdictions. We may not obtain any regulatory approvals on a timely basis, if at all. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our product candidates by regulatory authorities in countries outside the United States, the commercial prospects of that product candidate may be significantly diminished and our business prospects could decline.

Development of our product candidates is not complete, and we cannot be certain that our product candidates will be commercialized.

We began the commercial launch of Xtampza, our first approved product, in June 2016. Accordingly, we have not generating any material revenues from product sales. To be profitable, and in addition to commercializing Xtampza, we must successfully research, develop, obtain regulatory approval for, manufacture, launch, market and distribute product candidates under development. For each product candidate that we intend to commercialize, we must successfully meet a

number of critical developmental milestones, including:

- selecting and developing a drug delivery technology to deliver the proper dose of drug over the desired period of time;
- determining the appropriate drug dosage that will be tolerated, safe and effective;
- demonstrating the drug formulation will be stable for commercially reasonable time periods;
- demonstrating that the drug is safe and effective in patients for the intended indication; and
- completing the manufacturing development and scale-up to permit manufacture of our product candidates in commercial quantities and at acceptable prices.

The time necessary to achieve these developmental milestones for any individual product candidate is long and uncertain, and we may not successfully complete these milestones for any of our product candidates in development. We may not be able to finalize the design or formulation of any product candidate. In addition, we may select components, solvents, excipients or other ingredients to include in our product candidates that have not been previously approved for use in pharmaceutical products, which may require us to perform additional studies and may delay clinical testing and regulatory approval of our product candidates. Even after we complete the design of a product candidate, the product candidate must still be shown to be bioequivalent to an approved drug or safe and effective in required clinical trials before approval for commercialization.

We are continuing to test and develop our product candidates and may explore possible design or formulation changes to address bioavailability, safety, efficacy, manufacturing efficiency and performance issues. We may not be able to complete development of any product candidates that will be safe and effective and that will have a commercially reasonable treatment and storage period. If we are unable to complete development of our product candidates, we will not be able to earn revenue from them.

Xtampza is, and we anticipate that our product candidates, if approved, will be, subject to mandatory REMS programs, which could increase the cost, burden and liability associated with the commercialization of such product and product candidates.

The FDA has approved a REMS for extended release, or ER, and long acting, or LA, opioid drugs formulated with the active 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. One of the primary goals of the ER/LA opioid REMS is to ensure that the benefits of these drugs continue to outweigh the risks.

The ER/LA opioid REMS introduces new safety measures designed to reduce risks and improve the safe use of ER/LA opioids, while continuing to provide access to these medications for patients in pain. The ER/LA opioid REMS applies to more than 20 companies that manufacture opioid analgesics. Under the ER/LA opioid REMS, companies are required to make education programs available to prescribers based on the FDA Blueprint for Prescriber Education for Extended Release and Long Acting Opioid Analgesics. 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 ER/LA opioid 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 ER/LA opioid 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.

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. As part of its approval of the Xtampza NDA, the FDA indicated that the REMS requirement for ER/LA opioids will apply to Xtampza. The 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 ER/LA opioid REMS requirements, which could reduce the commercial benefits to us from the sale of these product candidates.

If we fail to obtain the necessary final regulatory approvals, or if such approvals are limited, we will not be able to commercialize our product candidates, and we will not generate product revenues.

Even if we comply with all FDA pre-approval regulatory requirements, the FDA may determine that our product candidates are not safe or effective, and we may never obtain final regulatory approval for such product candidates. If we fail to obtain final regulatory approval for some or all of our product candidates, we will have fewer commercial products, if any, and correspondingly lower product revenues, if any. Even if our product candidates receive final regulatory approval, such final regulatory approval may involve limitations on the indications and conditions of use or marketing claims for our products, or may not include certain abuse-deterrence claims or clinical trial data that we have sought, and will seek, to include in the product label. If we do not receive regulatory approval to include certain abuse-deterrence claims, or certain clinical data, in our product labels, our ability to successfully commercialize our products may be limited and our financial results may be adversely impacted. Further, later discovery of previously unknown problems or adverse events could result in additional regulatory restrictions, including withdrawal of products and addition of warnings or other statements on the product label. The FDA is likely to require us to perform lengthy Phase 4 post-approval clinical efficacy or safety trials. As part of the FDA's approval of Xtampza, the FDA identified a number of studies that we will have to conduct, including required pediatric assessments and the post-marketing studies that have been required for other ER/LA opioid analgesics to estimate the serious risks of misuse, abuse, addiction, overdose, and death associated with long-term use of these medications for the management of chronic pain. The FDA will also require studies specific to Xtampza, including: (i) an epidemiologic study to evaluate whether the abuse-deterrent properties of Xtampza actually result in a significant and meaningful decrease in misuse and abuse, and their consequences with respect to addiction, overdose, and death; (ii) several long-term animal studies to evaluate the mixture of beeswax, carnauba wax, and myristic acid that is representative of Xtampza's composition; (iii) a study to characterize the levels of lead in Xtampza to inform a proposed release specification to adequately control levels of lead; and (iv) an evaluation of the beeswax employed in Xtampza's composition for potential residual levels of contaminants. The FDA also requires us to participate, with other manufacturers of ER/LA opioid analgesics, in a clinical trial of at least a year in length that would assess the known serious risk of hyperalgesia, or increased sensitivity to pain, with ER/LA opioid analgesics and the development of tolerance following use of these medications. The FDA may also impose additional post-marketing requirements, which will be very expensive to satisfy.

In jurisdictions outside the United States, we must receive marketing authorizations from the appropriate regulatory authorities before commercializing our product candidates. Regulatory approval processes outside the United States generally include requirements and risks similar to, and in many cases in excess of, those associated with FDA approval.

The FDA may not approve product labeling for our product candidates that would permit us to market and promote our products in the United States by describing their abuse-deterrent features.

We will invest substantial time and money conducting Category 1, Category 2 and Category 3 abuse deterrent studies to ensure that our product candidates developed with our DETERx technology comply with the FDA's April 2015 guidance regarding opioid abuse deterrence. Our failure to achieve FDA approval of product labeling containing such information will prevent or substantiality limit our promotion of the abuse deterrent features of our product candidates in order to differentiate them from other opioid products containing the same active ingredients. This would make our products less competitive in the market. There can be no assurance that any of our product candidates will receive final FDA-approved product labeling that describes the abuse deterrent features of such products. Furthermore, the FDA's April 2015 final guidance on abuse deterrent opioids makes clear that the FDA expects sponsors to compare their formulations against approved abuse deterrent versions of the same opioid based on the relevant categories of testing. If a proposed product is less resistant to manipulation than an approved product, the FDA has stated that the proposed product may not be eligible for product labeling regarding abuse deterrent properties. If the FDA does not approve product labeling containing abuse deterrence claims, we will not be able to promote such products based on their abuse deterrent features, may not be able to differentiate such products from other opioid products containing the same active ingredients, and may need to lower the price of our products to the extent that there are competing products with abuse

deterrent claims on their product labels.

Because the FDA closely regulates promotional materials and other promotional activities, even if the FDA initially approves product labeling that includes a description of the abuse deterrent characteristics of our product, 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 our products.

Even if any of our product candidates are approved for marketing with certain abuse-deterrence claims, 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.

Even if our product candidates receive regulatory approval, they will be subject to ongoing regulatory requirements, and we may face regulatory enforcement action if we do not comply with the requirements.

Even after a product is approved, we will remain subject to ongoing FDA and other regulatory requirements governing the product labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, import, export, record-keeping and reporting of safety and other post-market information. If we experience delays in obtaining FDA approval of our advertising and promotional materials for Xtampza or any product candidate that receives marketing approval, or if FDA approval of such materials is contingent upon substantial modifications, our promotional efforts relating to Xtampza and any approved product candidate may be impaired, and sales of such products may suffer.

The holder of an approved NDA is obligated to monitor and report adverse events, or AEs, and any failure of a product to meet the specifications in the NDA. In addition, manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, and other regulations. If we or a regulatory agency discover problems with a product which were previously unknown, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing, among other things. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include the imposition of various fines, reimbursements for inspection costs and penalties for noncompliance, and require due dates for specific actions;
- seek an injunction or impose civil, criminal and/or administrative penalties, damages, monetary fines, require disgorgement, consider exclusion from participation in Medicare, Medicaid and other federal healthcare programs and require curtailment or restructuring of our operations;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;

· suspend or impose restrictions on operations, including costly new manufacturing requirements;

· seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall; or

· refuse to allow us to enter into government contracts.

Similar post-market requirements may apply in foreign jurisdictions in which we may seek approval of our products. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue and may cause a material adverse impact on our financial condition and cash flows.

In addition, the FDA's regulations, policies or guidance may change and new or additional statutes or government regulations in the United States and other jurisdictions may be enacted that could further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our products and/or product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

Failure to comply with ongoing governmental regulations for marketing any product, including Xtampza, 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 obtains approval in the United States, including Xtampza, will be heavily scrutinized by, among others, the FDA, the Department of Justice, or the DOJ, the Office of Inspector General of the Department of Health and Human Services, or HHS, state attorneys general, members of Congress and the public. Violations, including promotion of Xtampza, and any product for which we receive final regulatory approval, 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. Additionally, advertising and promotion of any product that obtains approval outside the United States will be heavily scrutinized by foreign regulatory authorities.

In the United States, engaging in off-label promotion of Xtampza, or any 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. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, 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. Any of the following or other similar events, if they were to occur, could delay or preclude us from further developing, marketing or realizing the full commercial potential of Xtampza and our product candidates:

- failure to obtain or maintain requisite governmental approvals;
- failure to obtain approvals of product labeling with abuse-deterrent claims; or
- FDA required product withdrawals or warnings arising from identification of serious and unanticipated adverse side effects in our product candidates.

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

Xtampza and our product candidates contain, and our future product candidates will likely contain, controlled substances which are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Xtampza's active ingredient, oxycodone, is classified as a controlled substance under the Controlled Substances Act of 1970, or CSA, and regulations of the U.S. Drug Enforcement Administration, or DEA. A number of states also independently regulate these drugs, including oxycodone, as controlled substances. Controlled substances are classified by the DEA as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredient in Xtampza, oxycodone, is listed by the DEA as a Schedule II controlled substance under the CSA. For our product candidates containing controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign 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. We may not be able to obtain sufficient quantities of these controlled substances in order to complete our clinical trials or meet commercial demand.

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 Xtampza and product candidates 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 Xtampza and product candidates 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 products containing controlled substances.

Clinical development is a lengthy and expensive process with an uncertain outcome, and failure can occur at any stage of clinical development. If we are unable to design, conduct and complete clinical trials successfully, our product candidates will not be able to receive regulatory approval.

In order to obtain FDA approval for any of our product candidates, we must submit to the FDA an NDA with substantial evidence that demonstrates that the product candidate is both safe and effective in humans for its intended use. This demonstration requires significant research, preclinical studies and clinical trials.

Other than Xtampza, all of our product candidates are in preclinical and clinical development. Clinical trials are time-consuming, expensive and difficult to design and implement, in part because they are subject to rigorous requirements and their outcomes are inherently uncertain. Clinical testing may take many years to complete, and failure can occur at any time during the clinical trial process, even with active ingredients that have previously been approved by the FDA as being safe and effective. We could encounter problems that halt our clinical trials or require us to repeat such clinical

trials. If patients participating in clinical trials suffer drug-related adverse reactions during the course of such clinical trials, or if we or the FDA believe that patients are being exposed to unacceptable health risks, such clinical trials may be suspended or terminated. Suspensions, termination or the need to repeat a clinical trial can occur at any stage.

The clinical trial success of each of our product candidates depends on reaching statistically significant changes in patients' symptoms based on clinician-rated scales. There is a lack of consensus regarding standardized processes for assessing clinical outcomes based on clinician-rated scales. Accordingly, the scores from our clinical trials may not be reliable, useful or acceptable to the FDA or other regulatory agencies.

Changes in standards related to clinical trial design could have a material adverse effect on our ability to design and conduct clinical trials as planned. For example, we have conducted or will conduct clinical trials comparing our product candidates to both placebo and other approved drugs, but regulatory authorities may not allow us to compare our product candidates to a placebo in a particular clinical indication where approved products are available. In that case, both the cost and the amount of time required to conduct a clinical trial could increase. The FDA may disagree with our trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials. The FDA may also approve a product candidate for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials. In addition, the FDA may not approve the product labeling claims or removal of certain warnings that we believe are necessary or desirable for the successful commercialization of our product candidates.

Approval may be contingent on a REMS, which could have a material adverse effect on the product labeling, distribution or promotion of a drug product.

Any of these delays or additional requirements could cause our product candidates to not be approved, or if approved, significantly impact the timing of commercialization and significantly increase our overall costs of drug development.

Because the results of preclinical studies and early-stage clinical trials are not necessarily predictive of future results, any product candidate we advance into additional clinical trials may not continue to have favorable results or receive regulatory approval.

Other than Onsolis, all of our product candidates are in preclinical or early-stage clinical development. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. Many companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in clinical trials, even after positive results in earlier clinical trials. Despite preliminary preclinical studies for our other extended-release, abuse deterrent product candidates, including hydrocodone and oxymorphone for pain, and methylphenidate for the treatment of ADHD, we do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety or otherwise provide adequate information to result in regulatory approval to market any of our product candidates in any particular jurisdiction. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be compromised.

Conducting clinical trials of Xtampza and our product candidates and any commercial sales of Xtampza and/or 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 with coverage up to approximately $10 million. Product liability claims may be brought against us by patients enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our products or product candidates 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 product or product candidates that we may develop;
- termination of clinical trial sites or entire trial programs;

- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- 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;
- the inability to commercialize any products that we may develop; 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 Xtampza and our product candidates. Any agreements we may enter into in the future with collaborators in connection with the development or commercialization of Xtampza and our product candidates 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 indemnifications obligations may exceed the coverage under our product liability insurance policy.

Xtampza and our product candidates may be associated with undesirable adverse reactions or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of their approved product label, or result in significant negative consequences following any marketing approval.

Undesirable adverse reactions associated with Xtampza and our product candidates 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 or foreign regulatory authorities. For example, even though Xtampza has generally been 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 Xtampza or any product candidate for which we receive final regulatory approval, 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 Xtampza or any of our

product candidates, if approved.

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 develop product candidates and commercialize products without infringing the intellectual property rights of others. Our current or future product candidates or 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 elsewhere in the world 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, oxymorphone, hydrocodone, morphine, and methylphenidate drugs and 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 Xtampza or our product candidates, 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 Xtampza or our product candidates or force us to cease some of our business operations.

In connection with any NDA that we file under Section 505(b)(2), including the NDA for Xtampza, 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 product candidates only to be subject to significant delay and patent litigation before our product candidates 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 approval or commercialization of our product candidates 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 in countries outside 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 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 technology, products and product candidates, we may lose valuable assets or experience reduced market share.

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 and other countries with respect to our proprietary technology and product candidates.

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, both inside and outside 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, product candidates or future product candidates. Even if our owned 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 and in foreign jurisdictions is highly uncertain, and changes in U.S. and foreign patent law have increased that uncertainty and could diminish the value of patents in general, thereby impairing our ability to protect our product candidates and any future products.

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 and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and these foreign laws may also be subject to change.

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions 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, both in the United States and abroad, are highly uncertain.

Recent 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, only became effective on March 16, 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 and abroad. 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 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, products and product candidates, 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 both within and outside 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 not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and sell their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents or our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or the marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

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 and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents are required to be paid to the USPTO and foreign patent agencies 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 product candidates, our competitive position would be adversely affected.

Risks Related to the Commercialization of Our Product Candidates

We currently have limited sales and marketing capabilities and, if we are unable to expand our own sales and marketing capabilities or enter into strategic alliances with marketing collaborators, we may not be successful in commercializing Xtampza and our product candidates and may be unable to generate any material product revenue.

Although our executive officers have experience marketing pharmaceutical products, we currently have limited sales, marketing or distribution capabilities. Our sales and marketing team has worked together for only a limited period of time. We cannot guarantee that we will be successful in marketing Xtampza or any of our product candidates which may be approved for marketing. In addition, we will have to 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 establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate material product revenue and may not become profitable. Factors that may inhibit our efforts to commercialize our product candidates 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 obtain access to or persuade adequate numbers of physicians to prescribe Xtampza and our product candidates;
- 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 Xtampza or our product candidates. To the extent we commercialize Xtampza or our product candidates 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 Xtampza or our product candidates, 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 Xtampza or any of our product candidates, for which we receive final regulatory approval. Acceptance and use of Xtampza and any product candidates for which we receive final regulatory approval will depend on a number of factors including:

- the timing of market introduction of Xtampza and the product candidates as well as 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 Xtampza and our product candidates, and, in particular, the relevance and efficacy of our abuse deterrent technology in reducing potential risks of unintended use;
- perceptions by physicians regarding the cost benefit of Xtampza and our product candidates in reducing potential risks of unintended use;
- published studies demonstrating the cost-effectiveness of Xtampza and our product candidates relative to competing products;
- the potential and perceived advantages of Xtampza and our product candidates over alternative treatments;
- the convenience and ease of administration to patients of Xtampza and our product candidates;
- actual and perceived availability of coverage and reimbursement for Xtampza and our product candidates from government or other third-party payors;
- any negative publicity related to our or our competitors' products that include the same active ingredient as Xtampza and our product candidates;
- the prevalence and severity of adverse side effects, including limitations or warnings contained in a product's FDA approved product labeling;
- our ability to implement a REMS; and
- effectiveness of marketing and distribution efforts by us and any licensees and distributors.

If Xtampza or our product candidates for which we receive final regulatory approval, fail to achieve an adequate level of acceptance by physicians, healthcare payors, patients or the medical community, we will not be able to generate significant revenue, and we may not become or remain profitable. Because we expect to rely on sales generated by Xtampza for substantially all of our revenues for the foreseeable future, the failure of Xtampza to find market acceptance would harm our business prospects.

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

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and

proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities or affect our ability to profitably sell Xtampza or any product candidates for which we obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. 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 reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

The pricing of pharmaceutical products, in general, and specialty drugs, in particular, has also been a topic of concern in the U.S. government. There can be no assurance as to how this scrutiny on pricing of pharmaceutical products will impact future pricing of our products or orphan drugs or pharmaceutical products generally.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Affordable Care Act revised the definition of “average manufacturer price” for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. A significant number of provisions are not yet, or have only recently become, effective, but the Affordable Care Act is likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. We expect that the Affordable Care Act, as well as other healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may compromise our ability to generate revenue, attain profitability or commercialize our products. Finally, there are ongoing efforts to modify or eliminate the ACA. It is unknown what form any such modifications or any law proposed to replace the ACA would take, and how or whether it may affect our business in the future.

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 approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In 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 Xtampza or our product candidates, which could significantly diminish demand for them and significantly impact our ability to successfully commercialize our products and generate revenues.

Even if we are able to commercialize Xtampza and any of our product candidates, 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.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could

involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. Pricing limitations may hinder our ability to recoup our investment in Xtampza and our product candidates even if our product candidates obtain marketing approval.

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 predetermined discounts from list prices and are challenging the prices charged for medical 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. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

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 or foreign regulatory authorities. 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 any approved products that we develop 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 Xtampza and our product candidates.

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 Xtampza and our product candidates.

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; 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 Xtampza and our product candidates 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 opioids.

Efforts by the FDA and other regulatory bodies to combat abuse of opioids may negatively impact the market for our product candidates. 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 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 Scientific Board to broaden the understanding of the public risks of opioid abuse. The FDA's Scientific Advisory Board met to address these issues on March 1, 2016. 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. Also 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 new 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. Many of these changes and others could cause us to expend additional resources in developing and commercializing Xtampza and our product candidates 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 product candidates and cause our product candidates to be less commercially successful.

If the FDA or other applicable regulatory authorities approve generic products with abuse deterrent claims that compete with Xtampza or any of our product candidates, it 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 abbreviated NDA, or 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 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 product and product candidates.

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

Government agencies promulgate regulations and guidelines directly applicable to us and to Xtampza and our product candidates. 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 fails to devote sufficient time and resources to Xtampza, or its performance is substandard, our costs may be higher than expected and could have a material adverse effect on our business.

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 and our product candidates. We currently rely, and expect to continue to rely, on a limited number of experienced personnel and one contract manufacturer for Xtampza and each product candidate, as well as other vendors to formulate, test, supply, store and distribute Xtampza and our product candidates for our clinical trials and FDA registration, and we control only certain aspects of their activities. 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, as our single manufacturer for Xtampza, exposes us to the following risks, any of which could delay FDA approval of our product candidates and 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, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical 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 its agreement with us to meet our requirements for commercial supplies of Xtampza.

- 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 or any product candidate for which we receive regulatory approval, 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.

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 and our product candidates that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. 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 product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. 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.

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

We presently depend upon a single supplier for the active ingredient for Xtampza — oxycodone base — and we intend to contract with this supplier, as necessary, for commercial supply of our products. Although we have identified an alternate source for oxycodone base, it would be time-consuming and costly to qualify this source. Since we currently obtain our active ingredient from this manufacturer on a purchase-order basis, either we or our supplier may terminate our arrangement, without cause, at any time without notice. If our supplier were to terminate our arrangement 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.

We rely on third parties to conduct our 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 obtain regulatory approval for or commercialize our product candidates 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 preclinical and clinical programs. We rely on these parties for execution of our 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 Good Clinical Practices, or 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 product candidates in clinical development. 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 product candidates may require us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process.

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 or successfully commercialize our product candidates. As a result, the commercial prospects for our product candidates 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 product candidates 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.

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

We may not be successful in establishing development and commercialization collaborations which could adversely affect, and potentially prohibit, our ability to develop or commercialize Xtampza and our product candidates. These collaborations, including our license agreement for the development and marketing of Onsolis, 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 product candidates 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 or product candidate, repeat or conduct new clinical trials or require a new formulation of our product or product candidate for clinical testing.
- collaborators may 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 or product candidates.
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product or product candidates 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 one or more 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 product and product candidates 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 product or product candidates.
- collaboration agreements may not lead to development or commercialization of products or product candidates 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.

We may rely on collaborators to market and commercialize Xtampza and, if approved, our product candidates, 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 Xtampza and our product candidates, if approved by the FDA. 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 and product candidates 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 product and product candidates would diminish our revenues.

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 product candidates 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.

Risks Related to Our Business and Strategy

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 product candidates, if approved, will 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, Depomed, Egalet, Endo, Mallinckrodt, Pernix, 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 product and product candidates. 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. For example, several competitors have developed extended-release hydrocodone products, and if the FDA grants exclusivity, we could be subject to a delay that would dramatically reduce the expected market penetration for our hydrocodone product candidate. Additionally, even if our 505(b)(2) application is approved for marketing, we may still be subject to competition from other hydrocodone products, including approved products or other approved 505(b)(2) NDAs for different conditions of use that would not be restricted by any grant of exclusivity to us.

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 product candidates. Our competitors may develop products that are safer, more effective or less costly than our product candidates and, therefore, present a serious competitive threat to our product offerings.

The widespread acceptance of currently available therapies with which our product and product candidates, if approved, compete may limit market acceptance of our product and product candidates even if commercialized. 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 product and product candidates, if approved, and the established use of these competitive products may limit the potential for our product and product candidates to receive widespread acceptance if commercialized.

The use of legal and regulatory strategies by competitors with innovator products, including the filing of citizen petitions, may delay or prevent the introduction or approval of our product candidates, increase our costs associated with the introduction or marketing of our products, or significantly reduce the profit potential of our product candidates.

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:

- filing "citizen petitions" with the FDA that may delay competition by causing delays of our product approvals;
- 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 product and product candidates.

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, Michael T. Heffernan, and our Chief Commercial Officer, Barry Duke. Each employee is employed by us at will and is permitted to terminate his employment with us at any time pursuant to the terms of his employment agreement. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of Mr. Heffernan or Mr. Duke could impede the achievement of our development and commercialization objectives.

If we are unable to attract and retain highly qualified scientific and technical 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 scientific 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 for the development of our 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 could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. 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 product and product candidates 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, that 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 product candidates, businesses or 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 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 alliance or collaborators or identify other investment opportunities, and we may experience losses related to any such investments.

To finance any acquisitions or collaborations, 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 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.

Our employees, independent contractors, principal investigators, CROs, 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, 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 be in compliance 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 Xtampza and any product candidates for which we may obtain marketing approval. Our future 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 Xtampza 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, state and foreign 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 and foreign 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 and foreign 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 and foreign 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 and product candidates, 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, or CMO, and other third parties on which we rely, are vulnerable to damage from computer

viruses, unauthorized access, 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 development of our product candidates 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 various 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 product and product candidates or our competitors' products or product candidates;
- actual or anticipated changes in our growth rate relative to our competitors;
- the outcome of any patent infringement or other litigation that may be brought against us, including the ongoing Purdue litigation;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- results of clinical trials of our product and product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- 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 product and product candidates 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 product candidates or 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.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Holders of an aggregate of approximately 6.3 million shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders. Once we register these shares, they can be freely sold in the public market, subject to volume limitations applicable to affiliates.

Actual or potential sales of our common stock by our directors or employees, including our executive officers, pursuant to pre-arranged stock trading plans 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.

We expect that significant additional capital will 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 majority of our stock and have the ability to exert significant control over matters subject to shareholder approval.

As of December 31, 2016, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned a majority of our voting stock, including shares subject to outstanding options and warrants. 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.

In addition, persons associated with Longitude Capital Partners, LLC, Skyline Venture Partners V, L.P., and TPG Biotechnology Partners IV, L.P. currently serve on our board of directors. The interests of Longitude Capital Partners, LLC, Skyline Venture Partners V, L.P., and TPG Biotechnology Partners IV, L.P. may not always coincide with the interests of the other shareholders, and the concentration of control in Longitude Capital Partners, LLC, Skyline Venture Partners V, L.P., and TPG Biotechnology Partners IV, L.P. limits other shareholders' ability to influence corporate matters. We may also take actions that our other shareholders do not view as beneficial, which may adversely affect our results of operations and financial condition and cause a decline in our stock price.

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.

We are an "emerging growth company" and we intend to take advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in our common stock being less attractive to investors and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our shares of common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various reporting requirements applicable to other public companies, but not to emerging growth

companies, including, but not limited to, an exemption from the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act, reduced disclosure about executive compensation arrangements pursuant to the rules applicable to smaller reporting companies and no requirement to seek non-binding advisory votes on executive compensation or golden parachute arrangements. We will remain an emerging growth company until the earliest of (i) December 31, 2020, (ii) the first fiscal year after our annual gross revenue are $1.0 billion or more, (iii) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt securities or (iv) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700 million as of the end of the second quarter of that fiscal year.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we are choosing to “opt out” of such extended transition period and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

We cannot predict if investors will find our common stock less attractive as a result of our taking advantage of these exemptions. If some investors find our common stock less attractive as a result of our choices, there may be a less active trading market for our common stock and our stock price may be more volatile.

If investors find our common stock less attractive as a result of our reduced reporting requirements, there may be a less active trading market for our common stock and our stock price may be more volatile. We may also be unable to raise additional capital as and when we need it.

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. Commencing with our annual report on Form 10-K for the year ended December 31, 2016, we will be 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 will need to 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. However, for as long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirement.

Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion, which could potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. 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.

In addition, as of December 31, 2016, there were (a) outstanding options to purchase an aggregate of 2,326,801 shares of our common stock at a weighted average exercise price of $13.07 per share, of which options to purchase 556,040 shares of our common stock were then exercisable, and (b) 2,445 shares of common stock issuable upon the exercise of warrants to purchase common stock at a weighted-average exercise price of $12.27 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 your 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 or development of our product and product candidates.

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 your 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 your sole source of gain for the foreseeable future.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our corporate headquarters are located in Canton, Massachusetts, where we lease 19,335 square feet of office space (including chemistry and pilot/formulation laboratories) under a lease agreement that was amended in March 2015. The lease term terminates on the date that is five years following August 2015, which is the date that the landlord delivered the expansion space with certain improvements substantially completed. The lease term may be extended for an additional five-year term at our election.
We believe that our existing facility is 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

We filed the NDA for Xtampza 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 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, which was late-listed in the Orange Book and therefore could not trigger any stay of FDA approval. In June 2016, Purdue filed another follow-on suit asserting infringement of another non-Orange Book listed patent, Patent No. 9,155,717. These suits were consolidated by the District of Massachusetts into the original action where Purdue's infringement claim relating to the '497 patent remains pending. Purdue continues to assert infringement of these three patents against us,

none of which is associated with any stay of FDA approval. All of Purdue's pending patents claims against us are now consolidated into the action pending before the District of Massachusetts. Purdue has made a demand for monetary relief but has not quantified their alleged damages. Purdue has also requested a judgment of infringement 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 2017. The parties are also in the claims construction stage of the patent litigation. The parties have briefed their proposed constructions and are scheduled to argue their positions in front of the Court in the second quarter of 2017. We have also filed a fully dispositive motion for summary judgment that the asserted claims of the '933, '497, and '717 patents are invalid and not infringed. We are not able to predict with certainty when the Court will decide our motion. No trial date has been scheduled.

We are, and 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.

From time to time, we may be subject to various claims and legal proceedings. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount is reasonably estimated, we will accrue a liability for the estimated loss.

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, 2016	High	Low
First quarter	$ 28.47	$ 13.80
Second quarter	$ 20.03	$ 11.55
Third quarter	$ 20.25	$ 8.24
Fourth quarter	$ 20.55	$ 13.81

Year Ended December 31, 2015	High	Low
Second quarter (from May 7, 2015)	$ 20.62	$ 11.92
Third quarter	$ 24.88	$ 12.58
Fourth quarter	$ 30.58	$ 15.51

Holders

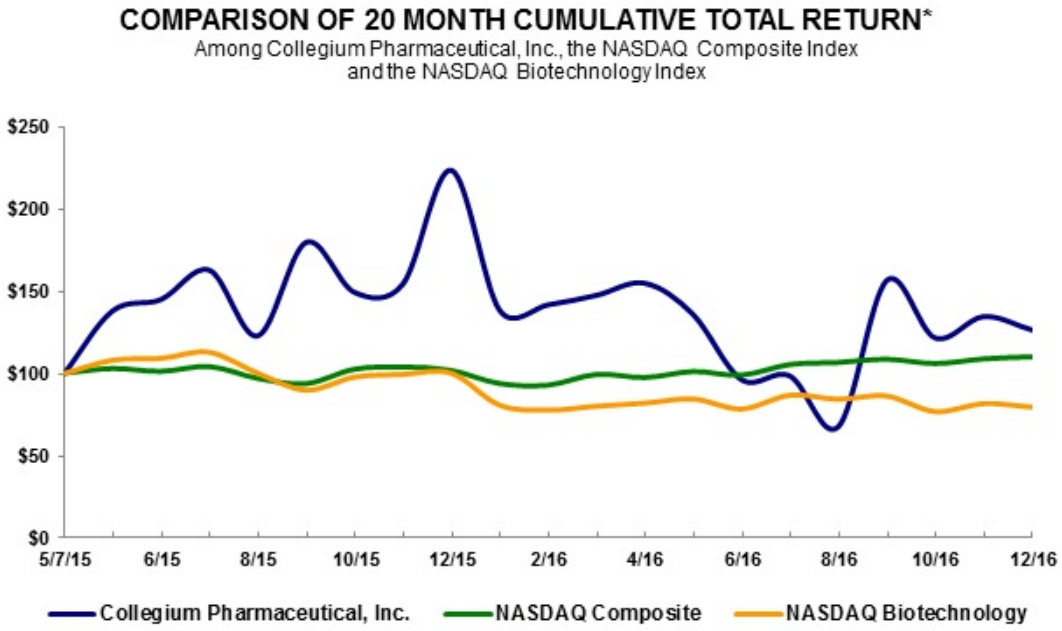
As of March 1, 2017, there were 45 holders of record of our common stock. The number of holders of record does not include beneficial owners whose shares are held by nominees in street name.

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, 2016. 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 invested on 5/7/15 in stock or 4/30/15 in index, including reinvestment of dividends.
Fiscal year ending December 31.

$100 investment in stock or index	May 7, 2015	December 31, 2015	December 31, 2016
Collegium Pharmaceutical, Inc. (COLL)	$ 100.00	$ 223.76	$ 126.69
NASDAQ Composite Index (IXIC)	$ 100.00	$ 101.48	$ 109.84
NASDAQ Biotechnology Index (NBI)	$ 100.00	$ 99.51	$ 79.90

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 Annual Report on Form 10-K.

Use of Proceeds

Our IPO was effected through a Registration Statement on Form S-1 (File No. 333-203208) that was declared effective by the SEC on May 6, 2015, which registered an aggregate of 6,670,000 shares of our common stock. On May 12, 2015, 6,670,000 shares of common stock were sold on our behalf at an IPO price of $12.00 per share, including 870,000 shares of common stock upon the exercise by the underwriters of their option to purchase additional shares at the public offering price, for aggregate gross proceeds to us of $74.4 million. As of the date of filing this report, the offering has terminated, and all of the securities registered pursuant to the offering have been sold prior to termination. Jefferies LLC and Piper Jaffray & Co. acted as joint book-running managers. Wells Fargo Securities, LLC acted as lead manager and Needham & Company, LLC acted as co-manager in the offering.

The net proceeds of the offering to us, after deducting underwriting discounts and commissions of $5.6 million and offering expenses of $2.4 million, were approximately $72.0 million. On May 12, 2015, the closing date of the offering, we received the proceeds from the offering, all of which have been utilized for the development of our commercial infrastructure, research and development of our other product candidates and general corporate purposes, including working capital.

The foregoing expenses are a reasonable estimate of the expenses incurred by us in the offering and do not represent the exact amount of expenses incurred. All of the foregoing expenses were direct or indirect payments to persons other than (i) our directors, officers or any of their associates; (ii) persons owning 10% or more of our common stock; or (iii) our affiliates.

There has been no material change in the use of proceeds from the IPO as described in the final prospectus filed with the SEC on May 7, 2015 under “Use of Proceeds.”

In January 2016, we issued and sold in a public offering an aggregate of 2,750,000 shares of its common stock at $20.00 per share. We received net 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 its 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.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not repurchase any of our equity securities during the fourth quarter of the fiscal year ended December 31, 2016.

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,		
	2016	2015	2014
	(in thousands, except share and per share amounts)		
Statement of Operations Data:			
Product revenues, net	$ 1,711	$ —	$ —
Costs and expenses			
Cost of product revenues	213	—	—
Research and development	14,948	7,975	14,959
Selling, general and administrative	80,632	18,932	2,706
Total costs and expenses	95,793	26,907	17,665
Loss from operations	(94,082)	(26,907)	(17,665)
Interest expense, net	94	439	252
Gain on extinguishment of debt	—	(91)	—
Net loss	$ (94,176)	$ (27,255)	$ (17,917)
Basic and diluted net loss per common share[(1)]:	$ (3.88)	$ (1.48)	$ (22.72)
Weighted-average shares used to compute loss per common share[(1)]:	24,262,945	13,542,282	933,997

(1) See Note 3 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,		
	2016	2015	2014
Balance Sheet Data:			
Cash and cash equivalents	$ 153,225	$ 95,697	$ 1,634
Working capital[(1)]	132,979	88,451	(5,921)
Total assets	162,017	97,718	5,090
Other long-term liabilities	1,513	4,214	6,914
Total shareholders' equity (deficit)	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 Annual Report on Form 10-K. The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those discussed below and as set forth under "Risk Factors." Please also refer to the section under heading "Forward-Looking Statements."

Overview

We are a specialty pharmaceutical company developing and commercializing next-generation abuse-deterrent products that incorporate our patented DETERx platform technology for the treatment of chronic pain and other diseases. Our first product, Xtampza, is an abuse-deterrent, extended-release, oral formulation of oxycodone, a widely prescribed opioid medication. In April 2016, the U.S. Food and Drug Administration, or FDA, approved our new drug application, or NDA, filing for Xtampza 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. Certain human abuse potential studies are included in the approved label, as well as data supporting the administration of the product as a sprinkle or administered through feeding tubes. In June 2016, we announced the commercial launch of Xtampza. In October 2016, we announced the submission of a New Drug Submission to Health Canada seeking marketing approval of Xtampza for the same indication for which we obtained approval from the FDA.

Xtampza has the same active ingredient as OxyContin OP, which is the largest selling abuse-deterrent, extended-release opioid in the United States by dollars, with $2.1 billion in U.S. sales in 2016. We conducted a comprehensive preclinical and clinical program for Xtampza consistent with FDA guidance on abuse-deterrence. These studies and clinical trials demonstrated that chewing, crushing and/or dissolving Xtampza, and then taking it orally or smoking, snorting, or injecting it did not meaningfully change its drug release profile or safety characteristics. By contrast, clinical trials performed by us and others — including head-to-head clinical trials comparing Xtampza with OxyContin OP — have shown that drug abusers can achieve rapid release and absorption of the active ingredient by manipulating OxyContin OP using common household tools and methods commonly available on the Internet. In October 2016, we announced the submission of a Supplemental New Drug Application to the FDA for Xtampza to include comparative oral pharmacokinetic data from a recently completed clinical study evaluating the effect of physical manipulation by crushing Xtampza compared with OxyContin OP and a control (oxycodone hydrochloride immediate-release).

In addition, our preclinical studies and clinical trials have shown that the contents of the Xtampza capsule can be removed from the capsule and sprinkled on food or into a cup, and then directly into the mouth, or administered through feeding tubes, without compromising their drug release profile, safety or abuse-deterrent characteristics. By contrast, OxyContin OP, which is formulated in hard tablets, has a black box warning label stating that crushing, dissolving, or chewing can cause rapid release and absorption of a potentially fatal dose of the active ingredient. We believe that Xtampza can address the pain management needs of the approximately 11 million patients in the United States who suffer from chronic pain and have difficulty swallowing.

In May 2016, we entered into a License and Development Agreement with BioDelivery Science International, Inc. which grants us an exclusive license to make, use, sell, offer for sale, import, develop and commercialize Onsolis in the United States. We plan to commercialize Onsolis upon receipt of FDA approval of a Prior Approval Supplement for the manufacturing transfer. Subject to such approval, we expect to launch Onsolis in the first half of 2018.

Since 2010, when we divested our former subsidiary, Onset Therapeutics, LLC, to PreCision Dermatology, Inc., we have devoted substantially all of our resources to the development of our patented DETERx platform technology, the preclinical and clinical advancement of our product candidates, pre-commercialization activities and the creation and protection of related intellectual property. Since 2011, we have not generated any significant revenue from product sales and we continue to incur significant research, development and other expenses related to our ongoing operations. Prior to our initial public offering of common stock, or IPO, in May 2015, we funded our operations primarily through the private placement of preferred stock, convertible notes and commercial bank debt. Since our IPO, we have funded our operations primarily through the proceeds of public offerings and sale of our equity securities

Outlook

We expect to continue to incur significant commercialization expenses related to marketing, manufacturing, distribution, selling and reimbursement activities. Initially, we are detailing Xtampza to approximately 10,400 physicians who write approximately 60% of the branded extended-release oral opioid prescriptions in the United States with a sales team of approximately 120 sales representatives. In addition, we deploy a separate, focused sales team to detail Xtampza to

nursing homes, hospices and other institutions treating large populations of the elderly and other patients who need chronic pain relief and may have difficulty swallowing.

We have never been profitable and have incurred net losses in each year since inception. We incurred net losses of $94.2 million, $27.3 million and $17.9 million for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had an accumulated deficit of $223.2 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 foreseeable future as we continue to commercialize Xtampza. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect our expenses will increase in connection with our ongoing activities as we:

- expand our sales and marketing efforts for Xtampza, including hiring additional personnel to expand our commercial organization;
- expand our regulatory and compliance functions;
- conduct clinical trials of our product candidates;
- continue scale-up and improvement of our manufacturing processes;
- continue our research and development efforts;
- manufacture preclinical study and clinical trial materials;
- maintain, expand and protect our intellectual property portfolio;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- hire additional clinical, quality control and technical personnel to conduct our clinical trials;
- hire additional scientific personnel to support our product development efforts;
- implement operational, financial and management systems; and
- hire additional selling, general and administrative personnel to operate as a commercial stage public company.

We believe that our cash and cash equivalents at December 31, 2016, together with expected cash inflows from the commercialization of Xtampza, will enable us to fund our operating expenses, debt service and capital expenditure requirements into 2019. In addition, we will seek in the future to fund our operations through additional public or private equity or debt financings or other sources, including from net sales of our products. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If we are unable to obtain financing or increase profitability, the related lack of liquidity will have a material adverse effect on our operations and future prospects.

Financial Operations Overview

Product Revenues

Product revenue to date has been generated from product sales of Xtampza. Product sales of Xtamzpa are recorded net of estimated chargebacks, rebates, sales incentives and allowance, distribution service fees, as well as estimated product returns.

Cost of Product Revenues

Cost of product revenues include the cost of active pharmaceutical ingredient (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.

Research and Development Expenses

Research and development expenses consist of development costs associated with our DETERx platform technology and product candidates programs. 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 and laboratory equipment;
- 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 current or future preclinical studies and clinical trials of our product candidates. At this time, due to the inherently unpredictable nature of preclinical and clinical development, and given the early stage of our product candidates, we are unable to estimate with any certainty the costs we will incur and the timelines required for the development of our product candidates. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. In addition, we cannot forecast which product candidates 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. 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. We expect to track specific project costs when additional product candidates enter clinical trials in humans.

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.

We anticipate that our selling, general and administrative expenses will increase in the future as we increase our administrative headcount to support our continued research and development and potential commercialization of our product candidates, in addition to the potential expansion of commercialization efforts for Xtampza. We also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, and investor relations costs associated with being a public company.

Other Expense, Net

Other expense, net consists of interest income and interest expense.

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 financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("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 financial statements. We evaluate our estimates and judgments on an ongoing basis. Estimates include revenue recognition, including the estimates of discounts and to commercial sales of Xtampza, estimates utilized in the valuation of inventory, estimates of useful lives with respect to intangible assets, accounting for stock-based compensation, contingencies, intangible assets, tax valuation reserves and accrued expenses. We base our estimates on historical experience and on various other 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. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this 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 financial statements.

Revenue Recognition

Our accounting policy for revenue recognition will have a substantial impact on reported results and relies on certain estimates. Revenue for product sales is recognized when there is persuasive evidence of an arrangement, title and risk of loss have passed to the customer, when estimated provisions for chargebacks, rebates, sales incentives and allowances, distribution service fees, and returns are reasonably determinable, and when collectability is reasonably assured. Product revenue is recorded net of estimated chargebacks, rebates, sales incentives and allowance, distribution service fees, as well as estimated product returns.

We sell Xtampza in the United States principally to customers, which in turn sell the product to healthcare providers for the treatment of patients. We provide the right of return to our customers for unopened product for a limited time before and after its expiration date. Given our limited sales history for Xtampza and the inherent uncertainties in estimating product returns, we have determined that the shipments of Xtampza made to our customers thus far do not meet the criteria for revenue recognition at the time of shipment. Accordingly, we recognize revenue when the product is sold-through by our customers, provided all other revenue recognition criteria are met. We invoice customers upon shipment of Xtampza to them and record accounts receivable, with a corresponding liability for deferred revenue equal to the gross invoice price, less any realized adjustments to the gross invoice price. We then recognize revenue when Xtampza is sold-through, or when product is prescribed directly to the patient. Healthcare providers to whom distributors sell Xtampza hold limited inventory that is designated for patients, thereby limiting the risk of return.

Inventory

Upon approval of Xtampza by the FDA in April 2016, we began capitalizing inventory costs for Xtampza in preparation for the product launch. Prior to April 2016, we expensed costs associated with Xtampza, including raw materials, work in process and finished goods, as research and development expense. We have not capitalized inventory costs related to our other drug development programs.

We have capitalized $1.3 million of inventory as of December 31, 2016. We expect sales of the capitalized units to occur during the next twelve months. We expect costs of product revenues to increase due to the expected increases in net product sales of Xtampza and the fact that we had expensed all manufacturing costs as research and development expense in periods prior to FDA approval of Xtampza. The impact on cost of product revenues as a result of inventory not capitalized prior to FDA approval is immaterial

Impairment of Long-Lived Assets

Long-lived assets consist primarily of finite-lived intangible assets and property and equipment. We test long-lived 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 long-lived assets is less than the carrying amount of such assets, the long-lived assets would be written down to the estimated fair value, calculated based on the present value of expected future cash flows. While our current and historical operating losses and negative cash flows are indicators of impairment, we believe that expected future cash flows to be received support the carrying value of our long-lived assets and, accordingly, have not recognized any impairment losses on long-lived assets for the years ended December 31, 2016, 2015 and 2014.

Accrued Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees payable to:

- clinical research organizations and investigative sites in connection with clinical trials;

- vendors in connection with preclinical development activities;
- vendors related to product manufacturing, development, and distribution of clinical materials; and
- professional service fees for consulting and related services.

We base our expense accruals related to clinical trials on our estimates of the services received and efforts expended pursuant to our contractual arrangements. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows and expense recognition. There may be instances in which payments made to our service providers will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differs from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period. To date, there have been no material differences from our estimates to the amount actually incurred.

Stock-Based Compensation

We account for grants of stock options and restricted stock to employees based on their grant date fair value and recognize compensation expense over the vesting periods. We estimate the fair value of stock options as of the date of grant using the Black-Scholes option pricing model, and we estimate the fair value of restricted stock awards and restricted stock units based on the fair value of the underlying common stock as determined by our board of directors or the value of the services provided, whichever is more readily determinable. We account for stock options, restricted stock awards and restricted stock units to non-employees using the fair value approach. Stock options and restricted stock awards to non-employees are subject to periodic revaluation over their vesting terms.

Stock-based compensation expense represents the cost of the grant date fair value of employee stock option grants recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis, net of estimated forfeitures. We estimate the fair value of stock option grants using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (i) the risk-free interest rate, (ii) the expected volatility of our stock, (iii) the expected term of the award and (iv) the expected dividend yield. The risk-free interest rates for periods within the expected life of the option are based on the yields of zero-coupon U.S. Treasury securities. Prior to our IPO, there was no public market for the trading of our common stock. Due to the lack of a public market for the trading of our common stock and a lack of Company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. For these analyses, we have selected companies with comparable characteristics to ours, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. We compute the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of our stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. The expected term represents the period of time that options are expected to be outstanding. Because there was not enough historical exercise behavior through December 31, 2016, we determined the expected life assumption using the simplified method, which is an average of the contractual term of the option and the vesting period.

Fair Value of Common Stock. After our stock began trading on NASDAQ on May 7, 2015, the fair value of common stock underlying our options was determined by the closing price of our common stock on the date of the grant. Prior to the IPO, the fair value of the shares of our common stock underlying our stock options was determined by our board of directors. Because there was no public market for our common stock, our board of directors determined the fair value of our common stock at the time of grant of the option by considering a number of objective and subjective factors,

including valuations of comparable companies, sales of our convertible preferred stock to unrelated third parties, our operating and financial performance and general and industry specific economic outlook.

Net Operating Loss Carryforwards

Utilization of net operating loss, or NOL, and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred or that could occur in the future, as required by Section 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 of the Code, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percent of the outstanding stock of a company by certain shareholders. 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.

At December 31, 2016, we had U.S. federal NOL carryforwards of $190.9 million which may be available to offset future taxable income. The U.S. federal NOL carryforwards begin to expire in 2022.

As of December 31, 2016 and 2015, we have provided a full valuation allowance for deferred tax assets.

Income Taxes

We record uncertain tax positions on the basis of a two-step process whereby (i) we determine whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the positions and (ii) for those tax positions that meet the more-likely-than-not recognition threshold, we recognize the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. We recognize interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability. There were no uncertain tax positions as of December 31, 2016, 2015 and 2014.

Emerging Growth Company Status

Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for companies that are not emerging growth companies.

Results of Operations

Comparison of the Years Ended December 31, 2016, 2015 and 2014

The following table summarizes the results of our operations for the years ended December 31, 2016, 2015 and 2014:

	Years ended December 31,		
	2016	2015	2014
	(in thousands)		
Product revenues, net	$ 1,711	$ —	$ —
Cost of product revenues	213	—	—
Research and development	14,948	7,975	14,959
Selling, general and administrative	80,632	18,932	2,706
Other expense, net	94	348	252
Net loss	$ (94,176)	$ (27,255)	$ (17,917)

Comparison of the Years Ended December 31, 2016 and 2015

Product revenues, net were $1.7 million for the year ended December 31, 2016, compared to zero for the year ended December 31, 2015. The $1.7 million increase was due to the commercial launch of Xtampza in June 2016.

Cost of product revenues were $213,000 for the year ended December 31, 2016, compared to zero for the year ended December 31, 2015. The $213,000 increase was due to the commercial launch of Xtampza in June 2016.

Research and development expenses were $14.9 million for the year ended December 31, 2016, compared to $8.0 million for the year ended December 31, 2015. The $6.9 million increase was primarily related to:

- an increase in clinical trial costs of $5.2 million due to clinical trials with Xtampza and the commencement of clinical trials for our second product candidate;
- an increase in salaries, wages and benefits of $1.6 million primarily due to headcount, bonuses and stock compensation expense; and
- an increase in manufacturing and transfer costs of $1.2 million primarily related to the development of a manufacturing process for Onsolis;
- these increases were partially offset by a decrease in consulting costs of $1.1 million primarily due to the completion of FDA advisory committee preparation in 2015.

Selling, general and administrative expenses were $80.6 million for the year ended December 31, 2016, compared to $18.9 million for the year ended December 31, 2015. The $61.7 million increase was primarily related to:

- an increase in salaries, wages and benefits of $26.4 million primarily due to an increase from 35 to 206 employees, including the addition of a sales force of approximately 150 employees, and an increase in stock-based compensation expense;
- an increase in sales and marketing costs of $15.9 million primarily due to preparation for and support of the commercial launch of Xtampza;
- an increase in commercial costs of $9.0 million primarily due to consultant costs related to analytics and strategies for the commercialization of Xtampza;
- an increase in Post Marketing Requirement and PDUFA costs required for Xtampza of $7.5 million;
- an increase in professional fees of $1.2 million primarily due to audit, insurance, accounting, recruiting and board of director fees;
- an increase in distribution and commercial manufacturing costs of $1.0 million;
- an increase in legal fees of $600,000 primarily due to costs related to litigation; and
- an increase in amortization expense of $397,000 associated with the upfront fee for the Onsolis License Agreement.

Comparison of the Years Ended December 31, 2015 and 2014

Research and development expenses were $8.0 million for the year ended December 31, 2015, compared to $15.0 million for the year ended December 31, 2014.The $7.0 million decrease was primarily related to:

- a decrease in clinical trial costs of $9.9 million due to the completion of clinical trials for Xtampza during 2014;
- an increase in consulting costs of $1.0 million mainly due to costs associated with preparation for the FDA Joint Advisory Committee meeting held in September 2015;
- an increase in manufacturing costs of $1.0 million related to Xtampza; and
- an increase in salaries, wages and benefits of $673,000 primarily due to headcount, bonuses and stock compensation expense.

Selling, general and administrative expenses were $18.9 million for the year ended December 31, 2015 compared to $2.7 million for the year ended December 31, 2014. The $16.2 million increase was primarily related to:

- an increase in commercial costs of $6.4 million primarily due to consultant costs related to analytics and strategies for commercialization of Xtampza;
- an increase in salaries, wages and benefits of $6.0 million primarily due to headcount, bonuses and stock compensation expense;
- an increase in professional fees of $981,000 primarily due to audit, accounting, recruiting and board of director fees;
- an increase in legal fees of $910,000 primarily due to costs related to litigation; and
- an increase in insurance costs of $779,000 due to directors' and officers' liability insurance.

Liquidity and Capital Resources

Sources of liquidity

We have incurred net losses and negative cash flows from operations since inception. Since inception, we have funded our operations primarily through the private placements of our preferred stock, public offerings of common stock, convertible notes and commercial bank debt. As of December 31, 2016, we had $153.2 million in cash and cash equivalents.

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.

Although it is difficult to predict future liquidity requirements, we believe that our existing cash and cash equivalents, will be sufficient to fund our operations into 2019. We have based this estimate on assumptions that may prove to be incorrect and we could use our available capital resources sooner than we currently expect. We may never become profitable, or if we do, we may not be able to sustain profitability on a recurring basis.

Cash flows

	Years ended December 31,		
	2016	2015	2014
	(in thousands)		
Net cash used in operating activities	$ (75,053)	$ (21,567)	$ (17,947)
Net cash used in investing activities	(2,977)	(362)	(8)
Net cash provided by financing activities	135,558	115,992	12,038

Operating activities. Cash used in operating activities was $75.1 million in the year ended December 31, 2016 and $21.6 million in the year ended December 31, 2015. The $53.5 million increase in cash used in operating activities was primarily due to the change in net loss partially offset by changes in the working capital accounts. We expect cash used

in operating activities to increase for the foreseeable future as we continue to commercialize Xtampza and fund research, development and clinical activities for additional product candidates.

Cash used in operating activities was $21.6 million in the year ended December 31, 2015 and $17.9 million in the year ended December 31, 2014. The $3.7 million increase in cash used in operating activities was due primarily to the change in net loss partially offset by changes in the working capital accounts.

Investing activities. Cash used in investing activities was $3.0 million in the year ended December 31, 2016 and $362,000 in the year ended December 31, 2015. The increase in cash used in investing activities was primarily due to the payment of the upfront fee for the Onsolis License Agreement.

Cash used in investing activities for the years ended December 31, 2015 and December 31, 2014 was $362,000 and $8,000 respectively, and related to the purchase of property and equipment.

Financing activities. Cash provided by financing activities for the year ended December 31, 2016 primarily represents net proceeds of $137.3 million from the issuance of common stock partially offset by the repayment of term notes of $2.7 million.

Cash provided by financing activities for the year ended December 31, 2015 primarily represents net proceeds from the IPO and from the sale of Series D convertible preferred stock of $72.0 million and $44.8 million, respectively.

Cash provided by financing activities for the year ended December 31, 2014 primarily represents the $7.1 million drawdown of a term note payable and proceeds from a convertible bridgenote of $5.0 million.

Funding requirements

Since 2011, we have not generated any significant revenue from product sales and we continue to incur significant research, development and other expenses related to our ongoing operations. We are in the early stages of commercialization of Xtampza. We anticipate that we will continue to incur losses in the near future as we commercialize Xtampza and continue the development of, and seek regulatory approvals for, other product candidates. We are subject to all of 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. We will also incur additional costs associated with operating as a commercial stage public company. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Until we can generate a sufficient amount of revenue from our pharmaceutical products, if ever, we expect to finance future cash needs through public or private equity or debt offerings. Additional capital may not be available on reasonable terms, if 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 product candidates. 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 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. 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 cost of establishing sales, marketing and distribution capabilities for Xtampza and any other products for which we may receive regulatory approval;
- the generation of reasonable levels of revenue from the sale of Xtampza;
- the design, initiation, progress, size, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- the outcome, timing and cost of regulatory approvals by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities 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 Xtampza and our product candidates for preclinical studies, clinical trials and, if approved, for commercial sale;
- the number and characteristics of product candidates that we pursue;
- the cost of patent infringement litigation, including the our litigation with Purdue Pharma, L.P., or Purdue, relating to Xtampza or our product candidates, which may be expensive to defend and delay the commercialization of our product candidates;
- our need to expand our research and development activities, including our need and ability to hire additional employees;
- our need to implement additional infrastructure and internal systems and hire additional employees to operate as a public company;
- our need to expand our regulatory and compliance functions; and
- the effect of competing technological and market developments.

If we cannot expand our operations or otherwise 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, 2016 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]	$ 865	$ 226	$ 475	$ 164	$ —
Long term debt (including interest) [2]	4,146	2,667	1,479	—	—
Purchase obligations [3]	12,000	3,000	6,000	3,000	—
Total	$17,011	$5,893	$ 7,954	$ 3,164	$ —

[1] Operating lease obligations represent future minimum lease payments under our non-cancelable operating lease in effect as of December 31, 2016, reflecting remaining lease payments for our current facility in Canton, Massachusetts.

[2] Long-term debt obligations represent future principal and interest payments under our Original Term Loan, as amended as of December 31, 2016.

[3] Purchase obligations represent the minimum purchase obligations of up to $3.0 million under a manufacturing agreement as of December 31, 2016. The disclosed amounts represent the maximum amount that could be payable under the minimum purchase obligations.

Due to the uncertain nature, the table above does not include potential milestone payments or royalties to BDSI for the Onsolis License Agreement. During the term of the License Agreement, milestone payments in the aggregate amount of $21.0 million may become payable by us, subject to the satisfaction of certain commercialization, intellectual property, and net sales milestones, including $4.0 million upon the first commercial sale of the product in the U.S. We will be required to pay royalties in the upper teens based on annual net sales of the product in the U.S. In addition, we are contractually committed to reimburse BDSI up to a maximum of $2.0 million for its out-of-pocket expenses incurred in connection with the manufacturing transfer.

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.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, 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, 2016, we had cash and cash equivalents consisting of cash and money market funds of $153.2 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 Chief Executive Officer and our Chief Financial Officer 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, 2016.

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 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 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 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 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 at the reasonable assurance level as of December 31, 2016, the end of our most recent fiscal year.

Attestation Report of the Registered Public Accounting Firm

This Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting occurred during the fiscal quarter ended December 31, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 2017 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 2017 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 2017 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 2017 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 2017 Annual Meeting of Shareholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules

Consolidated Financial Statements

See Part II, Item 8 for the 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.(2)
4.1†	Eighth Amended and Restated Investor Rights Agreement, dated March 6, 2015, by and among Collegium Pharmaceutical, Inc. and certain of its shareholders.(1)
4.2†	Warrant to Purchase Stock, dated October 28, 2010, issued by Collegium Pharmaceutical, Inc. to Comerica Bank.(1)
10.1†	Office Lease Agreement, dated August 28, 2012, by and between 780 Dedham Street Holdings, LLC and Collegium Pharmaceutical, Inc.(1)
10.2†	Loan and Security Agreement, dated August 28, 2012, by and between Silicon Valley Bank and Collegium Pharmaceutical, Inc.(1)
10.3†	First Amendment to Loan and Security Agreement, dated January 31, 2014, by and between Silicon Valley Bank and Collegium Pharmaceutical, Inc.(1)
10.4†	Assumption and Second Amendment to Loan and Security Agreement, dated August 12, 2014, by and between Silicon Valley Bank and Collegium Pharmaceutical, Inc.(1)
10.5†	Third Amendment to Loan and Security Agreement, dated September 25, 2014, by and between Silicon Valley Bank and Collegium Pharmaceutical, Inc.(1)
10.6†	Fourth Amendment to Loan and Security Agreement, dated October 31, 2014, by and between Silicon Valley Bank and Collegium Pharmaceutical, Inc.(1)
10.7†	Subordination Agreement, dated November 14, 2014, by and among Collegium Pharmaceutical, Inc., Silicon Valley Bank and the creditors named therein.(1)
10.8†	Subordination Agreement, dated December 2, 2014, by and among Collegium Pharmaceutical, Inc., Silicon Valley Bank and the creditors named therein.(1)

10.9+†	Restricted Stock Award Agreement, dated June 13, 2012, by and between Collegium Pharmaceutical, Inc. and Michael T. Heffernan.(1)
10.10+†	Restricted Stock Award Agreement, dated July 18, 2012, by and between Collegium Pharmaceutical, Inc. and Gino Santini.(1)
10.11+†	Restricted Stock Award Agreement, dated March 5, 2014, by and between Collegium Pharmaceutical, Inc. and Gino Santini.(1)
10.12†	Form of Confidentiality and Inventions Agreement.(1)
10.13+†	Offer Letter, dated January 29, 2015, by and between Collegium Pharmaceutical, Inc. and Garen Bohlin.(1)
10.14†	Series D Convertible Preferred Stock Purchase Agreement, dated March 6, 2015, by and among Collegium Pharmaceutical, Inc. and the purchasers thereto.(1)
10.15†	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)
10.16+†	2015 Employee Stock Purchase Plan.(3)
10.17+†	Performance Bonus Plan. (4)
10.18(a)+†	Amended and Restated 2014 Stock Incentive Plan. (3)
10.18(b)+†	Form of Incentive Stock Option Agreement under the Amended and Restated 2014 Stock Incentive Plan. (3)
10.18(c)+†	Form of Non-Qualified Stock Option Agreement under the Amended and Restated 2014 Stock Incentive Plan. (3)
10.18(d)+†	Form of Restricted Stock Award Agreement under the Amended and Restated 2014 Stock Incentive Plan. (3)
10.19+†	Restricted Stock Award Agreement, dated April 2, 2015, by and between Collegium Pharmaceutical, Inc. and Michael T. Heffernan. (4)
10.20†	Form of Indemnification Agreement. (4)
10.21+†	Employment Agreement, dated August 4, 2015, by and between Michael Heffernan and Collegium Pharmaceutical, Inc.(5)
10.22+†	Employment Agreement, dated August 4, 2015, by and between Paul Brannelly and Collegium Pharmaceutical, Inc.(5)
10.23+†	Employment Agreement, dated August 4, 2015, by and between Barry S. Duke and Collegium Pharmaceutical, Inc.(6)
10.24†	License and Development Agreement, dated as of May 11, 2016, by and between Collegium Pharmaceutical, Inc. and BioDelivery Systems International, Inc.(7)
21.1	Subsidiaries of Collegium Pharmaceutical, Inc.
23.1	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.
23.2	Consent of Grant Thornton 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, 2016, formatted in XBRL: (i) Consolidated Balance Sheets as of December 31, 2016, 2015, (ii) Consolidated Statements of Operations for the years ended December 31, 2016, 2015 and 2014, (iii) Consolidated Statements of Convertible Redeemable Preferred Stock and Shareholders' Equity (Deficit) for the Years Ended December 31, 2016, 2015 and 2014, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2016, 2015 and 2014, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text.

†Previously filed.

+Indicates management contract or compensatory plan.

(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.

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/ Michael T. Heffernan, R.Ph.
Michael T. Heffernan, R.Ph.
President and Chief Executive Officer

Signature	Title	Date
/s/ Michael T. Heffernan, R.Ph. Michael T. Heffernan, R.Ph.	President and Chief Executive Officer (Principal Executive Officer) and Director	March 10, 2017
/s/ Paul Brannelly Paul Brannelly	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 10, 2017
/s/ Garen G. Bohlin Garen G. Bohlin	Director	March 10, 2017
/s/ John A. Fallon, M.D. John A. Fallon, M.D.	Director	March 10, 2017
/s/ John G. Freund, M.D. John G. Freund, M.D.	Director	March 10, 2017
/s/ David Hirsch, M.D., Ph.D. David Hirsch, M.D., Ph.D.	Director	March 10, 2017
/s/ Eran Nadav, Ph.D. Eran Nadav, Ph.D.	Director	March 10, 2017
/s/ Gino Santini Gino Santini	Director	March 10, 2017
/s/ Theodore R. Schroeder Theodore R. Schroeder	Director	March 10, 2017

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 Board of Directors and Shareholders of
Collegium Pharmaceutical, Inc.
Canton, Massachusetts

We have audited the accompanying consolidated balance sheet of Collegium Pharmaceutical, Inc. and subsidiary (the "Company") as of December 31, 2016, and the related consolidated statements of operations, convertible redeemable preferred stock and shareholders' equity (deficit), and cash flows for the year ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Collegium Pharmaceutical, Inc. and subsidiary as of December 31, 2016, and the results of their operations and their cash flows for the year ended December 31, 2016, in conformity with accounting principles generally accepted in the United States of America.

/s/ Deloitte & Touche LLP
Boston, Massachusetts
March 10, 2017

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Collegium Pharmaceutical Inc.

We have audited the accompanying consolidated balance sheet of Collegium Pharmaceutical, Inc. (a Virginia Corporation) and subsidiary (the "Company") as of December 31, 2015, and the related statements of operations, convertible redeemable preferred stock and shareholders' equity (deficit), and cash flows for the years ended December 31, 2015 and 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Collegium Pharmaceutical, Inc. and subsidiary as of December 31, 2015, and the results of their operations and their cash flows for the years ended December 31, 2015 and 2014 in conformity with accounting principles generally accepted in the United States of America.

/s/ Grant Thornton LLP
Boston, Massachusetts
March 18, 2016

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

	December 31, 2016	December 31, 2015
Assets		
Current assets		
Cash and cash equivalents	$ 153,225	$ 95,697
Accounts receivable	2,129	—
Inventory	1,316	—
Prepaid expenses and other current assets	1,905	1,186
Total current assets	158,575	96,883
Property and equipment, net	1,038	738
Intangible assets, net	2,103	—
Restricted cash	97	97
Other long-term assets	204	—
Total assets	$ 162,017	$ 97,718
Liabilities and shareholders' equity (deficit)		
Current liabilities		
Accounts payable	$ 9,106	$ 3,537
Accrued expenses	8,879	2,228
Deferred revenue	4,944	—
Current portion of term loan payable	2,667	2,667
Total current liabilities	25,596	8,432
Lease incentive obligation	34	68
Term loan payable, long-term	1,479	4,146
Total liabilities	27,109	12,646
Commitments and contingencies (see Note 9)		
Shareholders' equity (deficit):		
Preferred stock, $0.001 par value; authorized shares - 5,000,000 at December 31, 2016 and December 31, 2015; issued and outstanding shares - none at December 31, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value; authorized shares - 100,000,000 at December 31, 2016 and December 31, 2015; issued and outstanding shares - 29,364,100 at December 31, 2016 and 20,739,351 at December 31, 2015	29	21
Additional paid-in capital	358,063	214,062
Accumulated deficit	(223,184)	(129,008)
Treasury stock	—	(3)
Total shareholders' equity	134,908	85,072
Total liabilities and shareholders' equity	$ 162,017	$ 97,718

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,		
	2016	2015	2014
Product revenues, net	$ 1,711	$ —	$ —
Costs and expenses			
Cost of product revenues	213	—	—
Research and development	14,948	7,975	14,959
Selling, general and administrative	80,632	18,932	2,706
Total costs and expenses	95,793	26,907	17,665
Loss from operations	(94,082)	(26,907)	(17,665)
Other expense (income)			
Interest expense, net	94	439	252
Gain on extinguishment of debt	—	(91)	—
Total other expense, net	94	348	252
Net loss	$ (94,176)	$ (27,255)	$ (17,917)
Loss per share - basic and diluted	$ (3.88)	$ (1.48)	$ (22.72)
Weighted-average shares - basic and diluted	24,262,945	13,542,282	933,997

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

COLLEGIUM PHARMACEUTICAL, INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE REDEEMABLE PREFERRED STOCK AND SHAREHOLDERS' EQUITY (DEFICIT)
(In thousands, except share data)

	Series A Convertible Redeemable Preferred Stock		Series B Convertible Redeemable Preferred Stock		Series C Convertible Redeemable Preferred Stock		Series D Convertible Redeemable Preferred Stock		Common Stock		Additional Paid- In Capital	Treasury Stock, at cost	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2013	9,232,334	$ 12,277	27,324,237	$ 49,376	8,658,008	$ 12,154	—	$ —	962,960	$ 1	$ 12,313	$ (3)	$ (80,536)	$ (68,225)
Exercise of common stock options	—	—	—	—	—	—	—	—	32,390	—	72	—	—	72
Issuance of restricted stock awards to employees	—	—	—	—	—	—	—	—	10,869	—	—	—	—	—
Accruals of dividends and accretion to redemption value	—	504	—	1,836	—	960	—	—	—	—	—	—	(3,300)	(3,300)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	22	—	—	22
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(17,917)	(17,917)
Balance at December 31, 2014	9,232,334	12,781	27,324,237	51,212	8,658,008	13,114	—	—	1,006,219	1	12,407	(3)	(101,753)	(89,348)
Exercise of common stock options	—	—	—	—	—	—	—	—	173,251	—	517	—	—	517
Exercise of warrants	—	—	—	—	—	—	—	—	16,062	—	6	—	—	6
Issuance of restricted stock awards to employees	—	—	—	—	—	—	—	—	194,694	—	—	—	—	—
Issuance of Series D convertible redeemable preferred stock, net of issuance costs of $193	—	—	—	—	—	—	37,500,000	44,807	—	—	—	—	—	—
Conversion of notes to Series D convertible redeemable preferred stock	—	—	—	—	—	—	4,166,667	5,000	—	—	—	—	—	—
Extinguishment of prior preferred stock dividends	—	(3,733)	—	(23,341)	—	(4,110)	—	—	—	—	31,184	—	—	31,184
Accruals of dividends and accretion to redemption value	—	2,297	—	18,034	—	2,996	—	1,245	—	—	(24,572)	—	—	(24,572)
Conversion of preferred stock to common stock	(9,232,334)	(11,345)	(27,324,237)	(45,905)	(8,658,008)	(12,000)	(41,666,667)	(50,000)	12,591,463	13	119,237	—	—	119,250
Initial Public Offering, net of issuance costs of $2,408	—	—	—	—	—	—	—	—	6,670,000	7	72,022	—	—	72,029
Issuance of common stock in payment of Series D accrued dividends	—	—	—	—	—	—	—	(1,052)	87,662	—	1,052	—	—	1,052
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	2,209	—	—	2,209
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(27,255)	(27,255)
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

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,		
Operating activities	**2016**	**2015**	**2014**
Net loss	$ (94,176)	$ (27,255)	$ (17,917)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	655	171	187
Lease incentive	(34)	(34)	(34)
Stock-based compensation expense	5,787	2,209	22
Non cash interest expense	—	6	7
Change in fair value of derivative liability	—	—	7
Changes in operating assets and liabilities:			
Accounts receivable	(2,129)	—	—
Inventories	(1,316)	—	—
Prepaid expenses and other assets	(923)	(659)	183
Refundable PDUFA fee	—	2,335	(2,335)
Accounts payable	5,569	1,298	990
Accrued expenses	6,570	362	943
Deferred revenue	4,944	—	—
Net cash used in operating activities	(75,053)	(21,567)	(17,947)
Investing activities			
Purchase of intangible assets	(2,500)	—	—
Purchases of property and equipment	(477)	(362)	(8)
Net cash used in investing activities	(2,977)	(362)	(8)
Financing activities			
Proceeds from issuance of convertible bridge note	—	—	5,000
Proceeds from issuances of common stock from public offerings, net of issuance costs of $845 and $2,408	137,340	72,029	—
Proceeds from issuances of common stock from employee stock purchase plans	442	—	—
Proceeds from notes payable, net of original note payoff	—	—	7,056
Proceeds from issuance of Series D convertible redeemable preferred stock, net of issuance costs of $193	—	44,807	—
Repayment of term note	(2,667)	(1,286)	(28)
Repayment of lease note payable	—	(59)	(62)
Restricted cash	—	(16)	—
Proceeds from the exercise of stock options	443	517	72
Net cash provided by financing activities	135,558	115,992	12,038
Net increase (decrease) in cash and cash equivalents	57,528	94,063	(5,917)
Cash and cash equivalents at beginning of period	95,697	1,634	7,551
Cash and cash equivalents at end of period	$ 153,225	$ 95,697	$ 1,634
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 284	$ 353	$ 181
Supplemental disclosure of non-cash activities			
Acquisition of property and equipment in accrued expenses	$ 81	$ —	$ —
Preferred stock conversion to common stock	$ —	$ 120,302	$ —
Extinguishment of preferred stock	$ —	$ 31,184	$ —
Accruals of dividends and accretion to redemption value	$ —	$ 24,572	$ 3,300
Conversion of bridge note to preferred stock	$ —	$ 5,000	$ —
Repayment of term note with proceeds of notes payable	$ —	$ —	$ 944

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 Canton, Massachusetts. The Company is a specialty pharmaceutical company developing and commercializing next-generation abuse-deterrent products that incorporate the Company's patented DETERx® technology platform for the treatment of chronic pain and other diseases. The Company's first product, Xtampza ER®, or Xtampza, is an abuse-deterrent, extended-release, oral formulation of oxycodone, a widely prescribed opioid medication. In April 2016, the U.S. Food and Drug Administration ("FDA") approved the Company's new drug application ("NDA") filing for Xtampza 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.

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 product candidates (including development of competing products), changing regulatory environment and reimbursement landscape, negative outcome of clinical trials, inability or delay in completing clinical trials or obtaining regulatory approvals, the need to retain key personnel and protect intellectual property, patent infringement litigation and the availability of additional capital financing on terms acceptable to the Company.

Public Offerings of Common Stock

In May 2015, the Company closed an initial public offering ("IPO") of its common stock, which resulted in the sale of 6,670,000 shares of its common stock at a public offering price of $12.00 per share, including 870,000 shares of common stock upon the exercise by the underwriters of their option to purchase additional shares at the public offering price. The Company received proceeds from the IPO of approximately $72,029 after deducting underwriting discounts, commissions and expenses payable by the Company.

In April 2015, in connection with preparing for the IPO, the Company's board of directors and shareholders approved a one-for-6.9 reverse split of the Company's common stock. All common stock share and per share amounts in the financial statements have been retroactively adjusted for all periods presented to give effect to the reverse split of the Company's common stock, including reclassifying an amount equal to the reduction in par value to additional paid-in capital.

In connection with the closing of the IPO, all of the Company's outstanding convertible preferred stock and accrued dividends automatically converted to common stock in May 2015, resulting in an additional 12,591,463 shares of common stock of the Company becoming outstanding. The significant increase in common stock outstanding in May 2015 impacted the year-over-year comparability of the Company's net loss per share calculations.

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.

Basis of Accounting

The consolidated financial statements include the accounts of Collegium Pharmaceutical, Inc. (a Virginia corporation) as well as the accounts of Collegium Securities Corp. (a Massachusetts corporation), incorporated in December 2015, a wholly-owned subsidiary requiring consolidation, and are prepared in conformity with accounting principles generally accepted in the United States of America. All intercompany balances and transactions have been eliminated in consolidation.

Liquidity

The Company has experienced net losses and negative cash flows from operating activities since its inception, and as of December 31, 2016 and December 31, 2015, had an accumulated deficit of $223,184 and $129,008, respectively. The Company expects to continue to incur net losses in the foreseeable 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, 2016, together with expected cash inflows from the commercialization of Xtampza will enable the Company to fund its operating expenses, debt service and capital expenditure requirements into 2019. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional cash. Management intends to fund future operations through additional private or public debt or equity offerings, and may seek additional capital through arrangements with strategic partners or from other sources. If the Company is unable to obtain financing or increase profitability, the related lack of liquidity will have a material adverse effect on the Company's operations and future prospects.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of the Company's financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's financial statements and accompanying notes. The most significant estimates in the Company's financial statements relate to revenue recognition, including the estimates of units prescribed, discounts and allowances related to commercial sales of Xtampza, estimates utilized in the valuation of inventory, estimates of useful lives with respect to intangible assets, accounting for stock-based compensation, contingencies, intangible assets, tax valuation reserves and accrued expenses. 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. The carrying amounts reported in the Company's financial statements for cash and cash equivalents, accounts payable, term loan payable and accrued liabilities approximate their respective fair values because of the relative short-term nature of these accounts.
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: Quoted prices in (unadjusted) active markets for identical assets or liabilities
Level 2: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.
Level 3: 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, 2016 and 2015.

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, 2016 and 2015.

Description	Total	Quoted Prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2016				
Money market funds, included in cash equivalents	$ 125,515	$ 125,515	$ —	$ —
December 31, 2015				
Money market funds, included in cash equivalents	$ 94,912	$ 94,912	$ —	$ —

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 deposits in federally insured financial institutions in excess of federally insured limits. Three customers comprised 10% or more of the Company's accounts receivable balance as of December 31, 2016. These customers comprised 44%, 27% and 21% of the accounts receivable balance, respectively. Three customers comprised 10% or more of the Company's revenue during the year ended December 31, 2016. These customers comprised 35%, 28% and 27% of revenue, respectively. The Company has not experienced any 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. 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, 2016 and 2015, the carrying amount of cash equivalents was $125,515 and $94,912, 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 Xtampza, 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 for the foreseeable future and the expected shelf-life of the inventory components. Estimates of excess inventory consider various factors, including inventory levels, the level of product in the distribution channel, the Company's projected sales of the product, as well as the remaining shelf lives of the product. The Company recorded such adjustments of $100 in the year ended December 31, 2016, which were recorded as a component of cost of product revenues. Inventories that are not expected to be used within one year are recorded as a non-current asset.

The Company outsources the manufacturing of Xtampza 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 for Xtampza. Accordingly, the Company has concentration risk associated with its commercial manufacturing of Xtampza.

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

The Company has capitalized $1,316 of inventory as of December 31, 2016. The Company expects sales of the capitalized units to occur during the next twelve months. The Company expects costs of product revenues to increase due to the expected increases in net product sales of Xtampza and the fact that the Company had expensed all manufacturing costs as research and development expense in periods prior to FDA approval of Xtampza. The impact on cost of product revenues as a result of inventory not capitalized prior to FDA approval is immaterial.

Property and Equipment

Property and equipment are recorded at historical cost. Maintenance and repair costs are expensed as incurred. Costs which materially improve or extend the lives of existing assets are capitalized. The Company provides for depreciation and amortization using the straight-line method over the estimated useful lives of the assets, which are 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

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.

Intangible Assets

Intangible assets that are deemed to have a definite life are amortized over their useful lives and are evaluated separately for impairment at least annually or whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable (See Note 7). Amortization of intangible assets is recognized on a straight-line basis and the useful life of the Company's only intangible asset is approximately 3.7 years.

Restricted Cash

Restricted cash represents cash held in a depository account at a financial institution to collateralize a conditional stand-by letter of credit related to the Company's Canton, Massachusetts facility lease agreement. Restricted cash is reported as non-current unless the restrictions are expected to be released in the next twelve months.

Revenue Recognition

Revenue for product sales is recognized when there is persuasive evidence of an arrangement, title and risk of loss have passed to the customer, when estimated provisions for chargebacks, rebates, sales incentives and allowances, distribution service fees, and returns are reasonably determinable, and when collectability is reasonably assured. Product revenue is recorded net of estimated chargebacks, rebates, sales incentives and allowance, distribution service fees, as well as estimated product returns.

The Company sells Xtampza in the United States principally to distributors and retailers ("customers"), which in turn sell the product to healthcare providers for the treatment of patients. The Company provides the right of return to its customers for unopened product for a limited time before and after its expiration date. Given the Company's limited sales history for Xtampza and the inherent uncertainties in estimating product returns, the Company has determined that

the shipments of Xtampza made to its customers thus far do not meet the criteria for revenue recognition at the time of shipment. Accordingly, the Company recognizes revenue when the product is sold-through to patients, provided all other revenue recognition criteria are met. The Company invoices its customers upon shipment of Xtampza and records accounts receivable, with a corresponding liability for deferred revenue equal to the gross invoice price, less any realized adjustments to the gross invoice price. The Company then recognizes revenue when Xtampza is sold-through, or when product is prescribed directly to the patient at which time the right of return has expired. Healthcare providers to whom distributors sell Xtampza hold limited inventory that is designated for patients, thereby limiting the risk of return.

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 market research and design, costs associated with conducting 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 and laboratory equipment, 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. Government grants are recognized as a reduction of the qualifying cost being reimbursed.

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 $16,328 in the year ended December 31, 2016. 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 or the value of the services provided, whichever is more readily determinable.

Stock-based compensation expense represents the cost of the grant date fair value of employee stock option grants recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis, net of estimated forfeitures. The expense is adjusted for actual forfeitures as they occur.

For stock option grants with performance-based milestones, the expense is recorded over the remaining service period after the point when the achievement of the milestone is probable or the performance condition has been achieved. For stock option grants with both performance-based milestones and market conditions, expense is recorded over the derived service period after the point when the achievement of the performance-based milestone is probable or the performance condition has been achieved.

The Company accounts for stock options and restricted stock awards to non-employees using the fair value approach. Stock options and restricted stock awards to non-employees are subject to periodic revaluation over their vesting terms. There were no non-employee grants in 2016 and there was one non-employee grant in 2015.

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 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, 2016 and 2015, 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. For purposes of the diluted net loss per share calculation, stock options, warrants, redeemable convertible preferred stock and unvested restricted stock are considered potentially dilutive securities. Because the Company has reported a net loss for the years ended December 31, 2016, 2015 and 2014, diluted net loss per common share is the same as basic net loss per common share for those periods.

Diluted earnings per share is computed using the more dilutive of (i) the two-class method, or (ii) the if-converted method. The Company allocates earnings first to preferred shareholders based on dividend rights and then to common and preferred shareholders based on ownership interests. The weighted-average number of common shares included in the computation of diluted earnings (loss) gives effect to all potentially dilutive common equivalent shares, including outstanding stock options, warrants, convertible redeemable preferred stock and the potential issuance of stock upon the conversion of the Company’s convertible notes. Common stock equivalent shares are excluded from the computation of diluted earnings (loss) per share if their effect is antidilutive.

Recently Issued Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2014-09 (ASC 606), *Revenue from Contracts with Customers*, which affects any entity that either enters into contracts with customers to transfer goods and services or enters into contracts for the transfer of nonfinancial assets. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers*, which defers the effective date of ASU 2014-09 for all entities by one year. ASU 2014-09, which has been codified with the Accounting Standards Codification as Topic 606, is now effective for public companies for annual reporting periods beginning after December 15, 2017, including interim periods within those reporting periods. ASC 606 outlines a single comprehensive model for entities to

use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. In addition, ASC 606 provides guidance on accounting for certain revenue-related costs including, but not limited to, when to capitalize costs associated with obtaining and fulfilling a contract. ASC 606 provides companies with two implementation methods. Companies can choose to apply the standard retrospectively to each prior reporting period presented (full retrospective application) or retrospectively with the cumulative effect of initially applying the standard as an adjustment to the opening balance of retained earnings of the annual reporting period that includes the date of initial application (modified retrospective application). Since ASU 2014-09 was issued, several additional ASUs have been issued and incorporated within ASC 606 to clarify various elements of the guidance. The Company anticipates that this standard will have a material impact on its consolidated financial statements with respect to inventory and deferred revenues and is continuing to assess all potential impacts of the standard, including evaluating the impact of each potential method of adoption on the Company's consolidated financial statements and the impact to the pattern with which the Company will recognize revenue.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU 2014-15 requires management to evaluate, at each annual or interim reporting period, whether there are conditions or events that exist that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date the financial statements are issued and provide related disclosures. ASU 2014-15 is effective for annual periods ending after December 15, 2016 and earlier application is permitted. The Company adopted this standard during the three months ended December 31, 2016. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements.

In July 2015, the FASB issued ASU 2015-11, *Simplifying the Measurement of Inventory*. ASU 2015-11 applies to all inventory, except for inventory measured using the last-in, first-out method or the retail inventory method. The guidance allows an entity to measure inventory at the lower of cost and net realizable value. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The amendments in ASU 2015-11 are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, and may be applied prospectively with earlier adoption permitted. The Company adopted ASU 2015-11 during the three months ended June 30, 2016. The adoption of this ASU did not have a material impact on the Company's consolidated balance sheets or statements of operations for the year ended and as of December 31, 2016.

In March 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2016-09, *Compensation – Stock Compensation (Topic 718 Improvements to Employee Share-Based Payment Accounting)*. ASU 2016-09 simplifies several aspects of the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. Under this guidance, a company recognizes all excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement. ASU 2016-09 is effective for public companies for annual reporting periods beginning after December 15, 2016, including interim periods within those annual reporting periods; however, early adoption is permitted. The Company has early adopted ASU 2016-09 for its year ended December 31, 2016. The adoption of ASU 2016-09 did not have a material impact on the Company's effective tax rate. In addition, the Company no longer calculates an estimate of expected forfeitures and began recongizing forfeitures as they occur. The recognition of forfeitures, as well as the cumulative-effect decrease to retained earnings with the offset to increase additional paid-in capital recognized upon adoption did not have a material impact on the Company's consolidated balance sheets, statement of operations or cash flows for the year ended and as of December 31, 2016.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. ASU 2016-02 most 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 amortization/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 similar to existing guidance for operating leases today. In addition, ASU 2016-02 requires the use of the modified retrospective method, which will require adjustment to all comparative periods presented in the consolidated financial statements. This guidance is effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted for all entities. The Company has not chosen early adoption for this ASU and is currently evaluating its effect on the Company's consolidated financial statements.

3. NET LOSS PER COMMON SHARE

For the twelve months ended December 31, 2016, 2015 and 2014, these securities 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,		
	2016	2015	2014
Net loss	$ (94,176)	$ (27,255)	$ (17,917)
Extinguishment of preferred stock - see Note 12	—	31,806	—
Accretion and dividends of prior preferred stock - See Note 12	—	(23,327)	(3,300)
Accretion and dividends of Series D preferred stock	—	(1,245)	—
Loss attributable to common shareholders — basic and diluted	$ (94,176)	$ (20,021)	$ (21,217)
Weighted-average number of common shares used in net loss per share - basic and diluted	24,262,945	13,542,282	933,997
Loss per share - basic and diluted	$ (3.88)	$ (1.48)	$ (22.72)

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,		
	2016	2015	2014
Outstanding stock options	2,326,801	1,452,149	281,029
Warrants	2,445	2,445	18,809
Redeemable convertible preferred stock	—	—	6,552,820
Unvested restricted stock	82,512	75,718	15,387
Restricted stock units	41,741	—	—

4. INVENTORY

Inventory consisted of the following:

	As of December 31, 2016
Raw materials	$ 294
Work in process	67
Finished goods	955
Total inventory	$ 1,316

During the year ended December 31, 2016, the Company incurred aggregate charges of $100 related to excess inventory. These expenses were recorded as a component of cost of product revenues.

5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	As of December 31,	
	2016	2015
Prepaid regulatory fees	$ 512	$ —
Prepaid development costs	485	—
Prepaid insurance	328	420
Other current assets	304	205
Other prepaid expenses	276	208
Deferred financing costs	—	353
Prepaid expenses and other current assets	$ 1,905	$ 1,186

6. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	As of December 31,	
	2016	2015
Machinery and equipment	$ 863	$ 755
Leasehold improvements	700	678
Computers and office equipment	590	262
Furniture and fixtures	117	117
Construction-in-process	100	—
Total property and equipment	2,370	1,812
Less: accumulated deprecation	(1,332)	(1,074)
Property and equipment, net	$ 1,038	$ 738

Depreciation expense related to property and equipment amounted to $258, $171 and $187 for the years ended December 31, 2016, 2015 and 2014, respectively.

7. INTANGIBLE ASSETS

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. The Company expects to launch the product after the completion of the transfer of manufacturing and required submission to the FDA of a Prior Approval Supplement. Subject to FDA approval of the Prior Approval Supplement, the Company expects to launch Onsolis during the second half of 2017. In addition, during the term of the License Agreement, milestone payments in the aggregate amount of $21,000 may 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 U.S. Finally, the Company will be required to pay royalties in the upper teens based on annual net sales of the product in the U.S. As of December 31, 2016, the Company has not satisfied the criteria of any milestones or royalties payable under the License Agreement and has not recognized any liabilities for such milestones or royalties payable in its consolidated financial statements.

The Company made an upfront payment of $2,500 and is contractually committed to reimburse BDSI up to a maximum of $2,000 for its out-of-pocket expenses incurred in connection with the manufacturing transfer. The Company recorded the upfront payment as an intangible asset on the Consolidated Balance Sheet and will amortize it on a straight-line basis over the remaining patent life, a period of approximately 3.7 years. During the year ended December 31, 2016, the Company recognized amortization of expense of $397 related to the Onsolis intangible asset, which also represents the accumulated amortization to date. As of December 31, 2016, the remaining amortization period is approximately 3.1 years and estimated remaining amortization for 2017, 2018, 2019 and 2020 is expected to be $682, $682, $682, $57.

8. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of December 31, 2016	2015
Accrued bonuses	$ 2,210	$ 1,474
Accrued incentive compensation	1,160	—
Accrued development costs	2,485	80
Accrued payroll and related benefits	1,217	93
Accrued sales and marketing	801	157
Accrued other operating costs	572	186
Accrued audit and legal	416	209
Accrued interest	18	29
Total accrued expenses	$ 8,879	$ 2,228

9. 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.

The Company's NDA filing for Xtampza is 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. In connection with the 505(b)(2) process, the Company certified to the FDA and notified 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. Under the Hatch-Waxman Act of 1984 (the ''Hatch-Waxman Act''), 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 regulatory approval for Xtampza, unless the stay was earlier terminated. Purdue exercised its option and elected to sue the Company for infringement in the District of Delaware in March 2015 asserting infringement of three of Purdue's Orange Book-listed patents and one non-Orange Book-listed patent. In October 2015, the Delaware case was transferred to 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 favor of the Company 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 obtained final approval of its Xtampza ER products and has launched the products commercially.

In November 2015, Purdue filed a follow-on suit asserting infringement of another patent, Patent No. 9,073,933, which was late-listed in the Orange Book and therefore could not trigger any stay of FDA approval. In June 2016, Purdue filed another follow-on suit asserting infringement of another non-Orange Book listed patent, Patent No. 9,155,717. These suits were consolidated by the District of Massachusetts into the original action where Purdue's infringement claim relating to the '497 patent remains pending. Purdue continues to assert infringement of these three patents against the Company, none of which is associated with any stay of FDA approval. Purdue has made a demand for monetary relief but has not quantified their alleged damages. Purdue has also requested a judgment of infringement 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, and seeks 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 in the first half of 2017. The parties are also in the claims construction stage of the patent litigation. The parties have briefed their proposed constructions and will argue their positions in front of the Court in the second quarter of 2017. The Company has also filed a motion for summary judgment that the asserted claims of the ’933, ’497, and ’717 patents are invalid and not infringed. The Company is not able to predict with certainty when the Court will decide the Company’s motion. No trial date has been scheduled.

The Company is, and plans 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. At this time the Company is unable to provide meaningful quantification of how this potential litigation may impact its future financial condition, results of operations, or cash flows.

Operating Leases

The Company leases its office and research facility under a non-cancellable operating lease. Terms of the agreement provide for an initial two-month rent-free period and future rent escalation, and provide that in addition to minimum lease rental payments, the Company is responsible for a pro-rata share of operating expenses and taxes. In March 2015, the Company amended its lease to include an additional 9,660 square feet of space for a total of 19,335 square feet. In addition, the lease term was extended and now terminates on August 30, 2020. At the Company’s election, the lease term may be extended for an additional 5 -year term.

Aggregate minimum annual lease commitments of the Company under its non-cancellable operating lease as of December 31, 2016 are as follows:

2017	$	226
2018		234
2019		241
2020		164
Total minimum lease payments	$	865

Rent expense under the operating lease agreement amounted to approximately $182, $112 and $69 for the years ended December 31, 2016, 2015 and 2014, respectively. In addition, the Company maintained a stand-by letter of credit in connection with the Canton facility lease of $97 at December 31, 2016 and December 31, 2015. This amount is classified as restricted cash in the balance sheets.

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 balance sheet 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.

10. 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. In August 2012, October 2012 and February 2013, the Company borrowed $250, $250 and $500, respectively. 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 provided for interest-only payments for the first 12 months based on the date of each borrowing, and, thereafter, 36 monthly payments of principal and interest. In connection with the Original Term Loan, the Company granted SVB a warrant to purchase 11,850 shares of common stock at an exercise price of $0.07 per share (See Note 11).

In January 2014, the Original Term Loan was amended (“Amendment No. 1”) to provide for the following: borrowings of up to $6,000, repayment in full of the Original Term Loan balance outstanding, and an adjustment of the variable interest rate from 2.25% above the prime rate to 1.75% above the prime rate. In February 2014, the Company borrowed

$2,000. The proceeds from the initial borrowing were used to pay down the Original Term Loan balance outstanding resulting in the Company receiving $1,056. Borrowings under Amendment No. 1 bore interest at a rate of 5.0%. Amendment No. 1 provided for interest-only payments for the first 12 months based on the date of each borrowing, and thereafter, 36 monthly payments of principal and interest. In connection with Amendment No. 1, the Company granted to SVB a warrant to purchase 14,430 shares of common stock with an exercise price of $0.05 per share (See Note 11).

In August 2014 the Original Term Loan was further amended ("Amendment No. 2") to provide for total borrowings of up to $8,000. In August 2014 and September 2014 the Company drew down $3,000 and $3,000, respectively. Pursuant to Amendment No. 2, interest-only payments are to be made for the first 12 months based on the date of each borrowing; thereafter, 36 monthly payments of principal and interest are to be made. Borrowings under Amendment 2 bear interest at the rate of 5.0%. The warrant agreement contains a performance clause that the Company met, resulting in additional financing extended and issuance of a warrant to purchase 86,580 additional shares of common stock with an exercise price of $0.05 per share (See Note 11).

In September 2014, the Original Term Loan was further amended ("Amendment No. 3") to extend the loan draw period.

In November and December of 2014 the Company entered into a Note Purchase Agreement (the "Bridge Notes") allowing for the issuance of $5,000 of convertible promissory notes to a group of investors (the "Holders") bearing interest at a rate per annum of 6.0%. The Holders are related parties of the Company. In March 2015, in connection with the Series D convertible preferred stock financing, the Bridge Notes converted into 4,166,667 shares of Series D convertible preferred stock. Upon the conversion, the Company recognized a gain on extinguishment of $91. The accrued interest on the Bridge Notes was waived.

As of December 31, 2016, future payments under the Company's term loan are as follows:

2017	$ 2,667
2018	1,479
Balance	$ 4,146

11. WARRANTS

In November 2010, the Company issued a warrant to Comerica Bank. The warrant represents the right to purchase 2,445 shares of common stock with an exercise price of $12.27. The warrant expires in October 2017.

In connection with the Term Loan Financings with Silicon Valley Bank, the Company issued warrants to purchase a total of 16,357 shares of common stock. In June 2015, SVB exercised all of its warrants.

12. EQUITY

Common Stock

As of December 31, 2016 and 2015, the Company had reserved the following shares of common stock for the issuance of common stock for the exercise of stock options and warrants and the issuance of shares under the 2015 Employee Stock Purchase Plan (in thousands):

	As of December 31,	
	2016	2015
Options to purchase common stock	3,348	2,642
Employee stock purchase plan	364	200
Warrants	2	2
Total	3,714	2,844

Convertible Redeemable Preferred Stock

Series A, B and Series C Redeemable Convertible Preferred Stock

As of December 31, 2014, 54,481,000 shares of preferred stock were authorized, designated as Series A, Series B and Series C Preferred Stock of which 9,232,334, 27,324,237 and 8,658,008 were issued and outstanding, respectively.

In March 2015, the Company sold 41,666,667 shares of Series D convertible preferred stock for aggregate consideration of $50,000, comprised of $45,000 in cash and conversion of $5,000 in convertible notes with related parties. The convertible notes converted into 4,166,667 shares of Series D convertible preferred stock. The accrued interest on the convertible notes was waived. In this financing, the mandatory conversion for all series of preferred stock was modified so as to occur upon an initial public offering with gross proceeds in excess of $50,000.

13. 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, 2016, 1,021,509 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; however, certain options contain performance conditions. 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, 2015	1,452,149	$ 10.37	10.4	$ 24,887
Granted	1,063,981	16.46		
Exercised	(81,831)	5.41		
Cancelled	(107,498)	16.05		
Outstanding at December 31, 2016	2,326,801	$ 13.07	8.7	$ 7,927
Exercisable at December 31, 2016	556,040	$ 9.19	8.0	$ 3,917
Vested and expected to vest at December 31, 2016	2,291,971	$ 13.11	8.7	$ 8,090

The total intrinsic value of stock options exercised for the year ended December 31, 2016 was $952. As of December 31, 2016, the unrecognized compensation cost related to outstanding options was $14,499, and is expected to be recognized as expense over approximately 2.8 years.

As of December 31, 2016, the weighted average fair value of vested options was $6.35. The weighted-average grant date fair value of options granted during the year ended December 31, 2016 was $10.98. The fair value of options that vested during the year ended December 31, 2016 was $7.37.

Restricted stock awards under the Plan are summarized as follows:

	Shares	Weighted-Average Purchase Price per Share
Unvested at December 31, 2015	75,718	$ 5.73
Granted	—	—
Vested	(32,453)	5.73
Unvested at December 31, 2016 (1)	43,265	$ 5.73

(1) Excludes 39,247 shares of unvested restricted stock remaining from the early exercise of stock options as of December 31, 2016.

The total fair value of restricted stock awards vested during the years ended December 31, 2016, was $186. As of December 31, 2016, the unrecognized compensation cost related to restricted stock awards was $233, and is expected to be recognized as expense over approximately 1.2 years.

Restricted stock units under the Plan are summarized as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2015	—	$ —
Granted	41,741	16.15
Settled	—	—
Forfeited	—	—
Outstanding at December 31, 2016	41,741	$ 16.15

As of December 31, 2016, the unrecognized compensation cost related to restricted stock units was $509, and is expected to be recognized as expense over approximately 3.0 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 our 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 year ended December 31, 2016 was $457.

Stock-Based Compensation Expense

The Company granted stock options to employees for the years ended December 31, 2016, 2015 and 2014. 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 options and restricted stock issued to non-board member, non-employees are accounted for using the fair value approach and are subject to periodic revaluation over their vesting terms.

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,		
	2016	2015	2014
Research and development	$ 638	$ 223	$ 12
Selling, general and administrative	5,149	1,986	10
Total stock-based compensation expense	$ 5,787	$ 2,209	$ 22

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:

	Years ended December 31,		
	2016	2015	2014
Risk-free interest rate	1.5 %	1.7 %	1.8 %
Volatility	76.3 %	77.0 %	77.1 %
Expected term (years)	6.02	6.20	6.25
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 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, we consider 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, 2016 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.

14. INCOME TAXES

For the years ended December 31, 2016 and 2015, 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 domestic losses.

The Company has early adopted the provisions of ASU 2016-09, *Compensation – Stock Compensation (Topic 718 Improvements to Employee Share-Based Payment Accounting)*, for its year ended December 31, 2016. ASU 2016-09 requires companies to include the benefit of an option deduction in its net operating loss carryforward deferred tax asset. Prior to its adoption of ASU 2016-09, the Company's excess tax benefits associated with option deductions were maintained in the Company's APIC pool of windfall tax benefits, which was tracked off balance sheet and not included in its deferred tax assets. As a result of the Company's adoption of ASU 2016-09, it will track option deductions in its net operating loss deferred tax asset on a modified retrospective basis, and has included the option deductions in the December 31, 2016 deferred tax assets. The gross deferred tax asset and valuation allowance as of December 31, 2016 increased $406 as a result of the cumulative effect of adoption of ASU 2016-09. The Company has not recast its December 31, 2015 and December 31, 2014 deferred tax assets or its rate reconciliation, and therefore the option deductions in 2015 and 2014 are not included in the net operating loss deferred tax asset as originally reported. Since the

Company has historically maintained a full valuation allowance on its net worldwide deferred tax asset, there is no net impact to retained earnings from the adoption of ASU 2016-09.

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,		
	2016	2015	2014
Federal income tax expense at statutory rate	34.00 %	34.00 %	34.00 %
(Increase) decrease income tax (benefit) resulting from:			
State income tax, net of federal benefit	3.43	5.29	—
Permanent differences	(1.45)	(1.70)	(0.17)
Research and development credit	0.27	0.89	3.74
Change in valuation allowance	(36.25)	(38.48)	(37.57)
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,	
	2016	2015
Deferred tax assets:		
U.S. and state net operating loss carryforwards	$ 71,049	$ 38,405
Research and development credits	3,712	3,421
Accruals and other	1,541	144
Depreciation and amortization	261	94
Total deferred tax assets	76,563	42,064
Valuation allowance	(76,563)	(42,064)
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, 2016 and 2015, 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 be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of December 31, 2016 and 2015. The valuation allowance increased $34,499 and $10,539, during the years ended December 31, 2016 and 2015 respectively, due primarily to net operating losses generated.

As of December 31, 2016, 2015 and 2014, the Company had U.S. federal net operating loss carryforwards of $190,926, $104,888 and $78,276, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2036. As of December 31, 2016, 2015, and 2014, the Company also had U.S. state net operating loss carryforwards of $145,902, $59,875, and $34,184 respectively, which may be available to offset future income tax liabilities and expire at various dates through 2036. Included in the federal and state net operating loss carryforwards are approximately $1,539, $1,064, and $0, respectively, of deductions related to the exercise of stock options. As stated above, the company is electing to early adopt ASU 2016-09 on a modified retrospective basis. Therefore, the $1,539 of option deductions is included in the company’s net operating loss deferred tax asset at December 31, 2016. The company is not recasting its net operating loss deferred tax asset at December 31, 2015 and December 31, 2014, and therefore the option deduction of $1,064 and $0, respectively, is not included in the Company’s deferred tax assets.

As of December 31, 2016, 2015 and 2014, the Company had federal research and development tax credit carryforwards of approximately $3,367, $3,110, and $2,868, respectively, available to reduce future tax liabilities which expire at various dates through 2036. As of December 31, 2016, 2015 and 2014 the Company had state research and development

tax credit carryforwards of approximately $522, $469 and $226, respectively, available to reduce future tax liabilities which expire at various dates through 2031.

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 since its inception which may have resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code, or could result in a change in control in the future.

For all years through December 31, 2016, 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; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position for these two years. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the deferred tax asset established for the research and development credit carryforwards and the valuation allowance.

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, 2013 through December 31, 2016. 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.

15. 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 after completing 3 months of service. The Company is not required to contribute to this plan. Total expense for contributions made by the Company the years ended December 31, 2016, 2015 and 2014 was $613, $44 and $35 respectively.

16. UNAUDITED QUARTERLY OPERATING RESULTS

The following is a summary of unaudited quarterly results of operations for the years ended December 31, 2016 and 2015:

Year ended December 31, 2016	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Product revenues, net	$ -	$ -	$ 408	$ 1,303
Costs and expenses				
Cost of product revenues	-	-	29	184
Research and development	4,062	4,301	3,254	3,331
Selling, general and administrative	11,525	20,173	23,567	25,367
Total costs and expenses	15,587	24,474	26,850	28,882
Loss from operations	$ (15,587)	$ (24,474)	$ (26,442)	$ (27,579)
Other (expense) income, net	(66)	(46)	(2)	20
Net loss	$ (15,653)	$ (24,520)	$ (26,444)	$ (27,559)
Weighted-average shares - basic and diluted	23,130,153	23,417,378	23,460,340	27,100,231
Loss per share - basic and diluted	$ (0.68)	$ (1.05)	$ (1.13)	$ (1.02)

Year ended December 31, 2015	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Costs and expenses				
Research and development	$ 1,445	$ 1,641	$ 3,358	$ 1,531
Selling, general and administrative	2,186	2,934	5,907	7,905
Total costs and expenses	3,631	4,575	9,265	9,436
Loss from operations	$ (3,631)	$ (4,575)	$ (9,265)	$ (9,436)
Other expense, net	(63)	(99)	(97)	(89)
Net loss	$ (3,694)	$ (4,674)	$ (9,362)	$ (9,525)
Shares used in computing net loss per share-basic	1,001,704	11,791,546	20,531,406	20,558,205
Shares used in computing net loss per share-diluted	7,554,524	11,791,546	20,531,406	20,558,205
Net income (loss) per share-basic	$ 0.34	$ (0.45)	$ (0.46)	$ (0.46)
Net loss per share-diluted	$ (0.65)	$ (0.45)	$ (0.46)	$ (0.46)

17. SUBSEQUENT EVENTS

The Company has concluded that no subsequent events have occurred that require disclosure.

INDEX TO EXHIBITS

Exhibit Number	Exhibit Description
21.1	Subsidiaries of Collegium Pharmaceutical, Inc.
23.1	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.
23.2	Consent of Grant Thornton 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, 2016, formatted in XBRL: (i) Consolidated Balance Sheets as of December 31, 2016 and 2015, (ii) Consolidated Statements of Operations for the years ended December 31, 2016, 2015 and 2014, (iii) Consolidated Statements of Convertible Redeemable Preferred Stock and Shareholders' Equity (Deficit) for the Years Ended December 31, 2016, 2015 and 2014, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2016, 2015 and 2014, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text.

Exhibit 21.1

Subsidiaries of Collegium Pharmaceutical, Inc.

Subsidiary	Jurisdiction of Incorporation
Collegium Securities Corporation	Massachusetts

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 No. 333-207744 on Form S-8 of our report dated March 10, 2017, relating to the consolidated financial statements of Collegium Pharmaceutical, Inc. and subsidiary, appearing in this Annual Report on Form 10-K of Collegium Pharmaceutical, Inc. for the year ended December 31, 2016.

/s/ Deloitte & Touche LLP
Boston, Massachusetts
March 10, 2017

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 18, 2016 with respect to the consolidated financial statements included in the Annual Report of Collegium Pharmaceutical, Inc. on Form 10-K for the years end December 31, 2015 and December 31, 2014. We consent to the incorporation by reference of said report in the Registration Statements of Collegium Pharmaceutical, Inc. on Form S-3 (File No. 333-213964), and on Form S-8 (File No. 333-207744).

/s/ Grant Thornton LLP
Boston, Massachusetts
March 10, 2017

Exhibit 31.1

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

I, Michael T. Heffernan, 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/ MICHAEL T. HEFFERNAN
Michael T. Heffernan
President and Chief Executive Officer

Dated: March 10, 2017

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: March 10, 2017

/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, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Michael T. Heffernan, 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: March 10, 2017

/s/ MICHAEL T. HEFFERNAN
Michael T. Heffernan
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, 2016 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: March 10, 2017

/s/ PAUL BRANNELLY
Paul Brannelly
Executive Vice President and Chief Financial Officer