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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, 2017

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of June 30, 2017, 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 $272 million, based on the closing price of the registrant's common stock on The NASDAQ Global Select Market on June 30, 2017 of $12.51 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, 2018, there were 32,993,894 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 2018 Annual Meeting of Shareholders (the "Proxy Statement"), to be filed within 120 days of the registrant's year ended December 31, 2017, 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;
- our ability to effectively commercialize in-licensed products and manage our relationships with licensors, including our ability to satisfy our royalty payment obligations in connection with such products;
- 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 by or against us, including litigation with Purdue Pharma, L.P. and Teva Pharmaceuticals USA, Inc.;
- 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 secure adequate supplies of active pharmaceutical ingredient for each of our products and product candidates;
- 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;
- our customer concentration, which may adversely affect our financial condition and results of operations; 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 focused on becoming the leader in responsible pain management by developing and commercializing innovative, differentiated products for patients suffering from pain. 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.

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 $1.7 billion in U.S. sales in 2017. 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 November 2017, we announced the approval of a Supplemental New Drug Application to the FDA for Xtampza to include comparative oral pharmacokinetic data from a clinical study evaluating the effect of physical manipulation by crushing Xtampza compared with OxyContin OP and a control (oxycodone hydrochloride immediate-release), results from an oral human abuse potential study and the addition of an oral abuse deterrent claim.

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 patients in the United States who have difficulty swallowing and suffer from pain severe enough to require daily, around the clock, long-term opioid treatment and for which alternative treatment options are inadequate.

In December 2017, we entered into a Commercialization Agreement with Depomed, Inc., or Depomed, pursuant to which Depomed agreed to grant us a sublicense of certain of its intellectual property related to Nucynta ER and Nucynta IR, or the Nucynta Products, for commercialization of such products in the United States, the District of Columbia and Puerto Rico. We closed the transactions contemplated by the Commercialization Agreement, as amended, on January 9, 2018 and we began marketing the Nucynta Products in February 2018. Nucynta ER is an extended release formulation of tapentadol that is indicated for the management of pain severe enough to require daily, around the clock, long term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy in adults, and for which alternate treatment options are inadequate. Nucynta IR is an immediate release formulation of tapentadol that is indicated for the management of moderate to severe acute pain in adults.

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, pre-commercialization activities and the creation and protection of related intellectual property. Since 2011, we have generated limited 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 $5.0 billion (21 million prescriptions) of the approximately $13 billion U.S. opioid market in 2017. OxyContin OP generated U.S. sales of $1.7 billion in 2017, which represents approximately a 15% 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 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:

- *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.

- *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 similar legislation, including Florida, Maryland and West Virginia.

- *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.

- *Introduction of Comprehensive Addiction and Recovery Act 2.0:* On February 27, 2018, a bipartisan group of senators introduced Senate Bill 2456 (S.2456). S.2456 is characterized as "CARA 2.0," in reference to the Comprehensive Addiction and Recovery Act of 2016. CARA 2.0 would limit initial prescriptions for opioids to 3 days, while exempting initial prescriptions for chronic care, cancer care, hospice or end of life care, and palliative care. CARA 2.0 would also increase civil and criminal penalties for opioid manufacturers that fail to report suspicious orders for opioids or fail to maintain effective controls against diversion of opioids. The bill would increase civil fines from $10,000 to $100,000, and if a manufacturer fails to maintain effective controls or report suspicious orders with knowledge or willful disregard, the bill would double criminal penalties from $250,000 to $500,000. In addition, in 2017 several states, including Indiana, Louisiana, and Utah, enacted laws that further limit or restrict opioid prescriptions.

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.

- *Other approaches*: Some companies are taking different approaches to abuse deterrence, including attempting to slow the rate of the drug's entry into the brain. No opioids using such novel approaches 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 guidance in June 2015, 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.

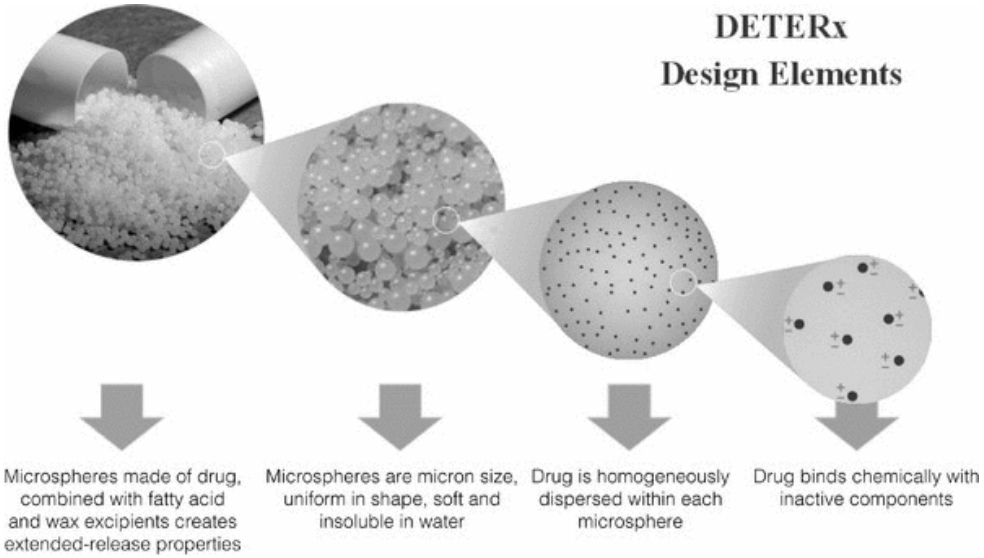
Except for Xtampza, all FDA-approved, orally administered extended-release opioids have a black box warning product label stating that "crushing, dissolving or chewing can cause rapid release and absorption of a potentially fatal dose of the active drug," making them unsuitable or unattractive for patients 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.

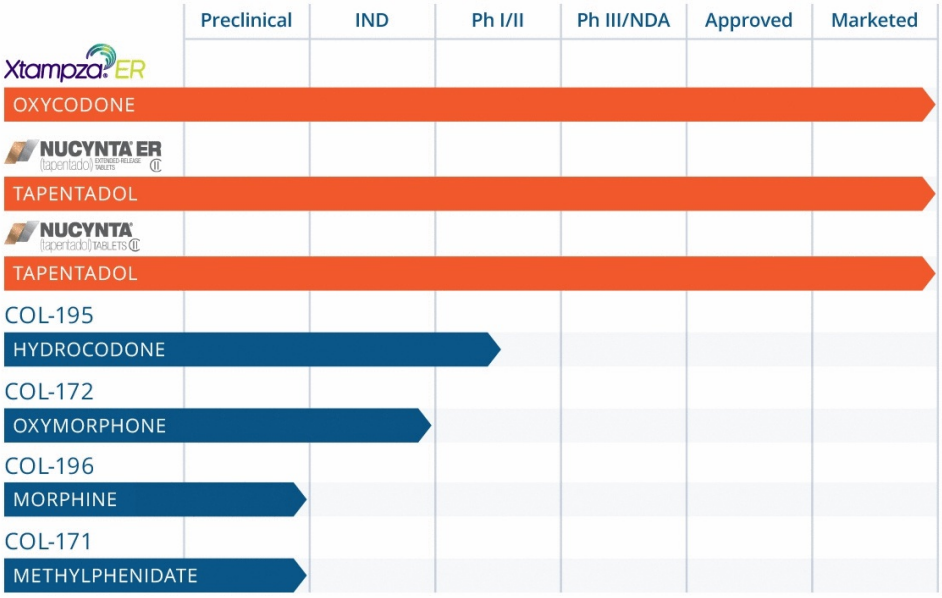
Abuse-Deterrent Features

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 the Nucynta Products. 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 $1.7 billion in U.S. sales in 2017. 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 November 2017, we announced the approval 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), results from an oral human abuse potential study and the addition of an oral abuse deterrent claim.

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 $5.0 billion U.S. extended-release opioid market, including a portion of the existing $1.7 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.

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 2017, there are approximately 18 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.

Nucynta ER and Nucynta IR

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

Nucynta ER is an extended release formulation of tapentadol that is indicated for the management of pain severe enough to require daily, around-the-clock, long term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy in adults, and for which alternate treatment options are inadequate. Nucynta IR is an immediate release formulation of tapentadol that is indicated for the management of moderate to severe acute pain in adults.

Pursuant to the Commercialization Agreement, we assumed all commercialization responsibilities, including sales and marketing, for the Nucynta Products, while Depomed continues to control manufacturing of the Nucynta Products. We began shipping and recognizing product sales on the Nucynta Products on January 9, 2018. We began commercial promotion of the Nucynta Products in February 2018. We will pay a royalty to Depomed on all revenues from the sale of Nucynta Products based on certain net sales thresholds, with a fixed annual minimum royalty during the first four years of the Commercialization Agreement, subject to certain conditions.

Onsolis

In May 2016, we licensed the U.S. rights to develop and commercialize Onsolis from BioDelivery Sciences International, Inc., or BDSI. 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. In December 2017, after a review of our product portfolio, we provided written notice to BDSI of termination of the License and Development Agreement dated May 11, 2016, or the License Agreement, which termination will be effective pursuant to the terms of such agreement on March 8, 2018. Upon such termination of the License Agreement, our rights to develop and commercialize Onsolis will revert to BDSI.

Manufacturing of DETERx Products and Product Candidates

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 a 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 and the Nucynta Products 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 and the Nucynta Products have substantial experience in pharmaceutical sales and marketing. We have a dedicated field sales force, consisting of approximately 131 sales professionals, to call on the approximately 11,000 physicians who write approximately 58% 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 14 specialty sales representatives to call on 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 and the Nucynta Products 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 twelve issued patents in the United States (seven of which claim compositions of matter, three of which claims both compositions of matter and methods of use, and two that claim methods of use), one granted and two pending applications in the European Patent Office, two issued patents in Canada, and one issued patent in each of Japan and Australia. Finally, we have six patent applications pending in the United States, one pending patent application in each of Canada and Japan, and one pending PCT application. Our issued U.S. patents are projected to expire in 2023, 2025, 2030, and 2036 and our pending patent applications in the United States, if issued, would be projected to expire in 2023, 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 leader in responsible pain management by developing and commercializing innovative, differentiated products for patients suffering from pain. Key elements of our strategy to achieve this goal are to:

- *Grow Xtampza in the United States.* 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 expanding sales, marketing and reimbursement functions to grow Xtampza sales in the United States. We are detailing Xtampza to approximately 11,000 physicians who write approximately 58% of the branded extended-release oral opioid prescriptions in the United States with a sales team of approximately 131 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 14 specialty sales representatives to detail Xtampza to hospitals.

- *Commercialize the Nucynta Products in the United States*. In December 2017, we entered into a Commercialization Agreement with Depomed, pursuant to which Depomed agreed to grant us a sublicense of certain of its intellectual property related to the Nucynta Products for commercialization of such products in the United States. We began shipping and recognizing product sales on the Nucynta Products on January 9, 2018, and we began commercial promotion of the Nucynta Products in February 2018. We are detailing the Nucynta Products to substantially the same physicians to whom we detail Xtampza, leveraging our existing sales organization.

- *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.

Our commercialization strategy for our products 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.

Xtampza

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 from Purdue, Embeda from Pfizer, MorphaBond ER from Inspirion Delivery Technologies and Arymo ER from Egalet. 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." 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.

In addition, there are five other approved extended-release opioids that have abuse deterrent product labeling, Vantrela ER from Teva, Targiniq from Purdue and Troxyca ER from Pfizer, 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. 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 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, including a generic version of Xtampza ER for which Teva recently submitted an Abbreviated New Drug Application, or ANDA, to the FDA and which is the subject of patent infringement litigation filed by us in February 2018.

Xtampza 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, long-term analgesia. Although no generic oxycodone extended-release products are currently commercially available, it is possible that generic forms of OxyContin OP could become available, in which case Xtampza 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, Nektar Therapeutics and Pain Therapeutics. If these products are successfully developed, approved for marketing and become commercially available, they could represent significant competition for Xtampza. It is also possible that a company that has developed an abuse-deterrent technology could initiate an abuse-deterrent oxycodone program at any time.

Nucynta

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

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

Government Regulation

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The 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 and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees. 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. The Nucynta Products are also listed by the DEA as Schedule II controlled substances under the CSA. Consequently, the manufacturing, shipping, storing, selling and using of 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 is 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, as with HIPAA in the United States, the collection and use of personal health data in the EU is governed by the EU General Data Protection Regulation (GDPR), with many requirements mandated by the GDPR for the consent of the individuals to whom the personal data relates, the information provided to the individuals, transfer of personal data within and outside of the EU and the security and confidentiality of the personal data. Enforcement of the GDPR is scheduled to begin on May 25, 2018, and failure to comply with the requirements of the GDPR may result in substantial fines and other administrative penalties.

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, the Nucynta Products 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, the Nucynta Products 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.

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

Other Regulatory Requirements

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA 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 $8.6 million, $14.9 million and $8.0 million for the years ended December 2017, 2016 and 2015, respectively.

Employees

As of December 31, 2017, we had a total of 250 full-time employees. Of these, 19 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, 2018:

Name	Age	Position(s)
Executive Officers:		
Michael T. Heffernan, R.Ph.	53	Chairman, President and Chief Executive Officer
Joseph Ciaffoni	46	Executive Vice President and Chief Operating Officer
Paul Brannelly	45	Executive Vice President and Chief Financial Officer
Alison B. Fleming	43	Executive Vice President and 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.

Joseph Ciaffoni, Executive Vice President and Chief Operating Officer. Mr. Ciaffoni has served as our Executive Vice President and Chief Operating Officer since May 2017. Prior to joining us, Mr. Ciaffoni served as President, U.S. Branded Pharmaceuticals of Endo International plc from August 2016 until May 2017. Before that, Mr. Ciaffoni held various positions of increasing responsibility at Biogen Idec since 2012, including Senior Vice President, Global Specialty Medicines Group, Senior Vice President, U.S. Commercial and Vice President, U.S. Neurology Field Operations and Marketing. Prior to joining Biogen Idec, Mr. Ciaffoni was Executive Vice President and Chief Operating

Officer of Shionogi Inc. and President of Shionogi Pharmaceuticals. Mr. Ciaffoni also previously served as Vice President, Sales for Schering-Plough (now Merck) and held several commercial leadership roles at Sanofi-Synthelabo (now Sanofi) and Novartis. Mr. Ciaffoni received a B.A. in Communications and an M.B.A. from Rutgers, The State University of New Jersey.

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.

Alison B. Fleming, Ph.D., Chief Technology Officer. Dr. Fleming has served as our Executive Vice President and Chief Technology Officer since January 2017. Prior to being our Chief Technology Officer, Dr. Fleming led our development team as our Vice President, Product Development since October 2002. Prior to joining us, Dr. Fleming's academic research focused on implantable drug delivery systems for cancer therapy. Dr. Fleming is an inventor on several U.S. patents and pending patent applications, and has authored numerous scientific publications and poster presentations in the field of novel drug delivery systems. 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 Nucynta Products, the acquisition and licensing of other products, 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 Annual Report on Form 10-K, including our financial statements, the notes thereto and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations." If any of the following risks actually occurs, our business, financial condition, operating results, prospects and ability to accomplish our strategic objectives could be materially harmed. As a result, the trading price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market price of our common stock.

Risks Related to Our Financial Position and Capital Needs

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, we have only generated limited 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, 2017, we reported a net loss of $74.9 million, and we had an accumulated deficit of $298.0 million at December 31, 2017.

We expect to continue to incur losses for the foreseeable future as we continue to commercialize Xtampza and the Nucynta Products 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 limited 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 assumed responsibility for the sales and marketing of the Nucynta Products in January 2018, and in each case have generated limited revenue from product sales. Our ability to generate additional revenue and become profitable depends upon our ability to successfully commercialize Xtampza, the Nucynta Products, our existing product candidates, and any other products and 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 and the Nucynta Products;
- 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 Xtampza and the Nucynta Products;
- manufacture commercial quantities of our products at acceptable cost levels;
- grow and sustain a commercial organization capable of sales, marketing and distribution for the products we intend to sell ourselves in the markets in which we have retained or acquired 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 regulatory submissions to the FDA and obtain regulatory approval;
- comply with existing and changing laws and regulations that apply to the pharmaceutical industry, including opioid manufacturers;
- respond to ongoing legal, regulatory, and public scrutiny of the pharmaceutical industry, including opioid manufacturers; 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 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 if regulatory approval is obtained.

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, the Nucynta Products 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 and the Nucynta Products will be sufficient to fund our operations into 2020, including from sales of Xtampza and the Nucynta Products, and the continuation of our development of our product candidates. However, we may require additional capital for the further commercialization of Xtampza, the Nucynta Products and 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;
- delay, scale back or discontinue the commercialization of the Nucynta Products;
- 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, including the Nucynta Products, 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:

- our ability to obtain and maintain abuse-deterrent claims in the product labels for our products and product candidates;
- our ability to successfully commercialize Xtampza and the Nucynta Products;
- 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 patent infringement claims against us and prosecuting patent infringement litigation against Teva in connection with its submission of an ANDA for a generic version of Xtampza;
- 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, the Nucynta Products 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 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, the Nucynta Products, 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. We are currently in the early years of operating as a commercial stage company, and although we have expanded our product portfolio to include Xtampza and the Nucynta products, we have a limited track record of successful commercialization of these products. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history.

The Commercialization Agreement with Depomed, pursuant to which we assumed responsibility for the sales and marketing of the Nucynta Products, requires us to pay significant license fees, some of which are payable whether or not our commercialization efforts are successful. Such licensing fees may adversely affect our cash flow and our ability to operate our business and our prospects for future growth.

In December 2017, we entered into the Commercialization Agreement, pursuant to which we assumed responsibility for the sales and marketing of the Nucynta Products. We closed the transactions contemplated by the Commercialization Agreement, as amended, on January 9, 2018 and we began marketing the Nucynta Products in February 2018. During the term of the Commercialization Agreement and through December 31, 2021, we are required to pay to Depomed a minimum annual license fee of $135.0 million paid quarterly in arrears, plus double-digit royalties on net sales of Nucynta Products in excess of $233.0 million per year. Beginning January 1, 2022 and for each year of the Commercialization Agreement term thereafter, we are required to pay double-digit royalties on all net sales of Nucynta Products. If our commercialization efforts of the Nucynta Products are unsuccessful, there can be no assurance that we will have sufficient cash flow to pay such licensing fees.

Our obligation to Depomed to pay such licensing fees could:

- make it more difficult for us to satisfy obligations with respect to our indebtedness, and any failure to comply with the obligations of any of our debt instruments, including financial and other restrictive covenants, could result in an event of default under the agreements governing such indebtedness;
- require us to dedicate a substantial portion of available cash flow to pay licensing fees, which will reduce the funds available for working capital, capital expenditures, acquisitions and other general corporate purposes;
- limit flexibility in planning for and reacting to changes in our business and in the industry in which we operate;
- limit our ability to engage in strategic transactions or implement our business strategies;
- limit our ability to borrow additional funds; and
- place us at a disadvantage compared to our competitors.

Any of the factors listed above could materially and adversely affect our business and our results of operations. If we do not have sufficient cash flow to pay the licensing fees under the Commercialization Agreement, we may be required to

terminate the Commercialization Agreement, sell assets, borrow money or sell securities, none of which we can guarantee we will be able to do on favorable terms, if at all.

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

As of December 31, 2017, we had a federal net operating loss, or NOL, carryforward of approximately $249.5 million and state net operating loss carryovers of approximately $205.1 million, which are available to offset future taxable income. The U.S. federal NOL carryforwards begin to expire in 2022, and the state NOL carryforwards begin to expire in 2030. We also had U.S. federal tax credits of approximately $3.4 million, and state tax credits of approximately $589,000. These tax attributes are generally subject to a limited carryover/carryback period, and are also subject to the annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended (Code), or Section 382.

The TCJA generally will allow losses incurred after 2017 to be carried over indefinitely, but limits the NOL deduction to the lesser of the NOL carryover or 80% of a corporation's taxable income (subject to Sections 382 and 383 of the Code and other conditions). Also, there will be no carryback for losses incurred after 2017. Losses incurred prior to 2018 will generally be deductible to the extent of the lesser of a corporation's NOL carryover or 100% of a corporation's taxable income, and be available for twenty years from the period the loss was generated. We have not finalized our review of the impact of TCJA on the NOL rules, and the impact, if any, to our ability to utilize and carryover net operating losses.

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

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

As of December 31, 2017 and 2016, we have provided a full valuation allowance for deferred tax assets including NOL and tax credit carryovers.

Risks Related to our Products and Product Candidates

Our success depends in large part on the commercial success of Xtampza, our lead product, and the Nucynta Products, which we will commercialize pursuant to a Commercialization Agreement with Depomed.

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 limited revenues from product sales and we may never be able to commercialize Xtampza, the Nucynta Products, 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 and its components;

- our ability to manufacture commercial quantities of Xtampza at reasonable cost and with sufficient speed to meet commercial demand;

- our ability to continue to build and retain a sales and marketing organization to market Xtampza;
- our success in educating physicians, patients and caregivers about the benefits, administration, use and coverage of Xtampza;
- the perceived availability and 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.

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

- develop and execute our sales and marketing strategies for the Nucynta Products;
- achieve, maintain and grow market acceptance of, and demand for, the Nucynta Products;
- obtain and maintain adequate coverage, reimbursement and pricing from managed care, government and other third-party payers;
- maintain and manage the necessary sales, marketing, manufacturing, managed markets, and other capabilities and infrastructure that are required to successfully integrate and commercialize the Nucynta Products;
- obtain adequate supply of Nucynta ER and Nucynta IR; and
- comply with applicable legal and regulatory requirements.

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

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

Despite receiving approval by the FDA, additional data may emerge that could change the FDA's position on the product labeling, and our ability to successfully market Xtampza or the Nucynta Products 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, 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 flexible dosing options, and we may not be able to market Xtampza for use by 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 will likely 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 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 reference 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 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.

To commercialize our product candidates, 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 and the Nucynta Products are subject to mandatory REMS programs, which could increase the cost, burden and liability associated with the commercialization of these products. We anticipate that our product candidates, if approved, will also be subject to mandatory REMS programs.

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. In September 2017, the FDA announced that immediate-release, or IR, opioid drugs will be subject to the same REMS as ER/LA opioids. One of the primary goals of the REMS is to ensure that the benefits of these drugs continue to outweigh the risks.

The REMS introduces new safety measures designed to reduce risks and improve the safe use of opioids, while continuing to provide access to these medications for patients in pain. The REMS applies to more than 20 companies that manufacture opioid analgesics. Under the REMS, companies are required to make education programs available to prescribers based on the FDA 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 REMS also requires companies to distribute FDA-approved educational materials to prescribers and patients on the safe use of these drugs. The companies must perform periodic assessments of the implementation of the REMS and the success of the program in meeting its goals. The FDA will review these assessments and may require additional elements to achieve the goals of the program.

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

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with Depomed or other licensors, we could lose license rights that are important to our business.

We are, or may become, a party to certain intellectual property license agreements, including the Commercialization Agreement, that are important to our business and may enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone, royalty and other obligations on us. If we fail to comply with the obligations under the Commercialization Agreement or other such agreements, Depomed or another such licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

In addition, Depomed may terminate the Commercialization Agreement under certain circumstances, regardless of whether we are compliant with the terms of such agreement. If annual net sales of the Nucynta Products are less than $180,000,000 through January 1, 2022, or if they are less than $140,000,000 per year in any 12-month period commencing on January 1, 2022, then Depomed will have the right to terminate the Commercialization Agreement without penalty. Depomed may also terminate the Commercialization Agreement for convenience at any time prior to December 31, 2018, provided it will be required to pay a termination fee to us.

In some cases, patent prosecution of our licenses is controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our

rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we control the prosecution of patents resulting from licenses. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected products or 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 and correspondingly lower product revenues. 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 may require us to perform lengthy Phase 4 post-approval clinical efficacy or safety trials. Post approval, the FDA may require us to study, as it has with respect to Xtampza, the serious risks of misuse, abuse, addiction, overdose, and death associated with long-term use of our medications for the management of chronic pain, as well as other risks. 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 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, the Nucynta Products, 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, the Nucynta Products, 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 and the Nucynta Products, could delay or inhibit our ability to generate revenues from their sale and could also expose us to claims or other sanctions.

Advertising and promotion of any product that obtains approval in the United States, including Xtampza and the Nucynta Products, 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 or the Nucynta Products, 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 the Nucynta Products, 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. False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth in recent years, leading to several substantial civil and criminal settlements based on certain sales practices promoting off-label drug uses. This increased focus and scrutiny has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting

and compliance obligations, and be excluded from the Medicare, Medicaid and other federal and state healthcare programs.

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

In addition, later discovery of previously unknown problems with a product, manufacturer or facility, or our failure to update regulatory files, may result in restrictions, including withdrawal of the product from the market. 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, the Nucynta Products 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, the Nucynta Products 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, the Nucynta Products and our product candidates contain, and our future product candidates will likely contain, controlled substances that are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Xtampza's active ingredient, oxycodone, and the Nucynta Products' active ingredient, tapentadol, are both classified as controlled substances 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 and tapentadol, 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. Oxycodone and tapentadol are both listed by the DEA as Schedule II controlled substances 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. If commercial demand for Xtampza, or any of our other approved products, increases and we cannot meet such demand in a timely fashion because of our limited supply of its active ingredient (in the case of Xtampza, oxycodone) then physicians may perceive such product as unavailable and may be less likely to prescribe it in the future.

In addition, controlled substances are also subject to regulations governing manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, recordkeeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of Xtampza, the Nucynta Products, 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, the Nucynta Products, 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.

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 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.

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, the Nucynta Products, 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 $10.0 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, the Nucynta Products, 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, the Nucynta Products, 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, the Nucynta Products, 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 was generally well tolerated by patients in our clinical trials, in some

cases there were adverse reactions, one of which was a serious adverse event, moderate in severity, of gastroesophageal reflux.

If we or others identify undesirable adverse events associated with Xtampza, the Nucynta Products, 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 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

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

Our commercial organization continues to grow and evolve, and in light of its short history and limited track record, we cannot guarantee that we will be successful in marketing Xtampza, the Nucynta Products or any of our product candidates that 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 continue to grow and maintain adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. Factors that may inhibit our efforts to commercialize our 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 adequate numbers of physicians who may prescribe Xtampza, the Nucynta Products 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, the Nucynta Products 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, the Nucynta Products or our product candidates, if approved, 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, the Nucynta Products or any of our product candidates (if regulatory approval is obtained), for which we receive final regulatory approval. Acceptance and use of Xtampza, the Nucynta Products 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 our products and 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, the Nucynta Products and our product candidates;
- perceptions by members of the healthcare community, including physicians, about the relevance and efficacy of our abuse deterrent technology in reducing potential risks of unintended use;

- published studies demonstrating the cost-effectiveness of Xtampza, the Nucynta Products and our product candidates relative to competing products;
- the potential and perceived advantages of Xtampza, the Nucynta Products and our product candidates over alternative treatments;
- the convenience and ease of administration to patients of Xtampza, the Nucynta Products and our product candidates;
- actual and perceived availability of coverage and reimbursement for Xtampza, the Nucynta Products 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, the Nucynta Products 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, the Nucynta Products, 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. Since we expect to rely on sales generated by Xtampza and the Nucynta Products for substantially all of our revenues for the foreseeable future, the failure of Xtampza or the Nucynta Products 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, the Nucynta Products, 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, the Nucynta Products, or any product candidates for which we obtain marketing approval.

Cost reduction legislation could decrease the coverage and price that we receive for any approved products, including for reimbursement through Medicare and 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 pharmaceutical products generally. The current administration has indicated that reducing the price of prescription drugs will be a priority of the administration. The implementation of any price controls on prescription drugs, whether at the federal or state level, may adversely affect our business, operating results and financial condition.

Laws intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms may continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. 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. At the same time, there have been significant ongoing efforts to modify or eliminate the Affordable Care Act. For example, the TCJA, enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate, beginning in 2019. The Joint Committee on Taxation estimates that the repeal will result in over 13 million Americans losing their health insurance coverage over the next ten years and is likely to lead to increases in insurance premiums. Further legislative changes to and regulatory changes under the Affordable Care Act remain possible. It is unknown what form any such changes or any law proposed to replace the Affordable Care Act would take, and how or whether it may affect our business in the future.

Newly enacted FDA regulations may require us to expend additional resources to obtain or maintain regulatory approval. For example, in August 2017 President Trump signed into law the Food & Drug Administration Reauthorization Act (FDARA). This legislation imposes significant new requirements for clinical trial sponsors which will affect, among other things, the development of drugs and biological products for pediatric use. This legislation may result in new regulations, which may affect future options or timelines for regulatory approval.

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.

On February 27, 2018, a bipartisan group of senators introduced Senate Bill 2456 (S.2456). S.2456 is characterized as "CARA 2.0," in reference to the Comprehensive Addiction and Recovery Act of 2016. CARA 2.0 would limit initial prescriptions for opioids to 3 days, while exempting initial prescriptions for chronic care, cancer care, hospice or end of life care, and palliative care. CARA 2.0 would also increase civil and criminal penalties for opioid manufacturers that fail to report suspicious orders for opioids or fail to maintain effective controls against diversion of opioids. The bill would increase civil fines from $10,000 to $100,000, and if a manufacturer fails to maintain effective controls or report suspicious orders with knowledge or willful disregard, the bill would double criminal penalties from $250,000 to $500,000. If this bill were signed into law, it could adversely affect our ability to successfully commercialize Xtampza, the Nucynta Products, and our product candidates if approved. In addition, in 2017 several states, including Indiana, Louisiana, and Utah, enacted laws that further limit or restrict opioid prescriptions.

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, the Nucynta Products, 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. Such pricing regulations may address the rebates that manufacturers offer to pharmaceutical benefit managers, or the discounts that manufacturers provide others within the pharmaceutical distribution chain.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products 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, the Nucynta Products, 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 discounts and rebates from list prices and are challenging the prices charged for medical products. We have agreed to provide such discounts and rebates to certain third-party payors. We expect increasing pressure to offer larger discounts and rebates. Additionally, a greater number of third-party payors may seek discounts and rebates in order to offer or maintain access for Xtampza, the Nucynta Products and our product candidates, if approved. 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, the Nucynta Products, 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, the Nucynta Products, 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 and the Nucynta Products; public inquiries and investigations into prescription drug abuse; litigation; or regulatory activity regarding sales, marketing, distribution or storage of opioid drugs could have a material adverse effect on our reputation. Such negative publicity could reduce the potential size of the market for Xtampza, the Nucynta Products, 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 and 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 the FDA's focus on implementing policies to reverse the opioid abuse epidemic, while maintaining access to effective treatments. The actions set forth in the FDA's plan include strengthening post marketing study requirements to evaluate the benefit of long-term opioid use, changing the REMS requirements to provide additional funding for physician education courses, releasing a draft guidance setting forth approval standards for generic-abuse deterrent opioid formulations, and seeking input from the FDA's Science

Board to broaden the understanding of the public risks of opioid abuse. The FDA's Science Board met to address these issues on March 1, 2016. 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 Guideline for Prescribing Opioids for Chronic Pain. The guideline is intended to assist primary care providers treating adults for chronic pain in outpatient settings. The guideline provides recommendations to improve communications between doctors and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy. The guideline states that no treatment recommendations about the use of abuse-deterrent opioids can be made at this time.

The FDA continues to evaluate extended release and abuse-deterrent opioids in the postmarket setting. In March 2017, the FDA's Advisory Committee met to discuss OPANA ER (oxymorphone hydrochloride) extended release tablets. A majority of the Advisory Committee voted that the benefits do not outweigh the risks of OPANA ER. Upon the FDA's subsequent request in June 2017, OPANA ER was removed from the market. Also, in July 2017, the FDA held a public workshop to discuss available data and methods to assess the impact of opioid formulations with abuse-deterrent properties on misuse, abuse, addiction, overdose, and death in the postmarket context. The FDA will continue to scrutinize the impact of abuse-deterrent opioids and in the future could impose further restrictions to products currently on the market, which may include changing labeling, imposing additional prescribing restrictions, or seeking a product's removal from the market.

The DEA continues to increase its efforts to hold manufacturers, distributors, prescribers and pharmacies accountable through various enforcement actions as well as the implementation of compliance practices for controlled substances. In addition, many state legislatures are considering various bills intended to reduce opioid abuse, for example by establishing prescription drug monitoring programs and mandating prescriber education. Further, the FDA is requiring "black-box" warnings on immediate release opioids highlighting the risk of misuse, abuse, addiction, overdose and death. In addition, during the 2016 presidential campaign, as well as implementing a REMS for immediate release opioids, many elected officials, including President Trump, called for the DEA to restrict the amount of opioids that can be manufactured in the U.S. The DEA recently proposed reducing the quota for controlled substances to be manufactured in the U.S. in 2018. In March 2017, President Trump announced the creation of a commission, through ONDCP, to make recommendations to the president on how to best combat opioid addiction and abuse. In August 2017, the commission issued a preliminary report calling on President Trump to officially declare the crisis of opioid abuse a national emergency. On October 26, 2017, President Trump declared the opioid crisis a "national public health emergency". The commission's final report was released in early November 2017.

Recently, CVS Pharmacy announced it would only fill first-time opioid prescriptions for acute pain for a seven day supply. In July 2017, the Pharmaceutical Care Management Association, a trade association representing pharmacy benefit managers, wrote a letter to the commissioner of FDA in which it expressed support for, among other things, the CDC guidelines and a seven-day limit on the supply of opioids for acute pain. In addition, states, including the Commonwealths of Massachusetts and Virginia and the States of New York, Ohio, Arizona, Maine, New Hampshire, Vermont, Rhode Island, Colorado, Wisconsin, Alabama, South Carolina, Washington and New Jersey, have either recently enacted, intend to enact, or have pending legislation or regulations designed to, among other things, limit the duration and quantity of initial prescriptions of immediate release forms of opiates and, mandate the use by prescribers of prescription drug databases and mandate prescriber education. Also, at the state and local level, a number of states and cities have brought separate lawsuits against various pharmaceutical companies marketing and selling opioid pain medications, alleging misleading or otherwise improper promotion of opioid drugs to physicians and consumers. In addition, the attorneys general from several states have announced the launch of a joint investigation into the marketing and sales practices of drug companies that market opioid pain medications. Many of these changes and others could cause us to expend additional resources in developing and commercializing Xtampza, the Nucynta Products, 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, the Nucynta Products, 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, the Nucynta Products, 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. Our commercialization partner also relies on a sole supplier to manufacture Nucynta ER, which presents a similar risk.

We do not own any manufacturing facilities and have limited experience in drug development and commercial manufacturing. We currently have no plans to build our own clinical or commercial scale manufacturing facility. We lack the resources and expertise to manufacture and test, on a commercial scale, the technical performance of Xtampza 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 be affected by natural disasters that interrupt or prevent manufacturing of our products, may experience shortages of qualified personnel to adequately staff production operations, may experience shortages of raw materials and may have difficulties finding replacement parts or equipment.

- Our contract manufacturers could default on their agreements 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.

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

Because we currently rely on a sole supplier to manufacture the active pharmaceutical ingredient of 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, the Nucynta Products 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, our products and our product candidates. These collaborations, including the Commercialization Agreement for Nucynta ER and Nucynta IR, 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.
- Our ability to successfully commercialize product candidates pursuant to collaboration agreements may be adversely affected by disputes or delays arising from supply and/or manufacturing agreements between such collaborators and third parties—agreements to which we may not be a party.

We may rely on collaborators to market and commercialize our products, 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, the Nucynta Products 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.

Our customer concentration may materially adversely affect our financial condition and results of operations.

A significant percentage of our product shipments are to a limited number of independent wholesale drug distributors. Three of our wholesale distributors represented 39%, 29% and 23% of our product shipments for the year ended December 31, 2017. If we were to lose the business of one or more of these distributors, or if any of these distributors failed to fulfill their obligations or refused or experienced difficulty in paying us on a timely basis, or negotiated larger discounts, it would have a material adverse effect on our business, financial condition, results of operations and cash flows.

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. Xtampza, the Nucynta Products, and 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, our Chief Financial Officer, Paul Brannelly, our Chief Operating Officer, Joseph Ciaffoni and our Chief Technology Officer, Alison Fleming, PhD. Each employee is employed by us at will and is permitted to terminate his or her employment with us at any time pursuant to the terms of his 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, Mr. Brannelly, Mr. Ciaffoni or Dr. Fleming 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, or businesses, in-licensing or out-licensing of products, product candidates or technologies, or other strategic alliances and collaborations, to expand our existing technologies and operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any such transaction, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. We have limited experience with acquiring other companies, products or product candidates, and limited experience with licensing and forming strategic alliances and collaborations. We may not find suitable acquisition candidates, and if we make an acquisition, we may not integrate the acquisition successfully into our existing business and we may incur additional debt or assume unknown or contingent liabilities in connection therewith. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business. We may not be able to find suitable strategic alliance or collaborators or identify other investment opportunities, and we may experience losses related to any such investments.

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

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 comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business and results of operations, including the imposition of civil, criminal and administrative penalties,

damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could have a material adverse effect on our ability to operate our business and our results of operations.

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

Healthcare providers, physicians and payors play a primary role in the recommendation and prescription of Xtampza, the Nucynta Products, 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, the Nucynta Products, and any product candidates for which we may obtain marketing approval. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal, 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, cyber attacks and other malfeasance, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our commercial and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our commercialization and drug development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further commercialization of our products and 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 numerous factors, some of which are beyond our control. In addition to the factors discussed in these Risk Factors, these factors include:

- the success of competitive products or technologies;
- regulatory actions with respect to our 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. As of December 31, 2017, holders of an aggregate of approximately 4.5 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 or otherwise could cause our stock price to fall or prevent it from increasing for numerous reasons, and actual or potential sales by such persons could be viewed negatively by investors.

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

potential sales by such persons could be viewed negatively by investors.

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

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, 2017, 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 and Skyline Venture Partners V, L.P. currently serve on our board of directors. The interests of Longitude Capital Partners, LLC and Skyline Venture Partners V, L.P. may not always coincide with the interests of the other shareholders, and the concentration of control in Longitude Capital Partners, LLC and Skyline Venture Partners V, 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 $1.07 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 are required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment must include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. 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, 2017, there were (a) outstanding options to purchase an aggregate of 3,037,690 shares of our common stock at a weighted average exercise price of $13.00 per share, of which options to purchase 1,025,252 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 in August 2020, five years following the date that the landlord delivered the expansion space with certain improvements substantially completed. The lease term may be extended for an additional five years 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

Xtampza Litigation

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

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

The current suits have been consolidated by the District of Massachusetts, where Purdue continues to assert infringement of five patents: the '497 patent, the '933 patent, the '717 patent, the '919 patent, and the '961 patent. None of these suits are associated with any stay of FDA approval for the Xtampza drug product. 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 second half of 2018. A claim construction and summary judgment hearing was held on June 1, 2017. On November 21, 2017, the Court issued its claim construction ruling, construing certain claims of the '933, '497, and '717 patents. At this time, the Motion for Summary Judgment, which asserted that claims of the '933, '497, and '717 patents are invalid and not infringed, remains pending. We are not able to predict with certainty when the Court will decide our motion. The Scheduling Order has been amended to stay the close of fact discovery until after the Court decides our Motion for Summary Judgment. 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.

Nucynta Litigation

On February 7, 2018, Purdue filed a patent infringement suit against Collegium NF, LLC and Collegium Pharmaceutical, Inc. in the District of Delaware. Specifically, Purdue argues that our sale of immediate release and extended release Nucynta infringes U.S. Patent Nos. 9,861,583, 9,867,784, and 9,872,836. Purdue has made a demand for monetary relief in the Complaint but has not quantified its alleged damages. Our response to the Complaint is currently due April 9, 2018.

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

Teva Litigation

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

Teva Pharmaceuticals USA filed a Notice Letter of Patent Certification against all twelve listed patents, alleging that they were invalid and/or not infringed by the proposed oxycodone product that is the subject of Teva's ANDA. On February 22, 2018—within the 45-day period that gives us a 30-month stay on FDA approval of Teva's ANDA while the parties have an opportunity to litigate—we sued Teva in the District of Delaware on eleven of the patents listed in the *Orange Book*. The case was assigned to the Hon. Judge Stark.

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

Opioid-Related Request and Subpoenas

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

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our common stock is publicly traded on the NASDAQ Global Select Market under the symbol "COLL" since May 7, 2015. Prior to May 7, 2015, there was no public trading market for our common stock. The following table sets forth, for the periods indicated, the high and low sales prices for our common stock as reported on NASDAQ:

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

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

Holders

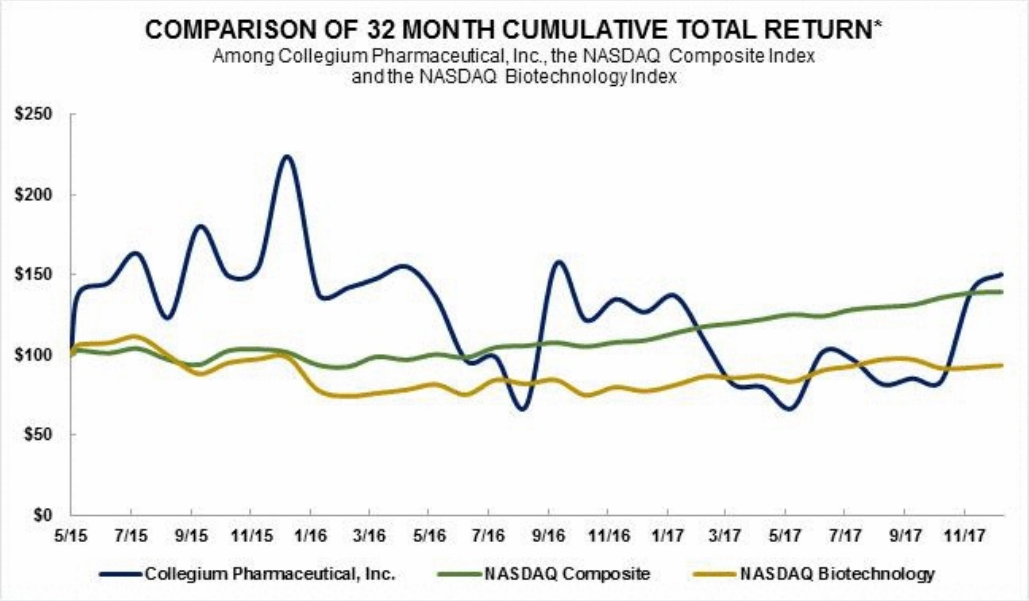
As of February 28, 2018, there were 36 holders of record of our common stock. The number of holders of record does not include beneficial owners whose shares are held by nominees in street name.

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, 2017. Such returns are based on historical results and are not intended to suggest future performance. Data for the NASDAQ Composite Index and NASDAQ Biotechnology Index assume reinvestment of dividends, however no dividends have been declared on our common stock to date.



$100 investment in stock or index	May 7, 2015	December 31, 2016	December 31, 2017
Collegium Pharmaceutical, Inc. (COLL)	$ 100.00	$ 126.69	$ 150.20
NASDAQ Composite Index (IXIC)	$ 100.00	$ 109.84	$ 139.59
NASDAQ Biotechnology Index (NBI)	$ 100.00	$ 79.90	$ 93.20

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

In March 2017, we commenced an "at-the-market" offering of our common stock and entered into a Controlled Equity Offering Sales Agreement (the "ATM Sales Agreement") with Cantor Fitzgerald, as agent, pursuant to which we may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $60.0 million. As of December 31, 2017, we had sold an aggregate of 3,126,998 shares of common stock under the ATM Sales Agreement at an average gross sales price of $11.36 per share, generating net proceeds of $34.3 million after deduction of underwriting discounts and commissions and expenses payable by us. The proceeds from the sales were used to fund

the continued commercialization of Xtampza, research and development efforts of our other product candidates, working capital and other general corporate purposes.

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, 2017.

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,				
	2017	2016	2015	2014	2013
	(in thousands, except share and per share amounts)				
Statement of Operations Data:					
Product revenues, net	$ 28,476	$ 1,711	$ —	$ —	$ —
Costs and expenses					
Cost of product revenues	2,595	213	—	—	—
Research and development	8,572	14,948	7,975	14,959	14,157
Selling, general and administrative	92,756	80,632	18,932	2,706	1,885
Total costs and expenses	103,923	95,793	26,907	17,665	16,042
Loss from operations	(75,447)	(94,082)	(26,907)	(17,665)	(16,042)
Interest income (expense), net	582	(94)	(439)	(252)	(76)
Other income (expense), net	—	—	91	—	(79)
Net loss	$ (74,865)	$ (94,176)	$ (27,255)	$ (17,917)	$ (16,197)
Basic and diluted net loss per common share[(1)]:	$ (2.47)	$ (3.88)	$ (1.48)	$ (22.72)	$ (4.06)
Weighted-average shares used to compute loss per common share[(1)]:	30,265,262	24,262,945	13,542,282	933,997	1,697,044

(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,				
	2017	2016	2015	2014	2013
Balance Sheet Data:					
Cash and cash equivalents	$ 118,697	$ 153,225	$ 95,697	$ 1,634	$ 7,551
Working capital[(1)]	101,996	132,979	88,451	(5,921)	5,643
Total assets	135,568	162,017	97,718	5,090	9,034
Other long-term liabilities	—	1,513	4,214	6,914	834
Total shareholders' equity (deficit)	104,080	134,908	85,072	(89,348)	(68,225)

(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 focused on becoming the leader in responsible pain management by developing and commercializing innovative, differentiated products for patients suffering from pain. 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 $1.7 billion in U.S. sales in 2017. 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 November 2017, we announced the approval of a Supplemental New Drug Application to the FDA for Xtampza to include comparative oral pharmacokinetic data from a clinical study evaluating the effect of physical manipulation by crushing Xtampza compared with OxyContin OP and a control (oxycodone hydrochloride immediate-release), results from an oral human abuse potential study and the addition of an oral abuse deterrent claim.

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 patients in the United States who suffer from chronic pain and have difficulty swallowing.

In December 2017, we entered into a Commercialization Agreement with Depomed, Inc., or Depomed, pursuant to which Depomed agreed to grant us a sublicense of certain of its intellectual property related to Nucynta ER and Nucynta IR, or the Nucynta Products, for commercialization of such products in the United States, the District of Columbia and Puerto Rico. Nucynta ER is an extended release formulation of tapentadol that is indicated for the management of pain severe enough to require daily, around‑the‑clock, long term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy in adults, and for which alternate treatment options are inadequate. Nucynta IR is an immediate release formulation of tapentadol that is indicated for the management of moderate to severe acute pain in adults.

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, pre-commercialization activities and the creation and protection of related intellectual property. Since 2011, we have generated limited 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. We are detailing Xtampza to approximately 11,000 physicians who write approximately 58% of the branded extended-release oral opioid prescriptions in the United States with a sales team of approximately 131 sales representatives. In addition, we deploy a separate, hospital focused sales team.

We began shipping and recognizing product sales on the Nucynta Products on January 9, 2018, and we began commercial promotion of the Nucynta Products in February 2018. We are detailing the Nucynta Products to substantially the same physicians to whom we detail Xtampza, leveraging our existing sales organization. We will pay a royalty to Depomed on all revenues from the sale of Nucynta Products based on certain net sales thresholds, with a minimum royalty of $135.0 million per year during the first four years of the Commercialization Agreement, subject to certain conditions. If Depomed or its contract manufacturers are unable to deliver a certain percentage of ordered quantities of the Nucynta Products for a period of two months or longer in calendar year 2018, then Depomed may be required to make a payment (or offset the minimum royalties) to ensure that we receive a minimum level of gross profit for 2018.

We have never been profitable and have incurred net losses in each year since inception. We incurred net losses of $74.9 million, $94.2 million and $27.3 million for the years ended December 31, 2017, 2016 and 2015, respectively. As of December 31, 2017, we had an accumulated deficit of $298.0 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 as we continue to commercialize Xtampza and the Nucynta Products. 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 and the Nucynta Products, 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;
- expand 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, 2017, together with expected cash inflows from the commercialization of Xtampza and the Nucynta Products, will enable us to fund our operating expenses, debt service and capital expenditure requirements into 2020. In addition, we may in the future seek to fund our operations through additional public or private equity or debt financings or other sources. 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 through the year ended December 31, 2017 has been generated from product sales of Xtampza. Product sales of Xtampza 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;
- 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 continued expansion of our commercialization efforts for Xtampza and the Nucynta Products. 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.

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.

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 product returns, units prescribed, discounts and allowances related to commercial sales of Xtampza, estimates utilized in the valuation of inventory, accounting for stock-based compensation, contingencies and tax valuation reserves. We base our estimates and assumptions 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. Estimates are based on historical experience, current conditions and on various other assumptions that are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity and the amounts of revenues and expenses. Actual results may differ from these estimates under different assumptions or conditions.

Product Revenue

Revenue for product sales is recognized when there is persuasive evidence of an arrangement; title and risk of loss have passed to the customer, which generally occurs upon delivery; 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 sales are recorded net of estimated chargebacks, rebates, sales incentives and allowances, distribution service fees, as well as estimated product returns.

Beginning in the third quarter of 2017, we determined that we have sufficient experience with sales of Xtampza to estimate our returns at time of shipment. We sell our products primarily to distributors and retailers ("customers"), which in turn sell the product to pharmacies for the treatment of patients. We provide the right of return to our customers for a limited time before and after the product expiration date. As a result of our experience to date with Xtampza sales, we determined that we can reasonably estimate the amount of future product returns. This determination has enabled us to recognize revenue earlier on the sell-in method, net of a provision for estimated returns, because we can record revenue once sold to the customer rather than waiting until the product is sold to the end user on a sell-through method. We recorded a one-time $4.4 million increase to revenues during the three months ended September 30, 2017 as a result of our change to the sell-in method in the third quarter of 2017.

Sales Deductions

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

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

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 $1.8 million of inventory as of December 31, 2017. 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.

As of December 31, 2017, our only intangible asset was the licensed right to develop and commercialize Onsolis from BioDelivery Sciences International, Inc. ("BDSI"). 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. On December 8, 2017, after a review of our product portfolio, we provided written notice to BDSI of the termination of the License and Development Agreement dated May 11, 2016, or the License Agreement, which termination will be effective pursuant to the terms of such agreement on March 8, 2018. Upon such termination of the License Agreement, our rights to develop and commercialize Onsolis will revert to BDSI. As such, we considered this notice a triggering event warranting an assessment of impairment indicators and test for recoverability. Based on the results of the impairment assessment and recoverability test, we recognized a full impairment of $1.8 million related to the license of Onsolis in December 2017.

We have not recognized any impairment losses on property and equipment assets for the years ended December 31, 2017, 2016 and 2015.

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 prior to our recent IPO 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, 2017, 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

As of December 31, 2017, we had a federal net operating loss, or NOL, carryforward of approximately $249.5 million

and state net operating loss carryovers of approximately $205.1 million, which are available to offset future taxable income. The U.S. federal NOL carryforwards begin to expire in 2022, and the state net operating losses begin to expire in 2030. We also had U.S. federal tax credits of approximately $3.4 million, and state tax credits of approximately $589,000. These tax attributes are generally subject to a limited carryover/carryback period, and are also subject to the annual limitations that may be imposed under Section 382 of the Code, or Section 382.

The TCJA generally will allow losses incurred after 2017 to be carried over indefinitely, but will limit the NOL deduction to the lesser of the NOL carryover or 80% of a corporation's taxable income (subject to Code Sections 382/383 and other limitations). Also, there will be no carryback for losses incurred after 2017. Losses incurred prior to 2018 generally will be deductible to the extent of the lesser of a corporation's NOL carryover or 100% of a corporation's taxable income, and be available for twenty years from the period the loss was generated. We have not finalized our review of the impact of TCJA on the NOL rules, and the impact, if any, to our ability to utilize and carryover net operating losses.

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

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

As of December 31, 2017 and 2016, we have provided a full valuation allowance for deferred tax assets including NOL and tax credit carryovers.

Uncertain Tax Positions and 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.

During 2017, the Company identified unrecognized tax benefits associated with the IRS audit of its 2015 corporate income tax return, and the risk of claiming R&D credits without a formal R&D study. The gross unrecognized tax benefits associated with these two items at December 31, 2017 is $1.4 million.

Results of Operations

Comparison of the Years Ended December 31, 2017, 2016 and 2015

The following table summarizes the results of our operations for the years ended December 31, 2017, 2016 and 2015:

	Years ended December 31,		
	2017	2016	2015
	(in thousands)		
Product revenues, net	$ 28,476	$ 1,711	$ —
Cost of product revenues	2,595	213	—
Research and development	8,572	14,948	7,975
Selling, general and administrative	92,756	80,632	18,932
Interest income (expense), net	582	(94)	(348)
Net loss	$ (74,865)	$ (94,176)	$ (27,255)

Comparison of the Years Ended December 31, 2017 and 2016

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

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

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

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

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

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

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 was $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; 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.

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 and convertible notes, public offerings of common stock, and commercial bank debt. As of December 31, 2017, we had $118.7 million in cash and cash equivalents.

Equity Financing

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

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

In March 2017, we commenced an "at-the-market" offering of our common stock and entered into the ATM Sales Agreement with Cantor Fitzgerald, as agent, pursuant to which we may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $60.0 million. As of December 31, 2017, we had sold an aggregate of 3,126,998 shares of common stock under the ATM Sales Agreement at an average gross sales price of $11.36 per share, generating net proceeds of $34.3 million after deduction of underwriting discounts and commissions and expenses payable by us, all of which were sold during the year ended December 31, 2017.

Silicon Valley Bank Term Loan Facility

Since August 2012, the Company has maintained a term loan facility with Silicon Valley Bank, which was amended and replaced in connection with, and as a condition to, consummation of the transactions contemplated by the Commercialization Agreement. Under the amended and replaced term loan, the Company now has a term loan facility in an amount of $11.5 million (the "New Term Loan"), which replaces the Company's previously existing term loan facility. The proceeds of the New Term Loan were used by the Company to finance certain payment obligations under the Commercialization Agreement and to repay the balance of the previously existing term loan. The New Term Loan also provided SVB's consent with respect to transactions contemplated by the Commercialization Agreement, including the delivery by SVB of a standby letter of credit in an aggregate amount of $33.75 million.

The New Term Loan bears interest at a rate per annum of 0.75% above the prime rate (as defined in the agreement governing the New Term Loan). The Company will repay the New Term Loan in equal consecutive monthly installments of principal plus monthly payments of accrued interest, commencing in July 2019, provided that, if the Company achieves EBITDA (as defined in the agreement governing the New Term Loan) in excess of $2.5 million for two (2) consecutive calendar quarters prior to June 2019, such payments will commence in January 2020. All outstanding principal and accrued and unpaid interest under the New Term Loan, and all other outstanding obligations with respect to the New Term Loan, are due and payable in full in December 2022. The Company may prepay the New Term Loan, in full but not in part, with a prepayment fee of (i) 3.0% of the outstanding principal balance prior to January 2019, (ii) 2.0% of the outstanding principal balance following January 2019 and prior to January 2020 and (iii) 1.0% of the outstanding principal balance following January 2020, plus, in each case, a final payment fee of $719.

Under the New Term Loan, the Company will be required to maintain a liquidity ratio of at least 2.0 to 1.0. Any amounts outstanding during the continuance of any event of default under the New Term Loan will bear additional interest at the per annum rate of 5.0%.

Cash flows

	Years ended December 31,		
	2017	2016	2015
Net cash used in operating activities	$ (67,018)	$ (75,053)	$ (21,567)
Net cash used in investing activities	(990)	(2,977)	(362)
Net cash provided by financing activities	33,480	135,558	115,992

Operating activities. Cash used in operating activities was $67.0 million in the year ended December 31, 2017 and $75.1 million in the year ended December 31, 2016. The $8.1 million decrease in cash used in operating activities was primarily due to the change in net loss, partially offset by changes in the working capital accounts, including significant changes in accounts receivable and accrued rebates, returns and discounts in the year ended December 31, 2017, and non-cash operating activities such as stock-based compensation expense, non-cash impairment charges and depreciation and amortization. We expect cash used in operating activities to increase in the foreseeable future as we continue to commercialize Xtampza and the Nucynta Products and fund research, development and clinical activities for additional product candidates.

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 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 $990,000 in the year ended December 31, 2017 and $3.0 million in the year ended December 31, 2016. The decrease in cash used in investing activities was primarily due to a one-time upfront fee paid to BDSI for the Onsolis License Agreement in the year ended December 31, 2016.

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 a one-time upfront fee paid to BDSI for the Onsolis License Agreement in the year ended December 31, 2016.

Financing activities. Cash provided by financing activities for the year ended December 31, 2017 primarily represents net proceeds of $34.3 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, 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.

Funding requirements

Since 2011, we have generated limited revenue from product sales and we continue to incur significant research, development and other expenses related to our ongoing operations. As we continue to commercialize Xtampza and add the Nucynta Products to our portfolio, we anticipate that we will continue to incur losses in the near future as we grow our commercial organization 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 products or 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 growing and maintaining sales, marketing and distribution capabilities for Xtampza, the Nucynta Products and any other products for which we may receive regulatory approval;
- the generation of reasonable levels of revenue from the sale of Xtampza and the Nucynta Products;
- our ability to pay license fees and royalties for our in-licensed products;
- 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 our litigation with each of Purdue Pharma, L.P., or Purdue, and Teva Pharmaceuticals USA, Inc., or Teva, relating to Xtampza, the Nucynta Products 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, 2017 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]	$ 639	$ 234	$ 405	$ —	$ —
Long term debt (including interest) [2]	1,479	1,479	—	—	—
Purchase obligations [3]	9,000	3,000	6,000	—	—
Total	$11,118	$ 4,713	$ 6,405	$ —	$ —

[1] Operating lease obligations represent future minimum lease payments under our non-cancelable operating lease in effect as of December 31, 2017, 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, 2017.

[3] Purchase obligations represent the minimum purchase obligations of up to $3.0 million under a manufacturing agreement as of December 31, 2017. The disclosed amounts represent the maximum amount that could be payable under the minimum purchase obligations.

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

Off-Balance Sheet Arrangements

We did not have during the periods presented 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, 2017, we had cash and cash equivalents consisting of cash and money market funds of $118.7 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

The Company's management, with the participation of the Chief Executive Officer and the Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and 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, 2017.

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, 2017, 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 during the fiscal quarter ended December 31, 2017 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 2018 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 2018 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 2018 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 2018 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 2018 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.(8)
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†	Consent and Sixth Amendment to Loan and Security Agreement, dated January 9, 2018, by and between Collegium Pharmaceutical, Inc. and Silicon Valley Bank.(9)
10.8†	Subordination Agreement, dated November 14, 2014, by and among Collegium Pharmaceutical, Inc., Silicon Valley Bank and the creditors named therein.(1)
10.9†	Subordination Agreement, dated December 2, 2014, by and among Collegium Pharmaceutical, Inc., Silicon Valley Bank and the creditors named therein.(1)
10.10+†	Restricted Stock Award Agreement, dated June 13, 2012, by and between Collegium Pharmaceutical, Inc. and Michael T. Heffernan.(1)
10.11+†	Restricted Stock Award Agreement, dated July 18, 2012, by and between Collegium Pharmaceutical, Inc. and Gino Santini.(1)
10.12+†	Restricted Stock Award Agreement, dated March 5, 2014, by and between Collegium Pharmaceutical, Inc. and Gino Santini.(1)
10.13†	Form of Confidentiality and Inventions Agreement.(1)

10.14+†	Offer Letter, dated January 29, 2015, by and between Collegium Pharmaceutical, Inc. and Garen Bohlin.(1)
10.15†	Series D Convertible Preferred Stock Purchase Agreement, dated March 6, 2015, by and among Collegium Pharmaceutical, Inc. and the purchasers thereto.(1)
10.16†	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)
10.17+†	2015 Employee Stock Purchase Plan.(3)
10.18+†	Performance Bonus Plan. (4)
10.19(a)+†	Amended and Restated 2014 Stock Incentive Plan. (3)
10.19(b)+†	Form of Incentive Stock Option Agreement under the Amended and Restated 2014 Stock Incentive Plan. (3)
10.19(c)+†	Form of Non-Qualified Stock Option Agreement under the Amended and Restated 2014 Stock Incentive Plan. (3)
10.19(d)+†	Form of Restricted Stock Award Agreement under the Amended and Restated 2014 Stock Incentive Plan. (3)
10.20+†	Restricted Stock Award Agreement, dated April 2, 2015, by and between Collegium Pharmaceutical, Inc. and Michael T. Heffernan. (4)
10.21†	Form of Indemnification Agreement. (4)
10.22+†	Employment Agreement, dated August 4, 2015, by and between Michael Heffernan and Collegium Pharmaceutical, Inc.(5)
10.23+†	Employment Agreement, dated August 4, 2015, by and between Paul Brannelly and Collegium Pharmaceutical, Inc.(5)
10.24+†	Employment Agreement, dated August 4, 2015, by and between Barry S. Duke and Collegium Pharmaceutical, Inc.(6)
10.25*†	License and Development Agreement, dated as of May 11, 2016, by and between Collegium Pharmaceutical, Inc. and BioDelivery Systems International, Inc.(7)
10.26+†	Employment Agreement, dated May 31, 2017, by and between Collegium Pharmaceutical, Inc. and Joseph Ciaffoni.(10)
10.27*	Commercialization Agreement, by and among, Depomed, Inc., Collegium Pharmaceutical, Inc. and Collegium NF, LLC, dated as of December 4, 2017.
10.28	Amendment dated January 9, 2018 to Commercialization Agreement by and among Depomed, Inc. and Collegium Pharmaceutical, Inc. and Collegium NF, LLC.
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, 2017, formatted in XBRL: (i) Consolidated Balance Sheets as of December 31, 2017, 2016, (ii) Consolidated Statements of Operations for the years ended December 31, 2017, 2016 and 2015, (iii) Consolidated Statements of Convertible Redeemable Preferred Stock and Shareholders' Equity (Deficit) for the Years Ended December 31, 2017, 2016 and 2015, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2017, 2016 and 2015, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text.

†Previously filed.

+Indicates management contract or compensatory plan.

* Subject to confidential treatment request.

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

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

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

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

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

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

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

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

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

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

Item 16. Form 10-K Summary

None.

COLLEGIUM PHARMACEUTICAL, INC.
Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Collegium Pharmaceutical, Inc. and subsidiaries (the "Company") as of December 31, 2017 and 2016, the related consolidated statements of operations, convertible redeemable preferred stock and shareholders' equity (deficit), and cash flows, for each of the two years in the period ended December 31, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 7, 2018

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
Collegium Pharmaceutical, Inc.

We have audited the consolidated balance sheet of Collegium Pharmaceutical, Inc. and its subsidiary (the "Company") as of December 31, 2015 (not presented herein), and the related statements of operations, convertible redeemable preferred stock and shareholders' equity (deficit), and cash flows for the year ended December 31, 2015. 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. We were not engaged to perform an audit of the Company's 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 provides 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 its subsidiary as of December 31, 2015, and the results of their operations and their cash flows for the year ended December 31, 2015 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,	
	2017	**2016**
Assets		
Current assets		
Cash and cash equivalents	$ 118,697	$ 153,225
Accounts receivable	9,969	2,129
Inventory	1,813	1,316
Prepaid expenses and other current assets	3,005	1,905
Total current assets	133,484	158,575
Property and equipment, net	1,826	1,038
Intangible assets, net	—	2,103
Restricted cash	97	97
Other long-term assets	161	204
Total assets	$ 135,568	$ 162,017
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 5,684	$ 9,106
Accrued expenses	8,541	8,879
Accrued rebates, returns and discounts	15,784	—
Deferred revenue	—	4,944
Current portion of term loan payable	1,479	2,667
Total current liabilities	31,488	25,596
Lease incentive obligation	—	34
Term loan payable, long-term	—	1,479
Total liabilities	31,488	27,109
Commitments and contingencies (see Note 9)		
Shareholders' equity:		
Preferred stock, $0.001 par value; authorized shares - 5,000,000 at December 31, 2017 and December 31, 2016; issued and outstanding shares - none at December 31, 2017 and December 31, 2016	—	—
Common stock, $0.001 par value; authorized shares - 100,000,000 at December 31, 2017 and December 31, 2016; issued and outstanding shares - 32,770,678 at December 31, 2017 and 29,364,100 at December 31, 2016	33	29
Additional paid-in capital	402,096	358,063
Accumulated deficit	(298,049)	(223,184)
Total shareholders' equity	104,080	134,908
Total liabilities and shareholders' equity	$ 135,568	$ 162,017

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,		
	2017	**2016**	**2015**
Product revenues, net	$ 28,476	$ 1,711	$ —
Costs and expenses			
Cost of product revenues	2,595	213	—
Research and development	8,572	14,948	7,975
Selling, general and administrative	92,756	80,632	18,932
Total costs and expenses	103,923	95,793	26,907
Loss from operations	(75,447)	(94,082)	(26,907)
Other income (expense)			
Interest income (expense), net	582	(94)	(439)
Gain on extinguishment of debt	—	—	91
Total other income (expense), net	582	(94)	(348)
Net loss	$ (74,865)	$ (94,176)	$ (27,255)
Loss per share - basic and diluted	$ (2.47)	$ (3.88)	$ (1.48)
Weighted-average shares - basic and diluted	30,265,262	24,262,945	13,542,282

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, 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
Exercise of common stock options	—	—	—	—	—	—	—	—	158,801	1	735	—	—	736
Issuance for employee stock purchase plan	—	—	—	—	—	—	—	—	110,841	—	1,141	—	—	1,141
Vesting of restricted stock units	—	—	—	—	—	—	—	—	14,757	—	—	—	—	—
Shares withheld for employee taxes upon vesting of restricted stock units	—	—	—	—	—	—	—	—	(4,819)	—	(68)	—	—	(68)
Public offerings of common stock, net of issuance costs of $1,253	—	—	—	—	—	—	—	—	3,126,998	3	34,280	—	—	34,283
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	7,945	—	—	7,945
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(74,865)	(74,865)
Balance at December 31, 2017	—	$ —	—	$ —	—	$ —	—	$ —	32,770,678	$ 33	$ 402,096	$ —	$ (298,049)	$ 104,080

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,		
	2017	2016	2015
Operating activities			
Net loss	$ (74,865)	$ (94,176)	$ (27,255)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	594	655	171
Non-cash impairment charges	1,845	—	—
Lease incentive obligation	(34)	(34)	(34)
Stock-based compensation expense	7,945	5,787	2,209
Non-cash interest expense	—	—	6
Changes in operating assets and liabilities:			
Accounts receivable	(7,840)	(2,129)	—
Inventories	(497)	(1,316)	—
Prepaid expenses and other assets	(1,057)	(923)	(659)
Refundable PDUFA fee	—	—	2,335
Accounts payable	(3,422)	5,569	1,298
Accrued expenses	(527)	6,570	362
Accrued rebates, returns and discounts	15,784	—	—
Deferred revenue	(4,944)	4,944	—
Net cash used in operating activities	(67,018)	(75,053)	(21,567)
Investing activities			
Purchase of intangible assets	—	(2,500)	—
Purchases of property and equipment	(990)	(477)	(362)
Net cash used in investing activities	(990)	(2,977)	(362)
Financing activities			
Proceeds from issuances of common stock from public offerings, net of issuance costs of $1,198, $845 and $2,408, respectively	34,338	137,340	72,029
Proceeds from issuances of common stock from employee stock purchase plans	1,141	442	—
Proceeds from issuance of Series D convertible redeemable preferred stock, net of issuance costs of $193	—	—	44,807
Repayment of term note	(2,667)	(2,667)	(1,286)
Repayment of lease note payable	—	—	(59)
Restricted cash	—	—	(16)
Proceeds from the exercise of stock options	736	443	517
Payments made for employee restricted stock tax withholdings	(68)	—	—
Net cash provided by financing activities	33,480	135,558	115,992
Net (decrease) increase in cash and cash equivalents	(34,528)	57,528	94,063
Cash and cash equivalents at beginning of period	153,225	95,697	1,634
Cash and cash equivalents at end of period	$ 118,697	$ 153,225	$ 95,697
Supplemental disclosure of cash flow information			
Cash paid for offering costs	$ 1,228	$ —	$ —
Cash paid for interest	$ 139	$ 284	$ 353
Supplemental disclosure of non-cash activities			
Offering costs in accrued expenses	$ 55	$ —	$ —
Acquisition of property and equipment in accrued expenses	$ 216	$ 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
Conversion of bridge note to preferred stock	$ —	$ —	$ 5,000

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 a specialty pharmaceutical company focused on becoming the leader in responsible pain management by developing and commercializing innovative, differentiated products for patients suffering from pain. 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.

Controlled Equity Offering Sales Agreement

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

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

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

As of December 31, 2017, the Company had sold an aggregate of 3,126,998 ATM Shares under the ATM Sales Agreement at an average gross sales price of $11.36 per share generating net proceeds of $34,283 after deduction of underwriting discounts and commissions and expenses payable by the Company, all of which were sold during the year ended December 31, 2017.

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, and Collegium NF LLC (a Delaware limited liability company), incorporated in December 2017, both wholly owned subsidiaries requiring consolidation. The consolidated financial statements are prepared in conformity with 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, 2017, had an accumulated deficit of $298,049. The Company expects to continue to incur net losses in the near future. A successful transition to profitable operations is dependent upon achieving a level of revenues adequate to support the Company's cost structure.

The Company believes that its cash and cash equivalents at December 31, 2017, together with expected cash inflows from sales of its products will enable the Company to fund its operating expenses, debt service, contractual obligations and capital expenditure requirements into 2020. 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 product returns, units prescribed, discounts and allowances related to commercial sales of Xtampza, estimates utilized in the valuation of inventory, accounting for stock-based compensation, contingencies and tax valuation reserves. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. The Company's actual results may differ from these estimates under different assumptions or conditions.

Fair Value Measurements

Disclosures of fair value information about financial instruments are required, whether or not recognized in the balance sheet, for financial instruments with respect to which it is practicable to estimate that value. 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 inputs: Quoted prices (unadjusted) in active markets for identical assets or liabilities
Level 2 inputs: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly
Level 3 inputs: Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability

Transfers are calculated on values as of the transfer date. There were no transfers between Levels 1, 2 and 3 during the years ended December 31, 2017 and 2016.

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, 2017 and 2016.

Description	Total	Quoted Prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2017				
Money market funds, included in cash equivalents	$ 81,225	$ 81,225	$ —	$ —
December 31, 2016				
Money market funds, included in cash equivalents	$ 125,515	$ 125,515	$ —	$ —

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to significant concentration of credit risk, consist primarily of cash and cash equivalents and accounts receivable. The Company maintains its cash deposits primarily with one financial institution and in federally insured financial institutions in excess of federally insured limits. In addition, as of December 31, 2017, the Company's cash equivalents were invested in one money market fund. Three customers comprised 10% or more of the Company's accounts receivable balance as of December 31, 2017. These customers

comprised 49%, 24% and 20% of the accounts receivable balance, respectively. Three customers comprised 10% or more of the Company's revenue during the year ended December 31, 2017. These customers comprised 39%, 29% and 23% of revenue, respectively. The Company has not experienced any material losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the financial institutions in which those deposits are held. 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, 2017 and 2016, the carrying amount of cash equivalents was $81,225 and $125,515, 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 and the expected shelf-life of the inventory components. As of December 31, 2017, cumulative estimates of excess inventory recorded as a component of cost of product revenues were immaterial. 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 $1,813 of inventory as of December 31, 2017. The Company expects sales of the capitalized units to occur during the next twelve months.

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.

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, which generally occurs upon delivery; 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 sales are recorded net of estimated chargebacks, rebates, sales incentives and allowances, distribution service fees, as well as estimated product returns.

Beginning in the third quarter of 2017, the Company determined that it had sufficient experience with sales of Xtampza to estimate its returns at time of shipment. The Company sells its products primarily to distributors ("customers"), which in turn sell the product to pharmacies for the treatment of patients. The Company provides the right of return to its customers for a limited time before and after its expiration date. As a result of its experience to date with Xtampza sales, the Company determined that it can reasonably estimate the amount of future product returns. This determination has enabled the Company to recognize revenue earlier on the sell-in method, net of a provision for estimated returns, because the Company can record revenue once sold to the customer rather than waiting until the product is sold to the end user on a sell-through method. The Company recorded a one-time $4,377 increase to revenues during the three months ended September 30, 2017 as a result of the Company's change to the sell-in method in the third quarter of 2017.

The following table summarizes activity in each of the Company's product revenue provision and allowance categories for the year ended December 31, 2017:

	Rebates and Incentives (1)	Product Returns (2)	Trade Allowances and Chargebacks (3)
Balance at December 31, 2016	$ -	$ -	$ -
Provision related to current period sales	23,505	3,523	6,476
Adjustment related to prior period sales	179	-	(140)
Credits/payments made	(11,037)	(386)	(4,080)
Balance at December 31, 2017	$ 12,647	$ 3,137	$ 2,256

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

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

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

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, costs to acquire, develop and manufacture preclinical study and clinical trial materials, facilities, depreciation and other expenses including allocated expenses for rent and maintenance of facilities.

Patent Costs

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

Advertising and Product Promotion Costs

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

Stock-Based Compensation

The Company accounts for grants of stock options, restricted stock awards and restricted stock units to employees, including members of the board of directors, based on their grant date fair value and recognizes compensation expense over their vesting period. The Company estimates the fair value of stock options as of the date of grant using the Black-Scholes option pricing model and restricted stock awards and restricted stock units based on the fair value of the underlying common stock as determined by management 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.

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, 2017 and 2016, 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, 2017, 2016 and 2015, 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 August 2015, FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers* (Topic 606): Deferral of the Effective Date ("ASU 2015-14"). ASU 2015-14 defers by one year the effective date of ASU No. 2014-09, Revenue from Contracts with Customers ("ASU 2014-09"). The deferral results in ASU 2014-09 being effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. The main provision of ASU 2014-09 is to recognize revenue when control of the goods or services transfers to the customer, as opposed to the existing guidance of recognizing revenue when the risks and rewards transfer to the customer. Companies may use either a full retrospective or a modified retrospective approach to adopt ASU 2014-09. The Company adopted ASU 2014-09 effective January 1, 2018, using the modified retrospective approach. Prior periods were not retrospectively adjusted. The implementation of this guidance did not have a material impact on its consolidated financial statements for the reasons discussed in detail below.

Currently, the Company's only source of revenue is derived through the sales of Xtampza. The Company sells its products primarily to customers, which in turn sell the product to pharmacies for the treatment of patients. Under current GAAP, revenue for product sales is recognized when there is persuasive evidence of an arrangement, title and risk of loss have passed to the customer, which generally occurs upon delivery, and 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 sales are recorded net of estimated chargebacks, rebates, sales incentives and allowances, distribution service fees, as well as estimated product returns. Beginning in the third quarter of 2017, the Company determined that it had sufficient experience with sales of Xtampza to estimate its returns at time of shipment,

resulting in the Company recognizing revenue once sold to customers.

Under Topic 606, revenue is recognized when, or as, obligations under the terms of a contract are satisfied, which occurs when control of the promised products or services is transferred to customers. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer ("transaction price"). Incidental items that are immaterial in the context of the contract are recognized as expense. To the extent that the transaction price includes variable consideration, the Company is required to estimate the amount of variable consideration that should be included in the transaction price utilizing the expected value method or most likely amount method to which the Company expects to be entitled. Variable consideration is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration and the determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company's anticipated performance and all information (historical, current and forecasted) that is reasonably available. Sales taxes and other taxes collected on behalf of third parties are excluded from revenue. All of the Company's performance obligations, and associated revenue, are generally transferred to customers at a point in time. Revenue will be recognized at the time the related performance obligation is satisfied by transferring control of a promised good or service to a customer.

As a result of the considerations discussed above, the Company concluded that it had sufficient information to conclude that the transaction price was fixed or determinable under current GAAP and would record revenue once sold to customers under either Topic 605 or Topic 606. The Company determined that the cumulative effect adjustment will have an immaterial impact to the Company's opening balance of retained earnings. The Company's adoption of ASU 2014-09 did not have a material impact on the Company's consolidated financial position, results of operations, equity or cash flows as of the adoption date or for periods beginning January 1, 2018.

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.

In August 2016, the FASB issued ASU 2016-15, *Classification of Certain Cash Receipts and Cash Payments*, and in November 2016, the FASB issued ASU 2016-18, *Restricted Cash*. The amendments in these updates are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company will adopt these standards in the first quarter of 2018 using the retrospective transition method as required with respect to each period presented. The Company does not expect the adoption of these standards to have a material impact on its consolidated financial statements for the years ended December 31, 2017 or December 31, 2016.

3. NET LOSS PER COMMON SHARE

For the years ended December 31, 2017, 2016 and 2015, the securities discussed below were anti-dilutive due to the net losses in those periods and, therefore, the number of shares used to compute basic and diluted earnings per share are the same for of those periods.

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

	Years ended December 31,		
	2017	2016	2015
Net loss	$ (74,865)	$ (94,176)	$ (27,255)
Extinguishment of preferred stock - see Note 11	—	—	31,806
Accretion and dividends of prior preferred stock - See Note 11	—	—	(23,327)
Accretion and dividends of Series D preferred stock	—	—	(1,245)
Loss attributable to common shareholders — basic and diluted	$ (74,865)	$ (94,176)	$ (20,021)
Weighted-average number of common shares used in net loss per share - basic and diluted	30,265,262	24,262,945	13,542,282
Loss per share - basic and diluted	$ (2.47)	$ (3.88)	$ (1.48)

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,		
	2017	2016	2015
Outstanding stock options	3,037,690	2,326,801	1,452,149
Warrants	2,445	2,445	2,445
Unvested restricted stock[1]	31,943	82,512	75,718
Restricted stock units	218,872	41,741	—

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

4. INVENTORY

Inventory consisted of the following:

	As of December 31, 2017	As of December 31, 2016
Raw materials	$ 616	$ 294
Work in process	322	67
Finished goods	875	955
Total inventory	$ 1,813	$ 1,316

As of December 31, 2017, the aggregate charges to date related to excess inventory were immaterial. 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,	
	2017	2016
Prepaid regulatory fees	$ 1,434	$ 512
Prepaid development costs	526	485
Prepaid insurance	310	328
Other prepaid expenses	279	276
Other current assets	456	304
Prepaid expenses and other current assets	$ 3,005	$ 1,905

6. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	As of December 31,	
	2017	2016
Machinery and equipment	$ 1,447	$ 863
Computers and office equipment	702	590
Leasehold improvements	700	700
Construction-in-process	528	100
Furniture and fixtures	117	117
Total property and equipment	3,494	2,370
Less: accumulated deprecation	(1,668)	(1,332)
Property and equipment, net	$ 1,826	$ 1,038

Depreciation expense related to property and equipment amounted to $336, $258 and $171 for the years ended December 31, 2017, 2016 and 2015, 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. 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, 2017, 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.

During the year ended December 31, 2016, the Company made an upfront payment of $2,500 and was 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. On December 8, 2017, the Company, after a review of its product portfolio, provided written notice to BDSI of termination of the License and Development Agreement. The termination will be effective pursuant to the terms of such agreement on March 8, 2018. Upon such termination of the License Agreement, the Company’s rights to develop and commercialize Onsolis will revert to BDSI. As a result of this notice of termination, the Company determined that the carrying amount of the intangible asset was not recoverable and that the carrying amount exceeded its fair value. As such, an impairment loss of $1,845 was recognized and included as a component of sales, general and

administrative expense during the year ended December 31, 2017 and the net intangible asset is zero as of December 31, 2017.

8. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of December 31, 2017	As of December 31, 2016
Accrued bonuses	$ 2,940	$ 2,210
Accrued incentive compensation	1,790	1,160
Accrued payroll and related benefits	1,382	1,217
Accrued sales and marketing	624	801
Accrued development costs	517	2,485
Accrued audit and legal	405	416
Accrued interest	6	18
Accrued other operating costs	877	572
Total accrued expenses	$ 8,541	$ 8,879

9. COMMITMENTS AND CONTINGENCIES

Legal Proceedings

Xtampza Litigation

The Company filed the NDA for Xtampza as a 505(b)(2) application, which allows the Company to reference data from an approved drug listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book), in this case OxyContin OP. The 505(b)(2) process requires that the Company certifies to the FDA and notify Purdue, as the holder of the NDA and any other Orange Book-listed patent owners, that the Company does not infringe any of the patents listed for OxyContin OP in the Orange Book, or that the patents are invalid. The Company made such certification and provided such notice on February 11, 2015 and such certification documented why Xtampza 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 the Company for infringement in the District of Delaware on March 24, 2015 asserting infringement of three of Purdue's Orange Book-listed patents (Patent Nos. 7,674,799, 7,674,800, and 7,683,072) and a non-Orange Book-listed patent (Patent No. 8,652,497), and accordingly, received a 30-month stay of FDA approval.

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

In November 2015, Purdue filed a follow-on suit asserting infringement of another patent, Patent No. 9,073,933, 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. In April 2017, Purdue filed another follow-on suit asserting infringement of another patent, Patent No. 9,522,919, which was late-

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

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

The current suits have been consolidated by the District of Massachusetts, where Purdue continues to assert infringement of five patents: the '497 patent, the '933 patent, the '717 patent, the '919 patent, and the '961 patent. None of these suits are associated with any stay of FDA approval for the Xtampza drug product. 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; the Company is also seeking a judgment that the case is exceptional, with an award to the Company of its fees for defending the case.

The parties are in the early stages of fact discovery. Written discovery has commenced with depositions expected to commence during the second half of 2018. A claim construction and summary judgment hearing was held on June 1, 2017. On November 21, 2017, the Court issued its claim construction ruling, construing certain claims of the '933, '497, and '717 patents. At this time, the Motion for Summary Judgment, which asserted that claims of the '933, '497, and '717 patents are invalid and not infringed, remains pending. The Company is not able to predict with certainty when the Court will decide the Company's motion. The Scheduling Order has been amended to stay the close of fact discovery until after the Court decides our Motion for Summary Judgment. No trial date has been scheduled.

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

Nucynta Litigation

On February 7, 2018, Purdue filed a patent infringement suit against Collegium NF, LLC and Collegium Pharmaceutical, Inc. in the District of Delaware. Specifically, Purdue argues that the Company's sale of immediate release and extended release Nucynta infringes U.S. Patent Nos. 9,861,583, 9,867,784, and 9,872,836. Purdue has made a demand for monetary relief in the Complaint but has not quantified its alleged damages. The Company's response to the Complaint is currently due April 9, 2018.

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

Teva Litigation

The Company filed the NDA for Xtampza as a 505(b)(2) application, which allows the Company to reference data from an approved drug listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book), in this case OxyContin OP. The Company has twelve patents listed in the FDA *Orange Book* as covering the Company's abuse-deterrent product and methods of using it to treat patients: Patents Nos. 7,399,488; 7,771,707; 8,449,909; 8,557,291; 8,758,813; 8,840,928; 9,044,398; 9,248,195; 9,592,200; 9,682,075; 9,737,530 and 9,763,883.

Teva Pharmaceuticals USA filed a Notice Letter of Patent Certification against all twelve listed patents, alleging that they were invalid and/or not infringed by the proposed oxycodone product that is the subject of Teva's ANDA. On February 22, 2018—within the 45-day period that gives the Company a 30-month stay on FDA approval of Teva's ANDA while the parties have an opportunity to litigate—the Company sued Teva in the District of Delaware on eleven of the patents listed in the *Orange Book*. The case was assigned to the Hon. Judge Stark.

The Company plans to assert and defend its intellectual property vigorously in this case. At this stage, the Company is unable to evaluate the likelihood of an unfavorable outcome or estimate the amount or range of potential loss, if any.

Operating Leases

The Company leases its office and research facility in Canton, Massachusetts under a non-cancellable operating lease (the "Canton Facility 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, 2017 are as follows:

2018	$	234
2019		241
2020		164
Total minimum lease payments	$	639

Rent expense under the operating lease agreement amounted to approximately $194, $182 and $112 for the years ended December 31, 2017, 2016 and 2015, respectively. In addition, the Company maintained a stand-by letter of credit in connection with the Canton Facility Lease of $97 at December 31, 2017 and December 31, 2016. This amount is classified as restricted cash in the Consolidated 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 Consolidated Balance Sheets as leasehold improvements, with the corresponding liabilities as deferred lease incentive and lease note payable. These liabilities are amortized on a straight-line basis over the term of the lease.

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.

In June 2015, SVB exercised all of its warrants.

As of December 31, 2017, future payments under the Company's term loan are $1,479 and are due in the year ended December 31, 2018.

11. EQUITY

Common Stock

As of December 31, 2017 and 2016, 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:

	As of December 31,	
	2017	2016
Options to purchase common stock	4,153,055	3,348,310
Employee stock purchase plan	547,276	364,476
Warrants	2,445	2,445
Total	4,702,776	3,715,231

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 May 2018.

As of December 31, 2017 and 2016, the 2,445 warrants issued to Comerica Bank were the Company's only outstanding warrants.

Series A, B, C and Series D 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.

12. 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, 2017, 1,134,495 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, 2016	2,326,801	$ 13.07	8.7	$ 7,927
Granted	1,380,123	12.30		
Exercised	(158,801)	4.63		
Cancelled	(510,433)	14.04		
Outstanding at December 31, 2017	3,037,690	$ 13.00	8.4	$ 16,829
Exercisable at December 31, 2017	1,025,252	$ 12.86	7.6	$ 5,871
Vested and expected to vest at December 31, 2017	2,920,652	$ 13.00	8.3	$ 16,183

The total intrinsic value of stock options exercised for the year ended December 31, 2017 was $1,100. As of December 31, 2017, the unrecognized compensation cost related to outstanding options was $14,829, and is expected to be recognized as expense over approximately 2.5 years.

As of December 31, 2017, the weighted-average grant date fair value of vested options was $8.69. The weighted-average grant date fair value of options granted during the year ended December 31, 2017 was $7.86. The weighted-average grant date fair value of options that vested during the year ended December 31, 2017 was $9.62.

Restricted stock awards under the Plan are summarized as follows:

	Shares	Weighted-Average Purchase Price per Share
Unvested at December 31, 2016	43,265	$ 5.73
Granted	—	—
Vested	(32,449)	5.73
Unvested at December 31, 2017 (1)	10,816	$ 5.73

(1) Excludes 21,127 shares of unvested restricted stock remaining from the early exercise of stock options as of December 31, 2017.

The total fair value of restricted stock awards vested during the years ended December 31, 2017, was $186. As of December 31, 2017, the unrecognized compensation cost related to restricted stock awards was $47, and is expected to be recognized as expense over approximately 0.2 years.

Restricted stock units under the Plan are summarized as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2016	41,741	$ 16.15
Granted	211,018	12.45
Settled	(14,757)	16.15
Forfeited	(19,130)	15.52
Outstanding at December 31, 2017	218,872	$ 12.64

As of December 31, 2017, the unrecognized compensation cost related to restricted stock units was $2,218, and is expected to be recognized as expense over approximately 3.1 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 years ended December 31, 2017 and 2016 was $380 and $457, respectively.

Stock-Based Compensation Expense

The Company granted stock options to employees for the years ended December 31, 2017, 2016 and 2015. 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:

	Year Ended December 31,		
	2017	2016	2015
Research and development expenses	$ 888	$ 638	$ 223
Selling, general and administrative expenses	7,057	5,149	1,986
Total stock-based compensation expense	$ 7,945	$ 5,787	$ 2,209

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

	Year ended December 31,		
	2017	2016	2015
Risk-free interest rate	2.0 %	1.5 %	1.7 %
Volatility	71.0 %	76.3 %	77.0 %
Expected term (years)	6.01	6.02	6.20
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, 2017 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.

13. INCOME TAXES

For the years ended December 31, 2017, 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 losses from domestic operations.

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

	As of December 31,		
	2017	2016	2015
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	3.93	3.43	5.29
Permanent differences	(2.49)	(1.45)	(1.70)
U.S. - TCJA	(43.32)	—	—
Research and development credit	0.53	0.27	0.89
Change in valuation allowance	7.35	(36.25)	(38.48)
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,		
	2017	2016	2015
Deferred tax assets:			
U.S. and state net operating loss carryforwards	$ 62,715	$ 71,049	$ 38,405
Research and development credits	3,892	3,712	3,421
Accruals and other	3,615	1,541	144
Depreciation and amortization	145	261	94
Total deferred tax assets	70,367	76,563	42,064
Valuation allowance	(70,367)	(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, 2017 and 2016, 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, 2017 and 2016. The valuation allowance decreased $6,196 primarily due to the enacted change in the corporate income tax rate from the enactment of TCJA signed into law in December 2017. The valuation allowance increased $34,499 during the years ended December 31, 2016 due primarily to net operating losses generated.

As of December 31, 2017, 2016, and 2015, the Company had U.S. federal net operating loss carryforwards of $249,511, $190,926, and $104,888, respectively, which may be available to offset future income tax liabilities. TCJA will generally allow losses incurred after 2017 to be carried over indefinitely, but will generally limit the NOL deduction to the lesser of the NOL carryover or 80% of a corporation’s taxable income (subject to Code Section 382/383). Also there will be no carryback for losses incurred after 2017. Losses incurred prior to 2018 will generally be deductible to the extent of the lesser of a corporation’s NOL carryover or 100% of a corporation’s taxable income, and be available for twenty years from the period the loss was generated. The Company has not finalized its review of the impact of TCJA on the NOL rules, and the impact, if any, to the Company’s ability to utilize and carryover net operating losses.

As of December 31, 2017, 2016, and 2015, the Company also had U.S. state net operating loss carryforwards of $205,074, $145,902, and $59,875 respectively, which may be available to offset future income tax liabilities and expire at various dates through 2037.

As of December 31, 2017, 2016 and 2015, the Company had federal research and development tax credit carryforwards of approximately $3,426, $3,367, and $3,110, respectively, available to reduce future tax liabilities which expire at various dates through 2037. As of December 31, 2017, 2016 and 2015 the Company had state research and development tax credit carryforwards of approximately $589, $522, and $469, respectively, available to reduce future tax liabilities which expire at various dates through 2032.

The TCJA was enacted in December 2017. Among other things, the TCJA reduces the U.S. federal corporate tax rate from 35 percent to 21 percent beginning in 2018. The SEC staff issued Staff Accounting Bulletin (SAB) 118, which provides guidance on accounting for enactment effects of the TCJA. SAB 118 provides a measurement period of up to one year from the TCJA’s enactment date for companies to complete their accounting under ASC 740. In accordance with SAB 118, to the extent that a company’s accounting for certain income tax effects of the TCJA is incomplete but it is able to determine a reasonable estimate, it must record a provisional estimate in its financial statements. If a company cannot determine a provisional estimate to be included in its financial statements, it should continue to apply ASC 740 on the basis of the provisions of the tax laws that were in effect immediately before the enactment of the TCJA.

In connection with the Company’s initial analysis of the impact of the enactment of the TCJA, the Company recorded no tax expense. For various reasons that are discussed more fully below, including the issuance of additional technical and interpretive guidance, the Company has not completed its accounting for the income tax effects of certain elements of the TCJA. However, with respect to the following, the Company was able to make reasonable estimates of the TCJA’s effects:

Remeasurement of deferred tax assets/liabilities and other impacts: The Company remeasured its deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21 percent under the TCJA. The impact of the remeasurement of the Company’s deferred tax assets and liabilities is included in the rate reconciliation above.

Code Section 162(m) Limitations: Employers can generally deduct reasonable compensation for personal services as an ordinary and necessary business deduction. Internal Revenue Code Section 162(m) limits the ability to deduct compensation expenses of certain “covered” employees of a publicly held corporation. TCJA has modified these rules by expanding the definition of “covered” employee and repealed the performance-based compensation and commissions exceptions of Section 162(m). The Company is still analyzing this issue to determine what impact, if any, this change

may have on the Company's ability to deduct performance-based compensation to its employees, and at this time cannot determine a provisional estimate to be included in its financial statements in accordance with SAB 118.

The Company is still analyzing certain aspects of the TCJA, considering additional technical guidance, and refining its calculations, which could potentially affect the measurement of these balances or potentially give rise to new deferred tax amounts.

Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50 percent, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed numerous financings as well as its IPO since its inception 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.

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, 2014 through December 31, 2017. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities to the extent utilized in a future period. The Company's 2015 return is currently under examination with the IRS, and as a result the IRS is challenging certain positions on its return that may result in a decrease to the Company's NOL carryover. The Company is protesting the matter with the IRS, but has reduced the NOL deferred tax asset for the amount of contested deductions. This is included in the tabular rollforward below of gross unrecognized tax benefits. Since a full valuation allowance has been provided against the Company's net operating loss carryover, the reduction in the gross deferred tax asset established for net operating losses does not result in any financial statement impact.

For all years through December 31, 2017, the Company generated research credits but has not conducted a study to document the qualified activities. This study may result in an adjustment to the Company's research and development credit carryforwards. The Company has reduced its deferred tax asset for its estimate of credits that could be reduced, and that is included in the tabular rollforward of uncertain tax positions. Since a full valuation allowance has been provided against the Company's research and development credits the reduction in the gross deferred tax asset established for the research and development credit carryforwards does not result in any financial statement impact.

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

Federal, State and Foreign Tax

	As of December 31,	
	2017	2016
Gross UTB Balance at January 1	$ —	$ —
Additions based on tax positions related to the current year	57	—
Additions for tax positions of prior years	1,307	—
Reductions for tax positions of prior years	—	—
Settlements	—	—
Reductions due to lapse of applicable statute of limitations	—	—
Gross UTB Balance at December 31	1,364	—
Net UTB impacting the effective tax rate at December 31 (included in the change in the valuation allowance in rate reconciliation)	$ 680	$ —

14. EMPLOYEE BENEFITS

The Company has a retirement savings plan, which is qualified under section 401(k) of the Code, for its employees. The plan allows eligible employees to defer, at the employee's discretion, pretax compensation up to the Internal Revenue Service annual limits. Employees become eligible to participate starting on the first day of the first full month of employment. The Company is not required to contribute to this plan. Total expense for contributions made by the Company for the years ended December 31, 2017, 2016 and 2015 was $969, $613 and $44 respectively.

15. UNAUDITED QUARTERLY OPERATING RESULTS

The following is a summary of unaudited quarterly results of operations for the years ended December 31, 2017 and 2016:

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

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)
Interest (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
Net loss	$ (0.68)	$ (1.05)	$ (1.13)	$ (1.02)

(1) - In the third quarter of 2017, the Company recorded a one-time $4,377 increase to revenues as a result of the Company's change to the sell-in method in the third quarter of 2017.

16. SUBSEQUENT EVENTS

Consummation of Commercialization Agreement

In December 2017, the Company and its wholly owned subsidiary, Collegium NF, LLC ("Collegium NF"), entered into a Commercialization Agreement with Depomed, Inc. ("Depomed"), pursuant to which Depomed agreed to grant a sublicense of certain of its intellectual property related to Nucynta ER and IR products (the "Nucynta Products") to Collegium NF for commercialization of the Nucynta Products in the United States, the District of Columbia and Puerto Rico. On January 9, 2018 (the "Closing Date"), the parties amended the Commercialization Agreement (as amended, the

"Commercialization Agreement") and consummated the transactions contemplated thereby.

Pursuant to the Commercialization Agreement, the Company paid a one-time non-refundable license fee (the "License Fee") of $10,000 to Depomed at the closing of the Commercialization Transaction, plus $6,200 for transferred inventory. During the term of the Commercialization Agreement and through December 2021, the Company will be required to pay (i) a minimum royalty of $135,000 per year, payable in quarterly payments of $33,750, plus (ii) 25% of annual net sales of the Nucynta Products between $233,000 and $258,000, plus (iii) 17.5% of annual net sales of the Nucynta Products above $258,000. After the first anniversary of the Closing Date, the Company may terminate the Commercialization Agreement for any reason upon one (1) year prior written notice to Depomed, provided that, if the effective date of termination designated in such notice is prior to the fourth anniversary of the Closing Date, then such termination will be contingent upon the payment by the Company to Depomed of a termination fee in the amount of $25,000.

Beginning January 2022 and for each year of the Commercialization Agreement term thereafter, the Company will continue to pay royalties on annual net sales of the Nucynta Products, but without a guaranteed minimum. The Company will pay to Depomed: (i) 58% of annual net sales of the Nucynta Products up to $233,000, payable quarterly within 45 days of the end of each calendar quarter, plus (ii) 25% of annual net sales of the Nucynta Products between $233,000 and $258,000, plus (iii) 17.5% of annual net sales of the Nucynta Products above $258,000. If Depomed or its contract manufacturers are unable to deliver a certain percentage of ordered quantities for a period of two months or longer in calendar year 2018, then Depomed may be required to make a payment (or offset the minimum royalties) to ensure that the Company receives a minimum level of gross profit of $40,000 for 2018 for the Nucynta Products.

Consent and Sixth Amendment to Loan and Security Agreement

In connection with, and as a condition to, consummation of the transactions contemplated by the Commercialization Agreement, the Company entered into a Consent and Sixth Amendment to Loan and Security Agreement (the "Consent and Amendment") with SVB to amend the Original Term Loan. The Consent and Amendment provided the Company with a new term loan facility in an original principal amount of $11,500 (the "New Term Loan"), which replaces the Company's existing term loan facility (the "Existing Term Loan") and the proceeds of which were used by the Company to finance certain payment obligations under the Commercialization Agreement and to repay the balance of the Existing Term Loan. The Consent and Amendment also provided SVB's consent with respect to transactions contemplated by the Commercialization Agreement, including the delivery by SVB of a standby letter of credit in an aggregate amount of $33,750.

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

Under the Consent and Amendment, the Company will be required to maintain a liquidity ratio of at least 2.0 to 1.0. Any amounts outstanding during the continuance of any event of default under the Consent and Amendment will bear additional interest at the per annum rate of 5.0%.

INDEX TO EXHIBITS

Exhibit Number	Exhibit Description
10.27*	Commercialization Agreement, by and among, Depomed, Inc., Collegium Pharmaceutical, Inc. and Collegium NF, LLC, dated as of December 4, 2017.
10.28	Amendment dated January 9, 2018 to Commercialization Agreement by and among Depomed, Inc. and Collegium Pharmaceutical, Inc. and Collegium NF, LLC.
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, 2017, formatted in XBRL: (i) Consolidated Balance Sheets as of December 31, 2017 and 2016, (ii) Consolidated Statements of Operations for the years ended December 31, 2017, 2016 and 2015, (iii) Consolidated Statements of Convertible Redeemable Preferred Stock and Shareholders' Equity (Deficit) for the Years Ended December 31, 2017, 2016 and 2015, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2017, 2016 and 2015, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text.

* Subject to confidential treatment request.

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 7, 2018
/s/ Paul Brannelly Paul Brannelly	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 7, 2018
/s/ Garen G. Bohlin Garen G. Bohlin	Director	March 7, 2018
/s/ John A. Fallon, M.D. John A. Fallon, M.D.	Director	March 7, 2018
/s/ John G. Freund, M.D. John G. Freund, M.D.	Director	March 7, 2018
/s/ David Hirsch, M.D., Ph.D. David Hirsch, M.D., Ph.D.	Director	March 7, 2018
/s/ Gwen Melincoff Gwen Melincoff	Director	March 7, 2018
/s/ Gino Santini Gino Santini	Director	March 7, 2018
/s/ Theodore R. Schroeder Theodore R. Schroeder	Director	March 7, 2018

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

Exhibit 10.27

Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions marked [***].

COMMERCIALIZATION AGREEMENT

by and among

DEPOMED, INC.,

COLLEGIUM PHARMACEUTICAL, INC.

and

COLLEGIUM NF, LLC

Dated as of December 4, 2017

Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions marked [***].

TABLE OF CONTENTS

Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions marked [***].

LIST OF EXHIBITS

Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions marked [***].

COMMERCIALIZATION AGREEMENT

This Commercialization Agreement (this "Agreement") is made as of December 4, 2017 (the "Effective Date"), by and among Depomed, Inc., a California corporation ("Depomed"), Collegium Pharmaceutical, Inc., a Virginia corporation ("Collegium"), and Collegium NF, LLC, a Delaware limited liability company and wholly owned subsidiary of Collegium ("Newco"). Each of Depomed, Collegium and Newco is referred to herein individually as a "party" and collectively as the "parties."

WHEREAS, the parties desire for Depomed to grant to Collegium certain rights to commercialize the Products and Line Extensions in the Territory (as such terms are defined below), upon the terms and subject to the conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing and of the mutual covenants herein contained, the parties, intending to be legally bound, hereby agree as follows:

ARTICLE 1
DEFINITIONS

As used in this Agreement, the following terms shall have the following meanings:

Section 1.1 "AbbVie" has the meaning set forth in Section 2.11(b).

Section 1.2 "Account Proceeds" has the meaning set forth in Section 7.7(b)(i).

Section 1.3 "Acuform Patent Action" has the meaning set forth in Section 11.2.

Section 1.4 "Adverse Drug Experience" means any "adverse drug experience," as defined or contemplated by 21 C.F.R. 314.80 or 312.32, associated with a Payment-Bearing Product.

Section 1.5 "Adverse Drug Experience Report" means any oral, written or electronic report of any Adverse Drug Experience transmitted to any Person.

Section 1.6 "Affiliate" means, with respect to any Person, any other Person that directly or indirectly controls, is controlled by or is under common control with such first Person, but only for so long as such control exists. For the purposes of this definition, "control" (including, with correlative meanings, the terms "controlling," "controlled by" and "under common control with"), as applied to any Person, means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of that Person, whether through the ownership of voting securities, by contract or otherwise.

Section 1.7 "Agreement" has the meaning set forth in the preamble to this Agreement.

Section 1.8 "Allocation" has the meaning set forth in Section 2.8.

Section 1.9 "Ancillary Agreements" has the meaning set forth in Section 14.3.

Section 1.10 "ANDA" means an Abbreviated New Drug Application.

Section 1.11 "ANDA Litigation" means the Legal Proceedings set forth on Schedule 1.11.

Section 1.12 "ANDA Settlement Distributor" means a Third Party, who, in connection with the settlement of the ANDA Litigation under the Hatch-Waxman Act and Medicare Prescription Drug, Improvement and Modernization Act of 2003, as amended, has been licensed or otherwise permitted by Depomed, as applicable (subject to Section 11.3), to sell a Generic Version of a Product in the Territory.

Section 1.13 "Annual Net Sales" means total Net Sales of the applicable Payment-Bearing Products in a particular calendar year.

Section 1.14 "API" means the composition of matter, tapentadol, used as an active pharmaceutical ingredient in Products and Line Extensions.

Section 1.15 "Assumed Liabilities" means the following Liabilities relating to the Products and the Transferred Assets, in each case other than the Retained Liabilities:

(a) all Liabilities arising solely out of or relating to Legal Proceedings commenced on or after the Closing, irrespective of the legal theory asserted, arising from the development, Commercialization, Manufacture or use of the Products or the use of the Transferred Assets, in each case, (i) other than by Depomed or its Affiliates pursuant to this Agreement and (ii) solely to the extent relating to the period of time on or after the Closing;

(b) all Liabilities arising out of or relating to products liability claims to the extent relating to the Products Manufactured and Commercialized on or after the Closing, including claims alleging defects in the Products and claims involving the death of or injury to any individual relating to the Products;

(c) all Liabilities to Third Party customers, Third Party suppliers or other Third Parties, solely to the extent relating to the Products or the Transferred Assets and ordered in the ordinary course of business (or at the express request of Collegium) on or after the Closing;

(d) all other Liabilities arising out of or relating to the Products or the Transferred Assets, to the extent relating to the period of time on or after the Closing, other than Liabilities arising out Depomed's activities pursuant to Section 3.2 or Section 4.9;

(e) all Taxes apportioned to Collegium pursuant to Section 2.9; and

(f) all Liabilities arising out of or relating to the return of the Products sold by Collegium on or after the Closing.

Section 1.16 "Authorized Generic" means a Generic Version sold by or on behalf of a party in the Territory without the NUCYNTA® trademark, including by an Authorized Generic Distributor, but excluding by any ANDA Settlement Distributor.

Section 1.17 "Authorized Generic Distributor" means a Third Party who has been contracted by Collegium to Commercialize a Generic Version on behalf of Collegium in the Territory, but excluding any ANDA Settlement Distributor.

Section 1.18 "Business" means the business of researching, developing, manufacturing or having made, packaging, importing, marketing, promoting, distributing, selling and commercializing the Products, in each of the foregoing cases, in the Territory, as conducted by the Depomed Entities.

Section 1.19 "Business Day" means any day other than a Saturday, a Sunday or a day on which banks in New York City, New York are authorized or obligated by law or executive order to close.

Section 1.20 "CDAPCA" means the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended.

Section 1.21 "Change of Control" means, with respect to a party, (a) a merger, reorganization or consolidation of such party with a Third Party which results in the voting securities of such party outstanding immediately prior thereto ceasing to represent at least fifty (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation, (b) a Third Party becoming the beneficial owner of fifty (50%) or more of the combined voting power of the outstanding securities of such party, or (c) the sale or other transfer to a Third Party of all or substantially all of such party's business or assets to which this Agreement relates.

Section 1.22 "Chargeback Claims" has the meaning set forth in Section 8.3(d)(i).

Section 1.23 "Claim" has the meaning set forth in Section 12.3.

Section 1.24 "Claim Amount" has the meaning set forth in Section 7.7(a)(ii).

Section 1.25 "Claim Notice" has the meaning set forth in Section 7.7(a)(ii).

Section 1.26 "Closing" means the consummation of the Transactions pursuant to the terms of this Agreement.

Section 1.27 "Closing Date" has the meaning set forth in Section 2.12(a).

Section 1.28 "CMO" has the meaning set forth in Section 3.2(a).

Section 1.29 "CMO Supply Agreements" means each agreement and all related material documents, including exhibits, attachments and amendments thereto, entered into by Depomed with a CMO prior to or during the Term pertaining to the Manufacture, production or supply of any Product Materials or Supplied Products. The CMO Supply Agreements in existence as of the Effective Date are listed in Schedule 1.29.

Section 1.30 "Code" means the Internal Revenue Code of 1986, as amended.

Section 1.31 "COGS" means, for a particular period, the applicable party's cost of goods sold (calculated in accordance with Section 7.4(b)) for the Products in the Territory for such period.

Section 1.32 "Collateral Agreement" has the meaning set forth in Section 14.3.

Section 1.33 "Collateral Agreements" means the Pledge Agreement, Collateral Agreement, any Control Agreement and any other document delivered by Collegium or Newco that creates or purports to create a Lien securing the obligations of Collegium and Newco under this Agreement.

Section 1.34 "Collegium" has the meaning set forth in the Preamble to this Agreement.

Section 1.35 "Collegium Indemnitees" has the meaning set forth in Section 12.1(a).

Section 1.36 "Collegium Material Adverse Event" has the meaning set forth in Section 10.2(a).

Section 1.37 "Collegium Prepaid Business Expense Allocation" has the meaning set forth in Section 7.5.

Section 1.38 "Collegium Products" has the meaning set forth in Section 10.2(i)(i).

Section 1.39 "Collegium Regulatory Inspection" has the meaning set forth in Section 5.10(a).

Section 1.40 "Collegium Sales Force" means the field force of Sales Representatives employed or engaged by Collegium, including field-based sales force management such as regional and district sales managers.

Section 1.41 "Collegium Sublicense" has the meaning set forth in Section 2.2(c).

Section 1.42 "Collegium Trademarks" means the trademarks set forth on Schedule 1.42, including the "Collegium" trademark and associated design and logo.

Section 1.43 "Commercial Agreement" has the meaning set forth in Section 8.3(h).

Section 1.44 "Commercial Rebates" has the meaning set forth in Section 8.3(b).

Section 1.45 "Commercialization Transaction" has the meaning set forth in Section 14.5.

Section 1.46 "Commercialize," "Commercialization" or "Commercializing" means to Promote, distribute and sell Payment-Bearing Products in the Territory, including all activities incident thereto and contemplated by the terms of this Agreement.

Section 1.47 "Commercially Reasonable Efforts" means, with respect to Commercialization of the Products by Collegium, those efforts and resources customarily used in the pharmaceutical business by a global pharmaceutical company for a product owned by such company or to which such company has rights, which product is of a market potential similar to the market potential of the applicable Product and at a similar stage of its product life as such Product, taking into account all relevant factors, including, without limitation, the risks inherent in the Commercialization of such Product, the competitiveness of the marketplace, the proprietary position of such Product in comparison to other products in a party's product portfolio, the regulatory status of such Product (including pricing and reimbursement status), the actual and potential profitability of such Product, and the general economic conditions of the marketplace, as well as other relevant factors.

Section 1.48 "Competing Product" means any product (other than a Product or Line Extension) in any dosage form, formulation, presentation or package configuration which contains a compound which is a centrally acting opioid analgesic of the benzenoid class with a dual mode of action as an agonist of the μ-opioid receptor and as a norepinephrine reuptake inhibitor, excluding any such product undergoing development or Commercialization by any Person acquiring Depomed or Collegium in a Change of Control prior to the closing of such Change of Control or that is developed or Commercialized by such Person after the closing of such Change of Control of Depomed or Collegium without the use of any Depomed Product Know-How or any Know-How Controlled by Collegium, respectively.

Section 1.49 "Competition Laws" means the Legal Requirements of any jurisdiction that are designed or intended to prohibit, restrict or regulate actions that may have the purpose or effect of creating a monopoly, lessening competition or restraining trade, including the HSR Act.

Section 1.50 "Confidentiality Agreement" means that certain Confidentiality Agreement, dated as of September 27, 2017, between Depomed and Collegium.

Section 1.51 "Consent Agreement" has the meaning set forth in Section 14.4.

Section 1.52 "Control" or "Controlled" means, with respect to Patents, Know-How or other IP Rights of any kind, the possession by a party of the ability to grant a license or sublicense of such rights as contemplated by this Agreement, without violating the terms of any agreement or other arrangement with any Third Party.

Section 1.53 "Control Agreement" has the meaning set forth in Section 7.7(b)(i).

Section 1.54 "Co-Pay Card Discounts" has the meaning set forth in Section 8.3(e).

Section 1.55 "Co-Pay Card Program" has the meaning set forth in Section 8.3(e).

Section 1.56 "Covered Action" means any suit, action or proceeding, whether at law or in equity, whether in contract or in tort or otherwise arising out of, or relating to, the Transactions and (a) brought against a party or an Affiliate of such party by the other party or an Affiliate of the other party, or (b) supported, by means of direct financial support or voluntary cooperation with any request for support from the Third Party bringing the suit, action or proceeding, by one party or an Affiliate of such party against the other party or an Affiliate of such other party.

Section 1.57 "CPR Mediation Procedure" has the meaning set forth in Section 17.12(a).

Section 1.58 "CPR Rules" has the meaning set forth in Section 17.12(b)(i).

Section 1.59 "CSA" means the Controlled Substances Act, as amended.

Section 1.60 "Customers" means Third Party wholesalers, retailer pharmacies, mail-order pharmacies, group purchasing organizations or other organizations similar to those that purchase the Products from Depomed in the Territory as of the Effective Date.

Section 1.61 "Data Room" means the electronic data room containing documents and materials relating to the Transferred Assets as of 5:00 P.M. Pacific Standard Time on December 3, 2017, as well as the computer containing documents and materials relating to the Transferred Assets made available to Collegium and/or its representatives prior to the Effective Date.

Section 1.62 "DEA" means the United States Drug Enforcement Agency or any successor agency performing comparable functions in the Territory.

Section 1.63 "Depo NF" means Depo NF Sub, LLC.

Section 1.64 "Depomed" has the meaning set forth in the preamble to this Agreement.

Section 1.65 "Depomed Acuform Patents" means the patents listed in Schedule 1.65.

Section 1.66 "Depomed Corporate Trademark" means any trademarks, trade names, corporate names, corporate logos, domain names, or other names or marks used or registered by Depomed or its Affiliates to identify itself, including the Depomed® trademark.

Section 1.67 "Depomed Entities" means, collectively, Depomed and Depo NF.

Section 1.68 "Depomed Indemnitees" has the meaning set forth in Section 12.2(a).

Section 1.69 "Depomed Names" means the names and logos of Depomed and its Affiliates.

Section 1.70 "Depomed Product Expiration Date" means the expiration date of the last Product in the channel bearing Depomed's NDC Number on a Product-by-Product basis.

Section 1.71 "Depomed Product Know-How" means, collectively, all Know-How that is Controlled by Depomed and its Affiliates as of the Closing Date or any time during the Term that is related to the Business, the Products or the Transferred Assets and is (a) necessary or otherwise used or held for use in the conduct of the Business (including the Manufacture of the Line Extensions) or (b) necessary for Collegium to perform its obligations under this Agreement or any Ancillary Agreement, excluding Know-How within the Grünenthal IP Rights; provided, however, that Depomed Product Know-How excludes any Know-How of any Person acquiring Depomed in a Change of Control that was Controlled by such Person prior to the closing of such Change of Control or that was generated by such Person without the use of any Depomed Product Know-How unless (i) such Know-How is actually used by such Person at any time during the Term of this Agreement in the Manufacture of any Line Extensions, or the Commercialization of any of the Products or (ii) such Know-How was already licensed to Collegium under Section 2.1(a) hereof prior to the closing of the Change of Control.

Section 1.72 "Depomed Promotional Materials" has the meaning set forth in Section 4.9(b)(ii).

Section 1.73 "Depomed Responsibility Period" means the period through and including the Closing Date.

Section 1.74 "Depomed Regulatory Inspection" has the meaning set forth in Section 5.10(b).

Section 1.75 "Depomed Sales Force" means the field force of Sales Representatives employed or contracted by Depomed.

Section 1.76 "Depomed Technology Trademark" means the Trademarks listed on Exhibit A of the Trademark License Agreement, including the ACUFORM® Trademark.

Section 1.77 "Detail" means an in-person, face-to-face sales presentation of a Product or Line Extension made by a Sales Representative to a Professional.

Section 1.78 "Dispute" has the meaning set forth in Section 17.12.

Section 1.79 "Domain Name Assignment" means a domain name assignment, in the form attached hereto as Exhibit A, dated as of the Closing Date.

Section 1.80 "Effective Date" has the meaning set forth in the preamble to this Agreement.

Section 1.81 "Environmental Laws" means all Legal Requirements related to the protection of the environment or human health and safety or the release, presence of, exposure to, or the management, manufacture, use, containment, storage, recycling, reclamation, monitoring, reuse, treatment, generation, discharge, transportation, processing, production, disposal, leaching, migration, emission or remediation of any contaminant or pollutant, toxic, radioactive or hazardous waste, chemical, substance, material or constituent.

Section 1.82 "ER/LA Opioid Analgesics REMS" has the meaning set forth in Section 5.3(a).

Section 1.83 "Excluded Assets" means, other than the Transferred Assets, all of the assets of Depomed and its Affiliates.

Section 1.84 "Expiration Date" has the meaning set forth in Section 7.7(a)(iii).

Section 1.85 "Expired Product" has the meaning set forth in Section 7.3(c).

Section 1.86 "FDA" means the United States Food and Drug Administration or any successor agency performing comparable functions in the Territory.

Section 1.87 "Financial Institution" has the meaning set forth in Section 7.7(a)(i).

Section 1.88 "Food and Drug Act" means the Federal Food, Drug, and Cosmetic Act of 1938, as amended.

Section 1.89 "Force Majeure Event" has the meaning set forth in Section 17.7.

Section 1.90 "Forward-Looking Statements" has the meaning set forth in Section 17.17.

Section 1.91 "Fundamental Representations" mean the representations and warranties (a) of Depomed contained in Section 10.1(a) (Organization), Section 10.1(b) (Authority; Binding Effect), Section 10.1(h)(i) (Contracts), Section 10.1(j) (Brokers), and Section 10.1(k) (Transferred Assets) and (b) of Collegium contained in Section 10.2(a) (Organization), Section 10.2(b) (Authority; Binding Effect), and Section 10.2(e) (Brokers).

Section 1.92 "GAAP" means accounting principles and practices generally accepted in the United States of America, as in effect on the Effective Date.

Section 1.93 "Generic Drug Act" means the Generic Drug Enforcement Act of 1992, as amended.

Section 1.94 "Generic Entry" means, with respect to a Product, the initiation of sales to wholesale or retail customers of one or more Generic Versions of such Product (other than an Authorized Generic) in the Territory by a Third Party, including an ANDA Settlement Distributor, but excluding any Authorized Generic Distributor.

Section 1.95 "Generic Version" means, with respect to a Product, any pharmaceutical product which (a) contains the same active ingredient(s) in the same dosage(s) and dosage form as such Product, (b) is approved in reliance on, and by reference to, the Product NDA, or is approved under the Product NDA, and (c) in the case of products approved by reference to, rather than under, the Product NDA, has been issued a therapeutic equivalence code of AB (as such term is used in the Approved Drug Products with Therapeutic Equivalence Evaluations published by the FDA Center for Drug Evaluation and Research or any successor publication) by the FDA with respect to such Product.

Section 1.96 "Government Rebates" has the meaning set forth in Section 8.3(c)(i).

Section 1.97 "Governmental Authority" means any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member, which has competent and binding authority to decide, mandate, regulate, enforce, or otherwise control the activities of the parties contemplated by this Agreement.

Section 1.98 "GPO" has the meaning set forth in Section 8.3(d)(i).

Section 1.99 "Grünenthal" means Grünenthal GmbH.

Section 1.100 "Grünenthal IP Rights" means the IP Rights out-licensed by Grünenthal under the Grünenthal License Agreement, including the Grünenthal Patents.

Section 1.101 "Grünenthal License Agreement" means that certain License Agreement (U.S.) dated January 13, 2015 among Grünenthal, Janssen Pharmaceuticals, Inc. and Janssen Research & Development, LLC, as assigned to Depomed and amended pursuant to that certain Assignment and Consent Agreement dated January 13, 2015 among Grünenthal, Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC and Depomed.

Section 1.102 "Grünenthal Patent Action" has the meaning set forth in Section 11.4.

Section 1.103 "Grünenthal Patents" has the meaning set forth in Section 10.1(i)(iv).

Section 1.104 "Health Laws" means any Legal Requirement the stated purpose of which is to ensure the safety, efficacy and quality of medicines by regulating the quality, identity, strength, purity, safety, efficacy, testing, sale or distribution, sale, import or export, good laboratory practices, good clinical practices, investigational use, product marketing authorization, manufacturing compliance and approval, good manufacturing practices, labeling, advertising, safety surveillance, including the relevant provisions of the CDAPCA, CSA, PPACA, Food, Drug, and Cosmetic Act, and applicable regulations promulgated thereunder by the FDA, DEA or other applicable Governmental Authority.

Section 1.105 "HSR Act" means the United States Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder.

Section 1.106 "HSR Clearance Date" means, with respect to the transactions contemplated under this Agreement, the earliest date on which the parties have actual knowledge that all applicable waiting periods have expired or have been terminated under the HSR Act.

Section 1.107 "Indemnified Party" has the meaning set forth in Section 12.3.

Section 1.108 "Indemnifying Party" has the meaning set forth in Section 12.3.

Section 1.109 "Indebtedness" means, with respect to any Person at any date of determination (without duplication), (a) all indebtedness of such Person for borrowed money or other similar monetary obligations, (b) all obligations of such Person evidenced by bonds, debentures, notes or other similar instruments, (c) all obligations of such Person as an account party in respect of letters of credit or other similar instruments (including reimbursement obligations with respect thereto), (d) all the obligations of such Person to pay the deferred and unpaid purchase price of property or services (other than trade payables reflecting expenses payable or reimbursable to service providers), which purchase price is due more than ninety (90) days after the date of purchasing such property or service or taking delivery and title thereto or the completion of such services, and payment deferrals arranged primarily as a method of raising funds to acquire such property or service, (e) all monetary obligations of such Person and its Subsidiaries under any leasing or similar arrangement that have been (or, in accordance with GAAP, should be) classified as capitalized leases, (f) all guarantees of such Person in respect of any of the foregoing, (g) all monetary obligations of such Person with respect to any interest rate hedge, cap, floor, swap, option or other interest rate hedge agreement, (h) all Indebtedness (as defined in clauses (a) through (g) of this definition) of other Persons secured by a lien on any asset of such Person, whether or not such Indebtedness is assumed by such Person, and (i) all Indebtedness (as defined in clauses (a) through (g) of this definition) of other Persons Guaranteed by such Person.

Section 1.110 "Infringement" means direct or indirect infringement, misappropriation or other unauthorized use of any IP Rights (including unfair trade practice or unfair competition under applicable Legal Requirements).

Section 1.111 "Intercreditor Agreement" has the meaning set forth in Section 14.3.

Section 1.112 "IND" means any "investigational new drug application" (as such term is used under the Food and Drug Act) filed or acquired by a party or its Affiliate with the FDA with respect to a Product or Line Extension and all subsequent submissions, supplements and amendments thereto (including the Product INDs with respect to Products).

Section 1.113 "IP Rights" means all (a) utility and design patents, design registrations, industrial designs, utility models, invention disclosures, certificates of invention and statutory invention registrations, including any and all applications and registrations, provisionals, divisions, continuations, continuations in part, extensions, substitutions, renewals, registrations, revalidations, reversions, reexaminations, reissues or additions, of or to any of the foregoing items, and all rights and priorities afforded under any applicable Legal Requirements with respect thereto (collectively, "Patents"); (b) trademark, brand features, domain names, logos, name, service marks, trade names, or goodwill from such, and other distinctive brand features; (c) copyrights, all applications, registrations and renewals therefor, and all code, technical or nontechnical documentation, schematics, drawings, hardware designs, diagrams, or implementations, as well as any original works of authorship, including any modifications, additions, or derivative works from an existing work (collectively, "Copyrights") (d) domain names, and all registrations and pending applications for registrations therefor (collectively, "Domain Names"; and (e) trade secrets, information, marketing know-how, knowledge, data, designs, ideas, concepts, methods, techniques, inventions, discoveries, trade secrets, formulae, compositions, expertise, experimental (whether clinical or not) data and other results of trials, studies or investigations, and processes, whether patentable or not, and whether or not capable of separate or precise definition or identification, whether acquired through trial and error, experience or other means, including regulatory information submitted to Governmental Authorities, Product specifications (and with regard to IP Rights of Collegium, Line Extension specifications), and information relating to the testing (including quality control standards, assay methods and stability studies), storage, manufacturing and use of the Products (and with regard to IP Rights of Collegium, Line Extensions), or the manufacturing, marketing or sale of the Products (and with regard to IP Rights of Collegium, Line Extensions) (collectively, "Know-How").

Section 1.114 "Janssen" has the meaning set forth in Section 2.11(b).

Section 1.115 "JMC" has the meaning set forth in Section 3.2(e).

Section 1.116 "Joinder Agreement" has the meaning set forth in Section 14.4.

Section 1.117 "Joint Litigation Agreement" means that certain Joint Litigation Agreement dated January 3, 2013 among Grünenthal, Janssen Pharmaceuticals, Inc. and Janssen Research & Development, LLC, as assumed by Depomed and amended pursuant to that certain Assignment and Consent Agreement dated January 13, 2015 among Grünenthal, Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC and Depomed.

Section 1.118 "Knowledge of Collegium" means the actual knowledge of any of the individuals listed on Schedule 1.118, in each case, after due inquiry of such named individual's files and records and of those employees of Collegium who are such named individuals' direct reports.

Section 1.119 "Knowledge of Depomed" means the actual knowledge of any of the individuals listed on Schedule 1.119, in each case, after due inquiry of such named individual's files and records and of those employees of Depomed who are such named individuals' direct reports.

Section 1.120 "Legal Proceeding" means any claim, action, suit, case, litigation, proceeding, investigation, charge, criminal prosecution, judicial, governmental or regulatory investigation, or arbitration, mediation or alternative dispute resolution proceeding.

Section 1.121 "Legal Requirements" means laws, rules and regulations of any Governmental Authority in the Territory.

Section 1.122 "Letter of Credit" has the meaning set forth in Section 7.7(a)(i).

Section 1.123 "Letter of Credit Documents" has the meaning set forth in Section 7.7(a)(i).

Section 1.124 "Liabilities" means any and all debts, liabilities, costs, guarantees, commitments, assessments, expenses, claims, losses, damages, deficiencies and obligations, whether accrued or fixed, known or unknown, liquidated or unliquidated, asserted or unasserted, absolute or contingent, matured or unmatured, determined or determinable, accrued or not accrued, due or to become due, direct or indirect, whenever or however arising (including whether arising out of any contract, common law or tort based on negligence or strict liability) and whether or not the same would be required by GAAP to be reflected in financial statements or disclosed in the notes thereto.

Section 1.125 "Licensed IP Rights" means the Depomed Product Know-How, the Depomed Acuform Patents, the Grünenthal IP Rights and the Licensed Trademarks.

Section 1.126 "Licensed Trademarks" means the Product Trademarks and the Depomed Technology Trademark.

Section 1.127 "Lien" means, with respect to any property or asset, any lien, security interest, mortgage, pledge, assessment, restriction, adverse claim, levy, charge, hypothecation, easement, restriction, title retention clause, encumbrance or other similar claim of any kind, character or description, whether of record or not, or any contract to give any of the foregoing, in respect of such property or asset.

Section 1.128 "Limited License Period" has the meaning set forth in Section 8.4(a).

Section 1.129 "Line Extension" means any modified form of a Product developed by or on behalf of Collegium or any of its Affiliates or any other Sublicensees during the Term, including new dosage forms or changes to the formulation or presentation of such Product (*e.g.*, without limitation, to make it tamper-resistant, to extend the release period of the active pharmaceutical ingredient or to make it harder to abuse), or combinations of such Product with any other product or device.

Section 1.130 "Long Term Collaboration Agreement" has the meaning set forth in Section 14.3.

Section 1.131 "Losses" mean losses, liabilities, claims, damages, deficiencies, costs, expenses, penalties, assessments, fines, fees, suits, actions, causes of action, judgments, Taxes and awards directly incurred or suffered (and, if applicable, reasonable attorneys' fees associated therewith).

Section 1.132 "Manufacture," "Manufactured" and "Manufacturing" mean all operations involved in the manufacture, receipt, incoming inspection, storage and handling of raw materials, and the manufacture, processing, purification, packaging, labeling, warehousing, quality control testing (including in-process release and stability testing), shipping and release of Products and Line Extensions.

Section 1.133 "Manufacturing Tech Transfer Plan" has the meaning set forth in Section 2.11(b).

Section 1.134 "Master Letter of Credit Agreement" has the meaning set forth in Section 7.7(a)(i).

Section 1.135 "Material Supply Failure" means any failure (other than a failure caused directly by Collegium or its Affiliates or other Sublicensees) by the applicable CMO to deliver to Customers, over the course of any two (2) consecutive calendar months, such quantity of Nucynta® ER ordered by Collegium in the ordinary course and in accordance with this Agreement and the applicable CMO Supply Agreement(s) which, if such Product was to be sold by such Customers in the ordinary course, would generate at least **[***]** in gross sales, which gross sales threshold shall be increased ratably to reflect any price increases taken by Collegium with respect to Nucynta® ER after the Closing Date.

Section 1.136 "Material Supply Failure Notice" has the meaning set forth in Section 7.3(f).

Section 1.137 "Maximum Stated Value" has the meaning set forth in Section 7.7(a)(i).

Section 1.138 "Minimum Cash Balance" means Eighty Million Dollars ($80,000,000).

Section 1.139 "Minimum Quarterly Payment" has the meaning set forth in Section 7.3(a).

Section 1.140 "NDA" means any "new drug application" (as such term is used under the Food and Drug Act) filed or acquired by a party or its Affiliate with the FDA with respect to a Product or Line Extension and all subsequent submissions, supplements and amendments thereto (including the Product NDAs with respect to Products).

Section 1.141 "NDC Number" means, with respect to a Product, the National Drug Code, which is the eleven (11)-digit code registered by a party with the FDA with respect to such Product.

Section 1.142 "Net Sales" means the gross amount billed, as of the date of invoicing, by or on behalf of Collegium or an Affiliate of Collegium or other Sublicensee(s) or assignee(s) for sales of a Payment-Bearing Product to a Third Party less, to the extent actually allowed or taken for the Territory: (a) normal and customary discounts, including cash discounts, discounts to managed care or similar organizations or government organizations, rebates paid, credited, accrued or actually taken, including government rebates such as Medicaid chargebacks or rebates, and retroactive price reductions or allowances actually allowed or granted from the billed amount, and commercially reasonable and customary fees paid to distributors (other than to a distributor that is an Affiliate of Collegium); (b) credits or allowances actually granted upon claims, rejections or returns of such sales of Payment-Bearing Product, including recalls, regardless of Collegium requesting such recalls; (c) freight, postage, shipping and insurance charges paid for delivery of such Payment-Bearing Product, to the extent billed separately on the invoice and paid by the buyer; (d) taxes, duties or other governmental charges levied on or measured by the billing amount when included in billing, as adjusted for rebates, charge-backs and refunds to the extent actually paid or allowed by the selling party; and (e) actual uncollectible accounts receivables determined in accordance with GAAP, consistently applied. For further clarity, Collegium shall not deduct from Net Sales any amounts for which Depomed bears financial responsibility under Section 8.3. In no event shall any particular amount identified above be deducted more than once in calculating Net Sales (*i.e.*, no "double counting" of deductions). Collegium will not, and will not authorize or permit its Affiliates or Sublicensees to sell any Payment-Bearing Product to select Customers at a price below its minimum profit margin for the purpose of stimulating commercial sales of other more profitable pharmaceutical products (*i.e.*, a "loss-leader"). For clarity, sales of Payment-Bearing Product at a price below its minimum profit margin in connection with Medicaid will not be deemed to be sales of Payment-Bearing Product as a loss leader.

Section 1.143 "Newco" has the meaning set forth in the Preamble to this Agreement.

Section 1.144 "Newco Deposits" has the meaning set forth in Section 7.7(b)(i).

Section 1.145 "Nucynta® ER" means NUCYNTA® extended release tablets, in strengths of 50 mg, 100 mg, 150 mg, 200 mg and 250 mg as described in New Drug Application 200533.

Section 1.146 "OPDP" means FDA's Office of Prescription Drug Promotion or any successor agency performing comparable functions in the Territory.

Section 1.147 "Orange Book" means the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" or any replacement thereof established or approved by the FDA.

Section 1.148 "Orange Book-Listed Patent" means, with respect to the applicable Product or Line Extension, a Patent listed for such Product or Line Extension in the Orange Book.

Section 1.149 "Order" means any award, decision, injunction, judgment, decree, order, ruling, or verdict entered, issued, made, or rendered by any Governmental Authority or by any arbitrator.

Section 1.150 "Payment-Bearing Product" means (a) any Product or (b) any Line Extension.

Section 1.151 "Payment Term" has the meaning set forth in Section 7.3(c).

Section 1.152 "Permitted Lien" means (a) all Liens set forth on Schedule 1.152 (b) statutory Liens arising out of operation of law with respect to a Liability incurred in the ordinary course of business and which is not delinquent; (c) Liens, other than Liens securing Indebtedness for borrowed money, that, individually and in the aggregate, do not and would not reasonably be expected to materially detract from the value or impair the use of the property subject thereto or make such property unmarketable; (d) Liens for Taxes not yet due, payable, delinquent or subject to penalties for nonpayment, or which are being contested in good faith through proper proceedings, in each case, with sufficient reserves maintained in accordance with GAAP; and (e) mechanics', materialmens', carriers', workmens', warehousemens', repairmens', landlords' or other like Liens and security obligations that are incurred in the ordinary course of business and are not delinquent.

Section 1.153 "Person" means any individual, corporation (including any non-profit corporation), general or limited partnership, limited liability company, joint venture, estate, trust, association, organization, labor union, or other entity or Governmental Authority.

Section 1.154 "Post-Marketing Development" means, with respect to any Product, the conduct of any phase IV clinical studies, quality of life assessments or pharmacoeconomic, label expansion or other post-marketing studies, in each case other than the Retained Post-Marketing Commitments.

Section 1.155 "PPACA" means the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care Education and Reconciliation Act of 2010.

Section 1.156 "Prepaid Business Expenses" means the expenses with respect to the Business that were prepaid by Depomed prior to the Closing as set forth on Schedule 1.156.

Section 1.157 "Product Complaints" means any report concerning the possible failure of a Product to meet any of its specifications, such as quality, purity, quantity, weight, pharmacologic activity, labeling, identity or appearance.

Section 1.158 "Product INDs" means Depomed's Investigational New Drug Applications filed with the FDA with respect to Products set forth on Schedule 1.158, including all supplements and amendments thereto.

Section 1.159 "Product Materials" has the meaning set forth in Section 3.2(a).

Section 1.160 "Product NDAs" means the NDAs filed with the FDA with respect to Products set forth on Schedule 1.160, including all supplements and amendments thereto.

Section 1.161 "Product Trademarks" means (a) the Trademarks listed on Exhibit B of the Trademark License Agreement, including the NUCYNTA® Trademark, and (b) such other Trademarks owned by Depomed as of the Closing Date that are used exclusively for Commercialization of the Products in the Territory as of the Closing Date.

Section 1.162 "Products" means the products set forth on Schedule 1.162 or any Authorized Generic thereof.

Section 1.163 "Professional" means a physician or other health care practitioner who is permitted by law to prescribe Products or Line Extensions.

Section 1.164 "Promote," "Promotional" and "Promotion" mean, with respect to a Product or Line Extension, any activities undertaken to encourage sales or use of such Product or Line Extension, including Details, product sampling, detail aids, drop-offs, coupons, discount cards, journal advertising, direct mail programs, direct-to-consumer advertising, convention exhibits and all other forms of marketing, advertising, public relations or promotion.

Section 1.165 "Promotional Materials" has the meaning set forth in Section 4.5(a).

Section 1.166 "Proprietary Information" means any proprietary or confidential information communicated from one party to the other in connection with or relating to this Agreement or the Confidentiality Agreement (whether before or after the Effective Date), which is identified as confidential or proprietary, or which the other party knows or has reason to know is confidential or proprietary, including financial, marketing, business, technical and scientific information or data and, in the case of Depomed, the Depomed Product Know-How, whether communicated in writing, orally or electronically. Proprietary Information shall not include information that the receiving party can show through written documentation:

(a) at the time of disclosure, is publicly known;

(b) after the time of disclosure, becomes part of the public domain, except by breach of an agreement between the disclosing party or any Affiliate thereof and the receiving party or any Affiliate thereof;

(c) is or was in the possession of the receiving party or any Affiliate thereof at the time of disclosure by the disclosing party and was not acquired directly or indirectly from the disclosing party or any Affiliate thereof or from any other party under an agreement of confidentiality to the disclosing party or any Affiliate thereof; or

(d) is or was developed by the receiving party or its Affiliates without use of or reference to the other party's Proprietary Information.

Section 1.167 "Protocol" has the meaning set forth in Section 17.12(b)(vi).

Section 1.168 "Quarterly Shortfall" has the meaning set forth in Section 7.7(a)(i).

Section 1.169 "Regulatory Approval" means any and all consents or other authorizations or approvals by the FDA or any other Regulatory Authority in the Territory that are required to develop, test, manufacture, market and sell a Product or Line Extension in the Territory, whether existing on the Closing Date or filed thereafter, including but not limited to, Product NDAs and Product INDs; but excluding (a) Third Party drug master files with respect to API or Products, (b) state licenses, and (c) any form of reimbursement approval.

Section 1.170 "Regulatory Authority" means any Governmental Authority, including FDA, in the Territory that is involved in granting approvals for the manufacturing, clinical testing, marketing, sale, reimbursement and/or pricing of pharmaceutical products.

Section 1.171 "Regulatory Communications" means, collectively, whether existing before or after the Closing Date: (a) all written or electronic filings or submissions made with Regulatory Authorities in satisfaction of applicable regulatory and notification requirements with respect to Products in the Territory (including, without limitation, Annual Periodic Reports, Serious Adverse Drug Experience Reports, Adverse Drug Experience Reports, and filings and submissions regarding recalls); (b) all written or electronic correspondence to or from the FDA

with respect to any of the foregoing; (c) minutes of any meeting between a party and the FDA regarding the Regulatory Approvals, or Manufacture or Commercialization of the Products in or for the Territory; and (d) written summaries of oral communications between a party and the FDA that would impact, or would reasonably be expected to be material to, the development, Manufacture or commercialization of the Products.

Section 1.172 "Regulatory Data" means (a) all processes and analytical methodologies used in development, testing, analysis and manufacture of Products and (b) all in vivo, clinical, pharmacology, toxicology, safety, efficacy and other scientific data and results relating to Products, that, in each case (clauses (a) and (b)), are either (i) contained in the Product NDAs or (ii) if not contained in the Product NDAs, are known to a party and required to be submitted to the FDA in support of the Product NDAs.

Section 1.173 "Representatives" has the meaning set forth in Section 14.5.

Section 1.174 "Retained Liabilities" means the following Liabilities (excluding the Assumed Liabilities) of Depomed:

(a) all Liabilities arising out of or relating to any Retained Post-Marketing Commitments;

(b) all Liabilities arising out of or relating to any ANDA Litigation;

(c) all Liabilities arising out of or relating to Legal Proceedings commenced prior to the Closing, irrespective of the legal theory asserted, arising from the development, Commercialization, Manufacture or use of the Products or the use of the Transferred Assets, in each case, (i) other than by Collegium or its Affiliates pursuant to this Agreement and (ii) solely to the extent relating to the period of time prior to the Closing;

(d) all Liabilities arising out of or relating to products liability claims to the extent relating to the Products Commercialized prior to the Closing, including claims alleging defects in the Products and claims involving the death of or injury to any individual relating to the Products;

(e) all Liabilities to Third Party customers, Third Party suppliers or other Third Parties relating to the Products and delivered in the ordinary course of business prior to the Closing;

(f) all other Liabilities arising out of or relating to the Products or the Transferred Assets, to the extent relating to the period of time prior to the Closing;

(g) all Taxes apportioned to Depomed pursuant to Section 2.9; and

(h) all Liabilities arising out of or relating to the return of the Products sold by Depomed prior to the Closing.

Section 1.175 "Retained Post-Marketing Commitments" means the ongoing clinical and/or post-marketing studies set forth on Schedule 1.175.

Section 1.176 "Sales Account" has the meaning set forth in Section 7.7(b)(i).

Section 1.177 "Sales Representatives" means sales representatives employed by Collegium or Depomed, or a Third Party engaged by Collegium or Depomed, to Detail the Products and/or Line Extensions, as applicable, who have been trained and equipped to Detail the Products (and with respect to Collegium, Line Extensions) in accordance with this Agreement.

Section 1.178 "SEC" has the meaning set forth in Section 13.3.

Section 1.179 "Senior Executives" means, together, the Chief Executive Officer of Collegium and the Chief Executive Officer of Depomed.

Section 1.180 "Serious Adverse Drug Experience" means any Adverse Drug Experience, including those subject to expedited reporting as defined in the regulations cited below, that is fatal or life-threatening, requires hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly/birth defect, or is of comparable medical significance or any other event which would constitute a "serious" Adverse Drug Experience pursuant to the terms of 21 C.F.R. 314.80 or 312.32.

Section 1.181 "Serious Adverse Drug Experience Report" means any Adverse Drug Experience Report that involves a Serious Adverse Drug Experience.

Section 1.182 "Solvent" has the meaning set forth in Section 10.2(g).

Section 1.183 "Straddle Period" has the meaning set forth in Section 2.9(c).

Section 1.184 "Subcontracting" means subcontracting Collegium's rights or obligations hereunder (a) pursuant to which a Third Party will Manufacture any Line Extension on behalf of Collegium; or (b) pursuant to which a Third Party Sales Representative is engaged to Promote any Product or Line Extension on behalf of Collegium; "Subcontract" has the correlative meaning. "Subcontractor" means the Third Party with whom the Subcontracting agreement is entered.

Section 1.185 "Sublicensee" has the meaning set forth in Section 2.2(c).

Section 1.186 "Supplied Products" has the meaning set forth in Section 3.2(a).

Section 1.187 "Tax" or "Taxes" mean all taxes, including income, corporation, gross receipts, transfer, excise, property, sales, use, value-added, goods and services, license, payroll, withholding, social security and franchise or other governmental taxes, in each case, imposed by any Governmental Authority (including any interest, penalties or additional tax attributable thereto).

Section 1.188 "Tax Return" means any return, report, declaration, information return, statement or other document filed or required to be filed with any Taxing Authority in connection with the determination, assessment or collection of any Tax or the administration of any Legal Requirements relating to any Tax.

Section 1.189 "Taxing Authority" means any Governmental Authority exercising any authority to impose, regulate or administer the imposition of Taxes.

Section 1.190 "Term" has the meaning set forth in Section 9.1.

Section 1.191 "Territory" means the United States of America, the District of Columbia and Puerto Rico.

Section 1.192 "Third Party" means any Person other than Collegium or Depomed or their respective Affiliates.

Section 1.193 "Third Party Claim" has the meaning set forth in Section 12.3.

Section 1.194 "Third Party Sales Representative" has the meaning set forth in Section 2.2.

Section 1.195 "Trademark License Agreement" means a trademark license agreement, in the form attached hereto as Exhibit B, dated as of the Closing Date.

Section 1.196 "Transaction Documents" means, collectively, this Agreement, the Ancillary Agreements and the certificates and other documents delivered pursuant hereto or thereto.

Section 1.197 "Transactions" means, collectively, the transactions contemplated by this Agreement and the Ancillary Agreements.

Section 1.198 "Transfer Taxes" mean any federal, state, county, local, foreign and other sales, use, transfer, value added, conveyance, documentary transfer, stamp duty, recording or other similar Tax imposed in connection with the Transactions or the recording of any sale, transfer or assignment of property (or any interest therein) effected pursuant to this Agreement.

Section 1.199 "Transferred Asset Purchase Price" has the meaning set forth in Section 2.8.

Section 1.200 "Transferred Assets" has the meaning set forth in Section 2.3(a).

Section 1.201 "Transferred Domain Names" means the domain names listed on Schedule 1.201.

Section 1.202 "Transferred Inventory" means Depomed's inventory of finished Products, in each case with at least twelve (12) months of remaining expiration dating as of the Closing Date.

Section 1.203 "Transferred Inventory Cost" means the amount equal to the aggregate COGS of the Transferred Inventory, as set forth on the Transferred Inventory Cost Statement.

Section 1.204 "Transferred Inventory Cost Statement" has the meaning set forth in Section 7.1(b).

Section 1.205 "Transferred IP Rights" means the Transferred Domain Names and the Transferred Websites.

Section 1.206 "Transferred Websites" means the Websites located at the domain names listed on Schedule 1.206.

Section 1.207 "Transition Lots" means those lots of a Product for which Product was partially sold prior to the Closing Date and partially sold on or after the Closing Date.

Section 1.208 "Transition Plan" has the meaning set forth in Section 3.1.

Section 1.209 "Transition Services Agreement" has the meaning set forth in Section 14.3.

Section 1.210 "Transition Team" has the meaning set forth in Section 3.1.

Section 1.211 "United States Bankruptcy Code" means the U.S. Bankruptcy Code, 11 U.S.C. §§ 101, et seq.

Section 1.212 "UPC" means Universal Product Code.

Section 1.213 "Upfront Payment" has the meaning set forth in Section 7.2.

Section 1.214 "Website" means the content of a website located at a specified domain name and all copyrights in such content, excluding trademarks and corporate names, content owned by Third Parties (such as stock photographs used in such website) and content unrelated to any Product or Line Extension.

ARTICLE 2
GRANTS AND TRANSFERS; CLOSING

Section 2.1 Licenses

(a) License Grants. During the Term, subject to the terms and conditions of this Agreement, Depomed hereby grants to Newco, and Newco hereby accepts:

(i) a non-exclusive license under the Depomed Acuform Patents and the Depomed Product Know-How to Commercialize and conduct Post-Marketing Development activities with respect to the Payment-Bearing Products solely in the Territory.

(ii) a non-exclusive license under the Depomed Acuform Patents and the Depomed Product Know-How to Manufacture and have Manufactured Line Extensions solely in the Territory for Commercialization.

(iii) an exclusive sublicense under Depomed's rights in and to the Grünenthal IP Rights under the Grünenthal License Agreement to Commercialize and conduct Post-Marketing Development activities with respect to the Payment-Bearing Products solely in the Territory. Such license shall be exclusive even as to Depomed solely with respect to Commercialization and Post-Marketing Development of the Payment-Bearing Products in the Territory, subject to the Retained Post-Marketing Commitments, the responsibilities of Depomed under the Transition Plan and Depomed's rights under this Agreement, including Section 4.9, Section 11.3 and Section 14.7.

(iv) an exclusive sublicense under Depomed's rights in and to the Grünenthal IP Rights under the Grünenthal License Agreement to Manufacture and have Manufactured Line Extensions solely in the Territory for Commercialization. Such license shall be exclusive even as to Depomed solely with respect to the Manufacture of Line Extensions in the Territory for Commercialization in the Territory, subject to Section 11.3.

(v) the licenses granted pursuant to the Trademark License Agreement.

(b) Generic Versions. For clarity, the parties agree that Newco shall have the exclusive (even as to Depomed) right to Commercialize Generic Versions of Products in the Territory, either directly or indirectly through Authorized Generic Distributors; provided, however, that, unless otherwise agreed by the parties, Newco shall not be permitted to ship, or authorize an Authorized Generic Distributor to ship, any Generic Version, including any Authorized Generic, to Customers before Generic Entry for such Product.

Section 2.2 Enforcement Rights and Sublicenses

(a) Subject to the terms and conditions of this Agreement, including Section 11.3, Depomed hereby grants and delegates to Newco, and Newco hereby accepts, all of Depomed's rights to enforce the Grünenthal Patents in any Legal Proceedings involving the Products or Line Extensions solely in the Territory during the Term (at Newco's sole cost and expense), in accordance with Section 11.4, to the extent set forth in and limited by the Grünenthal License Agreement and the Joint Litigation Agreement, and to the extent authorized by Grünenthal pursuant to the Consent Agreement. Upon request of Collegium, Depomed shall cause Grünenthal to join any such Legal Proceeding initiated by Collegium as a party plaintiff if reasonably determined by Collegium, based on advice of its outside counsel, to be required for standing purposes. No other enforcement rights with respect to IP Rights are granted hereunder, except to the extent Newco or Collegium cooperates with Depomed in a Depomed Acuform Patent Action pursuant to Section 11.2. Newco shall have the right, in its sole discretion, to delegate its rights under this Section 2.2(a), in whole or in part, to Collegium.

(b) Subject to Section 2.2(c), Newco is entitled to grant sublicenses to the rights granted to it under Section 2.1 to Collegium or other Affiliates of Newco or Third Parties (each, a "Sublicensee"). All sublicense agreements granted by Newco hereunder shall be consistent with the terms and conditions of this Agreement, and shall provide that the Sublicensee shall be bound by and subject to all applicable terms and conditions of this Agreement in the same manner and to the same extent as Newco is bound hereby. Newco shall provide an unredacted copy of each such sublicense agreement to Depomed, including the sublicense agreement with Collegium. Newco shall remain responsible for the performance of its Sublicensees hereunder including Collegium. The term of any such sublicense will terminate upon the expiration or the termination of this Agreement.

(c) Subject to the terms and conditions of this Agreement, Newco shall not, and Collegium shall cause Newco not to, sublicense any of its rights or obligations under Section 2.1(a) without the express written consent of Depomed (and, in the case of sublicenses granted under Section 2.1(a)(iii) and Section 2.1(a)(iv), without the express written consent of Grünenthal), unless such sublicense is to Collegium (the "Collegium Sublicense"). Collegium shall not grant further sublicenses, unless Depomed provides prior written consent.

(d) Collegium and Newco shall not, and Collegium shall cause Newco not to, Subcontract any of their rights or obligations under Section 2.1(a) without the express written consent of Depomed, unless such subcontract is in connection with the use of Third Party sales representatives or distributors (each, a "Third Party Sales Representative") to Commercialize the Products and Line Extensions solely in the Territory, provided that Newco and Collegium shall at all times be responsible and liable to Depomed for any breach of this Agreement by any such Third Party Sales Representatives.

Section 2.3 Transfers

(a) Assets. Subject to the terms and conditions of this Agreement, effective as of the Closing, Depomed shall, and shall cause Depo NF to, transfer, convey and assign to Newco, and Newco shall, and Collegium shall cause Newco to, accept and obtain from Depomed and Depo NF, free and clear of all Liens (other than Permitted Liens), all of Depomed's and Depo NF's rights, titles and interests in, to or under the properties, rights, interests and assets set forth below (collectively, the "Transferred Assets"):

(i) the Transferred Inventory;

(ii) the Transferred Domain Names; and

(iii) the Transferred Websites.

Notwithstanding anything to the contrary in this Agreement, the Transferred Inventory shall be delivered to Collegium, rather than to Newco. For clarity, Depomed and its Affiliates shall retain ownership of the Excluded Assets.

(b) Liabilities. Subject to the terms and conditions of this Agreement, effective as of the Closing, Newco agrees, and Collegium shall cause Newco, to assume and to timely satisfy and discharge the Assumed Liabilities, in each case other than the Retained Liabilities. For clarity, Depomed and its Affiliates shall retain responsibility for the Retained Liabilities.

Section 2.4 Records

To the extent not already made available in the Data Room, within ten (10) Business Days of the Closing Date, Depomed shall provide Collegium, at no additional charge, with copies of all of the following records in the possession of Depomed or any of its Affiliates, whether in hard copy format, electronic format or otherwise, but excluding records or files not reasonably separable from documents or databases that do not relate exclusively to the Products or the Transferred Assets (collectively, the "Product Records"):

(a) Regulatory Communications relating to the Products between Depomed and a Regulatory Authority (or, to the extent in the possession and Control of Depomed, between a Third Party and a Regulatory Authority);

(b) Regulatory Data;

(c) Current manufacturing, stability and release testing documentation for Product Manufactured for the Territory, which shall include, to the extent in the possession of Depomed, representative master and executed manufacturing batch records, test methods,

stability protocols, stability results, manufacturing guides, conformance guides and specifications for the Products;

(d) a list of suppliers and vendors relating to the Products;

(e) a list of Customer and Professional targets of Depomed and Details relating to the Products;

(f) a list of distributors relating to the Products;

(g) pricing lists, history, calculations and submissions relating to the Products;

(h) Promotional Materials relating to the Products;

(i) development, quality control and pharmacovigilance records relating to the Products; and

(j) historical sales and marketing data and analyses relating to the Products.

With respect to the preceding clause (g), the Product Records shall exclude any responsive items which are related to government programs identified in the Long Term Collaboration Agreement and for the period of time prior to the Closing Date (except where the terms of the Long Term Collaboration Agreement expressly provide for the transfer of such items). Depomed will notify Collegium at the time it provides the Product Records to Collegium whether Depomed is in possession or control of any of the records or files of the types described in (a)-(j) which are not reasonably separable from documents or databases that do not relate exclusively to the Products or the Transferred Assets, including a summary of the information contained in such records and files. Upon the request of Collegium, the parties will work in good faith to find a way for Depomed to provide Collegium with a copy of or access to the portions of such records or files relating exclusively to the Products or Transferred Assets which Collegium reasonably determines are necessary or useful for the exercise of its rights or performance of its obligations hereunder. In addition, upon the reasonable request of Collegium, Depomed will provide Collegium with a copy of or access to Product Records or other Regulatory Data related to the Retained Post-Marketing Commitments.

Section 2.5 Limitation on Competing Products

Newco and its Affiliates shall not, directly or indirectly, develop, manufacture, promote, market, distribute, sell or offer for sale any Competing Product in the Territory during the Term of this Agreement, other than Payment-Bearing Products as contemplated by this Agreement.

Section 2.6 Retention of Rights

(a) Depomed hereby expressly reserves the exclusive right (as between the parties) to practice, and to grant licenses under, the Depomed Acuform Patents and the Depomed Product Know-How for any and all purposes.

(b) Except as expressly set forth herein, nothing contained herein shall be deemed to grant Newco or any of its Affiliates and Sublicensees, including Collegium or its Affiliates, by implication, estoppel or otherwise, a license or other right or interest in any patent, trademark or other similar property or IP Rights of Depomed or its Affiliates. Except as expressly set forth herein, nothing contained herein shall be deemed to grant Depomed or any of its Affiliates, by implication, estoppel or otherwise, a license or other right or interest in any patent, trademark or other similar property or IP Rights of Collegium or any its Affiliates.

(c) Depomed hereby expressly reserves the exclusive right (as between the parties) to list all Orange Book-Listed Patents with respect to Products. Collegium shall have the exclusive right (as between the parties) to list any Patents, not otherwise retained by Depomed in the preceding sentence, in the Orange Book with respect to Line Extensions. To the extent any Patent may be listed in the Orange Book for both Products and Line Extensions, Depomed shall have the sole right to list such Patent in the Orange Book, and the parties will cooperate with respect to listing any such Patent.

Section 2.7 Negative Covenants

(a) Newco and Collegium, on behalf of themselves and their Affiliates, hereby covenant not to practice, and not to authorize or cause any Sublicensee or other Third Party to practice, any Depomed Acuform Patents, Depomed Product Know-How, or Grünenthal IP Rights for any purpose other than as expressly authorized in this Agreement. Unless otherwise agreed by the parties, Newco and Collegium, on behalf of themselves and their Affiliates, hereby further covenant not to Commercialize, and not to authorize or cause any Sublicensee or other Third Party to Commercialize a Generic Version, including an Authorized Generic, in the Territory, either directly or indirectly through a Third Party, until permitted under Section 2.1(b).

(b) Except as otherwise contemplated in the Transition Plan with respect to Detailing by Depomed, Depomed, on behalf of itself and its Affiliates, hereby covenants not to Commercialize, and not to authorize or cause any licensee, sublicensee or other Third Party to Commercialize, a Generic Version or any Competing Product in the Territory, either directly or indirectly through a Third Party.

Section 2.8 Allocation of Purchase Price of Transferred Assets

The parties will allocate the purchase price (including assumed liabilities) paid for the Transferred Assets for Tax purposes (the "Transferred Asset Purchase Price") in the manner set

forth in Schedule 2.8 (the "Allocation"). The parties covenant and agree (a) to report for Tax purposes the allocation of the Transferred Asset Purchase Price among the Transferred Assets in a manner entirely consistent with the Allocation, as it may be amended upon any adjustment to the calculation of the Transferred Asset Purchase Price, except upon a final determination (within the meaning of Section 1313(a) of the Code) by an applicable Taxing Authority, (b) that the parties will cooperate with each other in connection with the preparation, execution and filing of all Tax Returns related to such allocation and will take no position inconsistent with such allocation in the filing of any Tax Return, except upon a final determination (within the meaning of Section 1313(a) of the Code) by an applicable Taxing Authority and (c) that the parties will use commercially reasonable efforts to advise each other regarding the existence of any Tax audit, controversy or litigation related to such allocation.

Section 2.9 Certain Taxes

(a) All Transfer Taxes payable in connection with the transfer of the Transferred Assets to Newco under this Agreement and the Transactions shall be borne and paid one-half by Depomed (or its applicable Affiliate) and one-half by Collegium, provided that Collegium shall be responsible for any such Transfer Taxes resulting from the failure to comply with Section 14.5. Such Transfer Taxes shall be paid when due in compliance with applicable Transfer Tax laws by the party that is required by applicable Legal Requirements to pay them, and the other party shall, subject to receipt of satisfactory evidence of payment thereof, promptly reimburse the other party fifty percent (50%) of the amount. Each party shall reasonably cooperate with the other parties in minimizing the amount of, and obtaining any applicable exemptions with respect to, any such Transfer Taxes.

(b) All Tax Returns and other documentation with respect to any Transfer Taxes shall be filed, or caused to be filed, by the party required to file such Tax Returns or other documentation under applicable Legal Requirements.

(c) Any property or similar ad valorem Taxes levied with respect to the Transferred Assets for a taxable period that includes (but does not end on) the Closing Date ("Straddle Period"), if any, shall be apportioned between the pre-closing portion of the Straddle Period and the post-closing portion of the Straddle Period based on the number of days of such taxable period included in the pre-closing portion of the Straddle Period and the post-closing portion of the Straddle Period. Depomed shall be liable for the amounts of such taxes apportioned to the pre-closing portion of the Straddle Period, and Collegium and Newco shall be liable for the amounts of such Taxes apportioned to the post-closing portion of the Straddle Period. Within a reasonable period, the parties shall present a statement to the others setting forth the amount of reimbursement to which each is entitled under this Section 2.9(c), together with such supporting evidence as is reasonably necessary to calculate the proration amount. The proration amount shall be paid by the party owing it to the other party within ten (10) days after delivery of such statement.

(d) The parties shall reasonably cooperate, and shall cause their respective Affiliates to reasonably cooperate, in filing all Tax Returns and in resolving all examinations, audits, actions and other proceedings relating to the Business and the Transferred Assets. Newco, Collegium and their Affiliates shall provide Depomed access to (including the right to make copies of), and retain in their possession until the expiration of the applicable statute of limitations, such books and records relating to Taxes for which Depomed is liable under this Agreement or otherwise.

Section 2.10 Risk of Loss; Casualty

Prior to the Closing, any loss or damage to the Transferred Inventory from fire, casualty or otherwise shall be the sole responsibility of Depomed. Thereafter, any such loss or damage shall be the sole responsibility of Collegium.

Section 2.11 Certain Costs

(a) All out-of-pocket costs and expenses associated with shipping the Transferred Inventory to a location designated by Collegium shall be borne and paid by Collegium; provided, however, that if any out-of-pocket costs or expenses should be incurred by Depomed in connection with shipping any of the Transferred Inventory to a location designated by Collegium, Collegium shall, subject to receipt of satisfactory evidence of Depomed's incurrence thereof, promptly pay Depomed its reasonable, customary and documented out-of-pocket costs and expenses.

(b) Subject to the terms and conditions of the applicable CMO Supply Agreement, all out-of-pocket costs, expenses and Liabilities incurred directly by or on behalf of Depomed or AbbVie Ltd. ("AbbVie") in connection with the transfer of all technology and equipment related to the Manufacture of Nucynta® ER from the current manufacturer (Janssen Ortho LLC and Janssen Pharmaceuticals, Inc. (collectively, "Janssen")) to AbbVie, as contemplated in Exhibit B to that certain Development and Manufacturing Services Agreement, by and between Depomed and AbbVie, dated as of June 15, 2016 (the "Manufacturing Tech Transfer Plan") (including all of such costs and expenses associated with the following (regardless of whether or not they are expressly contemplated in the Manufacturing Tech Transfer Plan): removing and moving any equipment, materials or technology from Janssen's current manufacturing facility in Puerto Rico to AbbVie's designated location in Puerto Rico, implementation of the aforementioned technology in AbbVie's facilities and the associated requirements imposed by any Regulatory Authority (*e.g.*, to perform bioequivalence studies)) will be borne and paid by Depomed when due, and all Liabilities arising in connection therewith shall be borne by Depomed; provided, however, that if Depomed incurs any costs, expenses or Liabilities in excess of the costs and expenses associated with the aforementioned activities as a result of any modifications or additions made to the Manufacturing Tech Transfer Plan at the request of Collegium after the Closing Date, then Collegium shall, subject to receipt of satisfactory evidence of Depomed's incurrence thereof, promptly pay Depomed such incremental

amounts. For clarity, the parties agree and acknowledge that any modifications of the Manufacturing Tech Transfer Plan made at the request of Collegium shall be subject to the prior written consent of Depomed, which consent shall not be unreasonably withheld, conditioned or delayed.

Section 2.12 Closing

(a) The Closing shall take place at 12:01 A.M. Pacific Standard Time on January 1, 2018, or such other date as mutually agreed by the parties in writing (the "Closing Date"), provided that, as of the Closing Date: (i) the parties have actual knowledge that all applicable waiting periods have expired or have been terminated under the HSR Act, and (ii) the actions and conditions set forth in Section 2.12(b) and Section 2.12(c) have been completed, or fulfilled, as applicable. The Closing shall take place at the offices of Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, California (including any Persons connected by remote access to the Closing) or at such other location as the parties may mutually agree in writing.

(b) At the Closing, Depomed shall deliver, or cause to be delivered, to Collegium the following instruments and documents:

(i) A good standing certificate from the Secretary of State of California for Depomed;

(ii) A certificate executed by an authorized officer of Depomed certifying that (A) the representations and warranties of Depomed contained in the Agreement are true and correct on and as of the Closing Date as though made on and as of the Closing Date (other than representations and warranties made as of a specified date, which shall be true and correct as of the date specified), except for breaches and inaccuracies of such representations and warranties (without giving effect to any limitation as to "materiality" or "material adverse effect" set forth therein, but giving effect to any dollar threshold specified therein) that would not reasonably be expected to have a material adverse effect on the ability of Depomed to consummate the Transactions, and (B) Depomed shall have performed and complied in all material respects with all of its covenants and agreements under the Agreement and the other Transaction Documents to be complied with and performed by Depomed at or before the Closing.

(iii) A certificate executed by an authorized officer of Depo NF certifying that the rights and licenses necessary to grant and delegate the rights and licenses contemplated in this Agreement (excluding the rights and licenses not applicable to Depo NF) have been granted by Depo NF to Depomed.

(iv) A certificate of the Secretary or an Assistant Secretary of Depomed enclosing a copy of (A) its articles of incorporation certified by the Secretary of State of California, (B) its bylaws and (C) if applicable, board of director resolutions authorizing

Depomed to enter into this Agreement and the other Transaction Documents and to consummate the Transactions;

(v) A bill of sale, in substantially the form attached hereto as Exhibit C (the "Bill of Sale"), dated as of the Closing Date, executed by Depomed;

(vi) A Domain Name Assignment, executed by Depomed;

(vii) A Trademark License Agreement, executed by Depomed;

(viii) The Consent Agreement, executed by Grünenthal and Depomed;

(ix) The Control Agreement, dated as of the Closing Date, executed by Depomed;

(x) The Master Letter of Credit Agreement, dated as of the Closing Date, executed by Depomed;

(xi) The Long Term Collaboration Agreement, dated as of the Closing Date, executed by Depomed;

(xii) The Collateral Agreement, dated as of the Closing Date, executed by Depomed; and

(xiii) The Transition Services Agreement, dated as of the Closing Date, executed by Depomed.

(c) At the Closing, Collegium or Newco, as applicable, shall (1) deliver to Depomed the Transferred Inventory Cost, the Upfront Payment and the Collegium Prepaid Business Expense Allocation by wire transfer of immediately available funds, in accordance with written instructions given by Depomed to Collegium not less than two (2) Business Days prior to the Closing Date, and (2) deliver, or cause to be delivered, to Depomed the following instruments and documents:

(i) A good standing certificate from the Secretary of the Commonwealth of Virginia for Collegium;

(ii) A good standing certificate from the Secretary of State of Delaware for Newco;

(iii) A certificate executed by an authorized officer of Collegium certifying that (A) the representations and warranties of Collegium and Newco contained in the Agreement are true and correct on and as of the Closing Date as though made on and as of the Closing Date (other than representations and warranties made as of a specified date, which shall

be true and correct as of the date specified), except for breaches and inaccuracies of such representations and warranties (without giving effect to any limitation as to "materiality" or "material adverse effect" set forth therein, but giving effect to any dollar threshold specified therein) that would not reasonably be expected to have a material adverse effect on the ability of Collegium to consummate the Transactions, and (B) Collegium and Newco shall have performed and complied in all material respects with all of its covenants and agreements under the Agreement and the other Transaction Documents to be complied with and performed by Collegium at or before the Closing.

(iv) A certificate of the Secretary or an Assistant Secretary of Collegium enclosing a copy of (A) its articles of incorporation certified by the Secretary of the Commonwealth of Virginia, (B) its bylaws and (C) if applicable, board of director resolutions authorizing Collegium to enter into this Agreement and the other Transaction Documents and to consummate the Transactions;

(v) A certificate of the Secretary or an Assistant Secretary of Newco enclosing a copy of (A) its certificate of formation certified by the Secretary of the State of Delaware, (B) its operating agreement, in substantially the form attached hereto as Exhibit D, and (C) if applicable, board of director resolutions and the member consent, authorizing Newco to enter into this Agreement and the other Transaction Documents and to consummate the Transactions;

(vi) The Bill of Sale, dated as of the Closing Date, executed by Newco;

(vii) The Domain Name Assignment dated as of the Closing Date, executed by Newco;

(viii) The Trademark License Agreement, dated as of the Closing Date, executed by Newco;

(ix) The Joinder Agreement, executed by Newco;

(x) The Control Agreement, dated as of the Closing Date, executed by Newco and Collegium;

(xi) The Master Letter of Credit Agreement dated as of the Closing Date, executed by Newco and the Financial Institution;

(xii) The Letter of Credit, dated as of the Closing Date, executed by Newco and the Financial Institution;

(xiii) The Long Term Collaboration Agreement, dated as of the Closing Date, executed by Collegium and Newco;

(xiv) The Collateral Agreement, dated as of the Closing Date, executed by Collegium and Newco;

(xv) The Pledge Agreement, dated as of the Closing Date, executed by Collegium and Newco;

(xvi) The Transition Services Agreement, dated as of the Closing Date, executed by Collegium;

(xvii) The Collegium Sublicense, dated as of the Closing Date, executed by Collegium and Newco;

(xviii) The Intercreditor Agreement, dated as of the Closing Date, executed by Collegium, Newco and Silicon Valley Bank; and

(xix) Executed exemption certificates identified by Depomed prior to the Closing.

ARTICLE 3
TRANSITION PLAN

Section 3.1 Transition Plan

No later than five (5) Business Days following the Effective Date, a Transition Team shall be established by the parties (the "Transition Team") and shall be comprised of six (6) members, three (3) of whom shall be appointed by Newco and Collegium and three (3) of whom shall be appointed by Depomed. The Transition Team shall discuss, and to the extent necessary and mutually agreed by the parties, meet in person, to develop and draft a Transition Plan that outlines and facilitates the processes and mechanisms for transferring the Products and the Transferred Assets from Depomed to Newco and Collegium, in accordance with this Agreement, on mutually agreeable terms and conditions consistent with the terms of this Agreement (the "Transition Plan"). The parties agree that the Transition Plan shall provide that Depomed's services provided thereunder shall be at no charge to Collegium; provided that Collegium shall reimburse Depomed for any reasonable, documented out-of-pocket costs and expenses incurred by Depomed with respect to such services. The parties agree to (a) formulate the Transition Plan as soon as reasonably practical and not later than the Closing Date and (b) use commercially reasonable efforts to perform their respective obligations as set forth in the Transition Plan within the timelines set forth therein. The Transition Plan shall provide, without limitation, for Depomed to continue supporting the Products on a limited basis dependent upon the then-current Depomed Sales Force, to be described in the Transition Plan, until January 19, 2018. The parties will discuss in good faith any changes to the Transition Plan that become required or advisable. Except as otherwise set forth in the Transition Plan, the Ancillary Agreements or elsewhere in this Agreement, each party shall be responsible for its respective costs and expenses incurred in performing the Transition Plan. In connection with developing or implementing the Transition

Plan, the parties may elect to enter into additional agreements on mutually acceptable terms as the parties deem reasonably necessary or advisable.

The parties acknowledge that implementation of the Transition Plan will require the cooperation and/or consent of Third Parties as indicated therein, and, as a result, the timing of such implementation is not within the sole control of the parties.

Section 3.2 Manufacture and Supply Arrangements

(a) Manufacture by CMO. Subject to Section 2.1(b), all Manufacturing of the Products (excluding Line Extensions and NUCYNTA® oral solution, which is not currently Commercialized in the Territory) (the "Supplied Products") (including the components, intermediates and active pharmaceutical ingredients of such Supplied Products, collectively, the "Product Materials") for Commercialization in the Territory will be performed by one or more established, generally reliable Third Party contract manufacturers of pharmaceutical products engaged by Depomed (each, a "CMO").

(b) Notice by Depomed. Depomed shall promptly inform Collegium in the event that, prior to the Closing Date, Depomed becomes aware of any matters which would reasonably be expected to have an adverse impact on the ability of the applicable CMO to supply Supplied Products for Commercialization in the Territory in a timely manner.

(c) Supply by Depomed. Depomed has obtained and will continue to use commercially reasonable efforts to obtain supply of the Supplied Products for Commercialization in the Territory pursuant to one or more CMO Supply Agreements, and from and after the Closing Date shall supply the Supplied Products in finished goods form to Collegium on a pass-through basis, under the terms and conditions applicable to the supply of the Supplied Products, as applicable, to Depomed under the applicable CMO Supply Agreements. Collegium and its Affiliates and any other Sublicensees shall purchase all of their Supplied Product requirements for Commercialization in the Territory from Depomed in accordance with the terms and conditions of the applicable CMO Supply Agreements, unless otherwise agreed to by Collegium and Depomed. Collegium and its Affiliates agree that all Supplied Products supplied hereunder will be solely for Commercialization in the Territory by or on behalf of Collegium and its Affiliates and any other Sublicensees, as permitted hereunder and in accordance with applicable Legal Requirements. Depomed shall obtain such supply for Collegium and its Affiliates and any other Sublicensees from the applicable CMO(s) and shall cooperate reasonably to extend to Collegium, its Affiliates and any other Sublicensees all of the benefits of such CMO Supply Agreements with respect to such supply, including with respect to forecasting, ordering, delivery, inspection and audit rights, warranties, specifications and (subject to Section 3.2(c)(viii) below) changes thereto, subject to Collegium's compliance with the corresponding provisions of such CMO Supply Agreements. In addition, Depomed shall use commercially reasonable efforts to pursue any rights and remedies Depomed may have under the CMO Supply Agreements for the benefit of Collegium or any of its Affiliates or any other

Sublicensees with respect to supply of the Product Materials or Supplied Products for Commercialization in the Territory, as reasonably requested by Collegium in writing in its sole discretion, provided that Collegium shall reimburse Depomed for any reasonable, documented out-of-pocket expenses incurred by Depomed with respect to pursuit of such rights and remedies. Any such written request by Collegium to Depomed must be delivered within the applicable time frame provided for Depomed to exercise such rights or remedies in the applicable CMO Supply Agreement. To the extent Depomed is permitted to do so under a CMO Supply Agreement, Depomed will delegate or assign to Collegium the right to enforce the terms of a CMO Supply Agreement against the applicable CMO to the extent such enforcement is related to any Supplied Product ordered by Collegium under such CMO Supply Agreement. In connection with such supply:

(i) Collegium shall provide Depomed with all forecasts and purchase orders for any Product Materials or Supplied Products in the form and content, and at least five (5) Business Days prior to the applicable deadline, specified in the applicable CMO Supply Agreement, which forecasts and purchase orders shall be binding upon Collegium to the extent the same are binding on Depomed as provided in the applicable CMO Supply Agreement, and Depomed shall forward the same to the applicable CMO not later than such applicable deadline.

(ii) Promptly following Collegium's receipt of its own NDC Numbers for the Products, and in any event not later than October 31, 2018, Collegium shall provide to Depomed a new label and package insert for each Product bearing Collegium's name and such NDC Numbers, in compliance with applicable Legal Requirements and in such electronic format as requested by Depomed or the applicable CMO.

(iii) The price charged by Depomed for the Manufacture and supply of each Supplied Product in finished goods form hereunder shall equal the sum of the transfer price charged for such Supplied Product by the applicable CMOs plus any shipping and packaging expenses, insurance expenses, Taxes, duties, imposts and other amounts charged specifically for such Supplied Product by the applicable CMOs pursuant to the applicable CMO Supply Agreements, plus any other Taxes, duties, imposts or similar charges or fees incurred by Depomed in connection with the Manufacture and supply of such Supplied Product.

(iv) The price charged by Depomed for the manufacture and supply of any other Product Material purchased separately hereunder, including for use in the Manufacture of any Supplied Product, such as API, shall equal the sum of the transfer price charged for such Product Material by the applicable CMOs plus any shipping and packaging expenses, insurance expenses, Taxes, duties, imposts and other amounts charged specifically for such Product Material by the applicable CMOs pursuant to the applicable CMO Supply Agreements, plus any other Taxes, duties, imposts or similar charges or fees incurred by Depomed in connection with the manufacture and supply of such Product Material.

(v) Collegium shall have financial responsibility for any other amounts due pursuant to the CMO Supply Agreements with respect to the Manufacture and supply of Supplied Products for Commercialization in the Territory, including any minimum purchase obligations, provided that any Supplied Products Manufactured and supplied for Commercialization outside the Territory pursuant to the CMO Supply Agreements will be included in the calculation of any minimum purchase obligations.

(vi) Collegium shall pay the foregoing amounts referenced in subsections (iii), (iv) and (v) of this Section 3.2(c) with five (5) Business Days following receipt of any invoice therefor from Depomed, which amounts will be paid in U.S. Dollars, by wire transfer, pursuant to the instructions of Depomed. Collegium shall also pay to Depomed any interest assessed on late payments (to the extent attributable to Collegium's failure to pay Depomed within the aforementioned time period) under the applicable CMO Supply Agreements.

(vii) Collegium shall inspect all shipments of Product Materials and Supplied Products and provide Depomed with written notice of any defects or other non-conformities at least five (5) Business Days prior to the applicable deadline specified in the applicable CMO Supply Agreement, and Depomed shall forward the same to the applicable CMO not later than such applicable deadline. Any disputes regarding any defects or other non-conformities of Product Materials or Supplied Products will be resolved in accordance with the provisions of the applicable CMO Supply Agreement.

(viii) To the extent permitted under the applicable CMO Supply Agreement, title to the Supplied Products ordered hereunder by or on behalf of Collegium shall transfer to Collegium or its designated recipient upon fulfillment of the applicable CMO's delivery obligation pursuant to the applicable CMO Supply Agreement (which delivery is directed to Collegium or its designated recipient) and at no time shall title to such Supplied Products transfer to Depomed.

(ix) If Collegium requests that modifications be made to any Supplied Product or Product Materials supplied by the applicable CMO that do not apply to such Supplied Product or Product Materials supplied for use by Depomed (or the manufacture, storage or other aspects of such Supplied Product or Product Materials), then Depomed shall cooperate reasonably with Collegium in Collegium's efforts to cause such CMO to implement such modifications for Collegium's benefit, and to supply such modified Supplied Product or Product Materials to Collegium under a separate supply agreement to be negotiated between Collegium and such CMO, provided that Collegium shall reimburse Depomed for any reasonable, documented out-of-pocket costs incurred by Depomed in providing such assistance.

(x) Depomed has provided to Collegium a complete and correct copy of each CMO Supply Agreement existing as of the Effective Date, and will provide to Collegium a complete and correct copy of any new CMO Supply Agreements entered into by Depomed and

a CMO during the Term within thirty (30) days after the execution thereof, provided all such CMO Supply Agreements will be treated as Depomed's Proprietary Information under this Agreement. Depomed shall not, and shall not permit or authorize its Affiliates to, amend, modify, terminate or cause to be terminated any CMO Supply Agreement or release or waive its rights under any CMO Supply Agreement in any manner that would reasonably be expected to be materially adverse to Collegium's rights or obligations under this Agreement without the prior written consent of Collegium, which consent shall not be unreasonably withheld, conditioned or delayed. Notwithstanding anything herein to the contrary, Depomed shall not assign any CMO Supply Agreement, other than to an Affiliate of Depomed or otherwise in connection with an assignment of this Agreement in accordance with Section 17.9, without Collegium's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed. Prior to entering into any new CMO Supply Agreement, Depomed shall provide Collegium with reasonable advance notice that such new agreement is being negotiated as well as a draft copy to Collegium and consider in good faith any reasonable comments or suggestions with respect to the provisions thereof that Collegium may provide (it being understood that Depomed is not obligated to obtain Collegium's approval of any such new CMO Supply Agreement or the provisions thereof, unless such new CMO Supply Agreement includes any terms or conditions that provide for any material increase in the price of any Supplied Products or Product Materials or that otherwise would materially affect the overall price of any Supplied Products (e.g., minimum purchase commitments), which Collegium reasonably determines would reasonably be expected to be materially adverse to its interests under this Agreement, in which case Collegium's prior written approval will be required). Depomed shall, and shall cause its Affiliates to, fulfill all of its obligations, including payment obligations, under any CMO Supply Agreement. Depomed shall promptly notify Collegium of any default under or breach of any CMO Supply Agreement by Depomed or any of its Affiliates. In the event that Depomed, or any of its Affiliates, shall fail to make any payment when due or any other default or breach arises under any CMO Supply Agreement, Collegium shall have the right (but not the obligation) to make such payment or otherwise cure such default or breach on behalf of Depomed or its Affiliate. In such event, Depomed shall promptly reimburse Collegium any such amounts paid and/or costs and expenses incurred by Collegium or, at Collegium's election, Collegium may offset such amounts paid and/or costs and expenses incurred by Collegium against any amounts payable to Depomed hereunder.

(xi) Except in the event of Material Supply Failure as set forth in Section 7.3(f), and without limiting any of Depomed's obligations under Section 3.2(c), Depomed will not be liable for any default or failure of supply of any Supplied Product or other Product Material to the extent due to a default or failure of supply of the applicable CMO.

(xii) The objective of this Section 3.2 is that Collegium be able to obtain supply of the Supplied Products produced by the applicable CMO in sufficient quantities, on such timelines, at such prices and otherwise as is reasonably necessary and customary in the pharmaceutical industry for Collegium to Commercialize the Supplied Products in the Territory in accordance with and as contemplated by this Agreement. If for any reason Collegium or

Depomed believes that the provisions of this Section 3.2 are insufficient for purposes of such supply (*e.g.*, in substance or clarity), the parties shall bring such matter to the attention of the JMC for discussion and, if requested either by Depomed or Collegium following such discussion, Depomed and Collegium shall negotiate in good faith and enter into a supplemental agreement containing such provisions as are appropriate and reasonable to fulfill such objective.

(d) Coordination. From and after the Closing Date, Collegium shall coordinate its purchase orders for the Supplied Products so as to transition to Collegium's NDC Numbers as soon as practicable after the Closing Date, and in any event not later than October 31, 2018. Depomed and Collegium will cooperate to submit Supplied Product labels bearing Collegium's NDC Numbers to the FDA as soon as practicable after the Closing Date, as contemplated by the Transition Plan.

(e) Joint Manufacturing Committee. In order to coordinate the detailed activities of Depomed and Collegium under the Transition Plan, including with regard to the Manufacturing Tech Transfer Plan, and to oversee, coordinate and manage the parties' respective rights and obligations with regard to the Manufacture and supply of all Products, Line Extensions and Product Materials hereunder, Depomed and Collegium shall form a joint manufacturing committee ("JMC") within thirty (30) days after the Closing Date. The JMC shall consist of four (4) members, with Depomed and Collegium each designating two (2) members, each of whom shall be an employee of such party (other than a party's respective Senior Executives). Each party may replace any or all of its member representatives on the JMC at any time upon written notice to the other party. Depomed and Collegium may designate a substitute employee to temporarily attend and perform the functions of such party's designee at any meeting of the JMC. The JMC shall remain in existence for as long as Depomed is responsible for supplying all Products or Line Extensions under this Agreement.

(i) Responsibilities. The JMC shall perform the following functions:

(1) Review and discuss the progress of manufacturing activities with respect to the Product Materials, Products and Line Extensions, including any significant production, quality or timing difficulties encountered or anticipated to be encountered by Depomed, Collegium or any CMO in connection therewith;

(2) Review and attempt to determine and resolve with the applicable CMO the root cause of any Material Supply Failure;

(3) Review and discuss any feedback from Collegium with regards to any production or quality issues related to the Products or Line Extensions at the CMO level, including challenges faced by Collegium in obtaining supply of the Products or Line Extensions produced by the CMOs in sufficient quantities, on such timelines, at such prices and otherwise as is reasonably necessary and customary for Collegium to Commercialize the Products and Line Extensions in the Territory;

(4) Assess the need for, and review the details of, any proposed amendments to the Manufacturing Tech Transfer Plan;

(5) Review and discuss the regulatory strategy and interactions with Regulatory Authorities, including Regulatory Communications, with respect to the Products and Line Extensions as it relates to Manufacturing activities, including the results of any inspections by any Regulatory Authority of any CMO facility;

(6) Assess the need to conduct any inspections of CMO facilities for purposes of validating and ensuring required quality and legal requirements are met by the applicable CMO;

(7) Review any changes in circumstances or market conditions which are negatively affecting or are reasonably likely to negatively affect Collegium's ability to meet the minimum purchase obligation contained in any CMO Supply Agreement; and

(8) Assess the need for establishing any alternative or back-up sources of supply of any Products, Product Materials or Line Extensions.

(ii) Meetings. The JMC shall convene in person or remotely via electronic means at least once each calendar quarter, and more frequently (A) as mutually agreed between Depomed and Collegium and (B) as required to resolve disputes or disagreements between the parties concerning matters within the JMC's purview; provided that Depomed and Collegium shall endeavor to have the first meeting of the JMC not later than thirty (30) days after its establishment.

(iii) Decisions. The JMC may make decisions with respect to any subject matter within the JMC's responsibility and functions as set forth in Section 3.2(e)(i). All such decisions shall be decided by unanimous resolution at the JMC; provided that, (A) in the event of deadlock at the JMC, such matter shall be escalated to the Senior Executives for resolution and (B) in the event that Depomed and Collegium are unable to resolve such deadlock through diligent review and deliberation by the Senior Executives within thirty (30) days from the day that the issue was first referred to them, then Depomed shall have final decision-making authority with regard to the matter subject to the deadlock.

(iv) COLLEGIUM, ON BEHALF OF ITSELF AND ITS AFFILIATES AND ANY PERMITTED SUBLICENSEES, HEREBY ACKNOWLEDGES AND AGREES THAT ITS RIGHTS AND REMEDIES WITH RESPECT TO THE SUPPLY OF PRODUCT MATERIALS AND PRODUCTS FOR COMMERCIALIZATION IN THE TERRITORY HEREUNDER SHALL BE LIMITED TO THE RIGHTS AND REMEDIES OF DEPOMED UNDER THE CMO SUPPLY AGREEMENTS, AS APPLICABLE, AND DEPOMED'S MAXIMUM LIABILITY FOR ANY REASON WHATSOEVER UNDER THIS AGREEMENT FOR SUPPLYING PRODUCT MATERIALS AND PRODUCTS FOR COMMERCIALIZATION IN THE TERRITORY TO COLLEGIUM AND ITS AFFILIATES

AND PERMITTED SUBLICENSEES, OTHER THAN AS A RESULT OF DEPOMED'S GROSSLY NEGLIGENT OR WILLFUL ACTS OR OMISSIONS IN CONNECTION WITH ANY APPLICABLE CMO SUPPLY AGREEMENTS, SHALL NOT EXCEED THE TOTAL LIABILITY OF THE CMO UNDER THE APPLICABLE CMO SUPPLY AGREEMENT.

(v) Cooperation. In the event that (A) (1) a CMO breaches its obligations pursuant to the applicable CMO Supply Agreement such that Depomed is unable to fulfill its obligations to supply the applicable Supplied Product(s) to Collegium at any time during the Term, and (2) Depomed exercises its right to terminate such CMO Supply Agreement based upon such breach or (B) Collegium requests that Depomed establish an alternative or back-up CMO to supply the Supplied Product hereunder, then Depomed will, at Collegium's cost and expense, cooperate with Collegium to identify such a CMO and, at the reasonable direction of Collegium, shall qualify and engage directly (i.e., as the contracting party) an alternative CMO to supply such Supplied Product(s) on commercially reasonable terms, in accordance with Section 3.2(c)(x) (as such section pertains to new CMO Supply Agreements). For the avoidance of doubt, the establishment of any alternative or back-up CMO pursuant to this Section 3.2(e)(v) and Collegium's purchase of any Supplied Product(s) from such CMO will not relieve Collegium of any of its obligations (including any minimum purchase obligations) under any other existing CMO Supply Agreement.

ARTICLE 4
PRODUCT COMMERCIALIZATION

Section 4.1 Diligence

During the Term, Collegium, either directly or through its Affiliates or any other Sublicensees, shall use Commercially Reasonable Efforts to Commercialize the Products in the Territory. Collegium will cause the Collegium Sales Force and Collegium employees and agents acting on Collegium's behalf to comply with this Agreement and all applicable Legal Requirements in connection with the Commercialization of the Products. It is understood, and Collegium agrees, that it will be accountable for the acts or omissions of the Collegium Sales Force and its employees and agents.

Section 4.2 Commercial Terms

Subject to the terms and conditions of this Agreement, including Section 4.1, Section 4.9, Section 6.2 and Section 9.7(b), from and after the Closing Date, Collegium shall have sole authority over and control of the Commercialization of the Products and Line Extensions in the Territory, including all matters relating to the Promotion, sale, distribution and pricing (including the negotiation of pricing with Regulatory Authorities and other Third Parties, as applicable) and other terms of sale of the Products and Line Extensions. It is understood, and Collegium agrees,

that Depomed will not provide medical science liaison (MSL) support for Collegium's Commercialization of the Products or Line Extensions in the Territory.

Section 4.3 Representations to Customers

Collegium will not make any representations to Professionals, customers or others regarding Depomed or the Products which Collegium knows are false or misleading and will not make any representations, warranties or guarantees with respect to the specifications, features or capabilities of the Products that are not consistent with the applicable then-current FDA approved labeling and package insert. Collegium agrees to undertake timely and complete corrective action for any deviations from this Section 4.3.

Section 4.4 Staffing; Training

As between the parties, Collegium shall be solely responsible for all costs and expenses of compensating its Sales Representatives. Consistent with applicable Legal Requirements, Collegium shall pay incentive compensation to its Sales Representatives with respect to the Products which are consistent with Collegium's incentive compensation plan for Collegium's other products. Collegium shall periodically provide training to each of its Sales Representatives, and shall update its training materials as appropriate.

Section 4.5 Promotional Materials; Educational Materials

(a) Collegium and its Affiliates shall, at its and their own expense, have the right to create, develop, produce or otherwise obtain, and utilize sales, promotional, advertising, marketing, educational and training materials ("Promotional Materials") to support the Promotion and sales of the Products and Line Extensions, including the right to modify and create derivative works of the Promotional Materials used by Depomed in connection with the Products prior to the Closing Date, provided that any such modified and derivative forms do not include any Depomed Names. Such Promotional Materials may include, by way of example, detailing aids; leave behind items; journal advertising; educational programs; formulary binders; appropriate reprints and reprint carriers; product monographs; patient support kits; convention exhibit materials; direct mail; market research surveys and analysis; training materials; and scripts for telemarketing and teleconferences. All Promotional Materials created and used by, or on behalf of, Collegium and its Affiliates shall be in strict compliance with all applicable Legal Requirements, including but not limited to FDA's regulations and guidelines related to prescription drug promotion.

(b) Collegium shall own all copyrights to all Promotional Materials that are created during the Term of this Agreement in connection with and to the extent relating to the Promotion of the Products or Line Extensions.

Section 4.6 Medical Inquiries

(a) The parties acknowledge that each may receive requests for medical information concerning the Product and Line Extensions from members of the medical and paramedical professions and consumers regarding the Product and Line Extensions.

(b) From and after the Closing Date, any such requests will be referred to Collegium's medical department, and, as between the parties, Collegium shall be solely responsible for responding to such requests in compliance with all applicable Legal Requirements and the Product NDAs. Collegium shall be obligated for any costs associated with its responsibilities pursuant to this Section 4.6.

Section 4.7 Trademarks

(a) Subject to this Section 4.7 and applicable Legal Requirements, Collegium shall have the right to use the Collegium Trademarks, and include the name "Collegium" or any variation thereof in connection with its Commercialization activities and any materials related thereto.

(b) During the Term, subject to the terms and conditions of this Agreement, Collegium hereby grants to Depomed a non-assignable, non-sublicensable (except to any Third Party Sales Representatives), non-exclusive, royalty-free right and license to use the Collegium Trademarks in the Territory solely in connection with Depomed's Detailing of the Products in the Territory in accordance with this Agreement in the event Depomed elects to Detail the Products as set forth in Section 4.9. Depomed recognizes that Collegium owns the entire right, title and interest in and to the Collegium Trademarks and shall not at any time, during or after the Term, do or knowingly suffer to be done any act or thing which will in any way impair the rights of Collegium in or to the Collegium Trademarks. Depomed acknowledges and agrees that it shall not acquire and shall not claim any right (except as expressly granted under this Section 4.7(b) or Section 4.9), title or interest in or to the Collegium Trademarks by virtue of the rights granted under this Agreement or through Depomed's use of the Collegium Trademarks, and the parties agree that all goodwill and improved reputation associated with the Collegium Trademarks arising out of the use thereof by Depomed shall inure to the benefit of Collegium. Depomed shall as soon as practicable notify Collegium of any apparent infringement by a Third Party of any of the Collegium Trademarks of which Depomed becomes aware. Depomed agrees to cooperate with Collegium to enable Collegium to verify that the use of the Collegium Trademarks is consistent with Collegium's quality standards.

Section 4.8 Domain Names and Website

Depomed shall cooperate with Collegium and follow Collegium's reasonable instructions in order to effect the transfer of the Transferred Domain Name registrations, the hosting provider account(s) for the Transferred Domain Names and the Transferred Websites (including any third party content contained therein which Depomed is authorized to transfer to Collegium) promptly

(and in any event within thirty (30) days) after the Closing Date. Specifically with respect to the Transferred Domain Names, Depomed agrees to prepare and transmit the necessary InterNic Registrant Name Change Agreement (RNCA) and or to correspond with InterNic to authorize transfer of the Transferred Domain Names, effective as of the Closing Date.

Section 4.9 Election by Depomed to Detail in the Territory

(a) Depomed may elect, at any time during the Term, to have the Depomed Sales Force Detail the Products directly to Professionals in the Territory who are not on any of Collegium's then-current call plans with respect to the Products.

(b) If Depomed desires to make this election and to use the Depomed Sales Force for this purpose:

(i) Depomed will inform Collegium at least six (6) months in advance of the commencement of Details by the Depomed Sales Force. During such six (6) month period, Collegium shall provide Depomed with a list of Professionals in the Territory on Collegium's then-current call plans to be Detailed by the Collegium Sales Force so as to avoid overlap with Detailing performed by the Depomed Sales Force. To that end, the parties shall review and discuss any changes made by Collegium to its call plan on an annual basis so to ensure that they continue to coordinate their respective Detailing of the Products to Professionals in the Territory.

(ii) Depomed may purchase from Collegium, at Collegium's actual out-of-pocket costs of reproduction and shipment, copies of any Promotional Materials created by Collegium for the Products that are in Collegium's possession or Control. Upon Depomed's request, Collegium will provide to Depomed electronic copies of such Promotional Materials, which Promotional Materials may be modified for use by Depomed, and Depomed may create and develop its own Promotional Materials for use by the Depomed Sales Force ("Depomed Promotional Materials"). Depomed shall provide Collegium with the requisite number of copies of the final printed form of such Depomed Promotional Materials in a timely manner so as to allow Collegium to satisfy its obligation to file such Depomed Promotional Materials with the FDA prior to the first use by the Depomed Sales Force of such Depomed Promotional Materials, if applicable, and, upon request by Depomed, Collegium shall make such filing with the FDA within five (5) Business Days of its receipt of such copies.

(iii) Depomed may purchase from Collegium, at Collegium's actual out-of-pocket costs of reproduction and shipment, copies of training materials developed and Controlled by Collegium related to the Products for use by Depomed in the training of the Depomed Sales Force. Depomed shall be responsible for training of the Depomed Sales Force, and may, at its own expense, develop training materials for the Depomed Sales Force in other media or forms.

(iv) Prior to the initiation of any Detailing of Products by Depomed, the parties shall enter into a reasonable and customary pharmacovigilance agreement on mutually acceptable terms.

(v) Depomed shall be solely responsible for the costs and expenses related to any activities of the Depomed Sales Force, including for all compensation payable to the Depomed Sales Force in connection with their Detailing of the Products, costs for Depomed Promotional Materials, and training or training materials or the purchase from Collegium of Promotional Materials for the Depomed Sales Force. Without limiting the foregoing, Depomed shall be solely responsible for all taxes, benefits, withholding, worker's compensation, unemployment insurance and similar requirements pertaining to its Depomed Sales Force, and no member of the Depomed Sales Force shall be deemed an agent or employee of Collegium or have any authority to bind or act on behalf of Collegium.

(vi) Depomed will cause the Depomed Sales Force and Depomed employees and agents acting on Depomed's behalf (a) to comply with this Agreement and all applicable Legal Requirements in connection with the Promotion of the Products and (b) not to make any representations to Professionals, customers or others regarding the Products which Depomed knows are false or misleading and will not make any representations, warranties or guarantees with respect to the specifications, features or capabilities of the Products that are not consistent with the applicable then-current FDA approved labeling and package insert. It is understood, and Depomed agrees, that it will be accountable for the acts or omissions of its employees and agents and agrees to undertake timely and complete corrective action for any deviations from this Section 4.9(b)(vi).

(c) For the avoidance of doubt, Collegium and its Affiliates shall book all sales of the Products in the Territory, including Products Detailed by the Depomed Sales Force pursuant to this Section 4.9. Collegium and its Affiliates shall also be solely responsible for entering into any contracts and other arrangements with any Person regarding the sale of Products, and for establishing and approving the form, content and terms and conditions thereof, including any discount, allowance, rebate, chargeback or other term granted therein, including with respect to all Products Detailed by the Depomed Sales Force hereunder. Further, unless otherwise expressly agreed by the parties in the Transition Plan or by Collegium, Depomed shall not, during the Term, Detail the Products directly to Professionals in the Territory who are on any of Collegium's then-current call plans with respect to the Products.

ARTICLE 5
REGULATORY AFFAIRS

Section 5.1 Authorized Agent

(a) From and after the Closing Date, Depomed shall appoint Collegium as its authorized agent during the Term for regulatory activities relating to Products in the Territory, in accordance with the terms and conditions described in this Agreement. Depomed shall

provide written notification to FDA, including any specific offices and reviewing divisions within FDA as needed, and other applicable Regulatory Authorities of the appointment of Collegium as its authorized agent within fifteen (15) days after the Closing Date. This written notification shall specify: (i) the scope of the authorized agency, (ii) the names and contact information for the responsible individuals at Collegium who shall have the authority to communicate with FDA as Depomed's authorized agent, (iii) that this authorized agency shall remain in effect until written notification modifying or terminating the authorized agency is provided to FDA or the applicable Regulatory Authority by Depomed, and (iv) any other information requested by FDA or the applicable Regulatory Authority to make effective the appointment of Collegium as Depomed's authorized agent. Collegium agrees to cooperate, as required, to make effective its appointment as Depomed's authorized agent, and to make effective the elimination of such appointment upon termination or expiration of this Agreement (to the extent that notification from Depomed is insufficient).

(b) As Depomed's authorized agent, Collegium shall not take any action with respect to Products that could reasonably be expected to have an adverse impact upon the regulatory status or potential sales of Products; provided that the foregoing shall not restrict Collegium from taking actions reasonably required to avoid or address any safety or human health problems as required by Regulatory Authorities or Legal Requirements.

Section 5.2 Regulatory Approvals

(a) Prior to the Closing Date, Depomed shall properly maintain and keep current and active all Regulatory Approvals for the Products that are in effect in the Territory as of the Effective Date, including payment of any administrative fees required by FDA or applicable Regulatory Authorities with respect to the Regulatory Approvals. Depomed shall consult with Collegium regarding any proposed supplement, amendment or alteration to the Regulatory Approvals prior to the Closing Date, provided that Depomed shall have final decision-making authority as to whether and how to supplement, amend or otherwise alter the Regulatory Approvals for the Products in the Territory prior to the Closing Date.

(b) Depomed agrees that, from and after the Closing Date, all Regulatory Approvals, in the Territory with respect to the Products shall be in the name of, and shall be owned by, Depomed, except as provided otherwise by this Agreement.

(c) From and after the Closing Date, Collegium shall properly maintain and keep current and active all Regulatory Approvals for the Products that are in effect in the Territory as of the Effective Date. From and after the Closing Date, Collegium shall promptly prepare and file with the applicable Regulatory Authorities all applications, reports and related documentation and shall pay any administrative fees in order to maintain and continue all Regulatory Approvals for the Products in the Territory, including the Prescription Drug User Fee Act (PDUFA) fees and any additional fees that FDA may require for the Regulatory Approvals for the Products in the Territory. At the time of any such submission or payment of fees,

Collegium shall provide a copy of the submission or evidence of such payment to Depomed. Upon reasonable notice to Collegium, Depomed reserves the right to review and approve any documents before submission by Collegium to the Regulatory Authority.

(d) As applicable, Depomed shall keep Collegium reasonably informed of regulatory developments relating to Products outside the Territory of which Depomed becomes aware and shall promptly notify Collegium in writing of any material action or decision by any Regulatory Authority outside the Territory with respect to Products of which Depomed becomes aware.

(e) Depomed shall not take any action inside or outside the Territory with respect to Products that would reasonably be expected to have a material adverse impact upon the regulatory status or potential sales of Products in the Territory; provided that the foregoing shall not restrict Depomed from taking actions reasonably required to avoid or address any safety or human health problems as required by Regulatory Authorities or Legal Requirements.

(f) During the Term, Collegium will have full responsibility for the development, Manufacture and Commercialization of any Line Extensions in the Territory, at Collegium's sole cost. All INDs and Regulatory Approvals related to any Line Extensions will be submitted in the name of Collegium, its Affiliates or other Sublicensees, and all such Regulatory Approvals will be owned or controlled solely by Collegium, its Affiliates or other Sublicensees, as applicable. To the extent requested in writing by Collegium, Depomed shall (i) promptly grant to Collegium or its Affiliates or Sublicensees a right of reference to all regulatory documentation related to the Products, (ii) provide copies of such regulatory documentation and underlying data, under the control of Depomed that is necessary for Collegium, any of its Affiliates or other Sublicensees, to develop, register, Manufacture or Commercialize any Line Extensions, and (iii) reasonably cooperate with Collegium to implement such technology and equipment necessary to perform such Manufacture of Line Extensions, at Collegium's expense, in accordance with a mutually agreed plan.

Section 5.3 Compliance with Regulatory Requirements

(a) Unless otherwise required by Legal Requirement or expressly required by this Agreement, prior to the Closing Date, Depomed will be responsible for complying with all regulatory requirements with respect to the Products in the Territory, including complying with and updating all Regulatory Approvals and The Extended-Release and Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy ("ER/LA Opioid Analgesics REMS"), handling complaints, reporting any Adverse Drug Experiences to the FDA, submitting Promotional Materials to the FDA, complying with pre-clinical and clinical study requirements, and communicating with applicable Regulatory Authorities; provided that Depomed shall (i) consult with Collegium prior to submitting any related documentation to the FDA or applicable Regulatory Authority, and (ii) within two Business Days after receipt of any communication from the FDA or from any other Regulatory Authority relating to the Products, forward a copy of

the same to Collegium and reasonably respond to all inquiries by Collegium relating thereto. In addition, Depomed will collaborate with Collegium to make such filings as are required for Collegium to Commercialize the Products under Collegium's NDC Numbers.

(b) Unless otherwise required by Legal Requirement or expressly required by this Agreement, from and after the Closing Date, Collegium will be responsible for complying with all regulatory requirements with respect to the Products in the Territory, including but not limited to, complying with and updating all Regulatory Approvals and the ER/LA Opioid Analgesics REMS, handling complaints, reporting any Adverse Drug Experiences to the FDA, submitting Promotional Materials to the FDA, complying with pre-clinical and clinical study requirements, and communicating with applicable Regulatory Authorities. Depomed reserves the right to consult with Collegium on these regulatory activities, and Collegium agrees to cooperate with Depomed as may be reasonably requested.

Section 5.4 Communications with Regulatory Authorities

(a) All communications with Regulatory Authorities concerning the Products prior to the Closing Date shall be the responsibility of Depomed. Depomed shall consult with Collegium regarding any such communication. Depomed shall, within two Business Days after receipt of any communication from the FDA or from any other Regulatory Authority relating to the Products, forward a copy of the same to Collegium and reasonably respond to all inquiries by Collegium relating thereto.

(b) All communications with Regulatory Authorities concerning the Products and arising from Collegium's Commercialization of the Products from and after the Closing Date shall be the responsibility of Collegium, provided that Depomed shall have the right to communicate with the FDA or any other Regulatory Authority in the Territory regarding the Products if such communication is reasonably necessary to comply with the terms of this Agreement or any Legal Requirement or is related to Commercialization activities undertaken by or on behalf of Depomed or the Depomed Sales Force.

(c) Collegium shall, within two Business Days after receipt of any communication from the FDA or from any other Regulatory Authorities relating to the Products, forward a copy of the same to Depomed and reasonably respond to all inquiries by Depomed relating thereto. Depomed shall have the right to request review and approve, with reasonable notice, any and all Regulatory Communications, Regulatory Approvals, and related regulatory documents that pertain to the Product NDAs before they are submitted to FDA or other Regulatory Authorities by Collegium or Newco. At the time of any submission to FDA or other Regulatory Authorities, Collegium shall provide a copy of the communication to Depomed.

Section 5.5 Healthcare Compliance

As of the Effective Date and continuing throughout the Term, Collegium shall maintain a robust healthcare compliance program that complies with the Department of Health and Human

Services Office of Inspector General's "OIG Compliance Program Guidance for Pharmaceutical Manufacturers," 68 Fed. Reg. 23731 (May 5, 2003), including but not limited to: (a) implementing written policies and procedures governing compliance; (b) designating a compliance officer and compliance committee that is charged with overseeing compliance across the organization; (c) conducting effective employee training and education on at least an annual basis; (d) developing effective lines of communication including maintaining an anonymous reporting hotline; (e) conducting internal monitoring and auditing of marketing, sales and medical affairs activities; (f) enforcing compliance standards through disciplinary guidelines; and (g) responding promptly to detected problems and undertaking corrective action.

Section 5.6 Advertising and Promotion Compliance

(a) In performing its duties hereunder and without limiting any of Depomed's obligations under the Long Term Collaboration Agreement, each party shall, and shall cause the Collegium Sales Force or Depomed Sales Force, as applicable, and its employees and agents to, comply with all Legal Requirements, including the FDA's regulations and guidelines concerning the advertising and promotion of prescription drug products, OPDP's promotional guidance, the PhRMA Code on Interactions with Healthcare Providers, the Prescription Drug Marketing Act of 1987, as amended, and the rules and regulations promulgated thereunder, equal employment, non-discrimination and federal and state anti-kickback Legal Requirements, and Legal Requirements with respect to submission of false claims to governmental or private health care payors, which may be applicable to the activities to be performed by such party hereunder. None of Collegium, Depomed, the Collegium Sales Force, the Depomed Sales Force or either party's employees or agents shall offer, pay, solicit or receive any remuneration to or from Professionals in order to reward or induce referrals of or purchase of the Products in violation of applicable Legal Requirements, including without limitation federal or state anti-kickback Legal Requirements. The Collegium Sales Force and the Depomed Sales Force shall have been trained in compliance with applicable Legal Requirements prior to engaging in Promotion of the Products and shall be required to complete regularly scheduled training each fiscal year on Promotion of the Products.

(b) After the Closing Date, Collegium shall bear sole responsibility for submitting any Promotional Materials to the FDA and other applicable Regulatory Authorities and complying with all Legal Requirements applicable to the Commercialization of the Products by Collegium described in Article 4.

Section 5.7 Product Complaints

(a) From and after the Closing Date, Depomed shall refer any oral or written Product Complaints which it receives concerning the Products to Collegium as soon as reasonably practicable, but not more than two Business Days, after its receipt thereof; provided that all complaints concerning suspected or actual Product tampering, contamination or mix-up shall be delivered within twenty-four (24) hours after Depomed's receipt thereof. Depomed shall

not take any other action in respect of any such complaint without the consent of Collegium unless otherwise required by Legal Requirements. If requested by Collegium, Depomed will collaborate with Collegium to resolve any Product Complaints. All Product Complaints shall be directed to the attention of Collegium's customer service provider.

(b) From and after the Closing Date, Depomed reserves the right to obtain reasonable access to Product Complaint records and to obtain summaries of the Product Complaints from Collegium in a format to be agreed upon by the parties. Collegium shall provide Depomed with: (a) copies of all written Product Complaints which Collegium receives that relate to Products; and (b) a summary of all oral Product Complaints that Collegium receives that relate to Products, in each case (clauses (a) and (b)) as soon as reasonably practicable, but not more than two Business Days, after Collegium's receipt thereof; provided that all complaints concerning suspected or actual Product tampering, contamination or mix-up that relate to Products shall be delivered within twenty-four (24) hours after Collegium's receipt thereof.

(c) From and after the Closing Date, Collegium reserves the right to obtain reasonable access to Depomed's Product Complaint records and to obtain summaries of the Product Complaints from Depomed in a format to be agreed upon by the parties. Depomed shall provide Collegium with: (i) copies of all written Product Complaints which Depomed has received or receives that relate to Products; and (ii) a summary of all oral Product Complaints that Depomed has received or receives that relate to Products, in each case (clauses (i) and (ii)) as soon as reasonably practicable, but not more than two Business Days, after its receipt thereof; provided that all complaints concerning suspected or actual Product tampering, contamination or mix-up that relate to Products shall be delivered within twenty-four (24) hours after Depomed's receipt thereof.

Section 5.8 Adverse Drug Experience Reports

(a) Each party shall notify the other: (i) of all Serious Adverse Drug Experience Reports within forty-eight (48) hours after the time such Serious Adverse Drug Experience Report becomes known to such party (including its employees); and (ii) of all Adverse Drug Experience Reports as soon as reasonably practicable, but not more than two Business Days, after the time such Adverse Drug Experience Report becomes known to such party (including its employees).

(b) Until the Closing Date, (i) responsibility for maintaining the Adverse Drug Experience Report database shall be retained by Depomed at its sole expense, and (ii) Depomed shall maintain the Adverse Drug Experience Report database in accordance with all applicable Legal Requirements. Until the Closing Date, Depomed shall (A) review the scientific literature for safety report information, (B) report Adverse Drug Experience Reports, Periodic Adverse Drug Experience Reports (PADER) and Periodic Safety Update Reports (PSUR) in accordance with International Conference on Harmonization Clinical Safety Data Management:

Periodic Safety Update Reports for Marketed Drugs (ICH E2C) and 21 C.F.R. § 314.80, and (C) conduct all follow-up investigations concerning any reports described in this subsection.

(c) From and after the Closing Date, Collegium shall use **[***]**, at its sole expense, for maintaining the Adverse Drug Experience Report database and performing the activities described in this subsection. From and after the Closing Date, Collegium shall reimburse Depomed for all fees and costs it incurs with **[***]** relating to Products. Depomed shall send an invoice to Collegium at the end of each calendar quarter that summarizes such fees and costs for such just-ended quarter, and Collegium shall pay such invoice promptly (and in any event within thirty (30) days of receipt). From and after the Closing Date, Collegium shall (i) review the scientific literature for safety report information, (ii) report Adverse Drug Experience Reports, Periodic Adverse Drug Experience Reports (PADER) and Periodic Safety Update Reports (PSUR) in accordance with International Conference on Harmonization Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (ICH E2C) and 21 C.F.R. § 314.80, and (iii) conduct all follow-up investigations concerning any reports described in this subsection.

(d) Depomed shall have the right to participate in any such investigations relating to Products upon its request. Depomed shall provide reasonable cooperation with any such follow-up investigation, including documentation, as may be requested by Collegium from time to time. Depomed reserves the right to obtain reasonable access to the Adverse Drug Experience Reports and related records that are maintained by Collegium. Likewise, Collegium shall have the right to participate in any Depomed investigations relating to Products upon its request. Collegium shall provide reasonable cooperation with any such follow-up investigation, including documentation, as may be requested by Depomed from time to time. Collegium reserves the right to obtain reasonable access to the Adverse Drug Experience Reports and related records that are maintained by Depomed.

Section 5.9 Recalls or Other Corrective Action

(a) Prior to the Closing Date, Depomed shall have final decision-making authority with respect to any recall (including recall of packaging and Promotional Materials), market withdrawals or any other corrective action as may be reasonably required related to the commercial distribution of the Products. Depomed shall promptly consult with Collegium with respect to any such actions proposed to be taken by Depomed (and in all events prior to the taking of such actions), including all actions that are reasonably likely to result in a material adverse effect on the marketability of the Products in the Territory. Prior to the Closing Date, Depomed shall be responsible for all communications with the FDA with respect to any Product recall, market withdrawal or other corrective action related to the commercial distribution of the Products; provided that (i) Depomed shall consult with Collegium prior to submitting any related documentation to the FDA and (ii) Depomed shall provide Collegium with copies of all communications received from or submitted to the FDA with respect to any such recall, market withdrawal or other corrective action within two Business Days after receipt or submission

thereof. After the Closing Date, Depomed shall promptly consult with Collegium with respect to any recall, market withdrawal or other corrective actions proposed to be taken by Depomed outside the Territory, if any, that are reasonably likely to result in a material adverse effect on the marketability of the Products in the Territory. Depomed shall provide Collegium with copies of all communications received from regulatory authorities located outside the Territory with respect to any such recall, market withdrawal or other corrective action within two (2) Business Days after Depomed's receipt; and Depomed shall provide Collegium with a copy of any related communications sent by Depomed to such regulatory authorities at the time of submission.

(b) From and after the Closing Date, Collegium shall have final decision-making authority with respect to any recall (including recall of packaging and Promotional Materials), market withdrawals or any other corrective action related to the commercial distribution of the Products, and Collegium shall be responsible for the implementation thereof; provided that Collegium shall promptly consult with Depomed with respect to any such recall or corrective actions proposed to be taken by Collegium (and in all events prior to the taking of such actions), including all actions that are reasonably likely to result in a material adverse effect on the marketability of the Products in the Territory. Collegium shall be responsible for all communications with the FDA with respect to any Product recall, market withdrawal or other corrective action related to the commercial distribution of the Products. Collegium shall provide Depomed with copies of all communications received from FDA with respect to any such recall, market withdrawal or other corrective action within two (2) Business Days after receipt; and Collegium shall provide Depomed with a copy of any related communications sent by Collegium to FDA at the time of submission.

(c) With respect to any recall, market withdrawal or corrective action with respect to Products, (i) Depomed shall be responsible for all Liabilities associated with such recall, market withdrawal or corrective action to the extent relating to Product Manufactured prior to the Closing Date, and (ii) Collegium shall be responsible for all Liabilities associated with such recall, market withdrawal or corrective action to the extent relating to Product Manufactured on or after the Closing Date for sale in the Territory. To the extent the recall, market withdrawal or corrective action relates to Product Manufactured both before and after the Closing Date, the responsibility for Liabilities associated therewith shall be equitably apportioned between the parties based on the relative amount of Product affected that was Manufactured before the Closing Date and the relative amount of Product affected that was Manufactured on or after the Closing Date.

Section 5.10 Regulatory Inspections or Audits

(a) If FDA or other Regulatory Authority desires to conduct an inspection or audit at Collegium's facility or a facility under contract with Collegium with respect to the Products, including any facility that, tests, develops, stores, or handles Products ("Collegium Regulatory Inspection"), Collegium shall permit and cooperate with such Collegium Regulatory Inspection and cause any contract facility to permit and cooperate in the Collegium Regulatory

Inspection. Upon receipt of notice or any other indication from any Regulatory Authority of such Collegium Regulatory Inspection, Collegium will promptly notify Depomed within forty-eight (48) hours after receiving such notice. Collegium will permit a representative of Depomed to be present during applicable portions of the Collegium Regulatory Inspection, upon reasonable request by Depomed. Collegium will provide timely access to Depomed of all documents and any other relevant information available about the progress of the Collegium Regulatory Inspection. Collegium will provide to Depomed copies of any inspection reports or notifications received during or after the Collegium Regulatory Inspection, including any notices of observation or other reports of the outcome of such Collegium Regulatory Inspection. Collegium will prepare a written response to any communications from Regulatory Authorities relating to the Collegium Regulatory Inspection, and will provide a copy for Depomed's review before submission to the Regulatory Authority. Collegium agrees to conform its activities under this Agreement to any commitments made in response to a Collegium Regulatory Inspection, except to the extent any such commitment violates Legal Requirements.

(b) If FDA or other Regulatory Authority desires to conduct an inspection or audit at Depomed's facility or a facility under contract with Depomed with respect to the Products, including any facility that, tests, develops, stores, or handles Products ("Depomed Regulatory Inspection"), Depomed shall permit and cooperate with such Depomed Regulatory Inspection and cause any contract facility to permit and cooperate in the Depomed Regulatory Inspection. Upon receipt of notice or any other indication from any Regulatory Authority of such Depomed Regulatory Inspection, Depomed will promptly notify Collegium within forty-eight (48) hours after receiving such notice. Depomed will permit a representative of Collegium to be present during applicable portions of the Depomed Regulatory Inspection, upon reasonable request by Collegium. Depomed will provide timely access to Collegium of all documents and any other relevant information available about the progress of the Depomed Regulatory Inspection. Depomed will provide to Collegium copies of any inspection reports or notifications received during or after the Depomed Regulatory Inspection, including any notices of observation or other reports of the outcome of such Depomed Regulatory Inspection. Depomed will prepare a written response to any communications from Regulatory Authorities relating to the Depomed Regulatory Inspection, and will provide a copy for Collegium's review before submission to the Regulatory Authority. Depomed agrees to conform its activities under this Agreement to any commitments made in response to a Depomed Regulatory Inspection, except to the extent any such commitment violates Legal Requirements.

Section 5.11 Review of Regulatory Compliance

Each fiscal quarter after Closing, Depomed and its duly authorized representatives shall have the right to review, audit, and inspect the activities conducted by Collegium and Newco under this Agreement as they pertain to compliance with Health Laws and the Regulatory Approvals. Collegium and Newco agree to provide reasonable access to any records, facilities, or personnel requested for this review. All reviews by Depomed will be conducted without any undue disruption to the business and operations of Collegium. Any Third Parties conducting

such reviews on behalf of Depomed will enter into confidentiality agreements with Collegium. Collegium will correct, or cause the correction of, any deficiencies which are discovered by any such review.

If Depomed elects not to conduct a review in a fiscal quarter, Depomed shall have the right to request written certification by Collegium and Newco that they are in compliance with all applicable Health Laws, Regulatory Approvals, and this Article 5 of this Agreement.

Section 5.12 Assistance

Each party agrees to provide to the other all reasonable assistance and take all actions reasonably requested by the other party that are necessary to enable the other party to comply with its regulatory obligations under this Agreement and with any Legal Requirement applicable to the Products and Line Extensions in the Territory.

ARTICLE 6

SALES AND PRICING

Section 6.1 Sales

Commencing as of the Closing Date, Collegium or its Affiliates shall book all sales of the Products and Line Extensions in the Territory and shall be responsible for entering into any contracts and other arrangements with any Person regarding the sale of the Products or Line Extensions, and for establishing and approving the form, content and terms and conditions thereof, including any discount, allowance, rebate, chargeback or other term granted therein; provided, however, that Collegium may not sell Products as part of a bundled product without the prior written consent of Depomed. For purposes of this Section 6.1, a "bundled product" means Product that is sold together with at least one other pharmaceutical product for a single price or discounted price, whether sold together in the same package or merely price bundled.

Section 6.2 Pricing

Commencing as of the Closing Date, except as expressly set forth in Section 6.1, Collegium will have the sole authority to determine the prices of the Products or Line Extensions sold by it and to establish its own terms and conditions of sale and pricing policies for the Products and Line Extensions in the Territory, including price increases or decreases and the timing thereof, provided that, in the event Collegium elects to terminate the Agreement pursuant to Section 9.2(b), Collegium shall not, and shall cause its Affiliates not to, increase the price of any Product by more than **[***]** per annum at any time during the twelve (12) month period following the delivery of Collegium's notice of termination and prior to the effective date of termination, unless otherwise mutually agreed in writing by the parties.

ARTICLE 7
COMPENSATION

Section 7.1 Payment for Transferred Inventory

(a) In consideration of the transfer of the Transferred Inventory pursuant to Section 2.3(a)(i), Collegium shall pay to Depomed, on the Closing Date, the Transferred Inventory Cost as set forth on the Transferred Inventory Cost Statement. Such payment shall be non-refundable, and shall not be creditable against any other amount due hereunder.

(b) No more than five (5) Business Days prior to the Closing Date, Depomed shall deliver to Collegium a statement listing the Transferred Inventory and the Transferred Inventory Cost (the "Transferred Inventory Cost Statement").

Section 7.2 Upfront Payment

In partial consideration of the rights granted to Collegium hereunder, Collegium shall pay to Depomed, on the Closing Date, an initial fee in the amount of Ten Million Dollars ($10,000,000) (the "Upfront Payment"). The Upfront Payment shall be non-refundable, and shall not be creditable against any other amount due hereunder.

Section 7.3 Payments on Annual Net Sales

(a) Annual Net Sales through 2021. From and after the Closing Date through December 31, 2021 during the Payment Term, and subject to Section 7.3(f), Collegium shall pay to Depomed amounts based upon Annual Net Sales of Payment-Bearing Products in the Territory according to the schedule set forth below:

Portion of Annual Net Sales of Payment-Bearing Products	Amount / Rate
Up to Two Hundred Thirty-Three Million Dollars ($233,000,000)	One Hundred Thirty-Five Million Dollars ($135,000,000)
Above Two Hundred Thirty-Three Million Dollars ($233,000,000) up to Two Hundred Fifty-Eight Million Dollars ($258,000,000)	25% of such portion of Annual Net Sales
Above Two Hundred Fifty-Eight Million Dollars ($258,000,000)	17.5% of such portion of Annual Net Sales

For illustration purposes only, if Annual Net Sales of Payment-Bearing Products in the Territory are $253,000,000 for a particular calendar year, then the amount owed for such period would be $135,000,000 plus 25% of $20,000,000 for a total amount owed of $140,000,000.

Payments under this Section 7.3(a) (i) with respect to Annual Net Sales of Payment-Bearing Products up to Two Hundred Thirty-Three Million Dollars ($233,000,000), shall be due and payable in equal installments of Thirty-Three Million Seven Hundred and Fifty Thousand Dollars ($33,750,000) (each, a "Minimum Quarterly Payment") within forty-five (45) days after the last day of each calendar quarter, and (ii) with respect to any portion of Annual Net Sales of Payment-Bearing Products above Two Hundred Thirty-Three Million Dollars ($233,000,000), shall be due and payable within sixty (60) days after the last day of each calendar year. Notwithstanding anything in this Agreement to the contrary, if for any reason (other than a reason directly attributable to an action or omission entirely within the control of Collegium or Newco) the Closing Date occurs after January 8, 2018 but during the first calendar quarter of 2018, then the amount of the first Minimum Quarterly Payment (and thus the obligation to pay Depomed One Hundred Thirty-Five Million Dollars ($135,000,000) with respect to calendar year 2018) will be reduced, on a pro rata basis, to account for the total number of days in the first calendar quarter after the Closing during which Collegium was entitled to sell Payment-Bearing Products. Such reduction in the first Minimum Quarterly Amount, if any, shall be applied to all other provisions in this Agreement applicable to the first Minimum Quarterly Payment, including for purposes of determining whether there was any Quarterly Shortfall with respect to such calendar quarter pursuant to Section 7.7(a)(i). If the Closing Date occurs at any time after the last day of the first calendar quarter of 2018, then the parties will work in good faith to determine the appropriate adjustment, if any, to one or more of the Minimum Quarterly Payments to account for the reduced number of days in such calendar year during which Collegium is entitled to sell Payment-Bearing Products.

(b) Annual Net Sales after 2021. From and after January 1, 2022 during the Payment Term, Collegium shall pay to Depomed amounts based upon Annual Net Sales of Payment-Bearing Products in the Territory according to the schedule set forth below:

Portion of Annual Net Sales of Payment-Bearing Products	Rate
Up to Two Hundred Thirty-Three Million Dollars ($233,000,000)	58% of such portion of Annual Net Sales
Above Two Hundred Thirty-Three Million Dollars ($233,000,000) up to Two Hundred Fifty-Eight Million Dollars ($258,000,000)	25% of such portion of Annual Net Sales
Above Two Hundred Fifty-Eight Million Dollars ($258,000,000)	17.5% of such portion of Annual Net Sales

For illustration purposes only, if Annual Net Sales of Payment-Bearing Products are $358,000,000 for a particular calendar year, then the amount owed for such period would be 58%

of $233,000,000 plus 25% of $25,000,000 plus 17.5% of $100,000,000 for a total amount owed of $158,890,000.

Payments under this Section 7.3(b) (i) with respect to Annual Net Sales of Payment-Bearing Products up to Two Hundred Thirty-Three Million Dollars ($233,000,000), shall be due and payable within forty-five (45) days after the last day of each calendar quarter, and (ii) with respect to any portion of Annual Net Sales of Payment-Bearing Products above Two Hundred Thirty-Three Million Dollars ($233,000,000), shall be due and payable within sixty (60) days after the last day of each calendar year.

(c) Payment Term. Collegium's payment obligations under Section 7.3(a) and Section 7.3(b) shall commence on the Closing Date and remain in effect (with respect to each such Product and Line Extension in the following clauses (i) and (ii), as applicable, the "Payment Term"):

(i) with respect to each Product, for so long as Collegium or any of its Affiliates or other Sublicensees continues to sell the applicable Product in the Territory; provided, however, that following the occurrence of Generic Entry with respect to any Product (an "Expired Product"), the Annual Net Sales tiers in Section 7.3(a) and Section 7.3(b), as applicable, will thereafter be automatically adjusted downward on a percentage basis equal to ninety percent (90%) of the percentage of the prior calendar year's Annual Net Sales of all Payment-Bearing Products represented solely by such Product that became an Expired Product and the adjusted Annual Net Sales tiers will be applied, on a prospective basis, to calculate the royalties payable by Collegium to Depomed on the sales of Payment-Bearing Products occurring thereafter; provided further, that such adjustment shall occur only once, upon the occurrence of the first Expired Product, and shall not occur again thereafter upon the occurrence of other Expired Products. For example, with respect to Expired Products, if the Net Sales associated with any Expired Product were sixty percent (60%) of the Annual Net Sales of all Payment-Bearing Products during the prior calendar year, then the Annual Net Sales tiers in Section 7.3(a) and Section 7.3(b), as applicable, would each be reduced by fifty-four percent (54%, *i.e.*, 60% x 90%) (*i.e.*, the first tier would be up to $107,180,000, the second tier would be between $107,180,000 and $118,680,000, and the third tier would be above $118,680,000); and

(ii) with respect to each Line Extension, for so long as Collegium or any of its Affiliates or Sublicensees continues to sell the applicable Line Extension in the Territory until the expiration of the last Orange Book-Listed Patent associated with such Line Extension.

(d) Payments after Payment Term for Line Extensions. From and after the earlier of the termination of this Agreement or the expiration of the Payment Term with respect to Line Extensions, (i) Collegium shall pay to Depomed nine percent (9%) of Annual Net Sales of Line Extensions throughout the Territory, due and payable within forty-five (45) days after the last day of each calendar quarter, and (ii) the Net Sales of Line Extensions shall be excluded

from the calculation of Annual Net Sales for purposes of payments due pursuant to Section 7.3(a) and Section 7.3(b) with respect to Products and Authorized Generics.

(e) Grünenthal Obligations.

(i) Collegium, on behalf of Depomed, shall calculate, report directly to Grünenthal and, subject to Section 7.3(e)(ii) and Section 7.3(e)(iii), pay directly to Grünenthal all royalties (including minimum royalties, if applicable) due from Depomed pursuant to the Grünenthal License Agreement (but not, for clarity, any royalties or other payments due pursuant to the Consent Agreement, other than for "New Products" (as defined in the Consent Agreement) as set forth in Section 7.3(e)(iv)) with respect to the sale by Collegium and its Affiliates and any other Sublicensees of Payment-Bearing Products in the Territory, in each case in accordance and consistent with the terms and conditions of the Grünenthal License Agreement. Collegium shall provide Depomed with a copy of all such reports concurrently with the delivery thereof to Grünenthal. All such reports provided to Depomed by Collegium will be treated as Collegium's Proprietary Information under this Agreement, provided that Depomed may disclose such reports to Grünenthal (subject to the confidentiality provisions of the Grünenthal License Agreement). Further, the sublicenses granted to Newco in Section 2.1(a)(iii) and Section 2.1(a)(iv) shall be subject to the applicable terms and conditions of the Grünenthal License Agreement, which are hereby deemed to be incorporated into this Agreement, and if the practice of such sublicenses by Newco and its Sublicensees directly results in any payment obligations to Grünenthal pursuant to Sections 4.6(b), 6.1(f), 7.10, 7.13, 11.5(b) (with regard to the OMP Territory and the EU (as such terms are defined in the Grünenthal License Agreement), subject to Depomed's obligations to pay for Retained Post-Marketing Commitments as set forth in Section 14.7 below), 11.12 and 12.2 of the Grünenthal License Agreement, Depomed shall pass through such payment obligations to Collegium and Collegium, on behalf of Depomed, shall make the applicable payment(s) directly to Grünenthal and concurrently provide Depomed with evidence thereof.

(ii) From and after the Closing Date through December 31, 2021 during the Payment Term, Collegium shall pay to Grünenthal and/or Depomed, as applicable, amounts based upon annual "Net Sales" of "Products" (each, as defined the Grünenthal License Agreement), but excluding "New Products" (as defined in the Consent Agreement), in the Territory that would otherwise be payable solely to Grünenthal pursuant to Section 7.3(e)(i) according to the schedule set forth below:

Portion of annual "Net Sales" of "Products"	Rate Payable to Grünenthal	Rate Payable to Depomed
Up to Two Hundred Forty-Three Million Dollars ($243,000,000)	**[***]**	**[***]**

Above Two Hundred Forty-Three Million Dollars ($243,000,000) and up to Two Hundred Fifty-Eight Million Dollars ($258,000,000)	**[***]**	**[***]**
Above Two Hundred Fifty-Eight Million Dollars ($258,000,000) and less than Three Hundred Million Dollars ($300,000,000)	**[***]**	**[***]**
Equal to or greater than Three Hundred Million Dollars ($300,000,000) and less than Six Hundred Million Dollars ($600,000,000)	**[***]**	**[***]**
Equal to or greater than Six Hundred Million Dollars ($600,000,000)	**[***]**	**[***]**

For illustration purposes only, if annual "Net Sales" of "Products" are $358,000,000 for a particular calendar year, then the amount owed for such period pursuant to this Section 7.3(e)(ii) (A) to Grünenthal would be **[***]** of $243,000,000 plus **[***]** of $15,000,000 plus **[***]** of $100,000,000 for a total amount owed of **[***]**, and (B) to Depomed would be **[***]** of $243,000,000 plus **[***]** of $15,000,000 plus **[***]** of $42,000,000 plus **[***]** of $58,000,000 for a total amount owed of **[***]**.

(iii) From and after January 1, 2022 during the Payment Term, Collegium shall pay to Grünenthal and/or Depomed, as applicable, amounts based upon annual "Net Sales" of "Products" but, excluding "New Products" as defined in the Consent Agreement, in the Territory that would otherwise be payable solely to Grünenthal pursuant to Section 7.3(e)(i) according to the schedule set forth below:

Portion of annual "Net Sales" of "Products"	Rate Payable to Grünenthal	Rate Payable to Depomed
Up to Two Hundred Thirty-Three Million Dollars ($233,000,000)	**[***]**	**[***]**
Above Two Hundred Thirty-Three Million Dollars ($233,000,000) and up to Two Hundred Fifty-Eight Million Dollars ($258,000,000)	**[***]**	**[***]**
Above Two Hundred Fifty-Eight Million Dollars ($258,000,000) and less than Three Hundred Million Dollars ($300,000,000)	**[***]**	**[***]**

Equal to or greater than Three Hundred Million Dollars ($300,000,000) and less than Six Hundred Million Dollars ($600,000,000)	**[***]**	**[***]**
Equal to or greater than Six Hundred Million Dollars ($600,000,000)	**[***]**	**[***]**

For illustration purposes only, if annual "Net Sales" of "Products" are $358,000,000 for a particular calendar year, then the amount owed for such period pursuant to this Section 7.3(e)(iii) (A) to Grünenthal would be **[***]** of $233,000,000 plus **[***]** of $25,000,000 plus **[***]** of $100,000,000 for a total amount owed of **[***]**, and (B) to Depomed would be **[***]** of $233,000,000 plus **[***]** of $25,000,000 plus **[***]** of $42,000,000 plus **[***]** of $58,000,000 for a total amount owed of **[***]**.

(iv) From and after the expiration of the Payment Term with respect to Line Extensions which are "New Products" as defined in the Consent Agreement, Collegium shall pay to Grünenthal **[***]** of annual "Net Sales" of such "New Products" throughout the Territory, due and payable in accordance with Section 7.3(e)(i).

(v) Depomed shall cooperate reasonably to extend to Collegium, its Affiliates and any other Sublicensees all of the benefits of the terms and conditions of the Grünenthal License Agreement applicable to Collegium's obligations under this Section 7.3(e), subject to Collegium's compliance with this Section 7.3(e). In addition, Depomed shall use commercially reasonable efforts to pursue any rights and remedies Depomed may have under the Grünenthal License Agreement for the benefit of Collegium or any of its Affiliates or any other Sublicensees with respect to their practice of sublicenses under the Grünenthal License Agreement in the Territory, solely as requested by Collegium in writing, provided that Collegium shall reimburse Depomed for any reasonable, documented out-of-pocket expenses (including legal expenses) incurred by Depomed with respect to its pursuit of such rights and remedies. In addition, notwithstanding anything in Section 7.3(e)(ii) or Section 7.3(e)(iii) to the contrary, in the event any royalty rate reduction under Section 6.9 (Cost of Goods Sold Cap in OMP Territory) in the Grünenthal License Agreement would apply with respect to the sale of Payment-Bearing Products (except "New Products" as defined in the Consent Agreement) in the Territory, Collegium shall be entitled to apply such royalty rate reduction to the royalty rates owed to Depomed pursuant to Section 7.3(e)(ii) or Section 7.3(e)(iii). In the event such royalty rate reduction exceeds the royalty rate owed to Depomed pursuant to Section 7.3(e)(ii) or Section 7.3(e)(iii), then Depomed shall reimburse Collegium within sixty (60) days after the end of each calendar year for the portion of the amount paid by Collegium to Grünenthal during such calendar year that is equivalent to the amount Collegium would have been entitled to withhold from Depomed pursuant to the foregoing sentence. Except for (A) Collegium's payment obligations to Grünenthal, (B) Collegium's indemnification obligations under clause (vii) of Section 12.2(a), and (C) Depomed's activities in pursuing rights and remedies under the Grünenthal License Agreement for the benefit of Collegium upon Collegium's written request, in

the case of (A) and (C), as set forth in this Section 7.3(e), Collegium shall not be liable to Grünenthal or to Depomed or any of its Affiliates for any costs, Liabilities or expenses associated with Depomed's acts or omissions under or in connection with the Grünenthal License Agreement.

(vi) Depomed shall, and shall cause its Affiliates to, fulfill all of its and their respective obligations, including payment obligations, under the Grünenthal License Agreement and Consent Agreement. Depomed shall not, and shall cause its Affiliates not to, amend or waive, or take any action or omit to take any action that would alter, any of its rights under the Grünenthal License Agreement or Consent Agreement in any manner that adversely affects, or would reasonably be expected to adversely affect, Collegium's rights and benefits under this Agreement. Depomed shall promptly notify Collegium of any default or breach under the Grünenthal License Agreement or Consent Agreement. In the event that Depomed, or any of its Affiliates, shall fail to make any payment when due or any other default or breach arises under the Grünenthal License Agreement or Consent Agreement, Collegium shall have the right (but not the obligation) to make such payment or otherwise cure such default or breach on behalf of Depomed or its Affiliate. In such event, Depomed shall promptly reimburse Collegium any such amounts paid and/or costs and expenses incurred by Collegium or, at Collegium's election, Collegium may offset such amounts paid and/or costs and expenses incurred by Collegium against any amounts payable to Depomed hereunder. Notwithstanding anything herein to the contrary, Depomed shall not assign the Grünenthal License Agreement, other than in connection with a permitted assignment by Depomed of this Agreement under Section 17.9, without Collegium's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed. In addition, Depomed shall not consent to an assignment of the Grünenthal License Agreement without Collegium's consent, which consent shall not be unreasonably withheld, conditioned, or delayed (provided that Collegium shall not withhold its consent in a manner that would cause Depomed to breach any of Depomed's obligations under the Grünenthal License Agreement).

(f) Material Supply Failure. Notwithstanding anything to the contrary in this Agreement, in the event of a Material Supply Failure occurring after the Closing and not later than December 31, 2018, Collegium shall promptly (and in any event within fifteen (15) Business Days after the occurrence thereof) provide Depomed with written notice thereof (a "Material Supply Failure Notice") and indicate in such notice whether Collegium elects to exercise the option to modify its rights and obligations under this Agreement such that:

(i) (A) the payment obligations under Section 7.3(a) solely with respect to Annual Net Sales of Payment-Bearing Products during the period from January 1, 2018 through December 31, 2018 (including the obligation to pay Minimum Quarterly Payments with respect to such period) shall no longer apply, and (B) Collegium shall instead be subject to the payment obligations under Section 7.3(b) with respect to such period;

(ii) if, after payment of all amounts due under Section 7.3(b) by Collegium to Depomed with respect to Annual Net Sales of Payment-Bearing Products during the period from January 1, 2018 through December 31, 2018, the amount of Annual Net Sales with respect to such period retained by Collegium (*i.e.*, Annual Net Sales less any payments to Depomed pursuant to Section 7.3(a) or Section 7.3(e), any payments to Grünenthal pursuant to the Grünenthal License Agreement, and COGS) is less than Forty Million Dollars ($40,000,000), then Collegium shall provide Depomed with written notice thereof not later than forty-five (45) days after the end of such period, including reasonable supporting documentation, and Depomed shall pay to Collegium the difference between Forty Million Dollars ($40,000,000) and such amount actually retained by Collegium, within thirty (30) days after receipt of an invoice therefor; and

(iii) Collegium's right to give notice of termination of this Agreement pursuant to Section 9.2(b) shall not become effective until the second (2nd) anniversary of the Closing Date, such that any such termination of this Agreement pursuant to Section 9.2(b) shall not become effective until on or after the third (3rd) anniversary of the Closing Date after taking into account the one (1) year notice period set forth in Section 9.2(b).

In the event of a Material Supply Failure, if Collegium does not provide a Material Supply Failure Notice by the deadline set forth above or does not affirmatively elect to exercise the foregoing option in conjunction with timely delivery of a Material Supply Failure Notice, then Collegium's rights and obligations under this Agreement shall remain in full force and effect without modification, and without limitation of any other rights or remedies available to Collegium. Without limiting the foregoing, neither party will take any action or omit to take any action under this Agreement which it knows or reasonably should know is likely to result in a Material Supply Failure.

(g) Reports. Payments due to Depomed pursuant to this Section 7.3 shall be made via the sweep account mechanism set forth in Section 7.7(b)(i). Within forty-five (45) days after the last day of each calendar quarter, Collegium shall deliver a report in a mutually agreed form specifying: (A) the total gross invoiced amount from sales of Payment-Bearing Products by Collegium and its Affiliates; (B) the amounts deducted by category from gross invoiced amounts to calculate Net Sales; (C) Annual Net Sales (to date, as applicable) for the applicable calendar year; (D) amounts payable under this Section 7.3; and (E) any refund amounts due under Section 7.7(b). Within twenty-five (25) days after the last day of each month, Collegium shall provide a good faith estimate of Net Sales for the prior month. Within twenty-five (25) days after the last day of each calendar quarter, Collegium shall provide a good faith estimate of Net Sales for the prior quarter and estimated payments of all amounts due under this Section 7.3 for the prior quarter.

Section 7.4 Maintenance of Records

(a) Newco and Collegium agree, and Collegium shall cause Newco, to keep, for a period of at least three (3) years after the date of entry (or such longer period as may be required by Legal Requirements) full and accurate records maintained in accordance with GAAP in sufficient detail to enable a Third Party to accurately calculate all payments, reports and similar obligations of Collegium under this Agreement, including all payments, reports and similar obligations of Collegium with respect to the Grünenthal License Agreement pursuant to Section 7.3(e). Upon thirty (30) days prior written notice, such records shall be made available by Collegium for audit by an independent certified public accounting firm designated by Depomed and reasonably acceptable to Collegium. The auditor shall be required to enter into a non-disclosure agreement with Collegium prior to commencing its auditing activities. The auditor shall disclose to Depomed and Collegium only a summary of the audit results. The auditor will only examine such books and records during business hours but not more than once each calendar year while this Agreement remains in effect and for three (3) years thereafter. The fees and expenses of the auditor performing such verification examination shall be borne by Depomed; provided, however, that if any verification reveals that Collegium has reported incorrectly, and the amount of such discrepancy is at least five percent (5%) of the aggregate amount that should have been reported for the period examined, then Collegium shall pay the entire amount of the fees and expenses for such verification.

(b) Whenever in this Agreement a party is required to report its costs, or is entitled to receive or obligated to make a payment based on its costs, such costs (including COGS) shall be determined in accordance with GAAP, consistent with the terms of this Agreement. The term "out-of-pocket" costs or expenses means cost or expenses paid to Third Parties and shall not include any fixed costs or expenses, personnel costs or expenses, overhead costs or expenses, or other costs or expenses of a similar nature.

Section 7.5 Allocation of Prepaid Business Expenses

The Prepaid Business Expenses shall be prorated on a *per diem* basis such that Depomed shall have financial responsibility for the portion of the applicable billing period prior to the Closing Date and Collegium shall have financial responsibility for the portion of the applicable billing period after the Closing Date (the "Collegium Prepaid Business Expense Allocation"). Collegium shall pay to Depomed, on the Closing Date, the Collegium Prepaid Business Expense Allocation. Such payment shall be non-refundable, and shall not be creditable against any other amount due hereunder.

Section 7.6 Payments

Any payments required to be made by either party under this Agreement shall be made in United States Dollars via wire transfer of immediately available funds to such bank account as the other party shall designate in writing prior to the date of such payment. All payments shall bear interest from the date due until paid at a rate equal to the lesser of: (a) the prime rate

effective for the date that payment was due (as quoted by the Wall Street Journal, Internet Edition) plus eight percent (8%) or (b) the maximum rate permitted by applicable Legal Requirements.

Section 7.7 Security

(a) Letter of Credit.

(i) As of the Closing Date, Newco shall, and Collegium shall cause Newco to, deliver to Depomed an irrevocable standby letter of credit from a nationally recognized financial institution (the "Financial Institution"), in form and substance reasonably acceptable to Depomed, in favor of Depomed (the "Letter of Credit") in an aggregate amount of Thirty-Three Million Seven Hundred Fifty Thousand Dollars ($33,750,000) (the "Maximum Stated Value"), to be issued pursuant to a master agreement in form and substance reasonably acceptable to Depomed (the "Master Letter of Credit Agreement", and together with the Letter of Credit, the "Letter of Credit Documents"). Depomed shall have the right to draw upon the Letter of Credit, up to the Maximum Stated Value, in the event that there is a shortfall in the Minimum Quarterly Payment made to Depomed by Collegium pursuant to Section 7.3(a) hereof, solely to the extent of such quarterly shortfall as determined in good faith by Depomed (a "Quarterly Shortfall"), provided that Collegium does not pay the amount of such Quarterly Shortfall to Depomed within forty-five (45) days after the last day of such calendar quarter.

(ii) At any time prior to the Expiration Date (as defined below), Depomed may provide a written notice to the Financial Institution and Newco asserting a Quarterly Shortfall (the "Claim Notice"). The Claim Notice shall state the amount of such Quarterly Shortfall (the "Claim Amount"). Following its receipt of a Claim Notice, the Financial Institution shall permit Depomed to draw upon the Letter of Credit in the amount of the Claim Amount and shall deliver the applicable funds under the Letter of Credit in accordance with the Claim Notice.

(iii) Newco shall, and Collegium shall cause Newco to, maintain the Letter of Credit in effect until the earliest of (A) 5:00 p.m. eastern time on the day that is sixty-one (61) days after the fourth anniversary of the Closing Date, (B) the date on which the Financial Institution honors a drawdown on the Letter of Credit which exhausts the Maximum Stated Amount and (C) the termination of this Agreement by either party ((A), (B) or (C), the "Expiration Date"). For clarity, if there is any drawdown on the Letter of Credit pursuant to this Section 7.7(a)(iii), Newco shall not be obligated, and Collegium shall not be obligated to cause Newco to, reissue the Letter of Credit at the full Maximum Stated Value or at any value. Further, if there is any drawdown on the Letter of Credit pursuant to this Section 7.7(a)(iii), Newco shall not be obligated, and Collegium shall not be obligated to cause Newco, to maintain the Letter of Credit in an aggregate amount of the Maximum Stated Value for the term of this Agreement.

(b) Accounts

(i) Depomed and Newco shall, and Collegium shall cause Newco to, establish and maintain with a Financial Institution reasonably satisfactory to Depomed, in the name of Depomed and Newco a sales account (the "Sales Account"). Such account and any amounts deposited therein shall be pledged in favor of Depomed to secure the payment obligations of Newco and Collegium owed to Depomed pursuant to Section 7.3, and shall be subject to a first priority Lien and "control" (as defined in the applicable Uniform Commercial Code) pursuant to a deposit account control agreement or securities account control agreement in form and substance reasonably acceptable to Depomed (the "Control Agreement"). The Control Agreement shall be entered into by Depomed, Newco and the applicable Financial Institution as of the Closing Date.

(ii) Newco shall, and Collegium shall cause Newco to, cause all amounts from gross sales of the Payment-Bearing Products to be deposited directly into the Sales Account (including, requiring all Customers of the Payment-Bearing Products to remit all payments owed to Collegium or any of its Affiliates or any other Sublicensees directly into the Sales Account) and, on a daily basis, thirty-five percent (35%) of such day's deposits (the "Newco Deposits") shall be swept into an account designated by Depomed until the Minimum Quarterly Payment obligation is satisfied for each calendar quarter, and sixty-five percent (65%) shall be swept into an account designated by Newco. Once the Minimum Quarterly Payment obligation is satisfied for a given calendar quarter, then one hundred percent (100%) of the Newco Deposits shall be swept into an account designated by Newco. The sweep mechanism shall not be subject to change and shall be the only mechanism for disbursing funds from the Sales Account, unless in a writing signed by both Depomed and Newco; provided that upon an "Event of Default" (as defined in the Collateral Agreement), Depomed may exercise all remedies granted under the Collateral Agreement. Based on Newco's reports provided to Depomed calculating amounts payable under Section 7.3, Depomed shall refund to Newco any amounts overpaid to Newco from the Newco Deposits within ten (10) Business Days of receiving such reports.

(iii) Newco shall, and Collegium shall cause Newco to, pay all fees, expenses and charges of the Financial Institution at which the Sales Account is maintained. Neither Newco nor Collegium shall have any right to terminate the Financial Institution at which the Sales Account is maintained without Depomed's prior written consent. Any such consent, which Depomed may grant or withhold in its sole and absolute discretion, shall be subject to the satisfaction of each of the following conditions to the satisfaction of Depomed: (A) the successor Financial Institution shall be acceptable to Depomed; (B) Depomed shall have received evidence that all of the applicable parties making payments in respect of sales of the Payment-Bearing Product have been instructed to remit all future payments in respect of sales of the Payment-Bearing Product to the new accounts held at the successor Financial Institution; and (C) Depomed shall have received evidence to its satisfaction necessary to secure Depomed's security interest in the Sales Account, including the execution and delivery of the Control Agreement in favor of Depomed in form and substance satisfactory to Depomed.

Section 7.8 Other Fees

From and after the Closing Date, and without limiting Collegium's obligations under Section 5.2(c), Collegium shall reimburse Depomed for all fees and costs that Depomed incurs with respect to Third Parties (including Governmental Authorities) based upon its ownership and maintenance of the Regulatory Approvals for the Products, including branded prescription drug fees payable to the Internal Revenue Service and fees related to the ER/LA Opioid Analgesics REMS. Depomed shall send an invoice to Collegium at the end of each calendar quarter that summarizes such fees and costs for such quarter, and Collegium shall pay such invoice promptly (and in any event within thirty (30) days of receipt).

ARTICLE 8
TRANSITION MATTERS

Section 8.1 Customer Notifications

Within ten (10) days after the Closing Date, Depomed shall notify all of its Customers in the Territory that future orders for the Products in the Territory on or after the Closing Date shall be placed with Collegium. Depomed shall forward to Collegium any orders for the purchase of Products in the Territory by Customers that are unfulfilled as of the Closing Date within five (5) days after the Closing Date. Depomed shall refer to Collegium any orders for Products that it receives in the Territory that it receives any time after the Closing Date which provide for delivery after the Closing Date. From and after the Closing Date and subject to Depomed's manufacture of such Product, Collegium shall be responsible for supplying Products in fulfillment of such orders.

Section 8.2 NDC Numbers

Following the Closing, and in any event not later than October 31, 2018, Collegium shall obtain its own NDC Numbers for the Products and shall use commercially reasonable efforts to have in place as soon as reasonably practicable all authorizations from Governmental Authorities necessary for Collegium to use such NDC Numbers for the Products. Thereafter, Collegium shall use its new NDC Numbers on all invoices, orders and other communications with customers and Governmental Authorities.

Section 8.3 Product Returns, Rebates and Chargebacks

(a) Product Returns.

(i) Depomed shall be financially responsible for all returns of Product that are labeled with Depomed's lot numbers for lots sold prior to the Closing Date, provided, however, that Collegium shall be financially responsible for any incremental return credit amounts resulting from any price increases implemented by Collegium after the Closing Date for such lots.

(ii) Collegium shall be financially responsible for all returns of Product that are labeled with Collegium's lot numbers or Depomed's lot numbers for lots sold on or after the Closing Date.

(iii) Collegium and Depomed shall each be financially responsible for returns of the Transition Lots, on a proportional basis equal to the proportion of Product in such Transition Lots sold prior to and on or after the Closing Date, provided, however, that Collegium shall be financially responsible for any incremental return credit amounts resulting from any price increases implemented by Collegium after the Closing Date for such lots.

(b) Commercial Rebates.

(i) Depomed shall be responsible for (A) all commercial rebates with respect to Products ("Commercial Rebates") dispensed to patients prior to the Closing Date and (B) all Commercial Rebates with respect to Products dispensed to patients through the Depomed Responsibility Period, provided, however, that Collegium shall be financially responsible for any incremental rebate amounts resulting from any price increases implemented by Collegium after the Closing Date for such lots.

(ii) Collegium shall be responsible for all Commercial Rebates with respect to Products dispensed to patients after the Depomed Responsibility Period.

(c) Government Rebates.

(i) Depomed shall be responsible for (A) all government rebates with respect to Products ("Government Rebates") dispensed to patients prior to the Closing Date and (B) all Government Rebates with respect to Products dispensed to patients through the Depomed Responsibility Period, provided, however, that Collegium shall be financially responsible for any incremental rebate amounts resulting from any price increases implemented by Collegium after the Closing Date.

(ii) Collegium shall be responsible for all Government Rebates with respect to Products dispensed to patients after the Depomed Responsibility Period.

(d) GPO and Government Chargeback Claims.

(i) Depomed shall be financially and legally responsible for all group purchase organization ("GPO") and government chargeback claims ("Chargeback Claims") related to Products sold by the wholesaler or distributor prior to the Closing Date and through the Depomed Responsibility Period, provided, however, that Collegium shall be financially responsible for any incremental chargeback amounts resulting from any price increases implemented by Collegium after the Closing Date.

(ii) Collegium shall process and be financially and legally responsible for all Chargeback Claims related to Products sold by the wholesaler or distributor after the Depomed Responsibility Period.

(e) Co-Pay Card Program. Responsibility for co-pay card discounts with respect to Products ("Co-Pay Card Discounts") shall be allocated between Depomed and Collegium as follows:

(i) Depomed shall be responsible for (1) all Co-Pay Card Discounts with respect to Products dispensed to patients prior to the Closing Date and (2) all Co-Pay Card Discounts with respect to Products dispensed to patients through the Depomed Responsibility Period, provided, however, that Collegium shall be financially responsible for any incremental discount amounts resulting from any price increases implemented by Collegium after the Closing Date.

(ii) Collegium shall be responsible for all Co-Pay Card Discounts with respect to Products dispensed to patients beginning after the Depomed Responsibility Period.

(f) Limitation of Liability. Notwithstanding the foregoing, Collegium agrees that (i) Depomed's financial liability for GPO Commercial Rebates and Co-Pay Card Discounts shall be limited to those commercial customers with which the Business has a rebate obligation as of the Closing Date, and (ii) any payments by Depomed with respect to sales after the Closing Date shall be made in accordance with Depomed's rebate obligations on the Closing Date with respect to each commercial customer and shall be solely based on the terms and conditions of Depomed's agreements with the respective customer, as such terms and conditions existed as of the Closing Date.

(g) Long Term Collaboration Agreement. For the avoidance of doubt, the provisions of this Section 8.3 shall not apply to any matters addressed in the Long Term Collaboration Agreement.

(h) Commercial Agreements. After the Closing, Depomed shall use commercially reasonable efforts to maintain in full force and effect all commercial agreements relating to the Products (including GPO and Medicare part D) (each such commercial agreement, a "Commercial Agreement") through April 30, 2019; provided, however, that if Collegium enters into a commercial agreement relating to the Products with the counterparty or counterparties to a Commercial Agreement, Depomed shall be permitted to immediately terminate any such Commercial Agreement.

Section 8.4 Collegium Use of Depomed Names

(a) During the period commencing on the Closing Date and ending upon Collegium's receipt of its own NDC Numbers for the Products in accordance with Section 8.2 (the "Limited License Period"), Depomed grants, and shall cause its Affiliates to grant, to

Collegium and its Affiliates a limited, non-exclusive, royalty-free right and license to use the Depomed Names, and the UPCs and, subject to Section 8.2, the NDC Numbers for each of the Products, in each case solely for the purpose of utilizing the labels, packaging, and Promotional Materials for the Products as they exist on the Closing Date.

(b) Promptly upon the expiration of the Limited License Period, Collegium shall, and shall cause its Affiliates to, destroy and dispose of all labels and packaging, and all Promotional Materials, in each case in its possession or subject to its control, bearing any Depomed Names; provided, however, that the expiration of the Limited License Period shall not restrict Collegium and its Affiliates from selling the Transferred Inventory or any finished goods inventory of Product acquired by Collegium pursuant to an order that was outstanding as of the Closing Date. For clarity, the expiration of the Limited License Period shall not restrict Collegium or its Affiliates from exercising any of the rights granted to them with respect to the Promotional Materials under Section 4.5.

(c) In no event shall Collegium or any of its Affiliates (i) use any Depomed Names in any manner or for any purpose different from the use of such Depomed Names by Depomed and its Affiliates immediately prior to the Closing Date to market, distribute and sell the Products or (ii) manufacture or produce, or cause or authorize any Third Party to manufacture or produce, any new labels, packaging or advertising, marketing, sales and promotional materials using or otherwise incorporating any Depomed Names in any manner.

(d) Collegium shall use commercially reasonable efforts to ensure that the quality of the finished goods inventory of Products sold by Collegium under any Depomed Names is of a sufficiently high quality to be generally comparable to the quality of the Products sold by Depomed prior to the Closing Date. At the reasonable request of Depomed, Collegium will send Depomed samples of such finished goods inventory of Products. In the event Collegium materially breaches this Section 8.4(d) and fails to cure such breach within sixty (60) days after Depomed notifies Collegium in writing of such breach, Depomed may terminate the license granted under Section 8.4(a) by delivery to Collegium of a written notice of termination. If Collegium disputes in good faith the existence or materiality of an alleged breach specified in a notice provided by Depomed pursuant to this Section 8.4(d), and provides notice to Depomed of such dispute within the sixty (60) day period following the date that Depomed notified Collegium of the breach, Depomed will not have the right to terminate such license unless and until the existence of such material breach has been finally determined in accordance with the dispute resolution provisions of Section 17.12 and Collegium fails to cure such breach within twenty (20) days following such determination.

(e) Notwithstanding the transfer of any labels or packaging, or any advertising, marketing, sales and promotional materials, Collegium acknowledges that this Agreement does not, and shall not, transfer, convey or assign any right, title, license or interest in any trademarks of Depomed or any of its Affiliates other than the Licensed Trademarks pursuant to the Trademark License Agreement.

(f) Notwithstanding the foregoing, the parties acknowledge that this Agreement does not, and shall not, transfer, convey or assign any right, title, license or interest in any trademark of any Third Party.

Section 8.5 Customer Service

For the period from the Effective Date up to the Closing Date, Depomed will continue to provide all customer service with respect to the Products at a level comparable to that which was provided prior to the Effective Date. On and from the Closing Date, through the completion of the Term, Collegium shall assume all customer service responsibility and provide all customer service required by its customers with respect to the Products. As of the Closing Date, and through the completion of the Term, all customer service requests relating to the Product received by Depomed will be referred to Collegium to the attention of Collegium's customer service provider as designated by Collegium.

ARTICLE 9
TERM AND TERMINATION

Section 9.1 Term

(a) The term of this Agreement shall commence on the Effective Date and shall, unless terminated sooner in accordance with this Article 9, continue for so long as Collegium is engaging in any Commercialization activities with respect to a Payment-Bearing Product (the "Term").

Section 9.2 Early Termination

(a) Depomed may terminate this Agreement: (i) upon at least ninety (90) days' prior written notice to Collegium in the event that the aggregate Net Sales of the Payment-Bearing Products in the Territory during any period of twelve (12) consecutive calendar months ending on or before December 31, 2021 are less than One Hundred Eighty Million Dollars ($180,000,000) and Depomed does not receive the full amount of any Minimum Quarterly Payment that becomes due and payable during that same twelve (12) month period, either through direct payment of the Minimum Quarterly Payment by Collegium or by Depomed's recourse to the Letter of Credit or Sales Account pursuant to Section 7.7(a) or Section 7.7(b); (ii) without cause, upon at least sixty (60) days' prior written notice to Collegium given not later than December 31, 2018, provided that Depomed pays to Collegium a termination fee in the amount of Eighty Million Dollars ($80,000,000) not later than the effective date of termination; or (iii) upon at least ninety (90) days' prior written notice to Collegium in the event that the Annual Net Sales of Payment-Bearing Products for any period after December 31, 2021 are less than One Hundred Forty Million Dollars ($140,000,000).

(b) At any time on or after the first anniversary of the Closing Date (subject to Section 7.3(f)(iii)), Collegium and Newco may tender a written notice to Depomed

terminating this Agreement for any reason, with such termination to be effective one year from the delivery of such notice; provided that, if the effective date of termination designated in such notice is prior to the fourth anniversary of the Closing Date, then such termination shall be contingent upon the payment by Collegium to Depomed, not later than the termination date, of a termination fee in the amount of Twenty-Five Million Dollars ($25,000,000). After the delivery of notice of termination and prior to the effective date of termination pursuant to this Section 9.2(b), Collegium shall continue to comply with its diligence obligations as set forth in the first sentence of Section 4.1 and otherwise operate and maintain the business and assets relating to this Agreement in the ordinary course of business and consistent in all material respects with the twelve (12) month period prior to such delivery of notice of termination.

(c) Collegium and Newco may terminate this Agreement upon ten (10) days' prior written notice to Depomed, if the Grünenthal License Agreement is terminated by Grünenthal as a result of any breach of the Grünenthal License Agreement by Depomed (other than a breach of the Grünenthal License Agreement by Depomed which is caused by a breach by Newco or its Affiliates or Sublicensees, including Collegium or its Affiliates, of any of their obligations under this Agreement or any of Depomed's obligations under the Grünenthal License Agreement).

Section 9.3 Termination for Cause

(a) In the event of a material breach of this Agreement other than a failure to make any undisputed payment(s) hereunder, the non-breaching party shall have the right to terminate this Agreement by written notice to the breaching party specifying the nature of such breach in reasonable detail. Such termination shall become effective sixty (60) days from receipt of such notice by the breaching party, unless the allegedly breaching party disputes such breach in good faith.

(b) In the event of a material breach of this Agreement by a party as a result of any failure to make any undisputed payment(s) under this Agreement, the non-breaching party (excluding Newco, in the event the breaching party is Collegium, and Collegium, in the event the breaching party is Newco) shall have the right to terminate this Agreement by written notice to the breaching party and such termination shall become effective ten (10) days from receipt of such notice by the breaching party unless the breaching party has cured such breach within such period. If such breach is due to the action of Collegium, then this Agreement shall automatically terminate immediately, without the need for notice by the non-breaching party. For clarity, Collegium shall not be deemed to be in breach of its obligation to make any Minimum Quarterly Payment to Depomed under this Agreement in the event that Depomed does not receive its full Minimum Quarterly Payment through the Sales Account and Depomed is eligible to, and does, draw on the Letter of Credit in accordance with Section 7.7(a) to satisfy any such Quarterly Shortfall.

(c) If Collegium or Depomed disputes in good faith the existence or materiality of an alleged material breach specified in a notice provided by the other party pursuant to this Section 9.3, and provides notice to the other party of such dispute within the sixty (60) day period or ten (10) day period, as applicable, following the date that the other party notified the breaching party of the breach, the other party will not have the right to terminate this Agreement unless and until the existence of such material breach has been finally determined in accordance with the dispute resolution provisions of Section 17.12 and the breaching party fails to cure such breach within twenty (20) days following such determination. Notwithstanding the foregoing, Collegium shall not be entitled to dispute its obligation to make any of the Minimum Quarterly Payments to Depomed due and payable under Section 7.3(a).

Section 9.4 Termination for Bankruptcy.

To the extent permitted by law, each party (excluding Newco, in the event the other party is Collegium, and Collegium, in the event the other party is Newco) will have the right to terminate this Agreement immediately upon notice to the other party, in the event of (a) the entry of an order for relief under the United States Bankruptcy Code (or any corresponding remedy under successor laws) against the other party, (b) the filing of a petition by or against the other party under any bankruptcy, insolvency or similar law (which petition is not dismissed within sixty (60) days after filing), (c) the appointment of a receiver for the other party's business or property or (d) the other party's making of a general assignment for the benefit of its creditors. Where Collegium is the "other party," such term "other party" is hereby deemed to mean either Collegium or Newco. Notwithstanding the occurrence of any of the events specified in this Section 9.4, the parties acknowledge and agree that, to the extent Section 365(n) of the United States Bankruptcy Code applies to this Agreement, the non-insolvent party may elect to retain and exercise the rights granted to it hereunder with respect to the intellectual property owned or controlled by the insolvent party.

Section 9.5 Termination for Failure to Obtain HSR Clearance

If the HSR Clearance Date has not occurred on or before seventy (70) days after the Effective Date, then any party shall have the right to terminate this Agreement in its entirety upon notice to the other parties referencing this Section 9.5, and except for Article 13 and Section 17.12, none of the provisions of this Agreement shall remain in effect after such termination.

Section 9.6 Termination for Failure to Close

If the parties fail to close on or prior to February 28, 2018, then any party shall have the right to terminate this Agreement in its entirety upon notice to the other parties referencing this Section 9.6, and except for Article 13 and Section 17.12, none of the provisions of this Agreement shall remain in effect after such termination; provided, however, that the failure of the parties to close shall not be due to the action or inaction of the party invoking its right to terminate this Agreement pursuant to this Section 9.6; and provided, further, that if Depomed is

unable for any reason to extend the termination date set forth in the Consent Agreement beyond January 31, 2018 on the same terms and conditions as are set forth in the Consent Agreement as of the Effective Date (other than the revision to such termination date), then any party will have the right to terminate this Agreement pursuant to this Section 9.6 if the parties fail to close on or prior to January 31, 2018.

Section 9.7 Effects of Termination

(a) General Effects of Termination. Upon expiration or termination of this Agreement for any reason, the following terms and conditions shall apply:

(i) Expiration or termination of this Agreement shall not relieve either party of any obligations that accrued prior to such expiration or termination, including accrued payment obligations. For clarity, Collegium shall not be obligated to make any Minimum Quarterly Payments with respect to any period of time or sales of any Payment-Bearing Product following the effective date of termination and, following receipt or issuance of any notice of termination pursuant to Section 9.2 or Section 9.3, Collegium's obligation to pay any further Minimum Quarterly Payment(s) (or portion thereof) shall only apply with respect to the period of time between its receipt or issuance of the termination notice and the effective date of termination.

(ii) Except in the case of termination of this Agreement pursuant to Section 9.5 (the effects of which are addressed in Section 9.5), the following provisions shall survive expiration or termination of this Agreement and remain in effect, along with any other provisions to the extent required to interpret and enforce the parties' rights and obligations under this Agreement: Sections 3.2(e)(iv), 4.5(b), 5.1(a) (solely the last sentence), 7.3(d) (solely with respect to Line Extensions), 7.3(e)(iv) (solely with respect to Line Extensions which are "New Products"), 7.4, 7.6, 9.7 and 10.3 and Articles 1, 12, 13, 15, 16 and 17.

(iii) Expiration or termination of this Agreement shall be without prejudice to (A) any remedies which any party may then or thereafter have hereunder or at law or in equity, (B) a party's right to receive any payment accrued under the Agreement prior to the termination date but which becomes payable thereafter and (C) either party's right to obtain performance of any obligations provided for in clause (ii) above which survive termination. Except as expressly set forth herein, the rights to terminate this Agreement as set forth in this Agreement shall be in addition to all other rights and remedies available under this Agreement, at law, in equity or otherwise.

(iv) All licenses, rights, and sublicenses granted by Depomed to Newco pursuant to Section 2.1 and Section 2.2(a) shall automatically terminate and no longer be effective.

(v) Any sublicenses granted by Newco hereunder (including to Collegium and/or its Affiliates) shall automatically terminate and no longer be effective.

(vi) Depomed shall retain exclusive ownership of all Products. Collegium shall retain exclusive ownership of all Line Extensions.

(vii) Section 7.3(d) and Section 7.3(e)(iv) shall survive solely with respect to Line Extensions sold in the Territory by Collegium or its Affiliates or other Sublicensees after termination, with the payments specified in Section 7.3(d) becoming payable commencing as of the effective date of termination.

(viii) As soon as is reasonably practicable after expiration or termination of this Agreement, Collegium shall (and shall cause its Affiliates to) return to Depomed all applications, reports and related documentation that it prepared for filing with the applicable Regulatory Authorities, as well as the pharmacovigilance database and any other related data, in each case solely with respect to Products.

(ix) As soon as is reasonably practicable after expiration or termination of this Agreement, except as necessary or useful for the exercise of rights continuing after expiration or termination, the recipient party shall (and shall cause its Affiliates to) return to the disclosing party or destroy all originals of documents (in paper, electronic or other tangible form) and physical materials then in the recipient party's possession, and copies thereof, containing or embodying Proprietary Information received from the disclosing party, and destroy all documents and other materials that the recipient party created containing any such Proprietary Information, provided, however, that the recipient party may retain in confidence (a) one archival copy of the Proprietary Information of the disclosing party in its legal files solely to permit the recipient party to determine compliance with its obligations hereunder and (b) any portion of the Proprietary Information of the disclosing party which such recipient party is required by applicable Legal Requirements to retain. Notwithstanding the return or destruction of the documents and materials described above, the parties will continue to be bound by their obligations under Article 13.

(b) Additional Effects of Termination. Upon termination of this Agreement pursuant to Section 9.2, Section 9.3 or Section 9.4, the following additional terms and conditions shall apply:

(i) At Depomed's request, Collegium shall, and shall cause Newco to, promptly transfer, convey and assign to Depomed or its designee either, at Depomed's option, (A) each Transferred Asset then in existence that is selected by Depomed for assignment, or (B) all then outstanding membership interests in Newco.

(ii) At Depomed's request, Collegium shall cooperate in undertaking a reasonable wind-down or orderly transition to Depomed or its designee of Collegium's development and/or Commercialization activities with respect to the Products (including taking such reasonable actions in regard to Regulatory Approvals as may be directed by Depomed pending the assignment and transfer of such Regulatory Approvals pursuant to Section 9.7(b)(v)).

(iii) At Depomed's request, if on the effective date of such termination, there are any on-going clinical studies (including post-approval commitments, but not including investigator-initiated clinical studies) of any Product conducted by or on behalf of Collegium, Collegium shall transition such clinical studies to Depomed or its designee as promptly as practicable, at Depomed's cost and expense.

(iv) For any investigator-initiated clinical studies, Collegium shall either terminate such studies, such that Depomed is not responsible for any costs thereof, or continue such studies at Collegium's own cost and expense.

(v) At Depomed's request, Collegium shall promptly (A) transfer, convey and assign to Depomed or its designee all regulatory filings and Regulatory Approvals then owned by Collegium or its Affiliates that relate solely to the Products, and deliver to Depomed or its designee all pre-clinical and clinical data and information in Collegium's possession or Control relating solely to the Products, and (B) deliver or make available to Depomed or its designee copies of those reports, records and regulatory correspondence in Collegium's possession or Control that relate solely to the development of the Products.

(vi) At Depomed's request, Collegium shall promptly assign (or use commercially reasonable efforts to assign if the applicable contract does not freely permit assignment) to Depomed or its designee any manufacturing, supplier, distributor, clinical study, or other contracts relating solely to the development, Manufacture or Commercialization of the Products entered into by Collegium with Third Parties (in addition to any contracts assigned pursuant to Section 9.7(b)(i)) or otherwise use reasonable efforts to facilitate Depomed's establishment of similar relationships with such Third Parties.

(vii) At Depomed's request, Collegium shall promptly transfer, convey and assign to Depomed or its designee all right, title and interest in and to all then-existing inventory of Products in finished goods form that is in Collegium's possession or control (whether intended for clinical or commercial supply), subject to Depomed reimbursing Collegium's COGS with respect to such inventory.

(viii) At Depomed's request, Collegium shall promptly provide to Depomed or its designee all Promotional Materials used in connection with the Products in the Territory that are in Collegium's possession or Control (including electronic files of such Promotional Materials), subject to Depomed reimbursing Collegium's out-of-pocket cost for printing and delivering such Promotional Materials.

(ix) Collegium shall continue to be responsible for returns, Commercial Rebates, Chargeback Claims and Co-Pay Card Discounts with respect to Products Commercialized by Collegium prior to such termination, in accordance with Section 8.3.

(x) To the extent that Depomed has not previously commenced such activities pursuant to Section 4.9, Depomed may elect, at any time after delivery of the notice of

termination, to have the Depomed Sales Force Detail the Products directly to Professionals in the Territory in accordance with Section 4.9, except that the notice period set forth in Section 4.9(b)(i) shall not apply.

(xi) Each party agrees to execute, acknowledge and deliver such further instruments, consents and other documents, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Section 9.7(b), for no further consideration.

ARTICLE 10
REPRESENTATIONS AND WARRANTIES

Section 10.1 Representations and Warranties of Depomed

Depomed hereby represents and warrants to Collegium as follows:

(a) Organization. Depomed is a corporation duly incorporated, validly existing and in good standing under the Legal Requirements of the State of California. Depo NF Sub, LLC is a limited liability company duly formed, validly existing and in good standing under the Legal Requirements of the State of Delaware. Each Depomed Entity is authorized to do business under the Legal Requirements of all jurisdictions in which it is required to be so authorized.

(b) Authority; Binding Effect.

(i) Each Depomed Entity has all requisite corporate power and authority to own and operate its properties and assets and to carry on its business as it is now being conducted and as it is related to the Transferred Assets and the Business. Depomed has all requisite corporate power and authority to execute and deliver this Agreement and the Ancillary Agreements, and to carry out, or to cause to be carried out, the Transactions. The execution and delivery by Depomed of this Agreement and the Ancillary Agreements, and the performance by each Depomed Entity of its obligations hereunder and thereunder, have been duly authorized by all requisite corporate action on the part of such Depomed Entity.

(ii) This Agreement has been duly executed and delivered by Depomed and, assuming the valid execution and delivery by Collegium, constitutes a legal, valid and binding obligation of Depomed, enforceable against Depomed in accordance with its terms, except as enforcement may be limited by bankruptcy, insolvency, reorganization, fraudulent conveyance, moratorium or similar laws affecting creditors' rights generally or by general principles of equity (regardless of whether enforcement is sought in a proceeding in equity or law).

(iii) Each of the Ancillary Agreements has been duly authorized by all necessary action on the part of Depomed and has been, or will be at the Closing, duly executed

and delivered by Depomed and, assuming the valid execution and delivery by Collegium, constitutes or will constitute a legal, valid and binding obligation of Depomed, enforceable against Depomed in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, fraudulent conveyance, moratorium or similar laws affecting creditors' rights generally or by general principles of equity (regardless of whether enforcement is sought in a proceeding in equity or law).

(c) Non-Contravention. The execution, delivery and performance of this Agreement and the other Transaction Documents by Depomed, and the consummation of the Transactions, do not and will not (i) violate any provision of the articles of incorporation or bylaws of Depomed and the comparable organizational documents of Depo NF Sub, LLC; (ii) subject to obtaining the consents referred to in Schedule 10.1(c), result in the creation of any Lien (other than Permitted Liens) upon any of the Transferred Assets; or (iii) assuming compliance with the matters set forth in Section 10.1(d) and Section 10.2(d), violate or result in a breach of, or constitute a default under any Legal Requirement or other restriction of any Governmental Authority to which any Depomed Entity is subject, except, with respect to clause (iii), for any violations, breaches, or defaults, that would not, individually or in the aggregate, reasonably be expected to be materially adverse to the Transferred Assets or to the conduct of the Business, taken as a whole.

(d) Governmental Authorization. Except as set forth on Schedule 10.1(d) or in connection with the filings required by the Competition Laws, the execution and delivery of this Agreement and the other Transaction Documents by Depomed, and the consummation of the Transactions, do not require any consent or approval of, or any notice to or other filing with, any Governmental Authority.

(e) No Litigation.

(i) Except as set forth on Schedule 10.1(e)(i), no Legal Proceeding or Order that (A) is or is reasonably likely to be material to the Business, the Transferred Assets or the Assumed Liabilities, taken as a whole, (B) would enjoin, restrict or prohibit the transfer of all or any part of the Transferred Assets, or the performance by any Depomed Entity, as contemplated by this Agreement or the Ancillary Agreements, or (C) seeks to impose any material limitation on the ability of any Depomed Entity to operate the Business or the Transferred Assets as currently conducted or after the Closing or would impose any material limitation on the ability of Collegium to operate the Business or the Transferred Assets as currently conducted, is pending or outstanding against or, to the Knowledge of Depomed, threatened against any Depomed Entity. This Section 10.1(e)(i) does not relate to Legal Proceedings relating solely to the Licensed IP Rights, which are the subject of Section 10.1(i).

(ii) Except as set forth on Schedule 10.1(e)(ii), from April 2, 2015 through the date hereof, no Legal Proceeding related to product liability, product defect, fraud, misrepresentation, unjust enrichment, conspiracy or economic loss has been initiated or filed

against any Depomed Entity or their agents and, to the Knowledge of Depomed, no such Legal Proceeding has been threatened against any Depomed Entity relating to any of the Products.

(f) Compliance with Legal Requirements. Except as to matters set forth in Schedule 10.1(f):

(i) Each Depomed Entity is, and since April 2, 2015 has been, in material compliance with all Legal Requirements applicable to the ownership of the Transferred Assets or the operation of the Business, including applicable Health Laws and Environmental Laws.

(ii) Each Depomed Entity possesses, and is in compliance with, all Governmental Authorizations necessary for the conduct of the Business as it is currently conducted, except where the failure to possess or comply with any such Governmental Authorization would not, individually or in the aggregate, be materially adverse to the operation of the Business, and all such Governmental Authorizations are valid and in full force and effect. Each Depomed Entity, as applicable, have completed and filed all reports, documents, claims, permits and notices required by any Governmental Authority in order to maintain the Governmental Authorizations, except where failure to file such reports would not be materially adverse to the Business. To the Knowledge of Depomed, all such reports, documents, claims, permits and notices were complete and accurate in all material respects on the date filed (or were corrected in or supplemented by a subsequent filing). No event has occurred that would reasonably be expected to result in a penalty under or the revocation, cancellation, non-renewal or adverse modification of any Governmental Authorization, except as has not been and would not, individually or in the aggregate, reasonably be expected to be materially adverse to the Business.

(iii) To the Knowledge of Depomed, Depomed has calculated and reported all prices reported to or used to calculate pricing or discounts under the Medicaid Program (42 U.S.C. § 1396r-8), the 340B Drug Discount Program (42 U.S.C. § 256b), and Section 603 of the Veterans Healthcare Act of 1993 (Pub. L. 102-585) for the Products in compliance with applicable Legal Requirements.

(g) Regulatory Matters.

(i) Schedule 10.1(g) sets forth, as of the Effective Date, a list of all material Regulatory Approvals granted to any Depomed Entity by, or application therefor pending with, any Governmental Authority to manufacture, have made, test, market, package, import, distribute, sell and commercialize the Products in the Territory.

(ii) All Products sold under the Regulatory Approvals are manufactured, marketed, distributed and sold in accordance with such Regulatory Approvals, including the specifications and standards contained therein, except as has not been and would

not, individually or in the aggregate, reasonably be expected to be materially adverse to the Business.

(iii) With respect to the Business, neither any Depomed Entity, nor, to the Knowledge of Depomed, any officer, employee, or agent of any Depomed Entity, (A) has made an untrue statement of a material fact or a fraudulent statement to the FDA, failed to disclose a material fact required to be disclosed to the FDA or committed an act, made a statement, or failed to make a statement that, at the time such disclosure was made, would reasonably be expected to provide a basis for the FDA to invoke its Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities policy set forth in the FDA's Compliance Policy Guide Sec. 120.100 (CPG 7150.09), or (B) has been convicted of any crime or engaged in any conduct that would reasonably be expected to result in debarment under 21 U.S.C. 335a or any similar Legal Requirement.

(iv) Since April 2, 2015, no Depomed Entity has (A) voluntarily nor involuntarily initiated, conducted or issued, or caused to be initiated, conducted or issued, any recall, field alerts, market withdrawal or replacement, safety alert, "dear doctor" letter, investigator notice, or other notice or action relating to an alleged lack of safety, or efficacy of any Product, and to the Knowledge of Depomed, there are no facts which are reasonably likely to cause (1) the recall, market withdrawal or replacement of any Product sold or intended to be sold by any Depomed Entity, (2) a change in the marketing classification or a material change in the labeling of any such Products or (3) a termination or suspension of the marketing of such Products; or (B) received any written notice that any Governmental Authority has (1) commenced, or threatened to initiate, any action to request the recall or to enjoin the manufacture or distribution of any Product sold or intended to be sold by any Depomed Entity or (2) commenced, or threatened to initiate, any action to withdraw any Regulatory Approvals issued relating to any Product.

(v) Except for ordinary course inquiries or as set forth on Schedule 10.1(g)(v), since April 2, 2015, Depomed has not received, with respect to the Products marketed and sold in the Territory, any written notice or communications from any Governmental Authority alleging any safety or quality concerns with respect to any Product or noncompliance with any applicable Legal Requirements or Regulatory Approvals, except as would not, individually or in the aggregate, reasonably be expected to be materially adverse to the operation of the Business. Depomed is not subject to any enforcement proceedings by the FDA related to the Products and, to the Knowledge of Depomed, no such proceedings have been threatened.

(vi) All clinical trials and studies for the Products that have been or are being conducted by or on behalf of Depomed or its Affiliates, were conducted, and are being conducted, in all material respects in accordance with all applicable Legal Requirements, including Health Legal Requirements. To the Knowledge of Depomed, there is no Legal Proceeding pending or threatened by any Governmental Authority to suspend, investigate or terminate any ongoing clinical trials or studies for any Product.

(h) Contracts.

(i) As of the Effective Date, the Grünenthal License Agreement is valid and binding on Depomed and, to the Knowledge of Depomed, Grünenthal, and is in full force and effect in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, fraudulent conveyance, moratorium or similar laws affecting creditors' rights generally or by general principles of equity (regardless of whether enforcement is sought in a proceeding in equity or law). Neither Depomed nor, to the Knowledge of Depomed, Grünenthal is in material breach of or material default under, or has provided notice of its intent to terminate, the Grünenthal License Agreement, and no event has occurred that, with the giving of notice or lapse of time or both, would constitute a material breach or material default thereunder. During the Term, Depomed shall not amend, terminate or cause to be terminated the Grünenthal License Agreement in any manner that would reasonably be expected to be materially adverse to Collegium's rights or obligations under this Agreement without the prior written consent of Collegium, which consent shall not be unreasonably withheld, conditioned or delayed.

(ii) As of the Effective Date, Grünenthal has consented, in writing, to the grant of the sublicense under Section 2.1(a)(iii) and Section 2.1(a)(iv), and such consent has not been rescinded, revoked, modified or conditioned in any manner.

(i) Intellectual Property.

(i) Except as set forth on Schedule 10.1(i)(i):

(1) to the Knowledge of Depomed, the Transferred IP Rights and Licensed IP Rights are subsisting, the issued Patents and registered Trademarks included within the Transferred IP Rights and Licensed IP Rights are valid and enforceable, and there is no objection or claim being asserted or threatened in writing by any Person challenging the scope, ownership, inventorship, validity or enforceability of any Transferred IP Rights or Licensed IP Rights, other than the ANDA Litigation; provided that the foregoing "Knowledge of Depomed" qualifier shall not apply with respect to the Licensed Trademarks, the Transferred Domain Names or the Depomed Acuform Patents;

(2) on the Effective Date, a Depomed Entity is, and at the Closing, will be, (I) the sole and exclusive beneficial and, with respect to applications and registrations, record owner of, and hold good, saleable and sole title to the Transferred IP Rights and Licensed IP Rights, other than the Licensed IP Rights that are licensed to a Depomed Entity, in which case, a Depomed Entity is the holder of an assignable valid right or license to such Licensed IP Rights, and (II) the beneficial owner of the Depomed Product Know-How;

(3) no license of any kind relating to any Transferred IP Right or Licensed IP Right has been granted by any Depomed Entity to any Third Parties (except for

immaterial, non-exclusive licenses to use Transferred IP Rights or Licensed IP Rights to customers and suppliers in the ordinary course of business);

(4) the Transferred IP Rights and the Licensed IP Rights are (in the case of the Grünenthal IP Rights, to the Knowledge of Depomed and subject to the Grünenthal License Agreement) free and clear of any Liens, other than Permitted Liens;

(5) there are no Legal Proceedings or other claims pending or threatened by a Depomed Entity against any Person, and no Depomed Entity has provided notice of any Person's Infringement of any Transferred IP Right or the Licensed IP Right or misappropriation of Depomed Product Know-How;

(6) there are no Legal Proceedings or other claims pending, or to the Knowledge of Depomed, threatened in writing against Depomed or any of its other Affiliates by any Person, and none of Depomed or any of its other Affiliates received written notice (including in the form of offers, invitations to obtain a license or cease-and-desist letters) from any Person that the conduct of the Business (including the use of Depomed Product Know-How), including the marketing and sale of the Products in the United States, constitutes Infringement of any IP Right of such Person;

(ii) Except as set forth on Schedule 10.1(i)(ii), the Transferred IP Rights and the Licensed IP Rights constitute all of the IP Rights owned or licensed to or by Depomed and its Affiliates at the Closing that are used to commercialize the Products, except in respect of the manufacture and packaging of the Products. To the Knowledge of Depomed, all assignments, declarations and powers of attorney with respect to the Transferred IP Rights and the Licensed IP Rights have been properly obtained and recorded, provided that the foregoing "Knowledge of Depomed" qualifier shall not apply with respect to the Licensed Trademarks, Depomed Acuform Patents or the Transferred Domain Names.

(iii) Each Depomed Entity has taken and currently takes commercially reasonable measures to protect the confidentiality of confidential information material to the conduct of the Business and owned, used or held for use in the conduct of the Business by any Depomed Entity, and to the Knowledge of Depomed, there has not been any disclosure of any trade secret or confidential information owned, used or held for use in the conduct of the Business to any Person in a manner that has resulted in the loss of such trade secret or other rights in and to such information.

(iv) Schedule 10.1(i)(iv) lists all of the United States Patents licensed from Grünenthal under the terms of the Grünenthal License Agreement that relate to the Products (the "Grünenthal Patents").

(v) Nucynta® ER constitutes a Grünenthal-ADF-Formulation (as defined in the Grünenthal License Agreement).

(j) Brokers. No broker, finder or investment banker is entitled to any brokerage, finders or other fee or commission in connection with the Transactions based upon arrangements made by or on behalf of any Depomed Entity.

(k) Transferred Assets. Except as set forth on Schedule 10.1(k), the Depomed Entities (a) own, lease or have the legal right to use all of the Transferred Assets, and (b) have good title to all the Transferred Assets (other than those Transferred Assets that are licensed) free and clear of all Liens, except for Permitted Liens. Other than Depo NF, no Affiliate of Depomed has any right, title or interest in, to or under the Transferred Assets. Following the Closing, neither Depomed nor any of its Affiliates will own any right, title or interest in or to any of the Transferred Assets, except as otherwise expressly set forth in Section 9.7(b) and Article 13 or any of the Ancillary Agreements. This Section 10.1(k) does not relate to intellectual property, which is the subject of Section 10.1(i).

(l) Absence of Material Changes. Since September 30, 2017, and through the date hereof, and as of the Closing Date, except as set forth on Schedule 10.1(l), the Business has been operated in the ordinary course and there has not been:

(i) any sale, pledge, disposition, transfer, lease, license, encumbrance or authorization of the sale, pledge, disposition, transfer, lease, license or encumbrance of any assets, including any IP Rights, that are (or would otherwise be) Transferred Assets, other than (A) sales of Products in the ordinary course of business consistent with past practice or (B) Permitted Liens;

(ii) any waiver of any material claims or rights of material value that relate to the Transferred Assets;

(iii) any acquisition of any material properties, assets or IP Rights that constitute Transferred Assets, other than Transferred Assets that would not reasonably be expected to result in any material Assumed Liabilities;

(iv) any settlement of any Legal Proceeding or waiver of any material claims or rights of material value in a manner that constitutes an Assumed Liability or otherwise would reasonably be expected to be materially adverse to the Transferred Assets or the operation of the Business, taken as a whole;

(v) any termination, cancellation, lapse, amendment, waiver or modification of any Regulatory Approvals material to the Business or the Transferred Assets;

(vi) any abandonment, termination or lapse of any Transferred IP Rights or Licensed IP Rights, or rights relating to any Transferred IP Rights or Licensed IP Rights, in each case, relating to the Transferred Assets or the Business;

(vii) any failure to take any action necessary to protect or maintain any Transferred IP Rights or Licensed IP Rights or to prosecute any pending applications for any trademarks or file any documents or other information or pay any maintenance or other fees related thereto, in each case, relating to the Transferred Assets or the Business;

(viii) any transfer, assignment or grant of any license or sublicense of any rights under or with respect to any Transferred IP Rights or Licensed IP Rights relating to the Transferred Assets, the Products or the Business, other than immaterial, non-exclusive licenses to use Transferred IP Rights or Licensed IP rights to customers and suppliers in the ordinary course of business;

(ix) any (A) change in any Depomed Entity's activities and practices with respect to inventory levels of the Products maintained at the wholesale, chain or institutional levels inconsistent with past practice, (B) any change in the selling, distribution, advertising, pricing, terms of sale or collection practices inconsistent with past practice or (C) the entry into any program, activity or other action (including any rebate, discount, chargeback or refund policy or practice), in each case, that would reasonably be expected to result in a trade buy-in that is materially in excess of normal customer purchasing patterns consistent with past course of dealing with the Business during the twelve (12) months prior to the date hereof; or

(x) any agreement, commitment to take or authorization of any action described in this Section 10.1(l).

(m) Transferred Inventory. The Transferred Inventory is of usable or saleable quality in the ordinary course of business and has the expiration dates set forth on the Transferred Inventory Cost Statement (except for such inaccuracies as would not be material). All of the Transferred Inventory is, as of the Closing Date, free of material defects (including defects in packaging, labeling, and storage) and systematic or chronic problems and comply in all material respects with all applicable specifications and all applicable Legal Requirements, including all Health Legal Requirements and Environmental Legal Requirements. All Transferred Inventory that has been returned, has expired or has been deemed unusable or not fit for sale has been or will be destroyed in accordance with the policies of Depomed and applicable Legal Requirements.

(n) Taxes. Except as set forth on Schedule 10.1(n) to the extent a breach or inaccuracy of any of the following could result in a liability of Newco, Collegium (or any of their Affiliates) to any Person: (a) all material Tax Returns required to be filed by Depomed or its subsidiaries with respect to the ownership or use of the Transferred Assets have been duly and timely filed; (b) all material Taxes due and payable by Depomed or its subsidiaries with respect to the ownership or use of the Transferred Assets have been timely paid; (c) none of the Transferred Assets is subject to any Liens as a result of a failure to pay any Tax (excluding, any Permitted Liens); and (d) other than as relates to income taxes, there are no ongoing or pending Tax audits or administrative or similar proceedings with respect to any Tax Returns of Depomed

relating to the ownership or use of the Transferred Assets. Notwithstanding any provisions of this Agreement to the contrary, Section 10.1(e)(i) and the foregoing provisions of this Section 10.1(n) constitute the sole representations and warranties of Depomed and its Affiliates relating to Taxes.

Section 10.2 Representations and Warranties of Collegium and Newco

Collegium and Newco hereby jointly and severally represent and warrant to Depomed as follows:

(a) Organization. Collegium is a corporation duly organized, validly existing and in good standing under the Legal Requirements of the State of Virginia. Newco is a limited liability company duly formed, validly existing and in good standing under the Legal Requirements of Delaware. Collegium and Newco are each authorized to do business under the Legal Requirements of all jurisdictions in which they are required to be so authorized, except as would not, individually or in the aggregate, have a material and adverse effect on the ability of Collegium and Newco to consummate the Transactions (a "Collegium Material Adverse Effect").

(b) Authority; Binding Effect.

(i) Collegium has all requisite corporate power and authority to own and operate its properties and assets, to carry on its business as it is now being conducted and to execute and deliver this Agreement and the Ancillary Agreements, and to carry out or cause to be carried out, the Transactions. Newco has all requisite power and authority to own and operate its properties and assets, to carry on its business as it is now being conducted and to execute and deliver this Agreement and the Ancillary Agreements, and to carry out or cause to be carried out, the Transactions. The execution and delivery by Collegium and Newco of this Agreement and the Ancillary Agreements, and the performance by Collegium and Newco of their obligations hereunder and thereunder, have been duly authorized by all requisite corporate action on the part of Collegium and Newco.

(ii) This Agreement has been duly executed and delivered by Collegium and Newco, and assuming the valid execution and delivery by Depomed, constitutes a legal, valid and binding obligation of each of Collegium and Newco, enforceable against Collegium and Newco in accordance with its terms, except as enforcement may be limited by bankruptcy, insolvency, reorganization, fraudulent conveyance, moratorium or similar laws affecting creditors' rights generally or by general principles of equity (regardless of whether enforcement is sought in a proceeding in equity or law).

(iii) Each of the Ancillary Agreements has been duly authorized by all necessary corporate action on the part of Collegium and Newco, and has been, or will be at the Closing, duly executed and delivered by Collegium and Newco, and assuming the valid execution and delivery by Depomed, constitutes or will constitute a legal, valid and binding

obligation of each of Collegium and Newco, enforceable against Collegium and Newco in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, fraudulent conveyance, moratorium or similar laws affecting creditors' rights generally or by general principles of equity (regardless of whether enforcement is sought in a proceeding in equity or law).

(c) Non-Contravention. The execution, delivery and performance by Collegium and Newco of this Agreement and the other Transaction Documents, and the consummation of the Transactions, do not and will not (i) violate any provision of the certificate of formation, bylaws or other organizational documents of Collegium and the comparable organization documents of Newco; (ii) conflict with, or result in a breach of, constitute a default under or result in the termination, cancellation or acceleration (whether after the giving of notice or the lapse of time or both) of any right or obligation of Collegium or any of its Affiliates under, or to a loss of any benefit to which Collegium or any of its Affiliates is entitled under, any agreement, lease of real estate or license of intellectual property to which Collegium or any of its Affiliates is a party or to which its properties or assets are subject; or (iii) assuming compliance with the matters set forth in Section 10.1(d) and Section 10.2(d), violate or result in a breach of or constitute a default under any Legal Requirement or other restriction of any Governmental Authority to which Collegium or Newco is subject, except, with respect to clause (iii), for any violations, breaches, or defaults that would not, individually or in the aggregate, reasonably be expected to have a Collegium Material Adverse Effect.

(d) Governmental Authorization. Except as set forth on Schedule 10.2(d) and in connection with the filings required by the Competition Laws, the execution and delivery of this Agreement and the other Transaction Documents, and the consummation of the Transactions, do not require any consent or approval of, or any notice to or other filing with, any Governmental Authority.

(e) Brokers. No broker, finder or investment banker is entitled to any brokerage, finders or other fee or commission in connection with the Transactions based upon arrangements made by or on behalf of Collegium or any of its Affiliates.

(f) Financial Capability. As of the Closing, Collegium will have sufficient cash available to pay the Transferred Inventory Cost, the Upfront Payment and the Collegium Prepaid Business Expense Allocation on the terms and conditions contemplated by this Agreement.

(g) Solvency. As of the Effective Date, after giving effect to all of the Transactions, including the payment of the Transferred Inventory Cost, the Upfront Payment and the Collegium Prepaid Business Expense Allocation, Collegium and Newco shall be Solvent. For the purposes of this Section 10.2(g), the term "Solvent" when used with respect to any Person, means that, as of any date of determination, (i) the "fair saleable value" of the assets of such Person will, as of such date, exceed (A) the value of all "liabilities of such Person, including

contingent and other liabilities," as of such date, as such quoted terms are generally determined in accordance with applicable federal laws governing determinations of the insolvency of debtors, and (B) the amount that will be required to pay the probable liabilities of such Person on its existing debts (including contingent liabilities) as such debts become absolute and matured, (ii) such Person will not have, as of such date, unreasonably small capital for the operation of the businesses in which it is engaged or proposed to be engaged following such date and (iii) such Person will be able to pay its liabilities, including contingent and other liabilities, as they mature.

(h) No Litigation. No Legal Proceeding or Order that (i) would enjoin, restrict or prohibit the transfer of all or any part of the Transferred Assets, or the performance by Collegium or Newco, as contemplated by this Agreement or the Ancillary Agreements, or (ii) seeks to impose any material limitation on the ability of Collegium or Newco to operate the Business or the Transferred Assets after the Closing is pending or outstanding against or, to the Knowledge of Collegium, threatened in writing against Collegium.

(i) Regulatory Matters.

(i) Since April 26, 2016, Xtampza® ER FDA approval date, Collegium has manufactured, tested, marketed, distributed, and sold all of the products owned or controlled by it and subject to FDA regulation ("Collegium Products") in accordance with all applicable Legal Requirements, including all Health Laws, and applicable regulatory approvals, including the specifications and standards contained therein, except as has not been and would not, individually or in the aggregate, reasonably be expected to have a material adverse effect.

(ii) Since April 26, 2016, Xtampza® ER FDA approval date, Collegium has not (A) voluntarily nor involuntarily initiated, conducted or issued, or caused to be initiated, conducted or issued, any recall, field alerts, market withdrawal or replacement, safety alert, "dear doctor" letter, investigator notice, or other notice or action relating to an alleged lack of safety, or efficacy of any Collegium Products, and to the Knowledge of Collegium, there are no facts which are reasonably likely to cause (1) the recall, market withdrawal or replacement of any Collegium Products, or (2) a termination or suspension of the marketing of any Collegium Products. Neither Collegium nor Newco has received any written notice that any Governmental Authority has (1) commenced, or threatened to initiate, any action to request the recall or to enjoin the manufacture or distribution of any Collegium Products, or (2) commenced, or threatened to initiate, any action to withdraw any regulatory approvals relating to Collegium Products.

(iii) Except for ordinary course inquiries or as set forth on Schedule 10.2(i)(iii), since April 26, 2016, Xtampza® ER FDA approval date, Collegium has not received any written notice or communications from any Governmental Authority alleging any safety or quality concerns with respect to any Collegium Products or noncompliance with any applicable Legal Requirements, including Health Laws relating to the sale and marketing of Collegium Products, or applicable regulatory approvals, except as would not, individually or in the

aggregate, reasonably be expected to have a material effect. Collegium is not subject to any enforcement proceedings by the FDA related to Collegium Products and, to the Knowledge of Collegium, no such proceedings have been threatened.

(iv) All clinical trials and studies that have been or are being conducted by or on behalf of Collegium with respect to Collegium products, were conducted, and are being conducted, in all material respects in accordance with all applicable Legal Requirements, including Health Laws. To the Knowledge of Collegium and Newco, there is no Legal Proceeding pending or threatened by any Governmental Authority to suspend, investigate or terminate any ongoing clinical trials or studies conducted by or on behalf of Collegium.

(v) Neither Collegium nor, to the Knowledge of Collegium, any officer, employee, or agent of Collegium, (A) has made an untrue statement of a material fact or a fraudulent statement to the FDA, failed to disclose a material fact required to be disclosed to the FDA or committed an act, made a statement, or failed to make a statement that, at the time such disclosure was made, would reasonably be expected to provide a basis for the FDA to invoke its Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities policy set forth in the FDA's Compliance Policy Guide Sec. 120.100 (CPG 7150.09), or (B) has been convicted of any crime or engaged in any conduct that would reasonably be expected to result in debarment under 21 U.S.C. 335a or any similar Legal Requirement.

Section 10.3 Warranty Disclaimer

EXCEPT AS EXPRESSLY PROVIDED HEREIN, EACH PARTY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH REGARD TO THE PRODUCTS AND LINE EXTENSIONS, INCLUDING THE WARRANTY OF MERCHANTABILITY AND WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 11
INTELLECTUAL PROPERTY MATTERS

Section 11.1 Acuform Patent Prosecution and Maintenance

Depomed shall have the sole right, but not the obligation, to prosecute and maintain the Depomed Acuform Patents in the Territory. Depomed shall keep Collegium reasonably informed regarding material developments relating to the prosecution and maintenance of the Depomed Acuform Patents in the Territory that would reasonably be expected to have a material impact on any Product or Line Extension in the Territory.

Section 11.2 Acuform Patent Infringement

Each party shall promptly notify the other party in writing of any alleged or threatened Infringement of the Depomed Acuform Patents in the Territory by a Third Party of which such party becomes aware. Depomed shall have the sole right, but not the obligation, to prosecute any

such infringement of the Depomed Acuform Patents in the Territory at its sole expense and Depomed shall retain control of the prosecution of such claim, suit or proceeding (an "Acuform Patent Action"). Newco and Collegium shall cooperate fully with, and as reasonably requested by, Depomed in any Acuform Patent Action, and Depomed shall reimburse Newco and Collegium, as applicable, for such party's out-of-pocket expenses incurred in providing such cooperation. Newco and Collegium may be represented by counsel of its own selection at its own expense in any Acuform Patent Action.

Section 11.3 ANDA Litigation

As between Depomed and Collegium, from and after the Closing, Depomed shall, at its cost and expense, continue to control, direct and maintain control over the ANDA Litigation. Depomed shall keep Collegium reasonably informed with respect to the status of and any material developments in the ANDA Litigation, including any settlement discussions in connection therewith, and shall consider in good faith any reasonable input provided by Collegium or its counsel with respect thereto. As between Depomed and Collegium, Depomed may settle or otherwise resolve the ANDA Litigation, in its sole and absolute discretion, including by granting ANDA Settlement Distributors the right to Commercialize Generic Versions of Products in the Territory. Any awards for any motions, applications or other filings for recovery of funds (regardless of type or category), including costs, fees and sanctions related to the ANDA Litigation, whether or not they were on file prior to the Closing Date, shall be retained in full by Depomed.

Section 11.4 Grünenthal Patent Infringement

Each party shall promptly notify the other party in writing of any alleged or threatened Infringement of the Grünenthal Patents in the Territory by a Third Party of which such party becomes aware. Except for the ANDA Litigation, Depomed and Newco shall cooperate fully with, and as reasonably requested by, Collegium in any action to enforce any Grünenthal Patent in any Legal Proceedings (including ANDA litigation proceedings) initiated by Newco or Collegium after the Closing Date and involving the Products or Line Extensions, to the extent permitted under the Grünenthal License Agreement, the Joint Litigation Agreement and the Consent Agreement (a "Grünenthal Patent Action"), including agreeing to be joined as a party to any such action as Collegium determines is necessary for standing purposes. Collegium shall reimburse Depomed for its out-of-pocket expenses incurred in providing such cooperation and shall be represented in any Grünenthal Patent Action by counsel of its choosing that is reasonably acceptable to Depomed. For any such Grünenthal Patent Action, Newco and Collegium shall use counsel reasonably acceptable to Depomed. Any recovery received as a result of any such Grünenthal Patent Action pursuant to this Section 11.4 shall, as between the parties, be used first to reimburse the parties' documented, out-of-pocket costs and expenses (including court, attorneys' and professional fees) incurred in connection with such Grünenthal Patent Action, and the remainder of the recovery shall be retained by Collegium, provided that the imputed net sales upon which such remaining recovery was based shall be treated as Net

Sales of Payment-Bearing Products with respect to the applicable periods for which such recovery was calculated, for purposes of calculating payments due pursuant to Section 7.3. Collegium agrees not to settle any Grünenthal Patent Action, or make any admissions or assert any position in such action, in a manner that would materially adversely affect Depomed's rights or interests hereunder, including by authorizing a Third Party (as an Authorized Generic Distributor) to Commercialize a Generic Version, without the prior written consent of Depomed, which shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, any awards for any motions, applications or other filings for recovery of funds (regardless of type or category), including costs, fees and sanctions, that were on file prior to the Closing Date shall be retained in full by Depomed.

ARTICLE 12
INDEMNIFICATION

Section 12.1 Indemnification by Depomed

(a) Subject to the provisions of this Article 12, Depomed agrees to, from and after the Closing, defend, indemnify and hold harmless Collegium and its Affiliates and, if applicable, their respective directors, officers, agents, representatives, employees, successors and assigns (collectively, the "Collegium Indemnitees"), from and against any and all Losses to the extent arising out of or resulting from (i) any Retained Liability; (ii) any Excluded Asset; (iii) any breach by Depomed of any of its covenants or agreements contained in this Agreement; (iv) any breach of any warranty or representation of Depomed contained in this Agreement; (v) any Third Party claim based on the development, manufacture, use, testing, handling, storage or commercialization of the Products by or on behalf of Depomed or any of its Affiliates or Third Party licensees prior to the Closing Date; (vi) any Detailing of the Products by Depomed pursuant to Section 4.9; or (vii) any grossly negligent or willful acts or omissions by Depomed or any of its Affiliates, officers, directors, employees, agents or representatives in connection with the Transaction Documents. The indemnity obligation set forth in this Section 12.1(a) shall not apply to the extent Collegium has an obligation to indemnify Depomed Indemnitees in respect to such matter under Section 12.2(a).

(b) Newco and Collegium shall take, and shall cause Newco and the other Collegium Indemnitees to take, commercially reasonable actions to mitigate any Loss that a Collegium Indemnitee asserts under this Article 12 upon becoming aware of any event that would reasonably be expected to, or does, give rise thereto, provided that the foregoing shall not be deemed to limit the ability of Collegium and the other Collegium Indemnitees to incur reasonable costs and expenses in connection therewith.

Section 12.2 Indemnification by Collegium and Newco

(a) Subject to the provisions of this Article 12, Collegium and Newco, jointly and severally, agree to, from and after the Closing, defend, indemnify and hold harmless Depomed and its Affiliates and, if applicable, their respective directors, officers, agents,

representatives, employees, successors and assigns (collectively, the "Depomed Indemnitees"), from and against any and all Losses to the extent arising from or relating to (i) any Assumed Liability; (ii) any breach by Collegium or Newco of any of their covenants or agreements contained in this Agreement; (iii) any breach of any warranty or representation of Collegium or Newco contained in this Agreement; (iv) the use of any Depomed Names by Collegium, Newco or any of their Affiliates (or any Third Party acting on behalf of Collegium, Newco or any of their Affiliates) in a manner not authorized under Section 8.4; (v) any development, Manufacture, use, testing, handling, storage or Commercialization of the Products or Line Extensions by or on behalf of Collegium, Newco or any of their Affiliates or Third Party Sales Representatives after the Closing Date (other than by Depomed on behalf of Collegium or Newco pursuant to this Agreement), including any Regulatory Communications, Regulatory Approvals, Product Promotion, handling of product complaints, reporting of Product adverse events, product liability claims, Product recalls, and any related Product regulatory activities that are the subject of Health Laws; (vi) any grossly negligent or willful acts or omissions by Collegium, Newco or any of their Affiliates, officers, directors, employees, agents or representatives in connection with the Transaction Documents; (vii) any breach of the Grünenthal License Agreement caused, directly or indirectly, by Newco or its Affiliates or Sublicensees, including Collegium or its Affiliates; or (viii) any actions taken by Depomed or its Affiliates in performing the Transition Plan. The indemnity obligation set forth in this Section 12.2(a) shall not apply to the extent Depomed has an obligation to indemnify Collegium Indemnitees in respect to such matter under Section 12.1(a).

(b) Depomed shall take, and shall cause the other Depomed Indemnitees to take, commercially reasonable actions to mitigate any Loss that a Depomed Indemnitee asserts under this Article 12 upon becoming aware of any event that would reasonably be expected to, or does, give rise thereto, provided that the foregoing shall not be deemed to limit the ability of Depomed and the other Depomed Indemnitees to incur reasonable costs and expenses in connection therewith.

Section 12.3 Notice of Claims

Any Collegium Indemnitee or Depomed Indemnitee claiming that it has suffered or incurred any Loss for which it may be entitled to indemnification under this Article 12 (the "Indemnified Party") shall give prompt written notice to the party from whom indemnification is sought (the "Indemnifying Party") of the matter, action, cause of action, claim, demand, fact or other circumstances upon which a claim for indemnification under this Article 12 (each, a "Claim") may be based. Such notice shall contain, with respect to each Claim, such facts and information as are then reasonably available with respect to such Claim, including a description of the Losses suffered or incurred by the Indemnified Party, the amount or estimated amount of such Losses (if known or reasonably capable of estimation) and the method of computation of such Losses, and a reference to the provisions of this Agreement in respect of which such Loss shall have occurred. If any Claim is based on any action, claim, suit or proceeding (in equity or at law) instituted by a Third Party with respect to which the Indemnified Party intends to claim

any Loss under this Article 12 (a "Third Party Claim"), the Indemnified Party shall promptly notify (the "Third Party Claim Notice"), in writing, the Indemnifying Party of such Third Party Claim and offer to tender to the Indemnifying Party the defense of such Third Party Claim. A failure by the Indemnified Party to give written notice of and to offer to tender the defense of any Third Party Claim in a timely manner pursuant to this Section 12.3 shall not limit the obligation of the Indemnifying Party under this Article 12, except (a) to the extent such Indemnifying Party is actually prejudiced thereby or (b) as provided in Section 12.5.

Section 12.4 Third Party Claims

(a) The Indemnifying Party shall have the right, but not the obligation, exercisable by written notice to the Indemnified Party within thirty (30) days of receipt of a Third Party Claim Notice from the Indemnified Party with respect to a Third Party Claim, to assume the conduct and control, at the expense of the Indemnifying Party and through counsel of its choosing that is reasonably acceptable to the Indemnified Party, of such Third Party Claim; provided, however, that the Indemnifying Party shall not be entitled to assume or maintain control of the defense of such Third Party Claim and shall pay the fees and expenses of counsel retained by the Indemnified Party if (i) such Third Party Claim relates to or arises in connection with any criminal Legal Proceeding, (ii) such Third Party Claim seeks an injunction or equitable relief against the Indemnified Party or any of its Affiliates, (iii) the Indemnified Party reasonably concludes, based on the advice of counsel, that there is an irreconcilable conflict of interest between the Indemnifying Party and the Indemnified Party in the conduct of such defense or (iv) after assuming control of such defense, the Indemnifying Party withdraws from such defense or fails to diligently pursue and maintain such defense.

(b) If the Indemnifying Party is controlling the defense of a Third Party Claim, the Indemnifying Party may compromise or settle such Third Party Claim; provided, however, that the Indemnifying Party shall give the Indemnified Party advance written notice of any proposed compromise or settlement and shall not, without the prior written consent of the Indemnified Party, which consent shall not be unreasonably withheld, consent to or enter into any compromise or settlement that commits the Indemnified Party to take, or to forbear to take, any action or does not provide for a full and complete written release by the applicable Third Party of the Indemnified Party. No Indemnified Party may compromise or settle any Third Party Claim for which it is seeking indemnification hereunder without the consent of the Indemnifying Party, which consent shall not be unreasonably withheld. No Indemnifying Party may consent to the entry of any judgment that does not relate solely to monetary damages arising from any such Third Party Claim without the prior written consent of the Indemnified Party, which consent shall not be unreasonably withheld.

(c) Subject to Section 12.4(a), the Indemnifying Party shall permit the Indemnified Party to participate in, but not control, the defense of any such Third Party Claim through counsel chosen by the Indemnified Party, provided that the fees and expenses of such counsel shall be borne by the Indemnified Party. If the Indemnifying Party elects not to, or is not

permitted to pursuant to Section 12.4(a), control or conduct the defense of a Third Party Claim, the Indemnifying Party nevertheless shall have the right to participate in the defense of any Third Party Claim and, at its own expense, to employ counsel of its own choosing for such purpose.

(d) The parties shall cooperate in the defense of any Third Party Claim, with such cooperation to include (i) the retention and the provision to the Indemnifying Party of records and information that are reasonably relevant to such Third Party Claim and (ii) reasonable access to employees on a mutually convenient basis for providing additional information and explanation of any material provided hereunder.

Section 12.5 Expiration

If the Closing shall have occurred, all covenants, agreements, warranties and representations made herein or in any certificate delivered in accordance herewith shall survive the Closing. Notwithstanding the foregoing, all representations, warranties, covenants and agreements made herein or in any certificate delivered in accordance herewith, and all indemnification obligations under Section 12.1(a)(iii), Section 12.1(a)(iv), Section 12.2(a)(ii) and Section 12.2(a)(iii) with respect to any such representations, warranties, covenants or agreements shall (a) in the case of such representations and warranties other than the Fundamental Representations, terminate and expire on, and no action or proceeding seeking damages or other relief for breach of any thereof or for any misrepresentation or inaccuracy with respect thereto, shall be commenced after, the date that is twenty-four (24) months after the Closing Date, (b) in the case of the Fundamental Representations, terminate and expire, and no action or proceeding seeking damages or other relief for breach of any thereof or for any misrepresentation or inaccuracy with respect thereto, as provided in the relevant statute of limitations, or (c) in the case of any covenants or agreements, survive indefinitely or for such shorter period of time specified therein, in each case, unless prior to such date a claim for indemnification with respect thereto shall have been made, with reasonable specificity, by written notice given in accordance with Section 12.3.

Section 12.6 Certain Limitations

Notwithstanding any other provision in this Agreement, in no event shall Depomed or any of its Affiliates have any liability under any provision in this Agreement for any Taxes (and any Losses with respect thereto or resulting therefrom) to the extent such Taxes are attributable to Tax periods (or portions thereof) beginning after the Closing Date.

Section 12.7 Sole Remedy/Waiver

Except for either party's right to terminate the Agreement set forth in Section 9.3, and except as set forth in the penultimate sentence of this Section 12.7 and in Section 17.13, this Article 12 provides the sole recourse and exclusive means from and after the Closing by which a party may assert and remedy any Losses arising under or with respect to this Agreement or any certificate or instrument of transfer, assignment or assumption delivered under this Agreement,

and Section 17.12 and Section 17.13 provide the exclusive means by which a party may bring actions against the other party under or with respect to this Agreement or any certificate or instrument of transfer, assignment or assumption delivered under this Agreement. Notwithstanding the foregoing, nothing herein shall limit the liability of any party hereto for intentional or willful misrepresentation of material facts which constitutes common law fraud under applicable Legal Requirements. With respect to any Losses arising under or with respect to this Agreement or any certificate or instrument of transfer, assignment or assumption delivered under this Agreement, each party agrees that it shall only seek such Losses from the other parties, and each party hereby waives the right to seek Losses from any Affiliate of the other parties (except in the case of Newco, as an Affiliate of Collegium, and in the case of Collegium, as an Affiliate of Newco), or any director, officer or employee of the other parties (or any of its Affiliates).

Section 12.8 Right to Offset

Each party shall have the right to offset any amount owed by the other party to such first party under or in connection with this Agreement, including pursuant to this Article 12 or in connection with any breach, against any future payments owed by such first party to such other party under this Agreement, in each case based on a final determination by a court of competent jurisdiction pursuant to Section 17.11 (from which no appeal may be taken), any written agreement of the parties as to amounts owed or pursuant to an arbitration proceeding pursuant to Section 17.12, as applicable. Such offsets shall be in addition to any other rights or remedies available under this Agreement and applicable Legal Requirements. For clarity, in the event that Collegium is entitled to and does offset any amounts owed to it by Depomed in accordance with this Section 12.8 against any of the Minimum Quarterly Payments otherwise owed by it under Section 7.3(a), Collegium will not be deemed to be in breach of its payment obligations to Depomed hereunder and the amount of such offset shall not constitute a Quarterly Shortfall for which Depomed will be entitled to draw upon the Letter of Credit pursuant to Section 7.7(a)

Section 12.9 Indemnity Payments

In the event that any party agrees to, or is determined to have an obligation to, pay another party for Losses as provided in this Article 12, the Indemnifying Party shall, subject to its rights under Section 12.8, if applicable, promptly pay such amount to the Indemnified Party in U.S. Dollars via wire transfer of immediately available funds to the account(s) specified in writing by the Indemnified Party.

Section 12.10 Calculation of Damages

Except as otherwise provided in this Article 12, in any case where the Indemnified Party subsequently recovers from its insurance provider(s) any amount in respect of a matter with respect to which an Indemnifying Party has indemnified it pursuant to this Article 12 (which, for the avoidance of doubt, shall not include an amount recovered as a Tax benefit), such Indemnified Party shall promptly pay over to the Indemnifying Party the amount so recovered

(after deducting therefrom the full amount of the expenses incurred by it in procuring such recovery), but not in excess of any amount previously so paid by the Indemnifying Party to or on behalf of the Indemnified Party in respect of such matter and less any increase in premiums or other fees reasonably attributable to such insurance recovery.

Section 12.11 No Consequential Damages

NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED HEREIN, WITH THE EXCEPTION OF ANY BREACH OF SECTION 2.5 OR SECTION 2.7(B), NO PARTY SHALL BE LIABLE TO OR OTHERWISE RESPONSIBLE TO THE OTHER PARTY OR ANY AFFILIATE OF THE OTHER PARTY FOR LOST REVENUES OR PROFITS DAMAGES OR INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE, EXEMPLARY OR MULTIPLIED DAMAGES THAT ARISE OUT OF OR RELATE TO THIS AGREEMENT OR THE PERFORMANCE OR BREACH HEREOF OR ANY LIABILITY RETAINED OR ASSUMED HEREUNDER; PROVIDED, HOWEVER, THAT THE FOREGOING SHALL NOT BE CONSTRUED TO PRECLUDE RECOVERY IN RESPECT OF ANY LOSS DIRECTLY INCURRED OR SUFFERED FROM THIRD PARTY CLAIMS.

ARTICLE 13
CONFIDENTIALITY AND PUBLICITY

Section 13.1 Proprietary Information

Pursuant to this Agreement, a party receiving Proprietary Information from the other, directly or indirectly, will treat such Proprietary Information as confidential, will use such Proprietary Information only for the purposes of this Agreement and will not disclose, and will take all reasonable precautions to prevent the disclosure of, such Proprietary Information to (a) any of its officers, directors, managers, equity holders, actual or potential partners, acquirers, financing sources, licensees, sublicensees, research collaborators, subcontractors, employees, agents, representatives, Affiliates or consultants, except those who need to know such Proprietary Information and who are bound by a like obligation of confidentiality and non-use or (b) to Third Parties other than those referenced in clause (a).

Section 13.2 Disclosures Required by Law

In the event the recipient party is required under applicable Legal Requirements to disclose Proprietary Information of the disclosing party to any Governmental Authority to obtain any Regulatory Approval for the Products, is required to disclose Proprietary Information in connection with bona fide legal process (including in connection with any bona fide dispute hereunder) or is required to disclose Proprietary Information under the rules of the securities exchange upon which its securities are traded, the recipient party may do so only if it limits disclosure to that purpose after giving the disclosing party prompt written notice of any instance of such a requirement in reasonable time for the disclosing party to attempt to object to or to

limit such disclosure. In the event of disclosures required under applicable Legal Requirements, the recipient party shall cooperate with the disclosing party as reasonably requested thereby.

Section 13.3 Publicity

The parties have agreed upon the form and content of their own press releases to be issued by each of the parties promptly following the execution of this Agreement in the forms attached hereto as Schedule 13.3. Once such press release or any other written statement is approved for disclosure by the parties, either party may make subsequent public disclosure of the contents of such statement without the further approval of the other party. Any other publicity, news release, public comment or other public announcement, whether to the press, to stockholders, or otherwise, relating to this Agreement, shall first be reviewed and approved by the parties, except no such approval shall be required for such publicity, news release, public comment or other public announcement which, in accordance with the advice of legal counsel to the party making such disclosure, is required by Legal Requirement or for appropriate market disclosure; provided, however, that each party shall be entitled to refer publicly to the relationship of the parties reflected in this Agreement in a manner that is consistent with the joint press release issued by the parties. For clarity, any party making any announcement which is required by Legal Requirement will, unless prohibited by law, give the other party an opportunity to review the form and content of such announcement and comment before it is made. The parties shall work together to coordinate their respective filings with governmental agencies, including the United States Securities and Exchange Commission ("SEC"), as to the contents and existence of this Agreement as each party shall reasonably deem necessary or appropriate and each party shall provide the other party an opportunity to comment on any proposed filings to ensure consistent treatment. The parties acknowledge that this Agreement and one or more of the other Transaction Documents may need to be filed by one or both parties with the SEC. The parties agree, prior to making any such filing with the SEC, to provide the other party and its counsel with (i) a proposed redacted version of this Agreement (and any other Transaction Document, as applicable) which it intends to file with the SEC, and (ii) any draft correspondence proposed to be sent to the SEC requesting the confidential treatment by the SEC of those redacted sections of the Agreement (or any other Transaction Document, as applicable), and to give due consideration to any comments provided by the other party or its counsel and use reasonable efforts to ensure the confidential treatment by the SEC of those sections specified by such other party or its counsel.

Section 13.4 Survival

The provisions of this Article 13 shall survive termination of this Agreement and shall remain in effect until a date three (3) years after the Term of this Agreement.

ARTICLE 14
COVENANTS

Section 14.1 HSR Act Filing

Each party shall, as promptly as practicable, not later than three (3) Business Days following the Effective Date, file or cause to be filed with the U.S. Federal Trade Commission and the U.S. Department of Justice a Notification and Report Form (as defined in the HSR Act) with respect to the Transactions, which form shall specifically request early termination of the waiting period prescribed by the HSR Act. All HSR filing fees payable in connection with such filing shall be borne and paid one-half by Depomed (or its applicable Affiliate) and one-half by Collegium. Each party shall use its commercially reasonable efforts to respond promptly to any requests for additional information made by either of such agencies, and to cause the waiting periods under the HSR Act to terminate or expire at the earliest possible date after the date of filing. Each party shall instruct its counsel to cooperate with the other party's counsel to facilitate and expedite the identification and resolution of any such issues and, consequently, the expiration of the applicable HSR Act waiting period at the earliest practicable date.

Section 14.2 Conduct of Business

From the Effective Date to the Closing Date, except as consented to by an officer of Collegium in writing, Depomed agrees that it will conduct the Business, and will cause the Business to be conducted, in the ordinary course of business consistent with past practice since April 2, 2015 and in compliance in all material respects with all applicable Legal Requirements, pay or perform all material obligations relating to the Business as they become due and owing in the ordinary course of business, keep and maintain the Transferred Assets in good repair and normal operating condition, wear and tear excepted, and preserve, and cause Depo NF to preserve, intact the Business and preserve the related relationships with employees, Customers, suppliers, vendors, Regulatory Authority and other Third Parties in regards to the Products.

Section 14.3 Ancillary Agreements

"Ancillary Agreements" means, collectively, the following:

(a) The Consent Agreement;

(b) The Joinder Agreement;

(c) At the Closing, Collegium, Newco and Depomed, as applicable, shall enter into, execute and deliver:

(i) The Bill of Sale

(ii) The Domain Name Assignment;

(iii) The Trademark License Agreement;

(iv) A Transition Services Agreement in a form mutually agreed by the Parties (the "Transition Services Agreement");

(v) A Long-Term Collaboration Agreement (regarding government pricing) in a form mutually agreed by the Parties (the "Long-Term Collaboration Agreement");

(vi) A collateral agreement in substantially the form attached hereto as Exhibit E (the "Collateral Agreement");

(vii) A pledge agreement in substantially the form attached hereto as Exhibit F (the "Pledge Agreement");

(viii) The Master Letter of Credit Agreement;

(ix) The Letter of Credit;

(x) The Control Agreement; and

(xi) A subordination and intercreditor agreement with Silicon Valley Bank, pursuant to which Silicon Valley Bank will permit Depomed to secure a first-priority lien on all of the assets of Newco pursuant to the Collateral Documents, including cash receipts and the equity interests of Newco held by Collegium, in a form reasonably acceptable to Depomed (the "Intercreditor Agreement").

(d) At the Closing, Collegium and Newco shall enter into, execute and deliver the Collegium Sublicense in substantially the form attached hereto as Exhibit G.

Section 14.4 Grünenthal Consent Agreement

Simultaneously with the execution of this Agreement, Newco shall join the Consent Agreement, dated as of November 30, 2017, by and between Grünenthal and Depomed (the "Consent Agreement") by executing a joinder agreement in the form of the joinder agreement attached as Exhibit A to the Consent Agreement (the "Joinder Agreement"), upon which Collegium and Newco shall become parties to the Consent Agreement and shall be fully bound by, and subject to, all of the terms and conditions of the Consent Agreement as though Collegium and Newco were original parties thereto. Depomed shall, and shall cause its Affiliates to, fulfill all of its and their respective obligations, including payment obligations, under the Consent Agreement. Depomed shall not, and shall cause its Affiliates not to, amend or waive, or take any action or omit to take any action that would alter, any of its rights under the Consent Agreement in any manner that adversely affects, or would reasonably be expected to adversely affect, Collegium's rights and benefits under this Agreement or the Grünenthal License Agreement. Depomed shall promptly notify Collegium of any default or breach under

the Consent Agreement. In the event that Depomed, or any of its Affiliates, shall fail to make any payment when due or any other default or breach arises under the Consent Agreement, Collegium shall have the right (but not the obligation) to make such payment or otherwise cure such default or breach on behalf of Depomed or its Affiliate. In such event, Depomed shall promptly reimburse Collegium any such amounts paid and/or costs and expenses incurred by Collegium or, at Collegium's election, Collegium may offset such amounts paid and/or costs and expenses incurred by Collegium against any amounts payable to Depomed hereunder. Notwithstanding anything herein to the contrary, Depomed shall not assign the Consent Agreement, other than in connection with a permitted assignment by Depomed of this Agreement under Section 17.9, without Collegium's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed.

Section 14.5 No Negotiation

Between the Effective Date and the Closing Date, Depomed shall not, and shall not permit any of its Affiliates or Representatives to, directly or indirectly, solicit, initiate, encourage or entertain any inquiries or proposals, discuss or negotiate with, provide any information to, consider the merits of any inquires or proposals from any Person (other than Collegium) to enter into any contract or instrument relating to any transaction that would compromise the ability of Depomed or any Transferring Entity to consummate the Transactions. Depomed shall promptly advise Collegium, orally and in writing, of any such inquiry or proposal received from a third party. Depomed agrees that the rights and remedies for noncompliance with this Section 14.5 shall include having such provision specifically enforced by a court having equity jurisdiction, it being acknowledged that any such breach or threatened breach may cause irreparable injury to Collegium and that money damages will not provide an adequate remedy to Collegium.

Section 14.6 Resale Exemption Certificates

At the Closing (or within such reasonable time thereafter as may be necessary to perfect the resale or other exemption certificates), Collegium shall deliver to Depomed fully completed and executed resale exemption certificates or other applicable exemption certificates for all jurisdictions identified by Depomed prior to the Closing as jurisdictions in which inventory is to be transferred and for which resale exemption certificates are necessary to comply with Legal Requirements or to minimize Transfer Taxes.

Section 14.7 Depomed Responsibility for Retained Post-Marketing Commitments

As between Depomed and Collegium, from and after the Closing, Depomed shall, at its cost and expense, continue to control, direct and maintain control over the Retained Post-Marketing Commitments. Depomed shall keep Collegium reasonably informed with respect to the status of and any material developments in the Retained Post-Marketing Commitments, and shall consider in good faith any reasonable input provided by Collegium or its counsel with respect thereto.

Section 14.8 Collegium Minimum Cash Balance

Collegium shall maintain cash and cash equivalents constituting immediately available funds of at least the Minimum Cash Balance from the Effective Date until immediately prior to payment of the Transferred Inventory Cost, the Upfront Payment and the Collegium Prepaid Business Expense Allocation on the Closing Date.

Section 14.9 Newco Operations and Liabilities

(a) Collegium and Newco agree to, and Collegium agrees to cause Newco to, grant a security interest in all of Newco's property and rights to Depomed, including the exclusive licenses and sublicenses transferred under this Agreement and the Trademark License Agreement, the Transferred Assets, off membership interests in Newco, Newco's rights under the Sales Account, and all other rights of Newco under this Agreement and the Trademark License Agreement.

(b) Except as prohibited by law or by order of a court of competent jurisdiction, Newco shall, and Collegium shall cause Newco to, fully perform its obligations under the Transaction Documents to which Newco is a party, including, to the extent approval by Collegium is required prior to Newco performing such obligations, Collegium shall approve any such obligations.

(c) Newco shall, and Collegium shall cause Newco to, (i) establish and maintain the Sales Account, (ii) cause any amounts from sales of the Payment-Bearing Products to be deposited directly into the Sales Account, and (iii) cause the Newco Deposits to be swept daily into the account designated by Depomed.

(d) If Collegium, Newco or any of their Affiliates shall receive any amounts from sales of the Payment-Bearing Products, Collegium and Newco, as applicable, shall, and Collegium shall cause Newco, if applicable, to, deliver such amounts by wire transfer of immediately available funds to the Sales Account, and in any event not later than two (2) Business Days following its receipt thereof; provided further, that Collegium shall (i) take any and all steps necessary or desirable to collect all amounts becoming due and payable from the Commercialization of Payment-Bearing Products and deliver such amounts to the Sales Account to the extent required by this Agreement; and (ii) enforce its rights under any of its commercial contracts.

(e) Collegium and Newco shall not, and Collegium shall cause Newco not to, except as otherwise provided herein (including under Section 2.2 and Section 17.9) or, in any other Transaction Document, directly or indirectly, sell, assign (by operation of law or otherwise) or otherwise dispose of, or create, incur, assume or suffer to be created or to exist any Lien on any of its rights, title or beneficial interest in, to or under, whether directly or indirectly, (i) Newco; (ii) the Depomed Acuform Patents or Depomed Product Know-How; (iii) the Grünenthal IP Rights; or (iv) the Transferred Assets, in each case other than any Lien granted under the Collateral Agreements.

(f) Newco shall not, and Collegium shall cause Newco not to, (i) incur or guarantee any Indebtedness; (ii) create, incur, assume or permit to exist any Liens on its assets that are senior to the Liens contemplated by the Collateral Agreement; (iii) sell, assign, or otherwise transfer any of its assets, contracts or business, whether by sale, merger consolidation, acquisition, transfer, operation of law or otherwise; or (iv) engage in any business or activities or acquire any assets, lines of business or other Persons; except in each case other than pursuant to the rights, property and privileges granted by, and obligations required of it under, the Transaction Documents.

(g) Newco shall not, and Collegium shall cause Newco not to, take any action to waive, repeal, amend, vary, supplement or otherwise modify its organizational documents in a manner that would adversely affect the rights, privileges or preferences of Depomed under the Transaction Documents;

(h) Newco shall not, and Collegium shall cause Newco not to, take any action or cause or permit Newco (except as required by law) to take any action to cause Newco to become subject to a voluntary bankruptcy or an involuntary bankruptcy.

(i) Newco shall not, and Collegium shall cause Newco not to, take any action to dissolve Newco.

(j) Newco shall not, and Collegium shall cause Newco not to, enter into any lease of real property.

(k) Newco shall not, and Collegium shall cause Newco not to, have any employees.

(l) Newco shall, and Collegium shall cause Newco to, maintain its existence as a limited liability company, validly existing and in good standing under the laws of the State of Delaware, and duly qualified as a limited liability company licensed under the laws of each state necessary for the conduct of its business or activities.

(m) Newco shall, and Collegium shall cause Newco to, comply with all provisions of its organizational documents

(n) Newco shall, and Collegium shall cause Newco to, maintain all licenses permits, charters, governmental qualifications, registrations, consents, filings, certificates, waivers, approvals, notices or other authorizations necessary for it to carry on its activities and business as contemplated in the Transaction Documents.

(o) Newco shall, and Collegium shall cause Newco to, provide Depomed prompt notice of any adverse events, or threatened events, with which it becomes aware in

connection with the transactions contemplated by the Transaction Documents, including but not limited to a breach of any representation, warranty or covenant hereunder, a default by any of its customers, distributors, vendors, suppliers or any other Third Parties that it is under privity of contract with, or any Claim.

(p) Newco shall, and Collegium shall cause Newco to, pay any applicable taxes.

(q) Collegium and Newco shall not, and Collegium shall cause Newco not to, sell, assign or otherwise transfer any equity interests in Newco, or grant a proxy with respect to the voting rights of Newco or that otherwise would prohibit a de facto change of Control of Newco.

(r) Newco shall not, and Collegium shall cause Newco not to; enter into any transactions other than the Sublicense to Collegium.

(s) Newco shall not, and Collegium shall cause Newco not to; incur or otherwise suffer to exist or become effective or remain liable for any contractual obligation that would, or would reasonably be expected to, (i) restrict, hinder or limit the ability of Newco or Collegium to comply with each of its obligations under the Transaction Documents, or (ii) restrict or hinder the return of the Transferred Assets and Licensed IP Rights to Depomed in accordance with the Transaction Documents upon an "Event of Default" (as defined in the Collateral Agreement) or upon termination or expiration of this Agreement.

(t) With respect to the Collegium Sublicense, Newco shall, and Collegium shall cause Newco to, at Collegium's own expense:

(i) perform and observe all terms and provisions of the Collegium Sublicense to be performed or observed by Newco;

(ii) maintain the Collegium Sublicense in full force and effect and enforce the Collegium Sublicense in accordance with the terms thereof; and

(iii) furnish to Depomed promptly upon receipt thereof copies of all material notices, requests and other documents received by Newco under or pursuant to the Collegium Sublicense, and from time to time furnish to Depomed such information and reports related to the Collegium Sublicense as Depomed may reasonably request.

(u) Newco shall not, and Collegium shall cause Newco not to, cancel or terminate the Collegium Sublicense or consent to or accept any cancellation or termination thereof or take any other action in connection with the Collegium Sublicense that would materially impair the value of the interests or rights of Newco thereunder or that would materially impair the interests or rights of Depomed hereunder.

Section 14.10 Affiliates

(a) Depomed Affiliates. Depomed shall cause Depo NF and its other Affiliates to comply with the terms of, and to perform their respective obligations under, this Agreement.

(b) Collegium Affiliates. Collegium shall cause Newco and its other Affiliates to comply with the terms of, and to perform their respective obligations under, this Agreement.

Section 14.11 Further Assurances

Each party agrees, upon the reasonable request of another party, to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement, including the preparation and delivery, at the expense of the requesting party, of such financial information regarding the Products or Transferred Assets as may be required by a Governmental Authority having jurisdiction over the parties. Each party agrees, upon the reasonable request of another party, to discuss and cooperate in order to ensure consistent Tax and accounting positions.

ARTICLE 15
NOTICES

Section 15.1 Notices

All notices required or permitted hereunder shall be given in writing and sent by facsimile transmission (with a copy sent by first-class mail), or mailed postage prepaid by certified or registered mail (return receipt requested), or sent by a nationally recognized express courier service, or hand-delivered at the following address:

If to Depomed:

Depomed, Inc.
7999 Gateway Boulevard, Suite 300
Newark, CA 94560
Attention: Legal Department
Fax No.: (510) 744-8001

With a copy to (which shall not constitute notice hereunder):

Wilson Sonsini Goodrich & Rosati
650 Page Mill Road
Palo Alto, CA 94304
Attention: Lowell Segal
Fax No.: (650) 493-6811

and

Gibson, Dunn & Crutcher LLP
555 Mission Street, Suite 3000
San Francisco, CA 94105
Attention: Ryan Murr
Fax No.: (415) 374-8430

If to Collegium:

Collegium Pharmaceutical, Inc.
780 Dedham Street, Suite 800
Canton, MA 02021
Attention: Michael Heffernan
Fax No.: (781) 828-4697

With a copy to (which shall not constitute notice hereunder):

Gunderson Dettmer Stough Villeneuve Franklin & Hachigian
One Marina Park Drive, Suite 900
Boston, MA 02210
Attention: Tim Ehrlich
Fax No.: (617) 648-9199

All notices shall be deemed made upon receipt by the addressee as evidenced by the applicable written receipt.

ARTICLE 16
INSURANCE

Section 16.1 Insurance

(a) During the Term and for a period of two (2) years after any expiration or termination of this Agreement, each party shall maintain (i) a commercial general liability insurance policy or policies with minimum limits of **[***]** per occurrence **[***]** in the aggregate on an annual basis and (ii) a product liability insurance policy or policies with minimum limits of

[***] per occurrence and **[***]** in the aggregate on an annual basis. Upon request, each party shall provide certificates of insurance to the other evidencing the coverage specified herein. Neither party's liability to the other is in any way limited to the extent of its insurance coverage.

(b) As of the Closing Date, the coverage under all insurance policies of Depomed and its Affiliates shall continue in force only for the benefit of Depomed and its Affiliates, and not for the benefit of Collegium or any of its representatives. As of the Closing Date, Collegium (i) agrees to arrange for its own insurance policies with respect to the Transferred Assets covering all periods from and after the Closing Date and agrees not to seek, through any means, to benefit from any of Depomed's or its Affiliates' insurance policies which may provide coverage for claims relating in any way to the Transferred Assets and (ii) shall name Depomed as an additional insured under Collegium's product liability insurance policy.

ARTICLE 17
MISCELLANEOUS

Section 17.1 Headings

The titles, headings or captions and paragraphs in this Agreement are for convenience only and do not define, limit, extend, explain or describe the scope or extent of this Agreement or any of its terms or conditions and therefore shall not be considered in the interpretation, construction or application of this Agreement.

Section 17.2 Severability

In the event that any of the provisions or a portion of any provision of this Agreement is held to be invalid, illegal, or unenforceable by a court of competent jurisdiction or a governmental authority, such provision or portion of any provision will be construed and enforced as if it had been narrowly drawn so as not to be invalid, illegal, or unenforceable, and the validity, legality, and enforceability of the enforceable portion of any such provision and the remaining provisions will not be adversely affected thereby.

Section 17.3 Entire Agreement

This Agreement, together with the Schedules and Exhibits hereto, all of which are incorporated by reference, contains all of the terms agreed to by the parties regarding the subject matter hereof and supersedes any prior agreements, understandings, or arrangements between the parties, whether oral or in writing.

Section 17.4 Amendments

This Agreement may not be amended, modified, altered, or supplemented except by means of a written agreement or other instrument executed by both of the parties hereto. No

course of conduct or dealing between the parties will act as a modification or waiver of any provisions of this Agreement.

Section 17.5 Counterparts

This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and together shall constitute one and the same agreement and shall become effective when one or more counterparts have been signed by each of the parties and delivered to the other party, it being understood that the parties need not sign the same counterpart. This Agreement, following its execution, may be delivered via telecopier machine or other form of electronic delivery, which shall constitute delivery of an execution original for all purposes.

Section 17.6 Waiver

The failure of either party to enforce or to exercise, at any time or for any period of time, any term of or any right arising pursuant to this Agreement does not constitute, and will not be construed as, a waiver of such term or right, and will in no way affect that party's right later to enforce or exercise such term or right.

Section 17.7 Force Majeure

In the event of any failure or delay in the performance by a party of any provision of this Agreement due to acts beyond the reasonable control of such party (such as, for example, fire, explosion, strike or other difficulty with workmen, shortage of transportation equipment, accident, act of God, declared or undeclared wars, acts of terrorism, or compliance with or other action taken to carry out the intent or purpose of any law or regulation) (a "Force Majeure Event"), then such party shall have such additional time to perform as shall be reasonably necessary under the circumstances. In the event of such failure or delay, the affected party will use its diligent efforts, consistent with sound business judgment and to the extent permitted by law, to correct such failure or delay as expeditiously as possible. In the event that a party is unable to perform due to a Force Majeure Event its obligation to perform under the affected provision(s) of this Agreement shall be suspended during such time of nonperformance.

Neither party shall be liable hereunder to the other party nor shall be in breach for failure to perform its obligations caused by a Force Majeure Event. In the case of any such event, the affected party shall promptly, but in no event later than five (5) days of its occurrence, notify the other party stating the nature of the condition, its anticipated duration and any action being taken to avoid or minimize its effect. Furthermore, the affected party shall keep the other party informed of the efforts to resume performance. After fifteen (15) days of such inability to perform, the parties agree to meet and in good faith discuss how to proceed.

Section 17.8 Successors and Assigns

Subject to Section 17.9, this Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and assigns permitted under this Agreement.

Section 17.9 Assignment

This Agreement and the rights granted herein shall not be assignable (or otherwise transferred) by any party without the prior written consent of the other parties. Any attempted assignment without consent shall be void. Notwithstanding the foregoing or anything in this Agreement to the contrary (but subject to the fourth sentence of this Section 17.9), Collegium or Depomed may transfer, assign or delegate its rights and obligations under this Agreement without consent to: (a) an Affiliate reasonably capable of performing such party's obligations under this Agreement, for so long as such entity remains an Affiliate, provided that the assigning party shall remain primarily liable for any acts or omissions of such Affiliate; (b) in the case of Depomed, solely with respect to the transfer or assignment of its rights to receive payments (or any portion thereof) due to Depomed under this Agreement, provided that, in connection with such a transfer or assignment, Depomed may disclose to the transferee or assignee any reports or information provided to Depomed regarding such payments under a written agreement containing non-disclosure and non-use provisions no less stringent than as set forth in this Agreement; or (c) a successor to all or substantially all of the business or assets of the assigning party relating to this Agreement, whether by sale, merger, consolidation, acquisition, transfer, operation of law or otherwise. Notwithstanding anything to the contrary in this Agreement, this Agreement and the rights granted herein shall not be assignable (or otherwise transferred) by Collegium to a Third Party, other than to a successor in connection with a sale of all or substantially all of the business or assets of Collegium, prior to the expiration of the last-to-expire Grünenthal Patent, without the prior written consent of Depomed, which consent shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, or anything to the contrary in this Agreement, neither Collegium nor any of its Affiliates (other than Newco, which cannot assign (or otherwise transfer) this Agreement and the rights granted herein) shall transfer or assign its rights and obligations under this Agreement to any Person that (i) does not have at least an equal or greater amount of stockholders' equity, working capital, and a commercial sales force as Collegium as of the Closing Date; and (ii) is not a "United States person" for U.S. federal income tax purposes (including, for the avoidance of doubt, any Person that is disregarded from any Person that is not a "United States person" for U.S. federal income tax purposes). In connection with any permitted assignment of this Agreement by Collegium, or Subcontracting pursuant to which a Third Party Sales Representative is engaged by Collegium to Promote the Products, Collegium shall ensure that the assignee or Subcontractor, as applicable, provides representations and warranties in substantially the same form and substance as set forth in Section 10.2(i)(v). No party shall knowingly engage any Third Party appearing on the FDA's debarment list or the list of excluded individuals/entities of the Office of Inspector General of the Department of Health and Human Services to perform, or assist such party in the performance

of, its obligations under this Agreement, and the parties shall review each such list prior to engaging any such Third Party. No assignment under clause (a) of this Section 17.9 shall relieve the assigning party of any of its responsibilities or obligations hereunder and, as a condition of such assignment, the assignee shall agree in writing to be bound by all obligations of the assigning party hereunder. This Agreement shall be binding upon the successors and permitted assigns of the parties.

Section 17.10 Construction

The parties acknowledge and agree that: (a) each party and its representatives have reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; and (b) the terms and provisions of this Agreement will be construed fairly as to each party and not in favor of or against either party regardless of which party was generally responsible for the preparation or drafting of this Agreement. Unless the context of this Agreement otherwise requires: (i) words of any gender include each other gender; (ii) words using the singular or plural number also include the plural or singular number, respectively; (iii) the terms "hereof," "herein," "hereby," and derivative or similar words refer to this entire Agreement; (iv) the terms "Article," "Section," "Exhibit," "Schedule," or "clause" refer to the specified Article, Section, Exhibit, Schedule, or clause of this Agreement; (v) "or" is disjunctive but not necessarily exclusive; and (vi) the term "including" or "includes" means "including without limitation" or "includes without limitation." Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days are specified. Any references in this Agreement to an amount paid by Company as being "non-refundable" or "non-creditable" shall not be construed to limit Collegium's right to seek to recover or actually recover any amount of damages arising from any uncured breach of this Agreement by Depomed, subject only to the limitations and exclusions in Section 12.11.

Section 17.11 Governing Law; Jurisdiction; No Jury Trial.

(a) This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflicts of law, principles or rules of such state, to the extent such principles or rules are not mandatorily applicable by statute and would permit or require the application of the laws of another jurisdiction.

(b) The parties consent to the exclusive jurisdiction of the Federal and State courts located in the State of New York for the resolution of all disputes or controversies between the parties which, pursuant to applicable Legal Requirement, are not subject to the provisions of Section 17.12. Each of the parties (i) consents to the exclusive jurisdiction of each such court in any suit, action or proceeding relating to or arising out of this Agreement or the Transactions; (ii) waives any objection that it may have to the laying of venue in any such suit, action or proceeding in any such court; and (iii) agrees that service of any court paper may be made in such manner as may be provided under applicable Legal Requirements or court rules governing service of process. THE PARTIES HERETO HEREBY IRREVOCABLY WAIVE,

AND AGREE TO CAUSE THEIR RESPECTIVE AFFILIATES TO WAIVE, THE RIGHT TO TRIAL BY JURY IN ANY ACTION DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS AGREEMENT, ANY RELATED AGREEMENTS OR ANY TRANSACTIONS CONTEMPLATED HEREBY.

(c) Notwithstanding anything herein to the contrary, each party acknowledges and irrevocably agrees that with respect to any Covered Action, such party agrees and shall take (or refrain from taking) such actions as necessary (i) to procure that any Covered Action shall be subject to the exclusive jurisdiction of any New York State court or federal court of the United States of America sitting in the Borough of Manhattan in the county of New York, and any appellate court thereof, (ii) to procure that service of process, summons, notice or document by registered mail addressed to them at their respective addresses provided in Section 15.1 shall be effective service of process against it for any Covered Action, (iii) to waive and hereby waives, to the fullest extent permitted by applicable Legal Requirement, any objection which it may now or hereafter have to the laying of venue of, and the defense of an inconvenient forum to the maintenance of, any Covered Action, and (iv) to procure that a final judgment in any Covered Action shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by applicable Legal Requirement. Nothing in this paragraph shall affect or eliminate any right to serve process in any other manner permitted by applicable Legal Requirement. EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES ANY RIGHT TO TRIAL BY JURY IN RESPECT OF ANY COVERED ACTION.

Section 17.12 Dispute Resolution

The parties recognize that a dispute may arise relating to this Agreement (a "Dispute"). Other than with respect to Third Party Claims, any Dispute, including Disputes that may involve any Affiliates of a party, shall be resolved in accordance with this Section 17.12.

(a) Mediation.

(i) The parties shall first attempt in good faith to resolve any Dispute by confidential mediation in accordance with the then current Mediation Procedure of the International Institute for Conflict Prevention and Resolution (the "CPR Mediation Procedure") (www.cpradr.org) before initiating arbitration. The CPR Mediation Procedure shall control, except where it conflicts with these provisions, in which case these provisions control. The mediator shall be chosen pursuant to CPR Mediation Procedure. The mediation shall be held in New York, New York.

(ii) Either party may initiate mediation by written notice to the other party of the existence of a Dispute. The parties agree to select a mediator within twenty (20) days of the notice and the mediation will begin promptly after the selection. The mediation will continue until the mediator, or either party, declares in writing, no sooner than after the conclusion of one full day of a substantive mediation conference attended on behalf of each party by a senior business person with authority to resolve the Dispute, that the Dispute cannot be

resolved by mediation. In no event, however, shall mediation continue more than sixty (60) days from the initial notice by a party to initiate meditation unless the parties agree in writing to extend that period.

(iii) Any period of limitations that would otherwise expire between the initiation of mediation and its conclusion shall be extended until twenty (20) days after the conclusion of the mediation.

(b) Arbitration.

(i) If the parties fail to resolve the Dispute in mediation, and a party desires to pursue resolution of the Dispute, the Dispute shall be submitted by either party for resolution in arbitration pursuant to the then current CPR Non-Administered Arbitration Rules (the "CPR Rules") (www.cpradr.org), except where they conflict with these provisions, in which case these provisions control. The arbitration will be held in New York, New York. All aspects of the arbitration shall be treated as confidential.

(ii) The arbitrators will be chosen from the CPR Panel of Distinguished Neutrals, unless a candidate not on such panel is approved by the parties. Each arbitrator shall be a lawyer with at least fifteen (15) years' experience with a law firm or corporate law department of over twenty-five (25) lawyers or who was a judge of a court of general jurisdiction. To the extent that the Dispute requires special expertise, the parties will so inform CPR prior to the beginning of the selection process.

(iii) The arbitration tribunal shall consist of three (3) arbitrators, of whom each party shall designate one in accordance with the "screened" appointment procedure provided in CPR Rule 5.4. The chair will be chosen in accordance with CPR Rule 6.4. If, however, the aggregate award sought by the parties is less than Five Million Dollars ($5,000,000) and equitable relief is not sought, a single arbitrator shall be chosen in accordance with the CPR Rules. Candidates for the arbitrator position(s) may be interviewed by representatives of the parties in advance of their selection, provided that all parties are represented.

(iv) The parties agree to select the arbitrator(s) within forty-five (45) days of initiation of the arbitration. The hearing will be concluded within nine (9) months after selection of the arbitrator(s) and the award will be rendered within sixty (60) days of the conclusion of the hearing, or of any post hearing briefing, which briefing will be completed by both sides within forty-five (45) days after the conclusion of the hearing. In the event the parties cannot agree upon a schedule, then the arbitrator(s) shall set the schedule following the time limits set forth above as closely as practical.

(v) The hearing will be concluded in ten (10) hearing days or less. Multiple hearing days will be scheduled consecutively to the greatest extent possible. A

transcript of the testimony adduced at the hearing shall be made and shall be made available to each party.

(vi) The arbitrator(s) shall be guided, but not bound, by the CPR Protocol on Disclosure of Documents and Presentation of Witnesses in Commercial Arbitration (www.cpradr.org) (the " Protocol"). The parties will attempt to agree on modes of document disclosure, electronic discovery, witness presentation, etc. within the parameters of the Protocol. If the parties cannot agree on discovery and presentation issues, the arbitrator(s) shall decide on presentation modes and provide for discovery within the Protocol, understanding that the parties contemplate reasonable discovery.

(vii) The arbitrator(s) shall decide the merits of any Dispute in accordance with the law governing this Agreement, without application of any principle of conflict of laws that would result in reference to a different law. The arbitrator(s) may not apply principles such as "amiable compositeur" or "natural justice and equity."

(viii) The arbitrator(s) are expressly empowered to decide dispositive motions in advance of any hearing and shall endeavor to decide such motions as would a United States District Court Judge sitting in the jurisdiction whose substantive law governs.

(ix) The arbitrator(s) shall render a written opinion stating the reasons upon which the award is based. The parties consent to the jurisdiction of the United States District Court for the district in which the arbitration is held for the enforcement of these provisions and the entry of judgment on any award rendered hereunder. Should such court for any reason lack jurisdiction, any court with jurisdiction may act in the same fashion.

(x) Notwithstanding any provision to the contrary contained in this Agreement, each party has the right to seek from the appropriate court provisional remedies such as attachment, preliminary injunction, replevin or other equitable relief to avoid irreparable harm, maintain the status quo, preserve its status and priority as a creditor or preserve the subject matter of the Dispute. Rule 14 of the CPR Rules does not apply to this Agreement.

Section 17.13 Equitable Relief

Each party acknowledges that a breach by it of the provisions of this Agreement may not reasonably or adequately be compensated in damages in an action at law and that such a breach may cause the other party irreparable injury and damage. By reason thereof, each party agrees that the other party is entitled to, in addition to any other remedies it may have under this Agreement or otherwise, preliminary and permanent injunctive and other equitable relief to prevent or curtail any breach of this Agreement by the other parties; provided, however, that no specification in this Agreement of a specific legal or equitable remedy will be construed as a waiver or prohibition against the pursuing of other legal or equitable remedies in the event of such a breach. Each party agrees that the existence of any claim, demand, or cause of action of it against the other parties, whether predicated upon this Agreement, or otherwise, will not

constitute a defense to the enforcement by the other parties, or its successors or assigns, of the covenants contained in this Agreement.

Section 17.14 Relationship Between Parties

The parties are acting and performing as independent contractors, and nothing in this Agreement creates the relationship of partnership, joint venture, sales agency, or principal and agent. Neither party is the agent of the other, and neither party may hold itself out as such to any other party. Neither party shall have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other party, or to bind the other party in any respect whatsoever.

Section 17.15 Tax Treatment

Unless required by applicable Legal Requirements, the parties agree to treat, for U.S. federal and applicable state and local income Tax purposes, (i) the grant of any license pursuant to Section 2.1(a) as a license and not as a sale and (ii) the sale of the Transferred Assets pursuant to this Agreement as a sale of such Transferred Assets for the Transferred Asset Purchase Price. Collegium and Newco, and their respective Affiliates, agree that no Taxes shall be withheld from any amounts due to Depomed pursuant to this Agreement, provided that Depomed provides Collegium with a properly completed, executed IRS Form W-9.

Section 17.16 Bulk Transfer Laws

Collegium acknowledges that Depomed and its Affiliates have not taken, and do not intend to take, any action required to comply with any applicable bulk sale or bulk transfer laws or similar laws and hereby waives compliance therewith.

Section 17.17 Forward Looking Statements

Without limiting the foregoing, Collegium acknowledges and agrees that (a) it may have received from Depomed various forward looking projections, forecasts and business or commercial plans regarding the Products (collectively, the "Forward-Looking Statements") in connection with Collegium's investigation of the Transferred Assets; (b) there are uncertainties inherent in attempting to make such Forward-Looking Statements; (c) Collegium is familiar with such uncertainties; (d) Collegium is taking full responsibility for making its own evaluation of the adequacy and accuracy of all Forward-Looking Statements; (e) Collegium is not relying on any Forward-Looking Statement in any manner whatsoever; and (f) Collegium shall have no claim against Depomed or any of its Affiliates with respect to any Forward-Looking Statement. Collegium further acknowledges and agrees that Depomed makes no representation or warranty hereunder with respect to (i) the reasonableness of the assumptions underlying any Forward-Looking Statement; or (ii) any Forward-Looking Statement made in any materials in the Data Room, any supplemental due diligence information provided or made available to Collegium,

any of Collegium's discussions with management regarding the Products or any negotiations leading to this Agreement and the other Transaction Documents.

(The remainder of this page is intentionally left blank. The signature page follows.)

Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions marked [***].

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed on the date first above written.

DEPOMED, INC.

/s/ Arthur J. Higgins
Arthur J. Higgins
Chief Executive Officer

COLLEGIUM PHARMACEUTICAL, INC.

/s/ Michael Heffernan
Michael Heffernan
Chief Executive Officer

COLLEGIUM NF, LLC

/s/ Michael Heffernan
Michael Heffernan
Chief Executive Officer

Exhibit 10.28

EXECUTION VERSION

AMENDMENT NO. 1 TO COMMERCIALIZATION AGREEMENT

THIS AMENDMENT NO. 1 TO COMMERCIALIZATION AGREEMENT (this " Amendment No. 1") is entered into as of January 9, 2018, by and among Depomed, Inc., a California corporation ("Depomed"), Collegium Pharmaceutical, Inc., a Virginia corporation ("Collegium"), and Collegium NF, LLC, a Delaware limited liability company and wholly owned subsidiary of Collegium ("Newco") and amends that certain Commercialization Agreement, dated as of December 4, 2017 (the "Commercialization Agreement"), by and among Depomed, Collegium, and Newco. Each of Depomed, Collegium and Newco is referred to herein individually as a "party" and collectively as the "parties." Defined terms used herein but not otherwise defined herein shall have the meaning ascribed to such terms in the Commercialization Agreement.

WHEREAS, the parties entered into that certain Commercialization Agreement on December 4, 2017 and wish to amend certain terms of the Commercialization Agreement; and

WHEREAS, Section 17.4 of the Commercialization Agreement provides that the Commercialization Agreement may be amended by written agreement of the parties thereto.

NOW, THEREFORE, in consideration of the foregoing and of the mutual covenants herein contained, the parties, intending to be legally bound, hereby agree as follows:

1. Section 1.111 of the Commercialization Agreement is hereby amended and restated as follows:

""Consent and Sixth Amendment to Loan and Security Agreement" has the meaning set forth in Section 14.3(c)(xi)."

2. Section 1.123 of the Commercialization Agreement is hereby amended and restated as follows:

"Reserved."

3. Section 1.134 of the Commercialization Agreement is hereby amended and restated as follows:

""Pledge Agreement" has the meaning set forth in Section 14.3(c)(vii)."

4. Section 2.12(b)(x) of the Commercialization Agreement is hereby amended and restated as follows:

"Reserved."

5. Section 2.12(c)(x) of the Commercialization Agreement is hereby amended and restated as follows:

"The Control Agreement, dated as of the Closing Date, executed by Newco and the Financial Institution;"

6. Section 2.12(c)(xi) of the Commercialization Agreement is hereby amended and restated as follows:

"Reserved."

7. Section 2.12(c)(xviii) of the Commercialization Agreement is hereby amended and restated as follows:

"The Consent and Sixth Amendment to Loan and Security Agreement, dated as of the Closing Date, executed by Collegium and the Financial Institution; and"

8. Section 7.7(a)(i) of the Commercialization Agreement is hereby amended and restated as follows:

"As of the Closing Date, Newco shall, and Collegium shall cause Newco to, deliver to Depomed, an irrevocable standby letter of credit issued by Silicon Valley Bank (the "Financial Institution"), in form and substance reasonably acceptable to Depomed (the "Letter of Credit") in an aggregate amount of Thirty-Three Million Seven Hundred Fifty Thousand Dollars ($33,750,000) (the "Maximum Stated Value"). Depomed shall have the right to draw upon the Letter of Credit, up to the Maximum Stated Value, in the event that there is a shortfall in the Minimum Quarterly Payment made to Depomed by Collegium pursuant to Section 7.3(a) hereof, solely to the extent of such quarterly shortfall as determined in good faith by Depomed (a "Quarterly Shortfall"), provided that Collegium does not pay the amount of such Quarterly Shortfall to Depomed within forty-five (45) days after the last day of such calendar quarter."

9. Section 7.7(b)(ii) of the Commercialization Agreement is hereby amended and restated as follows:

"Collegium and Newco shall, and Collegium shall cause Newco to, cause all amounts from gross sales of the Payment-Bearing Products to be deposited directly into the Sales Account (including, requiring all Customers of the Payment-Bearing Products to remit all payments owed to Collegium or any of its Affiliates or any other Sublicensees directly into the Sales Account) and, on a daily basis, thirty-five percent (35%) of such day's deposits (the "Newco Deposits") shall be swept into an account designated by Depomed until the Minimum Quarterly Payment obligation is satisfied for each calendar quarter, and sixty-five percent (65%) shall be swept into an account designated and owned by Collegium. Once the Minimum Quarterly Payment obligation is satisfied for a given calendar quarter, then, on a daily basis, one hundred percent (100%) of the Newco Deposits shall be swept into an account designated and owned by Collegium for the remainder of such calendar quarter. Once the Minimum Quarterly Payment obligation is satisfied in its entirety (i.e., once Collegium's payment obligation is governed by Section 7.3(b)), then, on a daily basis, one hundred percent (100%) of the Newco Deposits shall be swept into an account designated and owned by Collegium for the remainder of the Payment Term. The sweep mechanism shall not be subject to change and shall be the only mechanism for disbursing funds from the Sales Account, unless in a writing signed by both Depomed and Newco; provided that upon an "Event of Default" (as defined in

the Collateral Agreement), Depomed may exercise all remedies granted under the Collateral Agreement. Based on Newco's reports provided to Depomed calculating amounts payable under Section 7.3, Depomed shall refund to Newco any amounts overpaid to Newco from the Newco Deposits within ten (10) Business Days of receiving such reports."

10. The Commercialization Agreement is hereby amended to add the following as a new Section 7.7(c) of the Commercialization Agreement:

"(c) Assignment of Proceeds. On the terms and subject to the conditions set forth in this Agreement, and in consideration for Newco granting Collegium certain rights under the Collegium Sublicense, Collegium hereby irrevocably contributes, assigns, transfers, conveys, grants and delivers to Newco, and Newco hereby acquires and accepts from Collegium, all of Collegium's present and future right, title and interest in, to and under all cash, royalties, fees, revenues, proceeds, payments, income or other amounts resulting from sales of Payment-Bearing Products, in each case solely to the extent required to be deposited directly into the Sales Account pursuant to Section 7.7(b)(ii) of this Agreement, free and clear of all Liens (except for any Lien granted to Depomed). Each of Collegium and Newco agree to execute such documents and to perform such other acts as are necessary to implement this Section 7.7(c), but in each case only upon Depomed's reasonable request."

11. Section 14.3(c)(viii) of the Commercialization Agreement is hereby amended and restated as follows:

"Reserved."

12. Section 14.3(c)(xi) of the Commercialization Agreement is hereby amended and restated as follows:

"An amendment to that certain existing Loan and Security Agreement by and between Silicon Valley Bank and Collegium, dated as of August 28, 2012 (as amended by that certain First Amendment to Loan and Security Agreement dated as of January 31, 2014, by and between Silicon Valley Bank and Collegium, as amended by that certain Assumption and Second Amendment to Loan and Security Agreement dated as of August 12, 2014, by and between Silicon Valley Bank and Collegium, as amended by that certain Third Amendment to Loan and Security Agreement dated as of September 25, 2014, by and between Silicon Valley Bank and Collegium, as further amended by that certain Fourth Amendment to Loan and Security Agreement dated as of October 31, 2014, by and between Silicon Valley Bank and Collegium, and as further amended by that certain Consent and Fifth Amendment to Loan and Security Agreement dated as of December 31, 2015, by and between Silicon Valley Bank and Collegium), in a form reasonably acceptable to Depomed (the "Consent and Sixth Amendment to Loan and Security Agreement"); provided, however, that the Consent and Sixth Amendment to Loan and Security Agreement shall not be deemed an Ancillary Agreement for purposes of Section 10.1 of this Agreement or Section 3.01 of the Collateral Agreement."

13. Except as herein expressly amended, the Commercialization Agreement is ratified and confirmed in all respects by each of the parties hereto and shall remain in full force and effect and enforceable against them in accordance with its terms. Unless the context otherwise requires, the term "Agreement" as used in the Commercialization Agreement shall be deemed to refer to the Commercialization Agreement as amended hereby.

14. This Amendment No. 1 may be executed in one or more counterparts, each of which shall be deemed an original, and together shall constitute one and the same agreement and shall become effective when one or more counterparts have been signed by each of the parties and delivered to the other party, it being understood that the parties need not sign the same counterpart. This Amendment No. 1, following its execution, may be delivered via telecopier machine or other form of electronic delivery, which shall constitute delivery of an execution original for all purposes.

15. This Amendment No. 1 shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflicts of law, principles or rules of such state, to the extent such principles or rules are not mandatorily applicable by statute and would permit or require the application of the laws of another jurisdiction.

(The remainder of this page is intentionally left blank. The signature page follows.)

IN WITNESS WHEREOF, the parties have caused this Amendment No. 1 to be executed on the date first above written.

DEPOMED, INC.

/s/ Matthew M. Gosling
Matthew M. Gosling
Senior Vice President, General Counsel and Secretary

COLLEGIUM PHARMACEUTICAL, INC.

/s/ Michael T. Heffernan
By: Michael T. Heffernan
Title: President and Chief Executive Officer

COLLEGIUM NF, LLC

/s/ Michael T. Heffernan
By: Michael T. Heffernan
Title: President and Chief Executive Officer

Exhibit 21.1

Subsidiaries of Collegium Pharmaceutical, Inc.

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

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-213964 on Form S-3 and Registration Statement Nos. 333-207744 and 333-218767 on Form S-8 of our report dated March 7, 2018, relating to the consolidated financial statements of Collegium Pharmaceutical, Inc. and subsidiaries, appearing in this Annual Report on Form 10-K of Collegium Pharmaceutical, Inc. for the year ended December 31, 2017.

/s/ Deloitte & Touche LLP
Boston, Massachusetts
March 7, 2018

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 year ended December 31, 2015. 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 Forms S-8 (File No. 333-207744 and 333-218767).

/s/ Grant Thornton LLP

Boston, Massachusetts
March 7, 2018

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 7, 2018

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 7, 2018

/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, 2017 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 7, 2018

/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, 2017 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 7, 2018

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