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As filed with the Securities and Exchange Commission on April 27, 2015.

Registration No. 333-203208

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

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AMENDMENT NO. 1 TO  
**FORM S-1**  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

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**Collegium Pharmaceutical, Inc.**

(Exact name of registrant as specified in its charter)

<b>Virginia</b> (State or other jurisdiction of incorporation or organization)	<b>2834</b> (Primary Standard Industrial Classification Code Number)	<b>03-0416362</b> (I.R.S. Employer Identification Number)
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**Collegium Pharmaceutical, Inc.**  
**780 Dedham Street**  
**Suite 800**  
**Canton, MA 02021**  
**(781) 713-3699**

(Address, including zip code and telephone number, including  
area code, of registrant's principal executive offices)

---

**Michael T. Heffernan**  
**President and Chief Executive Officer**  
**Collegium Pharmaceutical, Inc.**  
**780 Dedham Street**  
**Suite 800**  
**Canton, MA 02021**  
**(781) 713-3699**

(Name, address, including zip code and telephone number, including area code, of agent for service)

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**Approximate date of commencement of proposed sale to the public:**  
**As soon as practicable after the effective date of this registration statement.**

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If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"), check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

Large accelerated  
filer

Accelerated  
filer

Non-accelerated filer   
(Do not check if a  
smaller reporting  
company)

Smaller reporting  
company

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**CALCULATION OF REGISTRATION FEE**

<b>Title of Securities Being Registered</b>	<b>Amount to be Registered<sup>(1)</sup></b>	<b>Proposed Maximum Offering Price Per Share</b>	<b>Proposed Maximum Aggregate Offering Price<sup>(2)</sup></b>	<b>Amount of Registration Fee<sup>(3)</sup></b>
Common Stock, \$0.001 par value per share	6,670,000	\$14.00	\$93,380,000	\$10,851

(1) Includes 870,000 shares which the underwriters have the option to purchase from the registrant.

(2) Estimated solely for purposes of computing the amount of the registration fee pursuant to Rule 457(a) under the Securities Act of 1933, as amended. Includes the offering price of shares that the underwriters have the option to purchase to cover over-allotments, if any.

(3) Of this amount, \$10,023 was previously paid in connection with prior filings of this Registration Statement.

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**The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

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The information contained in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED APRIL 27, 2015

PRELIMINARY PROSPECTUS

5,800,000 Shares



**Collegium Pharmaceutical, Inc.**

**Common Stock**

We are offering 5,800,000 shares of our common stock. This is our initial public offering and no public market currently exists for our common stock. We expect the initial public offering price to be between \$12.00 and \$14.00 per share. We expect to receive approval to list our common stock on The NASDAQ Global Market ("NASDAQ") under the symbol "COLL."

**We are an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933, as amended, or the Securities Act, and will be subject to reduced public company reporting requirements. See "Prospectus Summary — Implications of Being an Emerging Growth Company."**

Investing in our common stock involves a high degree of risks. Please read "Risk Factors" beginning on page 14 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

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	<u>Per Share</u>	<u>Total</u>
Initial public offering price	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$
Proceeds, before expenses, to us	\$	\$

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<sup>(1)</sup> We refer you to "Underwriting" beginning on page 177 of this prospectus for additional information regarding total underwriter compensation.

Certain of our existing shareholders, or their affiliates, have indicated an interest in purchasing up to an aggregate of approximately \$30.0 million of shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these investors, and any of these investors may determine to purchase more, less or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these investors as they will on any other shares sold to the public in this offering.

Delivery of the shares of common stock is expected to be made on or about \_\_\_\_\_, 2015. We have granted the underwriters an option for a period of 30 days to purchase an additional 870,000 shares of our common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be \$ \_\_\_\_\_, and the total proceeds to us, before expenses, will be \$ \_\_\_\_\_.

**Jefferies**

**Piper Jaffray**

**Wells Fargo Securities**

**Needham & Company**

Prospectus dated \_\_\_\_\_, 2015

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Neither we nor any of the underwriters has authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we may have referred you in connection with this offering. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. Neither we nor any of the underwriters is making an offer to sell or seeking offers to buy these securities in any jurisdiction where, or to any person to whom, the offer or sale is not permitted. The information in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or of any sale of shares of our common stock and the information in any free writing prospectus that we may provide you in connection with this offering is accurate only as of the date of that free writing prospectus. Our business, financial condition, results of operations and future growth prospects may have changed since those dates.

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## **INDUSTRY AND MARKET DATA**

We obtained the industry, market and competitive position data in this prospectus 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 prospectus. 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."

## **TRADEMARKS AND TRADE NAMES**

We have registered Collegium Pharmaceutical, Inc., DETERx and Xtampza ER as U.S. trademarks. This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

## **BASIS OF PRESENTATION**

On April 24, 2015, we amended our articles of incorporation to effect a 1-for-6.9 reverse stock split of our common stock. Concurrent with the reverse stock split, we adjusted (x) the conversion price of our convertible preferred stock, (y) the number of shares subject to and the exercise price of our outstanding stock option awards under our equity incentive plan and (z) the number of shares subject to and the exercise price of our outstanding warrants, such that the holders of the preferred stock, options and warrants are in the same economic position both before and after the reverse stock split. In addition, immediately prior to the closing of this offering, the outstanding shares of our convertible preferred stock will convert into shares of our common stock. Unless otherwise indicated, all share data gives effect to the conversion of our preferred stock into common stock.

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## PROSPECTUS SUMMARY

*This summary highlights certain information about us and this offering contained elsewhere in this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in shares of our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. Before you decide to invest in our common stock, you should read the entire prospectus carefully, including "Risk Factors," "Special Note Regarding Forward-Looking Statements" and the financial statements and related notes included elsewhere in this prospectus.*

Unless the context indicates otherwise, as used in this prospectus, the terms "Collegium," "we," "us," "our," "our company" and "our business" refer to Collegium Pharmaceutical, Inc.

### Overview

We are a specialty pharmaceutical company developing and planning to commercialize next-generation abuse-deterrent products that incorporate our patented DETERx® platform technology for the treatment of chronic pain and other diseases. Our lead product candidate, Xtampza ER™, or Xtampza is an abuse-deterrent, extended-release, oral formulation of oxycodone, a widely prescribed opioid medication. Xtampza has received Fast Track status from the U.S. Food and Drug Administration, or FDA. Our new drug application, or NDA, filing for Xtampza was accepted by the FDA on February 10, 2015. On February 25, 2015, the FDA set a Prescription Drug User Fee Act, or PDUFA, goal date of October 12, 2015 for completion of its review of the Xtampza NDA.

Xtampza has the same active ingredient as OxyContin® OP, which is the largest selling abuse-deterrent, extended-release opioid in the United States by dollars, with \$2.5 billion in U.S. sales in 2014. 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 a head-to-head clinical trial 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 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, 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, if approved, can address the pain management needs of the approximately 11 million patients in the United States who suffer from chronic pain and have difficulty swallowing.

### Our DETERx Platform Technology

In our proprietary DETERx technology, we combine active ingredients such as oxycodone with fatty acid and waxes to form a molten solution which is spray-congealed into solid microspheres using a proprietary spinning disk manufacturing process. These solid wax-based microspheres are then filled into capsules. Each individual microsphere is designed to be extended-release and abuse-deterrent.

In addition to our Xtampza formulation of oxycodone, DETERx technology is applicable to many other opioid active ingredients, as well as other categories of abuseable drugs, such as amphetamines and methylphenidate.

## Prescription Drug Abuse

The U.S. Centers for Disease Control and Prevention 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 2012.

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. 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, including certain forms of extended-release opioids. 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.

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. Drug abusers find currently approved extended-release opioid tablets 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, they attempt to defeat the extended-release properties in order to achieve rapid release of the active ingredient.

In 2014, there were approximately 29 million prescriptions for extended-release and long-acting opioids in the United States. OxyContin OP accounted for approximately \$2.5 billion in total U.S. sales from approximately 6 million prescriptions. 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 OxyContin OP's 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 routes of abuse of OxyContin OP (i.e., injection, snorting and smoking) were used less 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***



## 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. Our preclinical studies and clinical trials have shown that the contents of the Xtampza capsules can be removed from the capsule and sprinkled on food, directly into the mouth or administered through feeding tubes, without compromising their extended-release properties. By contrast, all other FDA-approved, orally administered, extended-release opioids have 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 drug", making them unsuitable or unattractive for patients who suffer from chronic pain with dysphagia, or CPD. An external marketing study performed for us in 2013 estimated that Xtampza, if approved, has a peak revenue potential for U.S. patients with CPD in excess of \$700 million annually. We have performed what we believe to be all of the required preclinical studies and clinical trials to obtain FDA product labeling for sprinkling Xtampza microspheres directly in the mouth or on food, as well as administering the microspheres through gastric or nasogastric feeding tubes. If approved with such labeling and without such black box warning, Xtampza would be the only abuse-deterrent extended-release opioid product addressing this patient segment.

## **Xtampza**

Our lead product candidate, Xtampza, is an abuse-deterrent, extended-release, oral formulation of oxycodone in development for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The active ingredient in Xtampza is oxycodone, which is approved by the FDA and other regulators around the world in a number of both immediate-release and extended-release drug products. We developed Xtampza using our proprietary, DETERx abuse-deterrent technology to address common methods of abuse, including chewing, crushing and/or dissolving, and then taking it orally or snorting or injecting Xtampza.

## **Clinical Development**

In January 2013, the FDA issued a draft guidance document titled "Abuse-Deterrent Opioids — Evaluation and Labeling." Before this FDA draft guidance was finalized, it was followed by the FDA in the approval process of abuse-deterrence products. The FDA issued its final guidance in April 2015. Like the draft guidance, the final guidance specifically defines the studies and clinical trials required to evaluate the abuse-deterrent properties of a formulation and the associated claims that a manufacturer can make based on the results of those studies and clinical trials. This is meant to incentivize the development of improved abuse-deterrent products. We believe that all of our studies and clinical trials are consistent with the final FDA guidance. Also, because of the Fast Track status granted to Xtampza, we have had multiple interactions with the FDA. Based upon these interactions, we designed our studies and clinical trials with a goal of achieving a differentiated label from OxyContin OP with respect to the abuse-deterrent properties of Xtampza.

We have completed numerous studies and clinical trials on Xtampza, which have demonstrated:

- § *Safety and effectiveness for treatment of chronic pain.* In July 2014, we completed a prospective, randomized Phase 3 clinical trial that met its primary endpoint, demonstrating that Xtampza, compared to a placebo, was safe and effective in treating moderate-to-severe chronic lower back pain.
- § *Superior abuse-deterrent properties when compared with OxyContin OP in a head-to-head oral abuse-deterrence clinical trial.* In an abuse-deterrence clinical trial, we measured the drug release of both OxyContin OP and Xtampza when intact and when subjected to the most effective method of attempting to defeat their abuse-deterrent properties. This clinical trial showed that crushing OxyContin OP caused the active ingredient (oxycodone) to be released rapidly, with drug release that was bioequivalent to immediate-release oxycodone. By contrast, this clinical trial showed that the release of oxycodone from crushed Xtampza was bioequivalent to uncrushed Xtampza. Based on this data, we believe drug abusers may find Xtampza less desirable to abuse orally than OxyContin OP after crushing.



- § *Abuse-deterrent properties in an oral human abuse potential clinical trial.* Consistent with FDA guidance, we performed a human abuse potential clinical trial using the oral route of administration measuring "drug liking" in recreational drug users. We measured how well recreational drug users liked intact Xtampza (taken orally as intended) and chewed Xtampza compared with crushed immediate-release oxycodone taken orally. The clinical trial showed with statistical significance that both chewed and intact Xtampza were "liked" less than immediate-release oxycodone. The clinical trial also showed that opening our capsules and chewing the microspheres did not change the pharmacokinetics of Xtampza.
- § *Abuse-deterrent properties following snorting in a human abuse potential clinical trial.* Consistent with FDA guidance, we performed a human abuse potential clinical trial using the snorted route of administration. The clinical trial demonstrated that crushing and snorting Xtampza microspheres resulted in lower blood levels of oxycodone than taking intact Xtampza capsules orally. The clinical trial also demonstrated with statistical significance that crushed and snorted Xtampza microspheres were "liked" less than both intact Xtampza administered orally and snorted immediate-release oxycodone. Based on this data, we believe that drug abusers may not find it desirable to snort Xtampza.
- § *Ability to sprinkle microspheres for patients with difficulty swallowing.* In clinical trials we performed consistent with FDA guidance, we demonstrated that when Xtampza microspheres were removed from the capsule and chewed or crushed, or removed from the capsule and sprinkled onto soft food and administered orally, the drug release profile did not significantly change from administering intact Xtampza capsules. Additionally, in preclinical studies we showed that the drug release profile did not change when the microspheres were administered using various types of feeding tubes. We believe that we have performed the required preclinical studies and clinical trials to obtain FDA product labeling for sprinkling Xtampza microspheres directly in the mouth or on food, as well administering the microspheres through gastric or nasogastric feeding tubes.

### **Competitive Abuse-Deterrent Approaches**

To address the potential for abuse, the pharmaceutical industry has created a number of abuse-deterrent products and product candidates, using a variety of technical strategies that 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 intravenous abuse using common solvents such as water.
- § *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. 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 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. To date, the only extended-release product candidate using the prodrug approach in late-stage clinical development did not achieve its primary endpoint of demonstrating adequate pain relief compared to a placebo in a Phase 2 clinical trial. No opioids using a prodrug approach are currently marketed.

We believe Xtampza represents the best-in-class approach to creating an abuse-deterrent extended-release opioid formulation. Xtampza does not incorporate an opioid antagonist, is not a prodrug, and, based on the studies and clinical trials we conducted, is resistant to abuse through physical or chemical manipulation.

### **Patents and Proprietary Technology**

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 six issued patents in the United States, two pending applications in the European Union and one issued patent in each of Canada, Japan and Australia. In addition, we have six patent applications pending in the United States, and two pending foreign patent applications (excluding Europe), in Japan and Canada. Our issued U.S. patents are projected to expire in 2023 and 2025, and our pending patent applications in the United States, if issued, would be projected to expire in 2023 and 2030. 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 technology and products are not in-licensed from any third party, and we own all of the rights to our product candidates.

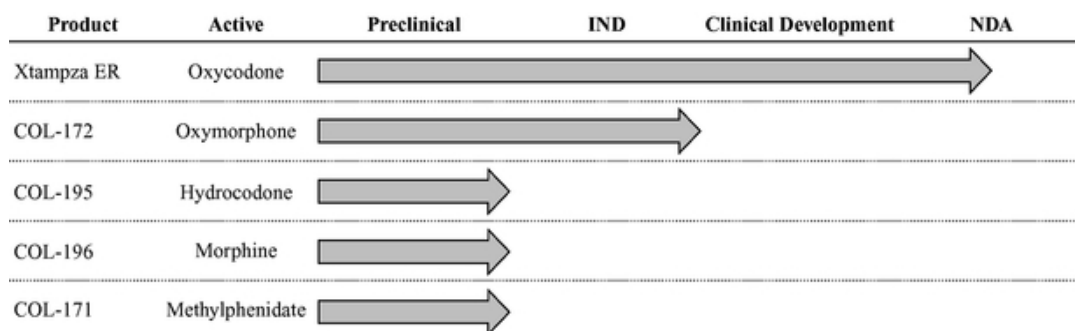
### **Patent Litigation Strategy**

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 Pharma, L.P., or 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 stand invalidated by the Federal District Court for the Southern District of New York, subject to a pending appeal. 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 can issue a final approval for Xtampza, unless the stay is 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 (all of which stand invalidated, subject to a pending appeal by Purdue) and a non-Orange Book-listed patent, and, accordingly, received a stay of up to 30 months before the FDA can issue a final approval for Xtampza, unless the stay is earlier terminated. The 30-month stay only applies to the Orange Book-listed patents. On March 26, 2015, Purdue filed a second suit against us in the District of Massachusetts asserting infringement of the same four patents. On April 6, 2015, in the District of Delaware case, we filed a motion to dismiss for lack of personal jurisdiction or, in the alternative, to transfer venue to the Southern District of New York where three of the patents have already been invalidated. Purdue's opposition to our motion was filed on April 23, 2015 and our reply in support of the motion is due on May 4, 2015. The complaint in the District of Massachusetts case had not yet been served.

In order to commercialize Xtampza, we will need both FDA approval and to dispose of the lawsuits filed by Purdue. The FDA is entitled to give Xtampza a tentative approval before the 30-month stay has expired, which means the product is approved and the key aspects of the label are agreed upon, subject to the expiration of the 30-month period or termination of the stay. If we receive a court order that the listed patents are invalid or not infringed, or if we settle the Purdue litigation before the 30-month period expires, the FDA can then provide final approval of Xtampza prior to the expiration of the 30-month period, at which point the product can be marketed.

## DETERx Pipeline

We have applied our DETERx platform technology to Xtampza as well as other product candidates in our pipeline. We have an extended-release, abuse-deterrent oxycodone program for the treatment of chronic pain for which we have filed an investigational new drug application, or IND. This program has received a grant from the National Institute on Drug Abuse, a constituent institute of the National Institutes of Health, and has been granted Fast Track status by the FDA. We also have other extended-release, abuse-deterrent product candidates that have completed preliminary preclinical studies, including hydrocodone and morphine for pain, and methylphenidate for the treatment of attention deficit hyperactivity disorder, or ADHD. We are targeting to begin clinical trials with our second product candidate in the first quarter of 2016. 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 our product candidates.



## Our Strategy

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

- § *Establish our leadership position by obtaining approval to market Xtampza with a best-in-class abuse-deterrent label.* If approved, we expect to receive differentiated abuse-deterrent claims in the Xtampza label compared to other approved abuse-deterrent opioids, which will allow us to detail Xtampza to physicians and highlight its unique abuse-deterrent characteristics.
- § *Commercialize Xtampza in the United States ourselves.* We are currently preparing for a potential U.S. commercial launch of Xtampza if approved, in the first quarter of 2016. Our management team has extensive experience commercializing pharmaceutical products, and we intend to establish sales, marketing and reimbursement functions to commercialize Xtampza in the United States. Initially, we plan to detail Xtampza to approximately 10,000 physicians who write more than 50% of the branded extended-release oral opioid prescriptions in the United States with a sales team of approximately 100 sales representatives. In addition, we plan to deploy a separate, focused sales team to detail Xtampza to nursing homes, hospices, and other institutions treating large populations of the elderly and other patients who need chronic pain relief and have difficulty swallowing.
- § *Establish Xtampza as the treatment of choice for patients with CPD.* If approved with product labeling for sprinkling Xtampza microspheres directly in the mouth or on food, as well as administering the microspheres through feeding tubes, Xtampza would be the only extended-release oxycodone product designed to be suitable for this 11 million patient segment.
- § *Establish strategic collaborations to accelerate and maximize the potential of our product candidates worldwide.* We intend to seek strategic collaborations with other pharmaceutical companies to commercialize 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 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. We have also begun advancing our development program for COL-195, an abuse-deterrent, extended-release hydrocodone for the treatment of chronic pain. We target beginning clinical trials for our second product candidate by the first quarter of 2016. In addition, we have COL-171, a proprietary preclinical DETERx extended-release, abuse-deterrent methylphenidate formulation for the treatment of ADHD, which we plan to advance with a collaborator.
- § *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.

### **Risk Factors**

Our ability to implement our business strategy is subject to numerous risks and uncertainties. As a clinical-stage biopharmaceutical company, we face many risks inherent in our business and our industry generally. You should carefully consider all of the information set forth in this prospectus and, in particular, the information under the heading "Risk Factors" in this prospectus prior to making an investment in our common stock. These risks include among others, the following:

- § our product candidates, including Xtampza, are subject to regulatory approval processes that are lengthy and unpredictable;
- § we may not obtain approval for Xtampza or any of our other product candidates from the FDA or foreign regulatory authorities. Even if Xtampza is approved, we may not be able to obtain the label claims that we are seeking from the FDA;
- § we are subject to patent infringement litigation relating to Xtampza and may, in the future, be subject to additional litigation relating to our other product candidates, which may be expensive to defend and delay the commercialization of Xtampza or our other product candidates;
- § we currently generate no commercial revenue, may never become profitable and may incur substantial and increasing net losses for the foreseeable future as we seek regulatory approval for, and potentially begin to commercialize, Xtampza;
- § we currently have no sales or marketing capabilities and, if we are unable to develop these capabilities, we may not be successful in commercializing Xtampza, if approved; and
- § we depend, or will depend in the future, on the performance of third parties for the supply of the active ingredient used in Xtampza, commercial manufacturing and testing of Xtampza, and the conduct of clinical trials relating to our product candidates.

### **Our Corporate Information**

We are incorporated in the Commonwealth of Virginia under the name Collegium Pharmaceutical, Inc. Our executive offices are located at 780 Dedham Street, Suite 800, Canton, MA 02021 and our telephone number is (781) 713-3699. Our website address is [www.collegiumpharma.com](http://www.collegiumpharma.com). The inclusion of our website address above and elsewhere in this prospectus is, in each case, intended to be an inactive textual reference only and not an active hyperlink to our website. The information contained in, or that can be accessed through, our website is not part of this prospectus.

## Implications of Being an Emerging Growth Company

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we are eligible to take advantage of exemptions from various disclosure and 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 auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act;
- § being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations, in each case, instead of three years;
- § being permitted to present the same number of years of selected financial data as the years of audited financial statements presented, instead of five years;
- § reduced disclosure obligations regarding executive compensation, including no Compensation Disclosure and Analysis;
- § not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements; and
- § exemptions from the requirements of holding a non-binding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some or all of the available exemptions. We have taken advantage of some of the reduced reporting burdens in this prospectus. Accordingly, the scope of the information contained herein may be different than the scope of the information you receive from other public companies in which you hold stock. We do not know if some investors will find our shares less attractive as a result of our utilization of these or other exemptions. The result may be a less active trading market for our shares and our share price may be more volatile.

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. In other words, 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 exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies."

We will remain an "emerging growth company" until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed \$1.0 billion; (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, the Exchange Act, which would occur if the market value of our shares that are held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the preceding three-year period; and (iv) the last day of our fiscal year containing the fifth anniversary of the date on which shares of our common stock become publicly traded in the United States.

## THE OFFERING

Common stock offered by us	5,800,000 shares (6,670,000 shares if the underwriters' option to purchase additional shares is exercised in full).
Common stock to be outstanding after this offering	19,707,935 shares (20,577,935 shares if the underwriters' option to purchase additional shares is exercised in full).
Option to purchase additional shares	The underwriters have the option to purchase from us up to a maximum of 870,000 additional shares of common stock. The underwriters can exercise this option at any time within 30 days from the date of this prospectus.
Use of proceeds	<p>We estimate that the net proceeds to us from this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately \$67.5 million. This assumes a public offering price of \$13.00, which is the midpoint of the price range set forth on the cover page of this prospectus. We intend to use the net proceeds from this offering as follows:</p> <ul style="list-style-type: none"><li>§ approximately \$45.0 million for the development of our commercial infrastructure to launch Xtampza, including sales, marketing and reimbursement functions, and if Xtampza is approved in the United States, a sales force;</li><li>§ approximately \$15.0 million to fund research and development efforts of our other product candidates, including approximately \$12.0 million to conduct clinical development for our second product candidate through its Phase 3 clinical trial (including Phase 1 bioequivalence clinical trials and abuse-deterrence studies and clinical trials); and</li><li>§ the remainder, if any, to fund working capital and general corporate purposes, which may include litigation expenses (including expenses relating to the Purdue litigation) and the acquisition or licensing of product candidates, technologies, compounds, other assets or complementary businesses.</li></ul> <p>See "Use of Proceeds" for more information.</p>

Directed share program	The underwriters have reserved for sale, at the initial public offering price, up to approximately 5% of the shares of our common stock being offered. These shares will be offered for sale to our directors; officers; existing shareholders and their affiliates and employees of both; and business associates, as well as certain friends and family members of our directors and officers. We will offer these shares to the extent permitted under applicable regulations in the United States. The number of shares available for sale to the general public in this offering will be reduced to the extent these persons purchase reserved shares. Any reserved shares not purchased will be offered by the underwriters to the general public on the same terms as the other shares.
Listing	We expect to receive approval to list our common stock on NASDAQ under the symbol "COLL."
Dividend policy	We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. See "Dividend Policy."
Risk factors	You should read the "Risk Factors" section of this prospectus for a discussion of certain factors to consider carefully before deciding to purchase any shares of our common stock.

The number of shares of our common stock to be outstanding after this offering is based on 1,316,479 shares of common stock outstanding as of April 2, 2015 and assumes:

- § the issuance by us of 5,800,000 shares of our common stock in this offering; and
- § the conversion of all of our convertible preferred stock outstanding immediately prior to the closing of this offering into an aggregate of 12,591,456 shares of common stock (which includes 41,666,667 shares of Series D convertible preferred stock issued in March 2015),

and excludes:

- § 803,565 shares of common stock issuable upon the exercise of outstanding stock options as of April 2, 2015, at a weighted-average exercise price of \$4.23 per share;
- § 18,809 shares of common stock issuable upon the exercise of warrants to purchase common stock as of April 2, 2015, at a weighted-average exercise price of \$1.91 per share;
- § the issuance by us of additional shares of common stock (which, based on an assumed initial public offering price of \$13.00 per share (the mid-point of the price range set forth on the cover page of this prospectus) will total approximately 61,000 shares), as payment of the accrued dividend on the outstanding shares of Series D convertible preferred stock payable to the holders of Series D convertible preferred stock upon the closing of this offering;
- § 1,751,803 shares of common stock reserved for future issuance under our Amended and Restated 2014 Stock Incentive Plan upon the closing of this offering; and
- § 200,000 shares reserved for future issuance under our 2015 Employee Stock Purchase Plan upon the closing of this offering.

Except as otherwise indicated, all information in this prospectus assumes:

- § a 1 for 6.9 reverse stock split of our common stock effected on April 24, 2015;

- § no exercise by the underwriters of the option to purchase up to an additional 870,000 shares of our common stock; and
- § the filing of our amended and restated articles of incorporation and the adoption of our amended and restated bylaws immediately prior to the closing of this offering.

Certain of our existing shareholders, or their affiliates, have indicated an interest in purchasing up to an aggregate of approximately \$30.0 million of shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these investors, and any of these investors may determine to purchase more, less or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these investors as they will on any other shares sold to the public in this offering.



**SUMMARY FINANCIAL DATA**

The following summary financial data for the years ended December 31, 2013 and 2014 are derived from our audited financial statements appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future. The summary financial data presented below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes thereto, included elsewhere in this prospectus. The summary financial data in this section is not intended to replace our financial statements and the related notes thereto.

	Years Ended December 31,	
	2013	2014
(in thousands, except share and per share amounts)		
<b>Statement of Operations Data:</b>		
Operating expenses:		
Research and development	\$ 14,157	\$ 14,959
General and administrative	1,885	2,706
Total operating expense	<u>16,042</u>	<u>17,665</u>
Loss from operations	(16,042)	(17,665)
Interest expense, net	76	252
Other expense, net	79	—
Net loss	<u>\$ (16,197)</u>	<u>\$ (17,917)</u>
Basic and diluted net loss per common share <sup>(1)</sup> :	<u>\$ (4.06)</u>	<u>\$ (22.72)</u>
Weighted-average shares used to compute earnings (loss) per common share <sup>(1)</sup> :	<u>1,697,044</u>	<u>933,997</u>
Pro forma net loss per share attributable to common shareholders — basic and diluted (unaudited) <sup>(1)(2)</sup>		<u>\$ (2.84)</u>
Weighted-average number of common shares used in pro forma net loss per share attributable to common shareholders — basic and diluted (unaudited) <sup>(1)(2)</sup> :		<u>7,471,303</u>

- (1) See Note 3 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate earnings (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.
- (2) Gives effect to the conversion of all our outstanding convertible preferred stock into an aggregate of 6,552,820 shares of our common stock (which excludes 41,666,667 shares of Series D convertible preferred stock issued in March 2015) upon the closing of this offering.

	As of December 31, 2014		
	Actual	Pro Forma <sup>(2)</sup>	Pro Forma As Adjusted <sup>(3)</sup>
	(in thousands)		
<b>Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 1,634	\$ 46,634	\$ 114,156
Working capital <sup>(1)</sup>	(5,921)	44,079	111,601
Total assets	5,090	50,090	117,612
Other long-term liabilities	6,914	6,914	6,914
Convertible redeemable preferred stock	77,107	—	—
Total shareholders' equity (deficit)	(89,348)	37,759	105,281

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

(2) Gives effect to the following:

§ our issuance and sale of 41,666,667 shares of our Series D convertible preferred stock in March 2015 at a price per share of \$1.20 for aggregate consideration of \$50.0 million, comprised of \$45.0 million in cash and \$5.0 million from conversion of convertible notes with related parties; and

§ the conversion of all our outstanding convertible preferred stock into an aggregate of 12,591,456 shares of our common stock (which includes 41,666,667 shares of our Series D convertible preferred stock issued in March 2015) upon the closing of this offering.

(3) Gives further effect to the matters described in note 2 above and the sale by us of 5,800,000 shares of our common stock in this offering at an assumed initial public offering price of \$13.00 per share (the midpoint of the price range set forth on the cover page of this prospectus), after deducting the estimated underwriting discounts and commission and estimated offering expenses payable by us.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained in this prospectus, including our financial statements and the related notes appearing elsewhere in this prospectus, before making your decision to invest in shares of our common stock. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition and cash flows, and our future prospects would likely be materially and adversely affected. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.*

### **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 a clinical-stage pharmaceutical company. To date, we have focused on developing our lead product candidate, Xtampza. Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. Since 2010, when we divested our former subsidiary, Onset Therapeutics, LLC, to PreCision Dermatology, Inc., we have not generated any revenue from product sales as we currently have no products approved by the FDA, and we continue to incur significant research, development 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, 2014, we reported a net loss of \$17.9 million, and we had an accumulated deficit of \$101.8 million at December 31, 2014.

We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize Xtampza, if approved. 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 the rate of future growth of our expenses and our ability to generate revenues. If any of our product candidates fails in clinical trials or does not gain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses and expected future losses have had and will continue to have an adverse effect on our shareholders' equity and working capital.

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

As we currently have no approved products, we are not generating any revenue from product sales. We have not generated any revenue since we divested our former subsidiary in 2010. Our ability to generate additional revenue and become profitable depends upon our ability to successfully commercialize our existing product candidates, including Xtampza, or other product candidates that we may in-license or acquire in the future. Even if we are able to successfully achieve regulatory approval for these product candidates, we do not know when any of these product candidates will generate revenue for us, if at all. Our ability to generate revenue from our current or future product candidates depends on a number of factors, including our ability to:

- § obtain regulatory approval for, and successfully commercialize, Xtampza;
- § successfully complete development activities, including the necessary clinical trials, with respect to our other product candidates;
- § complete and submit NDAs to the FDA and obtain regulatory approval for indications for which there is a commercial market;

- § 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;
- § set a commercially viable price for our products;
- § manufacture commercial quantities of our products at acceptable cost levels;
- § develop a commercial organization capable of sales, marketing and distribution for the products we intend to sell ourselves in the markets in which we have retained commercialization rights;
- § find suitable distribution collaborators to help us market, sell and distribute our products, if approved, in markets outside the United States; and
- § obtain coverage and adequate reimbursement from third-parties, including government payors.

In addition, because of the numerous risks and uncertainties associated with product development, including that our product candidates may not advance through development or achieve the safety and efficacy (including the efficacy of our abuse-deterrent technology) endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Furthermore, we anticipate incurring significant costs associated with commercializing these products.

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

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

Our operations have consumed substantial amounts of cash. We expect to continue to spend substantial amounts to advance the clinical development of our product candidates and launch and commercialize any product candidates for which we may receive regulatory approval, including potentially building our own commercial organization to address selected markets. We believe that the net proceeds from this offering, together with existing cash, will be sufficient to fund our projected operating requirements for the commercialization of Xtampza, if approved, and the completion of clinical development of our second product candidate. However, we may require additional capital for the further development and commercialization of our product candidates and may also need to raise additional funds sooner in order to accelerate 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, if/when applicable, the commercialization, of our product candidates or one or more of our other research and development initiatives;
- § seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- § relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or
- § significantly curtail operations.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available

capital resources sooner than we currently expect. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- § the ability to obtain abuse-deterrent claims in the labels for these product candidates;
- § clinical development plans we establish for Xtampza and any other future product candidates;
- § the FDA's approval of inclusion of claims in the label for Xtampza that will permit the sprinkling of Xtampza microspheres on food, directly in the mouth or administered through feeding tubes;
- § the outcome, timing and cost of the regulatory approval process by the FDA and foreign regulatory authorities, including the potential for the FDA or foreign 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;
- § the cost and timing of completion of existing or expanded commercial-scale outsourced manufacturing activities;
- § the cost of establishing sales, marketing and distribution capabilities for Xtampza and any other product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own; 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 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, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing shareholders. Debt, receivables and royalty financings may be coupled with an equity component, such as warrants to purchase stock, which could also result in dilution of our existing shareholders' ownership. The incurrence of additional indebtedness beyond our existing indebtedness with Silicon Valley Bank and our convertible note holders 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 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 innovative 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 platform technology and identifying and developing product candidates that utilize the DETERx technology, including our lead product candidate, Xtampza. We have not yet obtained regulatory approval for any of our product candidates or demonstrated an ability to commercialize a product candidate. 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 or approved products on the market.

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

As of December 31, 2014, we had net operating loss, or NOL, carryforwards of approximately \$78.3 million for U.S. federal income tax and state tax purposes available to offset future taxable income and U.S. federal and state research and development tax credits of \$3.1 million, prior to consideration of annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended, or Section 382. These carryforwards begin to expire in 2022. Under Section 382, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income may be limited. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership some of which are outside our control. We have not performed any current analyses under Section 382 and cannot forecast or otherwise rely on deriving benefit from our various federal or state tax attribute carryforwards. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

**Risks Related to Clinical Development and Regulatory Approval of Our Product Candidates**

**Our success depends in large part on the success of our lead product candidate, Xtampza. We cannot give any assurance that we will receive regulatory approval for Xtampza, which is necessary before it can be commercialized.**

To date, we have invested substantial resources in the development of our lead product candidate, Xtampza, and our business and future success are substantially dependent on our ability to successfully and timely obtain regulatory approval for and commercialize this product candidate, which may never occur. We currently generate no revenues from sales of any drugs and we may never be able to develop or commercialize a marketable drug.

The regulatory approval process that Xtampza must undergo is rigorous, time-consuming and difficult to predict, and there is no guarantee that successful late-stage clinical trials, including the pivotal Phase 3 clinical trial we completed in July 2014, will result in FDA approval of our NDA for Xtampza, which was accepted for filing on February 10, 2015. On February 25, 2015, the FDA set a PDUFA goal date of October 12, 2015 for completion of its review of Xtampza NDA. However, pursuant to FDA guidance, the PDUFA goal date is flexible and subject to change based on the timing and materiality of any amendments to the NDA, the FDA's existing workload, and other potential review issues. There can be no assurances that the FDA will not extend the PDUFA goal date that has been established for completion of its review of the Xtampza NDA.

Any delay or impediment in our ability to obtain approval to commercialize Xtampza may cause us to be unable to generate the revenues necessary to continue our research and development pipeline activities, thereby adversely affecting our business and our prospects for future growth.

Even if we are able to secure regulatory approval of Xtampza, our ability to successfully commercialize Xtampza will depend on many factors, including but not limited to:

- § the FDA's approval of the inclusion of abuse-deterrent claims in the label for Xtampza;
- § the FDA's approval of inclusion of claims in the label for Xtampza that will permit the sprinkling of Xtampza microspheres on food, directly in the mouth or administered through feeding tubes;
- § the ability to manufacture commercial quantities of Xtampza at reasonable cost and with sufficient speed to meet commercial demand;
- § our ability to build a sales and marketing organization to market Xtampza;
- § our success in educating physicians, patients and caregivers about the benefits, administration and use of Xtampza;
- § the availability, perceived advantages, relative cost, relative safety and relative efficacy of other abuse-deterrent products and treatments for chronic pain and CPD;
- § our ability to successfully defend any challenges to our intellectual property relating to Xtampza;
- § the availability of coverage and adequate reimbursement for Xtampza; and
- § a continued acceptable safety profile of Xtampza following approval.

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

**If we fail to obtain FDA approval of product labeling for sprinkling Xtampza microspheres directly in the mouth or on food, as well as administering the microspheres through feeding tubes, then our ability to successfully market Xtampza may be adversely affected.**

It is estimated that the U.S. market includes approximately 11 million patients with CPD. Our Xtampza microspheres are designed to be removed from the capsule and sprinkled on food, directly into the mouth or administered through feeding tubes, without compromising their extended-release properties. If the FDA approves Xtampza, but does not permit us to include a claim in the label for Xtampza regarding the ability to sprinkle the Xtampza microspheres directly in the mouth, on food or in feeding tubes, or requires us to have 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 drug," it will limit our ability to differentiate Xtampza from other abuse-deterrent opioid formulations on the basis of alternative dosing options and we may not be able to market Xtampza to patients with CPD. 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 Xtampza or our other product candidates 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 as we anticipate, 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 Xtampza and our other 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 Xtampza or any of our other 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 more quickly than our product candidates, which could have a material adverse effect on our competitive position and our business prospects. Even if we are allowed to pursue the Section 505(b)(2) approval pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization on a timely basis, if at all.

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

Even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

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

In connection with any NDA that we file under Section 505(b)(2), we will also be required to notify the patent holders of the Section 505(b)(2) listed drug, that we identify in our NDA if we have certified to the FDA that any patents listed for the listed drug in the FDA's Orange Book publication are invalid, unenforceable or will not be infringed by the manufacture, use or sale of our drug. If the patent holder files a patent infringement lawsuit against us within 45 days of its receipt of notice of our certification, the FDA is automatically prevented from approving our Section 505(b)(2) NDA until the earliest of 30 months, expiration of the patents, settlement of the lawsuit or a court decision in the infringement case that is favorable to us. Accordingly, we may invest significant time and expense in the development of our product candidates only to be subject to significant delay and expensive and time-consuming patent litigation before our product candidates may be commercialized. On March 24 and March 26, 2015, Purdue, as the sponsor for OxyContin OP, the listed drug for Xtampza, brought infringement claims against us in the District of Delaware and the District of Massachusetts, respectively, alleging infringement of U.S. Patent Nos. 7,674,799, 7,674,800, 7,683,072 and 8,652,497. On April 6, 2015, in the District of Delaware case, we filed a motion to dismiss for lack of personal jurisdiction or, in the alternative, to transfer venue to the Southern District of New York where three of the patents have already been invalidated. Purdue's opposition to our motion was filed on April 23, 2015 and our reply in support of the motion is due on May 4, 2015. The complaint in the District of Massachusetts case has not yet been served. We plan to continue to take all steps necessary to vigorously defend ourselves against these claims. The strength of our defenses will depend on the patents asserted and the interpretation of these patents. However, we could be unsuccessful in advancing non-infringement and invalidity arguments in our defense. Purdue need only prove infringement by a preponderance of the evidence, which is a low burden of proof. If before the expiration of the 30-month period, the Court issues a final order that any of the listed patents are valid and have been infringed, FDA approval would be delayed until either a date ordered by the Court or when the Court determines that the patents will expire.

Even if we are found not to infringe or Purdue's, or any other potential plaintiff's, patent claims are found invalid or unenforceable, defending any such infringement claim would be expensive and time-consuming,



and would delay the launch of our product candidates, including Xtampza, 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, including Xtampza. If we were to launch any of our product candidates, if approved by the FDA, including Xtampza, prior to a full and final determination that the listed 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 inherently 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 approvals 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. For example, we cannot guarantee that the FDA will not require additional or different clinical trials in support of our submission of an NDA for Xtampza. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any future product candidates we may in-license, acquire or develop will ever obtain regulatory approval from the FDA or any foreign regulatory authority.

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 Xtampza or our other 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 clinical trials, or may approve a product with a 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 clinical trials, or we may not be allowed to include the labeling claims necessary or desirable for the successful commercialization of such product candidate.

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

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

As we currently have no approved products, we are not generating any revenues from product sales. To be profitable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our product candidates under development. For our lead product candidate, Xtampza, and each additional product candidate that we intend to commercialize, we must successfully meet a number of critical developmental milestones, including:

- § selecting and developing a drug delivery platform 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 through clinical trials 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 have not yet completed development of any product. 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 Xtampza or any of our other product candidates, we will not be able to earn revenue from them.

**We anticipate that our product candidates, including Xtampza, will be subject to mandatory REMS programs, which could increase the cost, burden and liability associated with the commercialization of such product candidate.**

The FDA has indicated that extended-release and long-acting opioid drugs formulated with the active ingredients fentanyl, hydromorphone, methadone, morphine, oxycodone, oxymorphone, and others will be required to have a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of the drugs continue to outweigh the risks. The FDA has approved a REMS for extended release, or ER, and long-acting, or LA, opioids as part of a federal initiative to address prescription drug abuse and misuse, or the ER/LA opioid REMS. The ER/LA opioid REMS introduces new safety measures designed to reduce risks and improve the safe use of extended-release/long-acting opioids, while continuing to provide access to these medications for patients in pain. The ER/LA opioid REMS affects more than 20 companies that manufacture opioid analgesics. Under the ER/LA opioid REMS, companies are required to make education programs available to prescribers based on the FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics. It is expected that companies will meet this obligation by providing educational grants to continuing education providers, who will develop and deliver the training. The ER/LA opioid REMS also requires companies to distribute FDA-approved educational materials to prescribers and patients on the safe use of these drugs. The companies must perform periodic assessments of the implementation of the ER/LA opioid REMS and the success of the program in meeting its goals. The FDA will review these assessments and may require additional elements to achieve the goals of the program.

If the FDA determines that a REMS is necessary during review of an application, the drug sponsor must agree to the REMS plan at the time of approval. We anticipate that our product candidates, including Xtampza, will be subject to the ER/LA opioid REMS requirement. There may be increased cost, administrative burden and potential liability associated with the marketing and sale of these types of product candidates subject to the ER/LA opioid REMS requirement, which could reduce the commercial benefits to us from the sale of these product candidates.

**If we fail to obtain the necessary 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 Xtampza or our other product candidates are not safe or effective, and we may never obtain regulatory approval for such product candidates. If we fail to obtain regulatory approval for some or all of our product candidates, we will have fewer commercial products, if any, and correspondingly lower product revenues, if any. Even if our product candidates, including Xtampza, receive regulatory approval, such approval may involve limitations on the indications and conditions of use or marketing claims for our products, or may not include certain of the abuse-deterrence claims that we are seeking to include in the label for Xtampza and our other DETERx-based product candidates. Further, later discovery of previously unknown problems or adverse events could result in additional regulatory restrictions, including withdrawal of products and

addition of warnings or other statements on the product label. The FDA is likely to require us to perform lengthy Phase 4 post-approval clinical efficacy or safety trials. These trials could be very expensive.

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, the risks associated with FDA approval.

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

We have invested substantial time and money conducting Category 1, Category 2 and Category 3 abuse-deterrent studies to ensure Xtampza's compliance with the FDA's January 2013 draft guidance regarding opioid abuse deterrence, and we believe such studies are consistent with the April 2015 final FDA guidance. The commercial success of Xtampza and our other product candidates will depend upon our ability to do the following:

- § obtain FDA-approved labeling describing their abuse-deterrent features or benefits; and
- § obtain FDA-approved labeling that will allow for the Xtampza microspheres to be sprinkled on food, directly in the mouth or administered through feeding tubes.

Our failure to achieve FDA approval of product labeling containing such information will prevent or substantially 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.

The FDA has publicly stated that explicit claims that a product is expected to result in a meaningful reduction of abuse must be supported by randomized, double-blind, controlled clinical studies of the abuse potential of the drug and that explicit claims that a product has demonstrated reduced abuse in the community will be required to be supported by post-marketing data, including formal post-marketing studies evaluating the effect of abuse-deterrent formulations. Although we believe that we have conducted all of the preclinical studies and clinical trials that are required to support certain abuse-deterrent claims for Xtampza, there can be no assurance that Xtampza, or any of our other product candidates, will receive FDA-approved 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 labeling regarding abuse-deterrent properties. If the FDA does not approve 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 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 Xtampza and any of our other 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 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 labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, import, export, record-keeping and reporting of safety and other post-market information. 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 our product candidates 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 candidate that obtains approval in the United States 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 our product candidates, if approved, 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 candidate that obtains approval outside the United States will be heavily scrutinized by foreign regulatory authorities.

In the United States, engaging in off-label promotion of Xtampza (or any of our other product candidates), if approved can also subject us to false claims litigation under federal and state statutes, and other litigation and/or investigation, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which we promote or distribute our drug products. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements based on certain sales practices promoting off-label drug uses. This increasing 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 product candidates, if approved, 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 our product candidates:

- § failure to obtain or maintain requisite governmental approvals;
- § failure to obtain approvals of 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.

**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.**

Our product candidates, including Xtampza, contain, and our future product candidates will likely contain, controlled substances which are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Xtampza's active ingredient, oxycodone, is classified as a controlled substance under the Controlled Substances Act of 1970, or CSA, and regulations

of the U.S. Drug Enforcement Administration, or DEA. A number of states also independently regulate these drugs, including oxycodone, as controlled substances. Controlled substances are classified by the DEA as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredient in our lead product candidate Xtampza, oxycodone, is listed by the DEA as a Schedule II controlled substance under the CSA. For our product candidates containing controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription. Furthermore, the amount of Schedule II substances that can be obtained for clinical trials and commercial distribution is limited by the CSA and DEA regulations. We may not be able to obtain sufficient quantities of these controlled substances in order to complete our clinical trials or meet commercial demand, if our product candidates are approved for marketing.

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 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 our 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 our product candidates containing controlled substances.

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

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

Clinical trials are time-consuming, expensive and difficult to design and implement, in part because they are subject to rigorous requirements and their outcomes are inherently uncertain. Clinical testing may take many years to complete, and failure can occur at any time during the clinical trial process, even with active ingredients that have previously been approved by the FDA as being safe and effective. We could encounter problems that halt our clinical trials or require us to repeat such clinical trials. If patients participating in clinical trials suffer drug-related adverse reactions during the course of such clinical trials, or if we or the FDA believe that patients are being exposed to unacceptable health risks, such clinical trials may have to 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 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 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 and commercialization of our product candidates and significantly increase our overall costs of drug development.

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

Other than Xtampza, all of our product candidates are in preclinical 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 reporting promising results in earlier clinical trials. Despite the results reported in preliminary preclinical studies for our other extended-release, abuse-deterrent product candidates, including hydrocodone and oxycodone 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, other than Xtampza, may be compromised.

**Conducting clinical trials of our product candidates and any future commercial sales of a product candidate 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 \$5 million, which covers liability relating to our clinical trials. Even if we successfully commercialize one or more of our product candidates, we may face product liability claims, regardless of FDA approval for commercial manufacturing and sale. 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 product candidates or products caused injuries, we could incur substantial liabilities. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Regardless of merit or eventual outcome, liability claims may result in:

- § decreased demand for any product candidates or products 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 our product candidates. Any agreements we may enter into in the future with collaborators in connection with the development or commercialization of 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, several of our agreements require us to indemnify third parties and these indemnifications obligations may exceed the coverage under our product liability insurance policy.

**Xtampza and our other 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 label, or result in significant negative consequences following any marketing approval.**

Undesirable adverse reactions associated with Xtampza, or any of our other 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 label or the delay, denial or withdrawal of regulatory approval by the FDA or foreign regulatory authorities. For example, even though Xtampza has generally been well tolerated by patients in our clinical trials, in some cases there were adverse reactions, one of which was a serious adverse event, moderate in severity, of gastroesophageal reflux.

If Xtampza or any of our other product candidates receives marketing approval, and we or others later identify undesirable adverse events associated with such product, 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 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 other 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 future 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 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 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 Section 505(b)(2) 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. On March 24 and March 26, 2015, Purdue, as the sponsor for OxyContin OP, the listed drug for Xtampza, brought infringement claims against us in the District of Delaware and the District of Massachusetts, respectively, alleging infringement of U.S. Patent Nos. 7,674,799, 7,674,800, 7,683,072 and 8,652,497. On April 6, 2015, in the District of Delaware case, we filed a motion to dismiss for lack of personal jurisdiction or, in the alternative, to transfer venue to the Southern District of New York where three of the patents have already been invalidated. Purdue's opposition to our motion was filed on April 23, 2015 and our reply in support of the motion is due on May 4, 2015. The complaint in the District of Massachusetts case has not yet been served. We plan to continue to take all steps necessary to vigorously defend ourselves against these claims. The strength of our defenses will depend on the patents asserted and the interpretation of these patents. However, we could be unsuccessful in advancing non-infringement and invalidity arguments in our defense. Purdue need only prove infringement by a preponderance of the evidence, which is a low burden of proof.

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 Purdue 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 Purdue's, or any other potential plaintiff's, patent claims are found invalid or unenforceable, defending any such infringement claim would be expensive and time-consuming, and could delay the launch of Xtampza 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 and product candidates, we may lose valuable assets or experience reduced market share.**

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

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

**The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.**

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

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

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

The patent position of biotechnology and 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 have licensed 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.**

While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing or obtaining such an agreement with each party who, in fact, develops intellectual property that we regard as our own. In addition, they may breach the assignment agreements or such agreements may not be self-executing, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

In addition to seeking patents for some of our technology and products, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts 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 them, 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 so 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 and be a distraction to management.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents are required to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patents. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

## Risks Related to the Commercialization of Our Product Candidates

**We currently have no sales or marketing capabilities and, if we are unable to develop our own sales and marketing capabilities or enter into strategic alliances with marketing collaborators, we may not be successful in commercializing our product candidates and may be unable to generate any product revenue.**

Although our executive officers have experience marketing pharmaceutical products, we currently have no sales, marketing or distribution capabilities. We do not intend to begin to hire field sales representatives until several months prior to receiving FDA approval of one of our product candidates. Therefore, at the time of our anticipated commercial launch of Xtampza, assuming regulatory approval of the product candidate by the FDA, our sales and marketing team will have worked together for only a limited period of time. We cannot guarantee that we will be successful in marketing Xtampza or any of our other product candidates which may be approved in the United States. We may not be able to establish a targeted sales force in a cost-effective manner. In addition, we will have to compete with other pharmaceutical and biotechnology companies with extensive and well-funded sales and marketing operations to recruit, hire, train and retain sales and marketing personnel. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. Factors that may inhibit our efforts to commercialize our product candidates in the United States include:

- § our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- § the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe 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 an independent sales and marketing organization.

If we are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure or if we do not successfully enter into appropriate strategic alliances with marketing collaborators, agreements with contract sales organizations or collaboration arrangements, we will have difficulty commercializing our product candidates. To the extent we commercialize 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 our product candidates, we will not achieve sufficient product revenues and our business will suffer.**

Even if the FDA approves our product candidates, physicians, patients, healthcare payors and the medical community may not accept and use them. Acceptance and use of our product candidates will depend on a number of factors including:

- § the timing of market introduction of the product candidates as well as competitive products;
- § approved indications, warnings and precautions language that may be less desirable than anticipated;
- § perceptions by members of the healthcare community, including physicians, about the safety and efficacy of our product candidates, and, in particular, the efficacy of our abuse-deterrent technology in reducing potential risks of unintended use;
- § perceptions by physicians regarding the cost benefit of our product candidates in reducing potential risks of unintended use;
- § published studies demonstrating the cost-effectiveness of our product candidates relative to competing products;
- § the potential and perceived advantages of our product candidates over alternative treatments;
- § the convenience and ease of administration to patients of our product candidates;

- § availability of coverage and adequate reimbursement for 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 our product candidates;
- § the prevalence and severity of adverse side effects, including limitations or warnings contained in a product's FDA approved labeling;
- § our ability to implement a REMS prior to the distribution of any product candidates requiring a REMS; and
- § effectiveness of marketing and distribution efforts by us and other licensees and distributors.

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

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

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 any product candidates for which we obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the Medicare Modernization Act, established the Medicare Part D program and provided authority for limiting the number of drugs that will be covered in any therapeutic class thereunder. The Medicare Modernization Act, including its cost reduction initiatives, could decrease the coverage and reimbursement rate that we receive for any of our approved products. Furthermore, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates. Therefore, any reduction in Medicare reimbursement may result in a similar reduction in payments from private payors.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial new provisions intended to, among other things, broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, and impose additional health policy reforms, any of which could have a material adverse effect on our business. A significant number of provisions are not yet, or have only recently become, effective, but the Affordable Care Act is likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Other legislative changes have also been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of 2% per fiscal year, starting in 2013, and the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several types of 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 impose additional financial pressure on our customers, which could in turn diminish demand for our products or result in pricing pressure on us.



We expect that the Affordable Care Act, as well as other healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria 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.

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

**Even if we are able to commercialize Xtampza and any of our other product candidates, our products may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could have a material adverse effect on our business.**

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

Our ability to commercialize any products successfully will also depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be and whether it will be satisfactory. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for

lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage 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 opioid and regulatory efforts to combat abuse, could decrease the potential market for 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 that seek to limit the availability of opioids. Such efforts may inhibit our ability to commercialize 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 Xtampza; public inquiries and investigations into prescription drug abuse; litigation; or regulatory activity regarding sales, marketing, distribution or storage of opioid drugs could have a material adverse effect on our reputation. Such negative publicity could reduce the potential size of the market for 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.

Additionally, efforts by the FDA and other regulatory bodies to combat abuse of opioids may negatively impact the market for our product candidates. For example, on September 10, 2013, the FDA announced its intention to effect labeling changes to all approved extended-release/long-acting opioids. In particular, the FDA announced its intention to update the indication for extended-release/long-acting opioids so that extended-release/long-acting opioids 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. It is possible that such changes could reduce the number of prescriptions for opioids written by physicians and negatively impact the potential market for our product candidates.

**If the FDA or other applicable regulatory authorities approve generic products with abuse-deterrent claims that compete with any of our product candidates, it could reduce our sales of those product candidates.**

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 labeling, as our product candidate 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 candidate. 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 product candidates would substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our 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 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 we encounter difficulties in negotiating a commercial manufacturing agreement with the third party manufacturer of Xtampza or the third-party manufacturer fails to devote sufficient time and resources to Xtampza, or its performance is substandard, our product launch may be delayed and our costs may be higher than expected and could have a material adverse effect on our business.**

We do not own any manufacturing facilities and have limited experience in drug development and commercial manufacturing. We currently have no plans to build our own clinical or commercial scale manufacturing facility. We lack the resources and expertise to manufacture and test, on a commercial scale, the technical performance of our product candidates. We currently rely, and expect to continue to rely, on a limited number of experienced personnel and one contract manufacturer, Patheon, as well as other vendors to formulate, test, supply, store and distribute Xtampza for our clinical trials and FDA registration, and we control only certain aspects of their activities. We are currently negotiating a commercial manufacturing agreement with Patheon and we may not be able to obtain terms that are favorable to us or enter into a commercial manufacturing agreement at all. 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, 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, and may experience shortages of qualified personnel to adequately staff production operations.
- § our contract manufacturer could default on its agreement with us to meet our requirements for commercialization 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 before we may use the alternative manufacturer to produce Xtampza.
- § 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 product candidate 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 our product candidates and any products 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 product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, imposing civil penalties or pursuing criminal prosecution.

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

We presently depend upon a single source as the sole supplier of 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 cost 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.

Because we have relied on third parties, 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. Though we carefully manage our relationships with our CROs, 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 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 our product candidates. Collaborations involving our product candidates 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 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 a product candidate, repeat or conduct new clinical trials or require a new formulation of a 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 of our own programs.
- § collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our 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 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 candidates.
- § collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

**We may rely on collaborators to market and commercialize Xtampza and, if approved, our other product candidates, who may fail to effectively commercialize our product candidates.**

We may utilize strategic collaborators or contract sales forces, where appropriate, to assist in the commercialization of our product candidates, if approved, including Xtampza. 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 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 candidates would diminish our revenues.

**Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization.**

As we scale up manufacturing of our 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 and obtain regulatory approval for commercial marketing. 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 or failure to obtain or maintain approval for our product candidates.

## Risks Related to Our Business and Strategy

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

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

We face and will continue to face competition from other companies in the pharmaceutical and medical device industries. Our product candidates, if approved, will compete with currently marketed oral opioids, transdermal opioids, local anesthetic patches, stimulants and implantable and external infusion pumps that can be used for infusion of opioids and local anesthetics. Products of these types are marketed by Purdue, Johnson & Johnson, Pfizer, Endo, Mallinckrodt, Zogenix, Actavis 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 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, we believe that several competitors are developing extended-release oxycodone products, and if the FDA approves a competitor's 505(b)(2) application for an extended-release oxycodone product and grants exclusivity before our NDA for Xtampza is filed and approved, we could be subject to a delay that would dramatically reduce the expected market penetration for Xtampza. Additionally, even if our 505(b)(2) application for Xtampza is approved first, we may still be subject to competition from other oxycodone 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 candidates will compete may limit market acceptance of our product candidates even if commercialized. Oral medication, 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 candidates, if approved, and the established use of these competitive products may limit the potential for our 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, like the Purdue litigation, 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 associated with our product candidates.

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

We are highly dependent upon the services of our key personnel, including our President and Chief Executive Officer, Michael T. Heffernan, and our Vice President, Product Development and one of the inventors of the DETERx technology, Dr. Alison B. Fleming. Each employee is employed by us at will and is permitted to terminate his or her employment with us at any time. We anticipate entering into new employment agreements with Mr. Heffernan and Dr. Fleming following the consummation of this offering, but we expect that Mr. Heffernan and Dr. Fleming will continue to be employed at will. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of Mr. Heffernan or Dr. Fleming could impede the achievement of our research, 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 and technical 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 scientific and technical 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.**

As of April 2, 2015, we had 24 full-time employees. As our development and commercialization strategies develop, we will need additional managerial, operational, sales, marketing, financial and other resources. Our management, personnel and systems currently in place may not be adequate to support this 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 product candidates;
- § overseeing our ongoing 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 finance systems and procedures;
- § developing our compliance infrastructure and processes to ensure compliance with regulations applicable to public companies; and
- § expanding our facilities.

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 candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

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

As part of our business strategy, we may pursue acquisitions of assets, including preclinical, clinical or commercial stage products or product candidates, businesses or strategic alliances and collaborations, to expand our existing technologies and operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any such transaction, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. We have no experience with acquiring other companies, products or product candidates, and limited experience with forming strategic alliances and collaborations. We may not be able to find suitable acquisition candidates, and if we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business and we may incur additional debt or assume unknown or contingent liabilities in connection therewith. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business. We may not be able to find suitable strategic alliance or collaborators or identify other investment opportunities, and we may experience losses related to any such investments.

To finance any acquisitions or collaborations, we may choose to issue debt or shares of our common stock as consideration. Any such issuance of shares would dilute the ownership of our shareholders. If the price

of our common stock is low or volatile, we may not be able to acquire other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

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

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates:

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

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

**Our relationships with customers and payors will be 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 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 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 information related to payments and other transfers of value made to physicians and other healthcare providers, 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
- § 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.

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 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 resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We maintain insurance for environmental liability or toxic tort claims, but we may not continue to maintain such insurance in the future, and such insurance, to the extent maintained, may not be adequate to cover liabilities that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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

Despite the implementation of security measures, our internal computer systems, and those of our CROs, contract manufacturing organization, or CMO, and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our 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 drug development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

## Risks Related to this Offering and Ownership of Our Common Stock

**There is no existing market for our common stock, and we do not know if one will develop. Even if a market does develop, the stock prices in the market may not exceed the offering price.**

Prior to this offering there has been no market for shares of our common stock. An active trading market for our shares may never develop or be sustained following this offering. The initial public offering price for our common stock was determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of our common stock after this offering. The market value of our common stock may decrease from the initial public offering price. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration. The market price of our stock may be volatile, and you could lose all or part of your investment. The lack of an active market also may reduce the fair market value of your shares.

**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 following this offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, these factors include:

- § the success of competitive products or technologies;
- § regulatory actions with respect to our 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 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 any of our 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. After this offering, we will have outstanding 19,707,935 shares of common stock based on the number of shares outstanding as of April 2, 2015. This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. The remaining shares will be restricted as a result of securities laws or lock-up agreements but will be able to be sold after the offering as described in the "Shares Eligible for Future Sale" section of this prospectus. Moreover, after this offering, holders of an aggregate of 12,787,524 shares of our common stock will 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. We also intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus.

**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, including shares of common stock sold in this offering.

**We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.**

We will have broad discretion in the application of the net proceeds from this offering, and you will be relying on the judgment of our management regarding the application of these proceeds. Our management

may not apply the net proceeds of this offering in ways that ultimately increase the value of your investment. We expect to use the net proceeds from this offering in the manner described in the "Use of Proceeds" section of this prospectus. Our failure to apply these net proceeds 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 development of our product candidates. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our shareholders. If we do not invest or apply the net proceeds from this offering 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.

**Our principal shareholders and management own substantially all of our stock prior to this offering and will continue to be able to exert significant control over matters subject to shareholder approval after the offering.**

As of April 2, 2015, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 82% of our voting stock, including shares subject to outstanding options and warrants, and, upon the closing of this offering, we expect that same group will continue to hold approximately 58% of our outstanding voting stock. As a result, these shareholders, acting together, 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.

Certain of our existing stockholders, or their affiliates, have indicated an interest in purchasing up to an aggregate of approximately \$30.0 million of shares of our common stock in this offering at the initial public offering price. The previously discussed ownership percentage upon completion of this offering does not reflect the potential purchase of any shares in this offering by such investors. If these investors purchase an aggregate of \$30.0 million of shares of our common stock in this offering at \$13.00 per share (the midpoint of the price range set forth on the cover page of this prospectus), upon completion of this offering, our executive officers, directors, 5% stockholders and their affiliates will hold approximately 70% of our outstanding voting stock (assuming no exercise of the underwriters' option to purchase additional shares).

In addition, persons associated with Longitude Capital Partners, LLC, Skyline Venture Partners V, L.P., Frazier Healthcare VI, L.P., and TPG Biotechnology Partners IV, L.P. currently serve on our board of directors. Following this offering, the interests of Longitude Capital Partners, LLC, Skyline Venture Partners V, L.P., Frazier Healthcare VI, L.P., and TPG Biotechnology Partners IV, L.P. may not always coincide with the interests of the other shareholders, and the concentration of control in Longitude Capital Partners, LLC, Skyline Venture Partners V, L.P., Frazier Healthcare VI, L.P., and TPG Biotechnology Partners IV, L.P. will limit 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 the value of your investment to decline.

**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 the 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, should they choose to do so, to remove our board of directors or management or elect new directors to our board of directors. See "Description of Capital Stock."

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

We expect to receive approval to list our common stock on The NASDAQ Global Market. If approved, we will need to satisfy the continued listing requirements of NASDAQ for inclusion in the Global Market to maintain such listing, including, among other things, the maintenance of a minimum 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 will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, 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.

**If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.**

The initial public offering price is substantially higher than the net tangible book value per share of our common stock. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of \$7.57 per share, based on an assumed initial public offering price of \$13.00 per share, which is the midpoint of the price range set forth on the cover of this prospectus. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. Further, investors purchasing common stock in this offering will contribute approximately 40% of the total amount invested by shareholders since our inception, but will own, as a result of such investment, only approximately 29% of the shares of common stock outstanding immediately following giving effect to this offering. Furthermore, if the underwriters exercise their option to purchase additional shares or our previously issued options and warrants to acquire common stock at prices below the assumed initial public offering price are exercised, you will experience further dilution. For a further description of the dilution that you will incur as a result of purchasing shares in this offering, see "Dilution."

**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 capital 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 common stock will be your sole source of gain for the foreseeable future.

**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 we are eligible to take advantage of 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) the end of the fiscal year following the fifth anniversary of the completion of this offering, (ii) the first fiscal year after our annual gross revenue are \$1.0 billion or

more, (iii) the date on which we have, during the previous three-year period, issued more than \$1.0 billion in non-convertible debt securities or (iv) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded \$700 million as of the end of the second quarter of that fiscal year.

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

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

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

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

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting. Commencing with our annual report on Form 10-K for the year ending December 31, 2016, we will be required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirement.

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

**If we are unable to successfully remediate the existing material weaknesses in our internal control over financial reporting, the accuracy and timing of our financial reporting may be adversely affected.**

Our management team is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles in the United States, or GAAP, and SEC rules and regulations. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

During the course of preparing our December 31, 2014 financial statements, our management team determined that we had the following material weaknesses in our internal control over financial reporting:

- § Adequate controls are not in place to appropriately segregate duties in areas such as journal entries, cash disbursements, and the calculation, processing and recording of employee compensation and related accounts.
- § Our controls and procedures over the accounting for and reporting of complex accounting matters were not effectively designed due to a failure to design and implement appropriate policies and procedures to ensure that the accounting and valuation of complex debt and equity transactions, income taxes and certain other matters is in accordance with GAAP.
- § Our controls were not effectively implemented in the financial statement close process to ensure that proper cut-off of accrued expenses was achieved at interim periods.

The material weaknesses in our internal control over financial reporting were attributable to our lack of sufficient financial reporting and accounting personnel with appropriate training in GAAP and SEC rules and regulations. In response to these material weaknesses, we have hired, and plan to continue to hire, additional personnel with public company financial reporting expertise to build our financial management and reporting infrastructure, and further develop and document our accounting policies and financial reporting procedures. However, we cannot assure you that we will be successful in pursuing these measures or that these measures will significantly improve or remediate the material weaknesses described above. We also cannot assure you that we have identified all of our existing material weaknesses, or that we will not in the future have additional material weaknesses. We have not yet remediated our material weaknesses, and the remediation measures that we intend to implement may be insufficient to address our existing material weaknesses or to identify or prevent additional material weaknesses.

Neither we nor our independent registered public accounting firm has performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. In light of the control deficiencies and the resulting material weaknesses that were identified as a result of the limited procedures performed, we believe that it is possible that, had we and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses and significant control deficiencies may have been identified. However, for as long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of the exemption permitting us

not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

If we fail to remediate the material weaknesses or to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results, or report them within the timeframes required by law or stock exchange regulations. Failure to comply with Section 404 of the Sarbanes-Oxley Act could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. There is no assurance that we will be able to remediate these material weaknesses in a timely manner, or at all, or that in the future, additional material weaknesses will not exist or otherwise be discovered. If our efforts to remediate these material weaknesses identified are not successful, or if other material weaknesses or other deficiencies occur, our ability to accurately and timely report our financial position could be impaired, which could result in late filings of our annual and quarterly reports under the Exchange Act, restatements of our financial statements, a decline in our stock price, suspension or delisting of our common stock from NASDAQ, and could have a material adverse effect on our reputation, results of operations and financial condition.

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

Upon consummation of this offering, we will become 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.

**We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.**

Prior to the consummation of this offering, we have not been subject to public company reporting obligations. We will incur increased legal, accounting, administrative and other costs and expenses as a public company. Compliance with the Sarbanes-Oxley Act, the Dodd-Frank Act of 2010, the Exchange Act, as well as rules of the SEC and NASDAQ, for example, will result in significant initial costs to us as well as ongoing increases in our legal, audit and financial compliance costs, particularly after we are no longer an "emerging growth company." Any changes that we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. The Exchange Act, requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. Our board of directors, management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and require us to incur substantial costs to maintain the same or similar coverage.

We estimate that we will incur approximately \$2.0 million in incremental costs per year associated with being a publicly traded company, although it is possible that our actual incremental costs will be higher than we currently estimate. The increased costs will increase our net loss. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes forward-looking statements. The forward-looking statements are contained principally in the sections entitled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." 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 product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- § our plans to commercialize our product candidates;
- § the size and growth potential of the markets for our product candidates, and our ability to service those markets;
- § our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- § the rate and degree of market acceptance of our product candidates;
- § the outcome of any patent infringement or other litigation that may be brought against us, including the ongoing Purdue litigation;
- § 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 beyond this offering;
- § regulatory developments in the United States and foreign countries;
- § our ability to operate our business without infringing the intellectual property rights of others;
- § the performance of our third-party suppliers and manufacturers;
- § the success of competing products that are or become available;
- § 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 use of proceeds from this offering;
- § the accuracy of our estimates regarding expenses, future revenue, capital requirements and need for additional financing; and
- § our expectations regarding our ability to obtain and adequately maintain sufficient intellectual property protection for our product candidates.

In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions. 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 prospectus 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. The Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act do not protect any forward-looking statements that we make in connection with this offering. Any forward-looking statements that we make in this prospectus 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 prospectus 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.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

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.

## USE OF PROCEEDS

We estimate that our net proceeds from the sale of shares of our common stock in this offering will be approximately \$67.5 million (or \$78.0 million if the underwriters exercise their option to purchase additional shares from us in full), based on the assumed initial public offering price of \$13.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each \$1.00 increase (decrease) in the assumed initial public offering price of \$13.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our net proceeds, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and offering expenses, by approximately \$5.4 million.

We intend to use the net proceeds of this offering as follows:

- § approximately \$45.0 million for the development of our commercial infrastructure to launch Xtampza, including building our sales, marketing and reimbursement functions. If Xtampza is approved in the United States, we plan to hire a team of approximately 100 sales representatives for the initial launch. In addition, we expect to deploy a smaller sales force to detail Xtampza to nursing homes, hospices and other institutions;
- § approximately \$15.0 million to fund research and development efforts of our other product candidates, including approximately \$12.0 million to conduct clinical development for our second product candidate through its Phase 3 clinical trial (including Phase 1 bioequivalence clinical trials and abuse-deterrence studies and clinical trials); and
- § the remainder, if any, to fund working capital and general corporate purposes, which may include litigation expenses (including expenses relating to the Purdue litigation) and the acquisition or licensing of product candidates, technologies, compounds, other assets or complementary businesses.

The expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures depend on numerous factors, including regulatory approval of Xtampza and the progress of our preclinical and clinical development efforts with respect to our other product candidates. As a result, our management will have broad discretion in applying the net proceeds from this offering. Although we may use a portion of the net proceeds from this offering for the acquisition or licensing, as the case may be, of product candidates, technologies, compounds, other assets or complementary businesses, we have no current understandings, agreements or commitments to do so. Pending these uses, we plan to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

Although it is difficult to predict future liquidity requirements, we believe that the net proceeds from this offering, together with our existing cash resources, will be sufficient to enable us to fund our operations into mid-2017, including the commercialization of Xtampza, if approved, and the continuation of our development of our other product candidates. We have based this estimate on assumptions, including with respect to the Purdue litigation, that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

## DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business and do not intend to declare or pay any cash dividends in the foreseeable future. As a result, you will likely need to sell your shares of common stock to realize a return on your investment, and you may not be able to sell your shares at or above the price you paid for them. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. See "Risk Factors — 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."



**CAPITALIZATION**

The following table sets forth our cash and cash equivalents and our capitalization as of December 31, 2014 on:

- § an actual basis;
- § a pro forma basis, giving effect to the following: our issuance and sale of 41,666,667 shares of our Series D convertible preferred stock in March 2015 at a price per share of \$1.20 for aggregate consideration of \$50.0 million, comprised of \$45.0 million in cash and \$5.0 million from conversion of convertible notes with related parties; and the conversion of all our outstanding convertible preferred stock into an aggregate of 12,591,456 shares of our common stock (which includes 41,666,667 shares of our Series D convertible preferred stock issued in March 2015) upon the closing of this offering.
- § a pro forma as adjusted basis, giving further effect to the sale by us of 5,800,000 shares of our common stock in this offering at an assumed initial public offering price of \$13.00 per share (the midpoint of the price range set forth on the cover page of this prospectus), after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information below is illustrative only, and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with our financial statements and the related notes appearing at the end of this prospectus, the sections entitled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other financial information appearing elsewhere in this prospectus.

	<u>As of December 31, 2014</u>		
	<u>Actual</u>	<u>Pro Forma</u>	<u>Pro Forma as Adjusted</u>
	<u>(in thousands, except share and per share amounts)</u>		
Cash and cash equivalents	\$ 1,634	\$ 46,634	\$ 114,156
Long-term debt, net of discount	\$ 6,914	\$ 6,914	\$ 6,914
Series A convertible preferred stock, \$0.001 par value; 18,498,419 shares authorized; 9,232,334 issued and outstanding, actual; no shares issued and outstanding pro forma and pro forma as adjusted	12,781	—	—
Series B convertible preferred stock, \$0.001 par value; 27,324,237 shares authorized; 27,324,237 issued and outstanding, actual; no shares issued and outstanding pro forma and pro forma as adjusted	51,212	—	—
Series C convertible preferred stock, \$0.001 par value; 8,658,344 shares authorized; 8,658,008 issued and outstanding, actual; no shares issued and outstanding pro forma and pro forma as adjusted	13,114	—	—
Series D convertible preferred stock, \$0.001 par value, no shares authorized; none issued and outstanding, actual; no shares issued and outstanding pro forma and pro forma as adjusted	—	—	—
Common stock, \$0.001 par value; 72,000,000 shares authorized; 1,006,219 issued and outstanding, actual; 13,907,935 issued and outstanding, pro forma; and 19,707,935 issued and outstanding, pro forma as adjusted	1	14	20
Additional paid-in capital	12,407	139,501	207,017
Accumulated deficit	(101,753)	(101,753)	(101,753)
Treasury stock	(3)	(3)	(3)
Total shareholders' equity (deficit)	(89,348)	37,759	105,281
Total capitalization	<u>\$ (12,241)</u>	<u>\$ 37,759</u>	<u>\$ 105,281</u>

The number of shares of our common stock to be outstanding after this offering is based on 1,316,479 shares of common stock outstanding as of April 2, 2015 and assumes:

- § the issuance by us of 5,800,000 shares of our common stock in this offering; and
- § the conversion of all of our convertible preferred stock outstanding immediately prior to the closing of this offering into an aggregate of 12,591,456 shares of common stock (which includes 41,666,667 shares of Series D convertible preferred stock issued in March 2015),

and excludes:

- § 803,565 shares of common stock issuable upon the exercise of outstanding stock options as of April 2, 2015, at a weighted-average exercise price of \$4.23 per share;
- § 18,809 shares of common stock issuable upon the exercise of warrants to purchase common stock as of April 2, 2015, at a weighted-average exercise price of \$1.91 per share;
- § the issuance by us of additional shares of common stock (which, based on an assumed initial public offering price of \$13.00 per share (the mid-point of the price range set forth on the cover page of this prospectus) will total approximately 61,000 shares), as payment of the accrued dividend on the outstanding shares of Series D convertible preferred stock payable to the holders of Series D convertible preferred stock upon the closing of this offering;
- § 1,751,803 shares of common stock reserved for future issuance under our Amended and Restated 2014 Stock Incentive Plan upon the closing of this offering; and
- § 200,000 shares reserved for future issuance under our 2015 Employee Stock Purchase Plan upon the closing of this offering.

## DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering. Tangible book value per share represents our total tangible assets, less total liabilities, divided by the number of shares of our common stock outstanding.

Our historical net tangible book deficit as of December 31, 2014 was \$(89.3) million, or \$(88.80) per share of outstanding common stock.

Our pro forma net tangible book value as of December 31, 2014 was \$37.8 million, or \$2.78 per share of outstanding common stock. Pro forma net tangible book deficit per share represents pro forma net tangible book value divided by the pro forma number of shares of common stock outstanding, after giving effect to our issuance and sale in March 2015 of 41,666,667 shares of Series D convertible preferred stock for aggregate consideration of \$50.0 million, comprised of \$45.0 million in cash and \$5.0 million from conversion of convertible notes with related parties, and the conversion of all outstanding shares of our convertible preferred stock (including 41,666,667 shares of Series D convertible preferred stock issued in March 2015), into an aggregate of 12,591,456 shares of common stock upon the closing of this offering.

Pro forma as adjusted net tangible book value is our pro forma net tangible book value, plus the effect of the sale of shares of our common stock in this offering at an assumed initial public offering price of \$13.00 per share (the midpoint of the price range set forth on the cover page of this prospectus), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Our pro forma as adjusted net tangible book value as of December 31, 2014 was \$105.3 million, or \$5.43 per share. This amount represents an immediate increase in pro forma as adjusted net tangible book value of \$2.65 per share to our existing shareholders and an immediate dilution of \$7.57 per share to new investors participating in this offering. We determine dilution per share to new investors by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

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Assumed initial public offering price per share		\$ 13.00
Historical net tangible book value (deficit) per share as of December 31, 2014	\$ (88.80)	
Pro forma increase in net tangible book value per share attributable to the conversion of all outstanding shares of our preferred stock immediately prior to the closing of this offering	<u>91.58</u>	
Pro forma net tangible book value per share as of December 31, 2014	2.78	
Increase in pro forma net tangible book value per share attributable to investors participating in this offering	<u>2.65</u>	
Pro forma as adjusted net tangible book value per share after this offering		<u>5.43</u>
Dilution per share to investors purchasing in this offering		<u>\$ 7.57</u>

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A \$1.00 increase (decrease) in the assumed initial public offering price of \$13.00 per share (the midpoint of the price range set forth on the cover page of this prospectus) would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by \$0.28 per share and the dilution per share

to new investors participating in this offering by \$0.72 per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, a one million share increase in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase the pro forma as adjusted net tangible book value per share after this offering by \$0.32 and decrease the dilution per share to new investors participating in this offering by \$0.32, assuming the assumed initial public offering price of \$13.00 per share (the midpoint of the price range set forth on the cover page of this prospectus) remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. A one million share decrease in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the pro forma as adjusted net tangible book value per share after this offering by \$0.36 and increase the dilution per share to new investors participating in this offering by \$0.36, assuming the assumed initial public offering price of \$13.00 per share (the midpoint of the price range set forth on the cover page of this prospectus) remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option in full to purchase an additional 870,000 shares of our common stock in this offering, the pro forma as adjusted net tangible book value will increase to \$5.71 per share, representing an immediate increase to existing shareholders of \$94.51 per share and an immediate dilution of \$7.29 per share to new investors participating in this offering.

The following table summarizes, as of December 31, 2014, on a pro forma as adjusted basis described above, the differences between the number of shares of common stock purchased from us, the total consideration paid to us and the average price per share paid by existing shareholders and by new investors participating in this offering. The calculation below is based on an assumed initial public offering price of \$13.00 per share (the midpoint of the price range set forth on the cover page of this prospectus), before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing shareholders before this offering	13,907,935	71%	\$ 112,517,440	60%	8.09
Investors purchasing in this offering	5,800,000	29	75,400,000	40	13.00
<b>Total</b>	<b>19,707,935</b>	<b>100%</b>	<b>\$ 187,917,440</b>	<b>100%</b>	<b>9.54</b>

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In addition, if the underwriters' option to purchase 870,000 additional shares is exercised in full, the number of shares of common stock held by existing shareholders will be further reduced to 68% of the total number of common stock to be outstanding upon completion of this offering, and the number of shares of common stock held by investors participating in this offering will be further increased to 6,670,000 shares, or 32% of the total number of shares of common stock to be outstanding upon the completion of this offering.

The number of shares of our common stock to be outstanding after this offering is based on 1,316,479 shares of common stock outstanding as of April 2, 2015 and assumes:

§ the issuance by us of 5,800,000 shares of our common stock in this offering; and

§ the conversion of all of our convertible preferred stock outstanding immediately prior to the closing of this offering into an aggregate of 12,591,456 shares of common stock (which includes 41,666,667 shares of Series D convertible preferred stock issued in March 2015),

and excludes:

- § 803,565 shares of common stock issuable upon the exercise of outstanding stock options as of April 2, 2015, at a weighted-average exercise price of \$4.23 per share;
- § 18,809 shares of common stock issuable upon the exercise of warrants to purchase common stock as of April 2, 2015, at a weighted-average exercise price of \$1.91 per share;
- § the issuance by us of additional shares of common stock (which, based on an assumed initial public offering price of \$13.00 per share (the mid-point of the price range set forth on the cover page of this prospectus) will total approximately 61,000 shares), as payment of the accrued dividend on the outstanding shares of Series D convertible preferred stock payable to the holders of Series D convertible preferred stock upon the closing of this offering;
- § 1,751,803 shares of common stock reserved for future issuance under our Amended and Restated 2014 Stock Incentive Plan upon the closing of this offering; and
- § 200,000 shares reserved for future issuance under our 2015 Employee Stock Purchase Plan upon the closing of this offering.

Furthermore, we may choose to raise additional capital through the sale of equity or convertible debt securities due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that any of these options are exercised, new options are issued under our equity incentive plans or we issue additional shares of common stock or other equity or convertible debt securities in the future, there will be further dilution to investors participating in this offering.

**SELECTED FINANCIAL DATA**

The following selected financial data for the years ended December 31, 2013 and 2014 are derived from our audited financial statements, included elsewhere in this prospectus. Our historical results are not necessarily indicative of results to be expected for the year ending December 31, 2015 or any period in the future. The selected financial data presented below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes thereto, included elsewhere in this prospectus. The selected financial data in this section is not intended to replace our financial statements and the related notes thereto.

	Year Ended December 31,	
	2013	2014
	(in thousands, except share and per share amounts)	
<b>Statement of Operations Data:</b>		
Operating expenses:		
Research and development	\$ 14,157	\$ 14,959
General and administrative	1,885	2,706
<b>Total operating expense</b>	<b>16,042</b>	<b>17,665</b>
Loss from operations	(16,042)	(17,665)
Interest expense, net	76	252
Other expense, net	79	—
<b>Net loss</b>	<b>\$ (16,197)</b>	<b>\$ (17,917)</b>
Basic and diluted net loss per common share <sup>(1)</sup> :	\$ (4.06)	\$ (22.72)
Weighted-average shares used to compute earnings (loss) per common share <sup>(1)</sup> :	1,697,044	933,997
Pro forma net loss per share attributable to common shareholders — basic and diluted (unaudited) <sup>(1)(2)</sup>		\$ (2.84)
Weighted-average number of common shares used in pro forma net loss per share attributable to common shareholders — basic and diluted (unaudited) <sup>(1)(2)</sup> :		7,471,303

<sup>(1)</sup> See Note 3 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate earnings (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.

<sup>(2)</sup> Gives effect to the conversion of all our outstanding convertible preferred stock into an aggregate of 6,552,820 shares of our common stock (which excludes 41,666,667 shares of Series D convertible preferred stock issued in March 2015) upon the closing of this offering.

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	As of December 31,	
	2013	2014
<b>Balance Sheet Data:</b>		
Cash and cash equivalents	\$ 7,551	\$ 1,634
Working capital <sup>(1)</sup>	5,643	(5,921)
Total assets	9,034	5,090
Other long-term liabilities	834	6,914
Convertible redeemable preferred stock	73,807	77,107
Total shareholders' equity (deficit)	(68,225)	(89,348)

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<sup>(1)</sup> Working capital is calculated as current assets minus current liabilities.

## 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 in conjunction with the "Selected Financial Data" and our financial statements and related notes appearing elsewhere in this prospectus. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results could differ materially from those anticipated by these forward-looking statements as a result of many factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this prospectus, including those set forth under "Risk Factors" and "Special Note Regarding Forward-Looking Statements."*

### Overview

We are a specialty pharmaceutical company developing and planning to commercialize next-generation abuse-deterrent products that incorporate our patented DETERx platform technology for the treatment of chronic pain and other diseases. Our lead product candidate, Xtampza, is an abuse-deterrent, extended-release, oral formulation of oxycodone, a widely prescribed opioid medication. Xtampza has received Fast Track status from the FDA. Our NDA filing for Xtampza was accepted by the FDA on February 10, 2015. On February 25, 2015, the FDA set a PDUFA goal date of October 12, 2015 for completion of its review of the Xtampza NDA.

Xtampza has the same active ingredient as OxyContin OP, which is the largest selling abuse-deterrent, extended-release opioid in the United States by dollars, with \$2.5 billion in U.S. sales in 2014. 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 a head-to-head clinical trial 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 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, 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, if approved, can address the pain management needs of the approximately 11 million patients in the United States who suffer from chronic pain and have difficulty swallowing.

Since 2010, when we divested our former subsidiary, Onset Therapeutics, LLC, to PreCision Dermatology, Inc., we have devoted substantially all of our resources to the development of our patented DETERx platform technology, the preclinical and clinical advancement of our product candidates, and the creation and protection of related intellectual property. Since 2011, we have not generated any revenue from product sales as we currently have no approved products, and we continue to incur significant research, development and other expenses related to our ongoing operations. We have funded our operations primarily through the private placement of preferred stock, convertible notes and commercial bank debt.



## **Outlook**

We have never been profitable and have incurred net losses in each year since inception. We incurred net losses of \$16.2 million and \$17.9 million in the years ended December 31, 2013 and 2014, respectively. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur net losses in the foreseeable future as we seek regulatory approval for, and, if approved, begin to commercialize Xtampza. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect our expenses will increase substantially in connection with our ongoing activities as we:

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

If we obtain regulatory approval for Xtampza, we expect to incur significant commercialization expenses related to marketing, product sales and reimbursement functions. Initially we plan to detail Xtampza to approximately 10,000 physicians who write more than 50% of the branded extended-release oral opioid prescriptions in the United States with a sales team of approximately 100 sales representatives. In addition, we plan to deploy a separate, focused sales team to detail Xtampza to nursing homes, hospices and other institutions treating large populations of the elderly and other patients who need chronic pain relief and have difficulty swallowing. Accordingly, we will seek to fund our operations through 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. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and ability to develop our product candidates.

## **Financial Operations Overview**

### **Revenue**

Since 2011, we have not generated any revenue. In the future, we may generate revenue from product sales, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, or a combination of these sources. To the extent any of our product candidates are successfully commercialized, we expect that any revenue we generate will fluctuate from quarter to quarter as a result of the amount and timing of payments that we receive upon the sale of our products, the timing and amount of license fees, milestone and other payments.

### **Research and Development Expenses**

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

- § compensation and employee-related costs, including stock-based compensation;
- § costs associated with conducting our preclinical, clinical and regulatory activities, including fees paid to third-party professional consultants and service providers;
- § costs incurred under clinical trial agreements;
- § costs for laboratory supplies and laboratory equipment;
- § government grants are recognized as a reduction of the qualifying cost being reimbursed;

§ 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 other than Xtampza, we are unable to estimate with any certainty the costs we will incur and the timelines we will require in the continued 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 drug candidates enter clinical trials in humans.

### **General and Administrative Expenses**

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 and administrative functions. Other 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 general and administrative expenses will increase in the future as we increase our administrative headcount to support our continued research and development and the potential commercialization of our product development programs. 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, interest expense on convertible bridge notes, a term loan facility and the change in fair value of our derivative liability.

### **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 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. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values 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 prospectus, we believe the following accounting policies to be most critical to the significant judgments and estimates used in the preparation of our financial statements.

### **Accrued Expenses**

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

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

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

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

### **Impairment of Long-Lived Assets**

Long-lived assets consist primarily of property and equipment. We test long-lived assets for impairment at year end or whenever events or circumstances present an indication of impairment. If the sum of expected future cash flows (undiscounted and without interest charges) of the long-lived assets is less than the carrying amount of such assets, an impairment loss would be recognized in earnings. The long-lived asset would be written down to the estimated fair value, calculated based on the present value of expected future cash flows. While our current and historical operating losses and negative cash flows are indicators of impairment, we believe that future cash flows to be received support the carrying value of our long-lived assets and, accordingly, have not recognized any impairment losses on long-lived assets for the years ended December 31, 2013 and December 31, 2014.

### **Convertible Redeemable Preferred Stock**

Convertible redeemable preferred stock that is redeemable outside of the Company's control is classified outside of permanent equity. We record such redeemable preferred stock at fair value upon issuance, net of any issuance costs or discounts, and the carrying value is being increased by periodic accretion to its redemption value as if the redeemable preferred stock is redeemable at that date. In the absence of retained earnings these accretion charges are recorded against additional paid-in capital, if any, and then to accumulated deficit.

**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 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 and restricted stock awards to non-employees using the fair value approach. Stock options and restricted stock awards to non-employees are subject to periodic revaluation over their vesting terms.

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 highly 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. Due to the lack of a public market for the trading of our common stock and a lack of Company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. For these analyses, we have selected companies with comparable characteristics to ours, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. We compute the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of our stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. The expected term represents the period of time that options are expected to be outstanding. Because there was not enough historical exercise behavior through December 31, 2013 or through December 31, 2014, 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.

For employee stock option grants made during the year ended December 31, 2013 and 2014, the weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of those grants were as follows:

	Years Ended December 31,	
	2013	2014
Risk-free interest rate	1.09% – 1.22%	1.80%
Expected volatility	87.8%	77.1%
Expected term (in years)	6.25	6.25
Expected dividend yield	0%	0%

We had no non-employee stock option grants for the years ended December 31, 2013 and December 31, 2014.

§ *Fair Value of Common Stock.* As discussed below, the fair value of the shares of our common stock underlying our stock options has historically been determined by our board of directors. Because there has been no public market for our common stock, our board of directors has 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.

- § *Expected Term.* The expected term of stock options represents the weighted-average period that the stock options are expected to remain outstanding. We estimated the expected term using the simplified method, which is an average of the contractual term of the option and the vesting period.
- § *Expected Volatility.* Since there has been no public market for our common stock and lack of company-specific historical volatility, we have determined the share price volatility for options granted based on an analysis of the volatility used by a peer group of publicly traded medical device companies. In evaluating similarity, we consider factors such as industry, stage of life cycle and size.
- § *Risk-free Interest Rate.* The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for zero-coupon U.S. Treasury notes with remaining terms similar to the expected term of the options.
- § *Dividend Rate.* The expected dividend was assumed to be zero as we have never paid dividends and have no current plans to do so.
- § *Expected Forfeiture Rate.* We are required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent actual forfeitures differ from the estimates, the difference will be recorded as a cumulative adjustment in the period that the estimates are revised.

The following table summarizes by grant date the number of shares of common stock underlying stock options granted from January 1, 2013 through December 31, 2014, as well as the associated per share exercise price and the estimated fair value per share of our common stock on the grant date:

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<b>Grant Dates</b>	<b>Number of Common Shares Underlying Options Granted</b>	<b>Exercise Price per Common Share</b>	<b>Estimated Fair Value per Common Share</b>
January 30, 2013	66,952	\$ 0.48	\$ 0.35
May 30, 2013	79,778	0.48	0.35
March 5, 2014	89,641	0.28	3.11

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As of December 31, 2013 and December 31, 2014, the unrecognized compensation cost related to outstanding options was \$40 and \$215, respectively, and is expected to be recognized as expense over 1.1 years and 1.0 years, respectively.

Based on the assumed initial public offering price of \$13.00 per share (the midpoint of the price range set forth on the cover page of this prospectus), the intrinsic value of stock options outstanding as of December 31, 2014 would be \$3.5 million, of which \$1.4 million and \$2.1 million would have been related to stock options that were vested and unvested, respectively, at that date.

*Determination of the Fair Value of Common Stock on Grant Dates*

We have historically granted stock options at exercise prices not less than the fair value of our common stock. Our board of directors determined the fair value of our common stock considering, in part, the work of a third-party. The board determined the estimated per share fair value of our common stock at various dates considering contemporaneous and retrospective valuations performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, or the Practice Aid. Following the consummation of this offering, the fair value of our common stock will be determined based on the quoted market price of our common stock. In conducting the valuations, the third-party considered all objective and subjective factors that it believed to be relevant for each valuation conducted in accordance with the Practice Aid, including our best estimate of our business condition, prospects and operating performance at each valuation date. Other significant factors included:

- § the prices of our preferred stock sold to outside investors in arm's length transactions, and the rights, preferences and privileges of our preferred stock as compared to those of our common stock, including the liquidation preferences of our preferred stock;
- § our results of operations, financial position and the status of research and development efforts;
- § the composition of, and changes to, our management team and board of directors;
- § the lack of liquidity of our common stock;
- § our stage of development and business strategy and the material risks related to our business and industry;
- § the valuation of publicly traded companies in the specialty pharmaceutical sector, as well as recently completed mergers and acquisitions of guideline companies;
- § any external market conditions affecting the specialty pharmaceutical industry sector;
- § the likelihood of achieving a liquidity event for the holders of our common stock and stock options, such as an initial public offering or a sale of the Company, given prevailing market conditions; and
- § the state of the initial public offering market for similarly situated privately held specialty pharmaceutical companies.

The dates of our contemporaneous valuations have not always coincided with the dates of our stock option grants. In determining the exercise prices of the stock options on each grant date, our board of directors considered, among other things, the most recent contemporaneous valuation of our common stock and their assessment of additional objective and subjective factors that were relevant as of the grant dates. The additional factors considered when determining whether any changes in the fair value of our common stock had occurred between the most recent contemporaneous valuation and the grant dates included our stage of research and development, our operating and financial performance and current business conditions.

There are significant judgments and estimates inherent in the determination of the fair value of our common stock. These judgments and estimates include assumptions regarding our future operating performance, the time to completing an initial public offering or other liquidity event, the related valuations associated with such events, and the determinations of the appropriate valuation methods at each valuation date. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per share applicable to common shareholders could have been materially different.

*Common Stock Valuation Methodologies*

The valuations were prepared in accordance with the guidelines in the Practice Aid, which prescribes several valuation approaches for setting the value of an enterprise, such as the cost, market and income approaches, and various methodologies for allocating the value of an enterprise to its common stock.

We considered several types of approaches in the preparation of our valuations as follows:

- § *Market Approach.* The market approach values a business by reference to guideline companies, for which enterprise values are known. This approach has two principal methodologies. The guideline public company methodology derives valuation multiples from the operating data and share prices of similar publicly-traded companies. The guideline acquisition methodology focuses on comparisons between the subject company and guideline acquired public or private companies. A derivative of the guideline public company method is the guideline initial public offering, or IPO, method, which compares the enterprise values of newly public enterprises in our industry.
- § *Discounted Cash Flow Method, or DCF.* The discounted cash flow method estimates the value of the business by discounting the estimated future cash flows available for distribution after funding internal needs to present value.
- § *Option-Pricing Method Backsolve, or OPM Backsolve.* The OPM Backsolve method derives the implied equity value for a company from a recent transaction involving the company's own securities issued on an arms-length basis.

#### *Methods Used to Allocate Our Enterprise Value to Classes of Securities*

In accordance with the Practice Aid, we considered the various methods for allocating the enterprise value across our classes and series of capital stock to determine the fair value of our common stock at each valuation date. The methods considered consisted of the following:

- § *Option pricing method, or OPM.* Under the OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The values of the preferred and common stock are inferred by analyzing these options.
- § *Backsolve method.* Under this approach, the value of the company is estimated by matching value allocated to latest round of preferred financing with its Original Issue Price, or OIP. In this approach, the inputs of the Black-Scholes Option Pricing, or BSOP, allocation methodology, such as risk-free rate, volatility and time to exit event, are assumed to hold true and the BSOP calculation is worked backwards to estimate the implied valuation of the company at which the latest preferred series' OIP is met.
- § *Probability-weighted expected return method, or PWERM.* The PWERM is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.
- § *Hybrid method.* The hybrid method is a hybrid between the PWERM and the OPM. It is used to estimate the probability weighted across multiple scenarios, but using the OPM to estimate the allocation of value within one or more of those scenarios.

The foregoing valuation methodologies are not the only methodologies available and they will not be used to value our common stock once this offering is complete. We cannot make assurances as to any particular valuation for our common stock. Accordingly, investors are cautioned not to place undue reliance on the foregoing valuation methodologies as an indicator of future stock prices.

#### *Discussion of Specific Valuation Inputs*

Over time, a combination of factors caused changes in the fair value of our common stock. The following summarizes the changes in value since January 1, 2014 and the major factors that caused each change.

*January 2014 to March 2014.* In March 2015, we prepared a retrospective valuation, effective as of March 31, 2014, that considered the completion of enrollment in our Phase 3 Study and the positive intranasal Abuse-Deterrent Human Abuse Potential clinical trial. The March 31, 2014 valuation used the Hybrid method to value the common stock. We had two IPO scenarios, a short-term IPO and a longer-term IPO. We relied on market data related to recent public offerings of companies in the pharmaceutical sector. In the short-term scenario we selected an enterprise value between the 25<sup>th</sup> and the 50<sup>th</sup> percentile of the

recent public companies. We estimated it would be approximately 1.17 years to the short-term IPO and discounted the future projected enterprise value with a 30% discount rate based on the Venture Capital Rate of Return Studies. We applied a 15% Discount for Lack of Marketability under the short-term IPO scenario. In the longer-term IPO scenario we selected an enterprise value close to the 50<sup>th</sup> percentile. We estimated it would be approximately 1.59 years to the longer-term IPO. We used a 30% discount rate under this scenario and also applied a Discount for Lack of Marketability of 20% under the long-term IPO scenario. In the Mergers and Acquisitions, or M&A, scenario we relied on the guideline transactions method for determining enterprise value and the OPM allocation method to determine the fair value of our common stock under the M&A scenario. The selected enterprise value was close to the 50<sup>th</sup> percentile of the acquired companies. We utilized a 3.0 year term in the OPM as we believe that is the appropriate time to a potential M&A event. We utilized a volatility level of 87% which was based on the volatility levels of public companies in our industry. The fourth scenario was a sale of our company at or below the preferred shares' liquidation preference which would yield no value to the common stock. We assigned a weighting of 50% to the M&A scenario, 12.5% weighting to each of the IPO scenarios and 25% to the sale at or below the liquidation preference based on our assessment of the likelihood of the four liquidity events. Based in part on this valuation, our board of directors determined the new fair value of our common stock, as of March 31, 2014, to be \$3.11 per share.

*April 2014 to December 2014.* In March 2015, we prepared a retrospective valuation, effective as of December 31, 2014, which considered the following:

- § the issuance of our fifth and sixth U.S. patents;
- § the positive Phase 3 clinical trial results;
- § the positive Oral Human Abuse Potential clinical trial;
- § the positive Alcohol Interaction Study; and
- § the NDA submission to the FDA.

As with our prior valuation, the December 31, 2014 valuation utilized the Hybrid Method to determine the value of our common stock. We considered the market approach utilizing the market data from recent IPOs of companies in the pharmaceutical sector to determine the enterprise value under the two IPO scenarios. Under the short-term IPO scenario we estimated it would be approximately 0.41 years until this transaction. We selected an enterprise value between the 25<sup>th</sup> and 50<sup>th</sup> percentiles of the newly public companies in the pharmaceutical industry. We discounted this scenario with a 25% discount rate which was based on the Venture Capital Rate of Return Studies. We also applied a 10% Discount for Lack of Marketability under this scenario. In the longer-term IPO scenario we estimated it would be approximately 0.83 years until this transaction. The selected enterprise value was close to the 50<sup>th</sup> percentile under this scenario. We also used a 25% discount rate in this scenario and applied a Discount for Lack of Marketability of 15% to the concluded value under this scenario. In the M&A scenario, we utilized the guideline transactions method to determine the enterprise value. Based on the guideline transaction data, we selected an enterprise value between the 25<sup>th</sup> percentile and the median. We utilized the OPM to allocate the value in the M&A scenario. Within the OPM we selected a term of 2.0 years as we believe that is the timeframe in which an M&A transaction would occur. We utilized a volatility level of 86% which was based on public companies in the pharmaceutical industry. We applied a Discount for Lack of Marketability of 25% under the M&A scenario. To determine the common stock value under the Hybrid Method we assigned a 35% probability to the M&A scenario, a 25% probability to each of the IPO scenarios and a 15% probability to the sale at or below the liquidation preference. Based in part on this valuation, our board of directors determined the reassessed fair value of our common stock, as of December 31, 2014, to be \$6.07 per share.

#### *Warrants*

In connection with execution of an amendment, or Amendment No. 1, to our Loan and Security Agreement in January 2014, or the Original Term Loan, we issued 2,091 warrants to purchase shares of common stock with an exercise price of \$0.35 per share to Silicon Valley Bank, or SVB. These warrants expire on



January 30, 2024. The warrant agreement provides for additional warrants to be issued and immediately exercisable upon additional borrowings by us, which in turn are contingent upon meeting certain performance measures for Xtampza. We met the performance measures, and in August 2014, the Original Term Loan, as amended by Amendment No. 1, was further amended and additional financing was extended. Based on the terms of the warrant agreement, we issued 12,548 additional warrants to purchase shares of common stock with an exercise price of \$0.35 per share to SVB. The fair value of these warrants was *de minimis* as of December 31, 2014.

### **Net Operating Loss Carryforwards**

Utilization of net operating loss, or NOL, and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred or that could occur in the future, as required by Section 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 of the Code, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain shareholders. We have not completed a current study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation.

At December 31, 2014, we had U.S. federal NOL carryforwards of \$78.3 million which may be available to offset future taxable income. The U.S. federal NOL carryforwards begin to expire in 2022.

As of December 31, 2014 and 2013, we have provided a full valuation allowance for deferred tax assets.

### **Income Taxes**

We record uncertain tax positions on the basis of a two-step process whereby (i) we determine whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the positions and (ii) for those tax positions that meet the more-likely-than-not recognition threshold, we recognize the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. We recognize interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability. There were no uncertain tax positions as of December 31, 2014 and 2013.

### **JOBS Act**

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the JOBS Act. As such, we are eligible to take advantage of exemptions from various disclosure and 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 auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act;
- § being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations, in each case, instead of three years;
- § being permitted to present the same number of years of selected financial data as the years of audited financial statements presented, instead of five years;
- § reduced disclosure obligations regarding executive compensation, including no Compensation Disclosure and Analysis;
- § not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements; and

- § exemptions from the requirements of holding a non-binding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some or all of the available exemptions. We have taken advantage of some of the reduced reporting burdens in this prospectus. Accordingly, the scope of the information contained herein may be different than the scope of the information you receive from other public companies in which you hold stock. We do not know if some investors will find our shares less attractive as a result of our utilization of these or other exemptions. The result may be a less active trading market for our shares and our share price may be more volatile.

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. In other words, 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 exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies."

We will remain an "emerging growth company" until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed \$1 billion; (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our shares that are held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter; (iii) the date on which we have issued more than \$1 billion in nonconvertible debt during the preceding three-year period; and (iv) the last day of our fiscal year containing the fifth anniversary of the date on which shares of our common stock become publicly traded in the United States.

### **Recently Issued Accounting Pronouncements**

In July 2013, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exist*. ASU 2013-11 amends the presentation requirements of Accounting Standards Codification, or ASC, 740 and requires an unrecognized tax benefit to be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, similar tax loss, or a tax credit carryforward. To the extent the tax benefit is not available at the reporting date under the governing tax law or if the entity does not intend to use the deferred tax asset for such purpose, the unrecognized tax benefit should be presented as a liability and not combined with deferred tax assets. The ASU is effective for annual periods, and interim periods within those years, beginning after December 15, 2013, which is our fiscal year 2014. The amendments are to be applied to all unrecognized tax benefits that exist as of the effective date and may be applied retrospectively to each prior reporting period presented. The adoption of ASU 2013-11 did not have a material impact on our financial position or results of operations.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*. This ASU is a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services. This ASU is effective for annual reporting periods beginning after December 15, 2016 and early adoption is not permitted. Accordingly, we will adopt this ASU on January 1, 2017. Management does not believe the adoption of this ASU will have a material impact on our financial condition, results of operations or cash flows.

In June 2014, the FASB issued ASU 2014-12, *Compensation — Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period*. ASU 2014-12 applies to all reporting entities that

grant their employees share-based payments in which the terms of the award provide that a performance target that affects vesting could be achieved after the requisite service period. That is the case when an employee is eligible to retire or otherwise terminate employment before the end of the period in which a performance target (for example, an initial public offering or a profitability target) could be achieved and still be eligible to vest in the award if and when the performance target is achieved. The standard is required to be adopted by public business entities in annual periods beginning on or after December 15, 2015 and interim periods within those annual periods. We plan to implement this standard in the first quarter of fiscal year 2016 and management is currently evaluating the potential impact of this new guidance on our financial statements.

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

In November 2014, the FASB issued ASU No. 2014-16, *Derivatives and Hedging (Topic 815) — Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share is More Akin to Debt or to Equity*. ASU 2014-16 was issued to clarify how current U.S. generally accepted accounting principles should be interpreted in evaluating the economic characteristics and risk of a host contract in a hybrid financial instrument that is issued in the form of a share. In addition, ASU 2014-16 was issued to clarify that in evaluating the nature of a host contract, an entity should assess the substance of the relevant terms and features (that is, the relative strength of the debt-like or equity-like terms and features given the facts and circumstances) when considering how to weight those terms and features. The effects of initially adopting ASU 2014-16 should be applied on a modified retrospective basis to existing hybrid financial instruments issued in a form of a share as of the beginning of the fiscal year for which the amendments are effective. Retrospective application is permitted to all relevant prior periods. ASU 2014-16 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. Early adoption in an interim period is permitted. We are currently evaluating the impact of the adoption of ASU 2014-16 on our financial statements.

**Results of Operations****Comparison of the Years Ended December 31, 2013 and 2014**

The following table summarizes the results of our operations for the years ended December 31, 2013 and 2014:

	Years Ended December 31,		Change
	2013	2014 (in thousands)	
Research and development expenses	\$ 14,157	\$ 14,959	\$ 802
General and administrative expenses	1,885	2,706	821
Other expense, net	155	252	97
Net loss	<u>\$ (16,197)</u>	<u>\$ (17,917)</u>	<u>\$ 1,720</u>

**Research and Development Expenses.** Research and development expenses were \$14.2 million for the year ended December 31, 2013, compared to \$15.0 million for the year ended December 31, 2014. The \$802,000 increase was primarily related to:

- § an increase in consultant costs of \$818,000 due to regulatory consulting, including costs associated with filing the NDA;
- § an increase of \$797,000 in manufacturing costs, mainly due to costs incurred for pre-validation batches; and
- § an increase of \$240,000 in personnel costs, primarily due to increased headcount.

These increases were partially offset by a decrease in clinical trial expenses and other development costs of \$1.0 million.

**General and Administrative Expenses.** General and administrative expenses were \$1.9 million for the year ended December 31, 2013, compared to \$2.7 million for the year ended December 31, 2014. The \$821,000 increase was primarily related to:

- § An increase in professional fees including legal and audit fees of \$832,000, mainly due to prior year audits, accounting services and recruiting fees.

This increase was partially offset by a decrease in market research costs of \$129,000.

**Other Expense, Net.** Other expense, net was \$155,000 for the year ended December 31, 2013, compared to \$252,000 for the year ended December 31, 2014. The increase in interest expense of \$176,000 in 2014 was due to larger outstanding balances under our debt agreements, which was partially offset by the decrease to the periodic fair value adjustment of warrant liability of \$79,000.

**Liquidity and Capital Resources**

We have incurred net losses and negative cash flows from operations since inception. For the years ended December 31, 2013 and December 31, 2014, we incurred net losses of \$16.2 million and \$17.9 million, respectively.

Since our inception, we have funded our operations primarily through the private placement of preferred stock, convertible notes and commercial bank debt. As of December 31, 2014, we had cash and cash equivalents of \$1.6 million.

Although it is difficult to predict future liquidity requirements, we believe that the net proceeds from this offering, together with our existing cash resources, will be sufficient to fund our operations into mid-2017, including the commercialization of Xtampza, if approved, and the continuation of our development of our other product candidates. We have based this estimate on assumptions that may prove to be incorrect and we could use our available capital resources sooner than we currently expect. Our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. We may never become profitable, or if we do, we may not be able to sustain profitability on a recurring basis.

In March 2015, we issued 41,666,667 shares of Series D Convertible Preferred Stock in exchange for aggregate consideration of \$50.0 million, including \$45.0 million in cash. In connection with this financing, convertible notes with related parties in the aggregate principal amount of \$5.0 million automatically converted to an aggregate of 4,166,667 shares of Series D Preferred Stock. During 2013, we issued 8,658,008 shares of Series C Preferred Stock in exchange for net proceeds of \$12.0 million. In January 2014, our Original Term Loan was amended, pursuant to Amendment No 1, to provide for borrowings of up to \$6.0 million. In February 2014, we borrowed \$2.0 million. A portion of the proceeds from the initial borrowing were used to pay down the balance outstanding under the Original Term Loan resulting in us receiving \$1.1 million. In August 2014, the Original Term Loan, as amended by Amendment No. 1, was further amended to provide for borrowing of up to \$8.0 million. In August 2014 and September 2014, we drew down \$3.0 million and \$3.0 million, respectively under the Original Term Loan, as amended.

The following table sets forth a summary of the net cash flow activity for each of the periods indicated:

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	Years Ended December 31,	
	2013	2014
	(in thousands)	
Net cash used in operating activities	\$ (16,530)	\$ (17,947)
Net cash used in investing activities	(206)	(8)
Net cash provided by financing activities	12,351	12,038
Net decrease in cash and cash equivalents	<u>\$ (4,385)</u>	<u>\$ (5,917)</u>

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### ***Operating Activities***

Cash used in operating activities increased by \$1.4 million, from \$16.5 million for the year ended December 31, 2013 to \$17.9 million for the year ended December 31, 2014. The increase in cash used in operating activities was driven primarily by an increase in net loss.

### ***Investing Activities***

Cash used in investing activities decreased \$198,000 from \$206,000 for the year ended December 31, 2013 to \$8,000 for the year ended December 31, 2014. The difference was related to decreased purchases of property and equipment.

### ***Financing Activities***

Cash provided by financing activities decreased \$313,000 from \$12.4 million for the year ended December 31, 2013 to \$12.0 million for the year ended December 31, 2014. During 2013, we issued 8,658,008 shares of Series C Preferred Stock for net proceeds of \$12.0 million. In January 2014, the Original Term Loan was amended, pursuant to Amendment No. 1, to provide for borrowings of up to \$6.0 million. In February 2014, we borrowed \$2.0 million. A portion of the proceeds from the initial borrowing were used to pay down the original loan balance resulting in us receiving \$1.1 million. In August 2014, the Original Term Loan, as amended by Amendment No. 1, was further amended to provide for

borrowing of up to \$8.0 million. In August 2014 and September 2014 we drew down \$3.0 million and \$3.0 million, respectively under the Original Term Loan, as amended.

### **Operating Capital Requirements**

Since 2011, we have not generated any product revenue. We do not know when, or if, we will generate any revenue as we seek regulatory approval for, and potentially begins to commercialize, Xtampza. We anticipate that we will continue to incur losses for the next several years, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, Xtampza and our other product candidates, and begin to commercialize any approved products. We are subject to all of the risks common to the development of new pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Upon the completion of this offering, we will incur additional costs associated with operating as a public company. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Until we can generate a sufficient amount of revenue from our pharmaceutical products, if ever, we expect to finance future cash needs through public or private equity or debt offerings. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing shareholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

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

- § the 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 other product candidates for clinical trials, preclinical studies and, if approved, for commercial sale;
- § the number and characteristics of product candidates that we pursue;
- § the cost of patent infringement litigation, including the Purdue litigation, relating to Xtampza or our other product candidates, which may be expensive to defend and delay the commercialization of Xtampza or our other 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;
- § the effect of competing technological and market developments; and
- § the cost of establishing sales, marketing and distribution capabilities for any products for which we may receive regulatory approval.

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 and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2014 that will affect our future liquidity:

	Total	Less than 1 year	1 - 3 years (in thousands)	3 - 5 years	More than 5 years
Operating lease obligations <sup>(1)</sup>	\$ 333	\$ 106	\$ 227	\$ —	\$ —
Long-Term Debt <sup>(2)</sup>	13,000	6,194	6,806	—	—
<b>Total</b>	<b>\$ 13,333</b>	<b>\$ 6,300</b>	<b>\$ 7,033</b>	<b>\$ —</b>	<b>\$ —</b>

<sup>(1)</sup> Operating lease obligations represent future minimum lease payments under our non-cancelable operating lease in effect as of December 31, 2014, reflecting remaining lease payments for our current facility in Canton, Massachusetts.

<sup>(2)</sup> Long-term debt obligations represent future principal payments under our Original Term Loan, as amended, and our convertible notes as of December 31, 2014.

### Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

### Quantitative and Qualitative Disclosures about Market Risks

We are exposed to market risk related to changes in interest rates. As of December 31, 2014, we had cash and cash equivalents consisting of money market funds of \$1.6 million. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our money market accounts 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.

### Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

On or about September 24, 2014, we dismissed Walter & Shuffain, P.C., or W&S, as our independent public accounting firm. The dismissal of W&S was approved by our board of directors. The audit report of W&S on our financial statements as of and for the fiscal year ended December 31, 2012 did not contain any adverse opinion or disclaimer of opinion, nor was it qualified or modified as to uncertainty, audit scope or accounting principles, except for modifications for uncertainties related to going concern.

In connection with the audit of our financial statements for the fiscal year ended December 31, 2012, and for the subsequent interim period through the date of the dismissal of W&S, (i) there were no disagreements with W&S on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreements, if not resolved to W&S' satisfaction, would have caused W&S to make reference to the subject matter of the disagreement in connection with its report, and (ii) there were no "reportable events," as that term is described in Item 304(a)(1)(v) of Regulation S-K.

On September 24, 2014, we engaged Grant Thornton LLP, or Grant Thornton, to serve as our independent registered public accounting firm, to audit the fiscal year ended December 31, 2013. The engagement of Grant Thornton has been approved by our board of directors. During the two most recent fiscal years, neither we, nor anyone acting on our behalf, consulted with Grant Thornton regarding either: (i) the

application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on our financial statements, and no written report nor oral advice was provided by Grant Thornton, or (ii) any matter that was either the subject of a disagreement, as that term is defined in Item 304(a)(1)(iv) of Regulation S-K, or a reportable event, as that term is defined in Item 304(a)(1)(v) of Regulation S-K.

We requested that W&S furnish us with a letter addressed to the SEC stating whether it agrees with the above statements. A copy of the letter dated February 25, 2015, is filed as an exhibit to the registration statement of which this prospectus forms a part.



## BUSINESS

### Overview

We are a specialty pharmaceutical company developing and planning to commercialize next-generation abuse-deterrent products that incorporate our patented DETERx® platform technology for the treatment of chronic pain and other diseases. Our lead product candidate, Xtampza ER™, or Xtampza, is an abuse-deterrent, extended-release, oral formulation of oxycodone, a widely prescribed opioid medication. Xtampza has received Fast Track status from the U.S. Food and Drug Administration, or FDA. Our new drug application, or NDA, filing for Xtampza was accepted by the FDA on February 10, 2015. On February 25, 2015, the FDA set a Prescription Drug User Fee Act, or PDUFA, goal date of October 12, 2015 for completion of its review of the Xtampza NDA.

Xtampza has the same active ingredient as OxyContin® OP, which is the largest selling abuse-deterrent, extended-release opioid in the United States by dollars, with \$2.5 billion in U.S. sales in 2014. 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 a head-to-head clinical trial 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 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, 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, if approved, can address the pain management needs of the approximately 11 million patients in the United States who suffer from chronic pain and have difficulty swallowing.

### 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 \$6.0 billion (29 million prescriptions) of the approximately \$14 billion U.S. opioid market in 2014. OxyContin OP generated

U.S. sales of \$2.5 billion in 2014, which represents approximately a 20% 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 2012.

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

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

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

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

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



## Legislative and Regulatory Actions

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

In 2010, Purdue received approval for a new formulation of OxyContin, named OxyContin OP, designed to make it more difficult to abuse. In April 2013, the FDA approved new labeling for OxyContin OP, which, for the first time included abuse-deterrent label claims consistent with the FDA's January 2013 draft abuse-deterrent label guidance. At the same time, the FDA withdrew the approval of the original, non-abuse-deterrent OxyContin formulation, thus preventing the commercialization of generic versions of the original OxyContin that did not have abuse-deterrent properties. This decision by the FDA is consistent with its public statement that the development of abuse-deterrent opioid analgesics is a public health priority.

Recent actions to address the opioid abuse epidemic include:

- § *STOPP Act:* In July 2012, a bipartisan group of Congressional leaders introduced the STOPP (Stop the Tampering of Prescription Pills) Act. Reintroduced in February 2013, this bill, if approved, would require that non-abuse-deterrent opioids be removed from the market if an abuse-deterrent formulation of that opioid has already been approved for marketing by the FDA. Since being reintroduced in 2013, this bill was referred to the U.S. House of Representatives' Subcommittee on Health and there has been no further action taken.
- § *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 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 label claims that may be merited based on the results of the corresponding studies and clinical trials:
  - § Category 1 — the product is formulated with psychochemical barriers that are expected to deter intravenous abuse.
  - § Category 2 — the product is formulated with psychochemical properties that are expected to deter oral and nasal abuse.
  - § Category 3 — the results from the oral and intranasal clinical abuse potential studies indicate that the medication has properties expected to deter abuse via oral, intranasal and intravenous routes.
  - § Category 4 — there was a demonstrated reduction in abuse of this medication in the community setting compared to the levels of abuse, overdose and death that occurred when only formulations of the same opioid without abuse-deterrent properties were available.
- § *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 label changes:* On September 10, 2013, the FDA announced its intention to require label changes to all approved extended-release and long-acting opioids. In particular, the FDA

announced its intention to update the indications for these opioids so that they will be indicated only for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. On April 16, 2014, the FDA updated these indications. The FDA also requires post-marketing studies and clinical trials for any such opioids.

- § *29 state and territorial attorneys general speak out against the approval of non-abuse-deterrent narcotic:* In December 2013, the attorneys general of 29 states and territories urged the FDA to reconsider its approval of Zohydro™ ER, an extended-release hydrocodone formulation with no abuse-deterrent properties, or alternatively to set a rigorous timeline for reformulation of Zohydro ER in an abuse-deterrent form, with significant limitations on prescriptions of Zohydro ER in the interim. In early 2014, members of Congress from three states introduced a bill to revoke FDA approval of Zohydro ER and prevent the FDA from approving any new opioids that do not have abuse-deterrent features and the governor of Massachusetts signed an executive order (since overturned by a court) that attempted to ban the dispensing of Zohydro ER in Massachusetts.
- § *Health Canada Proposed Legislation Requiring Opioids to be Tamper Resistant Before Sale.* In June 2014, Health Canada issued a Notice of Intent for Interested Parties on Tamper Resistance under the Controlled Drugs and Substances Act. If approved, the proposed legislation would require that drugs at high risk for abuse, including extended-release oxycodone, have tamper-resistant properties before they can be sold in Canada.
- § *Massachusetts approved law to mandate that insurers cover abuse-deterrent opioids:* In August 2014, the governor of Massachusetts signed a law 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 law also requires insurers to cover abuse-deterrent opioid drugs on a basis not less favorable than corresponding non-abuse-deterrent drugs. Oregon, which has the highest incidence of non-medical use of opioids in the United States, is exploring legislation similar to the Massachusetts law.
- § *FDA held public meeting to discuss abuse-deterrent opioid formulations:* In September 2014, the FDA announced a public meeting to discuss the development, assessment and regulation of opioid medications. In its public notice, the FDA stated that it "looks forward to a future in which all or substantially all opioid medications are less susceptible to abuse than the conventional formulations that dominate the market today." In October 2014, the FDA held the public meeting with key stakeholders to solicit input regarding three primary topics: how to make abuse-deterrent opioid formulations the standard of care, how to best incentivize the pharmaceutical industry to develop next-generation opioid products, and how to ensure that patients have access to affordable abuse-deterrent opioids by implementing guidance for the release of generic abuse-deterrent opioids.
- § *Industry group letter to the FDA:* In January 2015, two major trade associations of the drug industry, Biotechnology Industry Organization, or BIO, and Pharmaceutical Research and Manufacturers of America, or PhRMA, sent a letter to the FDA urging the agency to take two actions: decline to approve generic formulations of opioid medications that lack abuse-deterrent properties comparable to those of already-approved branded formulations, and remove from the market any generic, non-abuse-deterrent formulations of opioid medications with abuse-deterrent formulations.

### **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. To date, the only extended-release product candidate using the prodrug approach in late-stage clinical development did not achieve its primary endpoint of demonstrating adequate pain relief compared to a placebo, in a Phase 2 clinical trial. No opioids using a prodrug approach are currently marketed.

We believe Xtampza represents the best-in-class approach to creating an abuse-deterrent extended-release opioid formulation. Xtampza does not incorporate an opioid antagonist, is not a prodrug, and, based on the studies and clinical trials we conducted, is resistant to abuse through physical or chemical manipulation.

### **Chronic Pain with Dysphagia**

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

and capsules and noted that these difficulties can precipitate a number of adverse events and noncompliance with treatment regimens.

Currently, all FDA-approved, orally administered extended-release opioids have 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 drug," making them unsuitable or unattractive for patients who suffer from chronic pain with dysphagia, or CPD. OxyContin OP's 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, if approved, has a peak revenue potential for U.S. patients with CPD in excess of \$700 million annually.

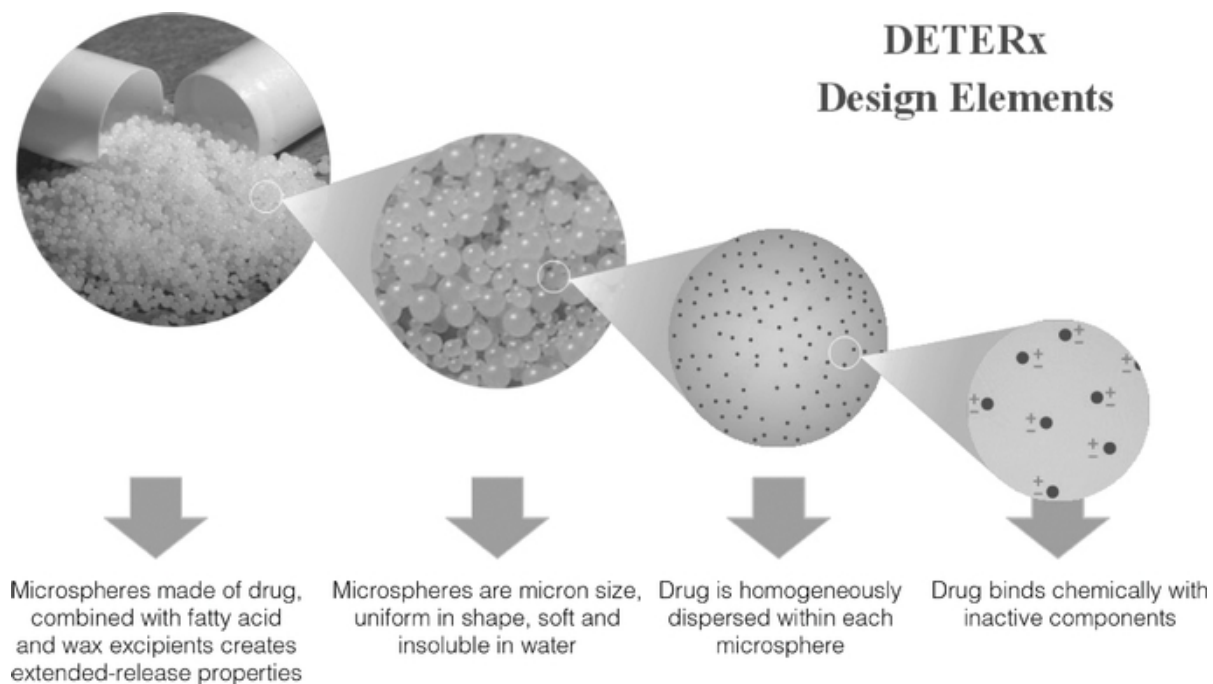
## **Our Solution: The DETERx Platform Technology**

### **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 our lead product candidate, 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 homogeneously 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 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 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**

<b>Method of Abuse</b>	<b>Abuse-Deterrent Feature:</b>	<b>Advantages</b>
Oral	<i>Particle Size, Matrix Composition and Fusing Effect</i>	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	<i>Less Soluble Salt Form</i>	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.
	<i>Matrix Composition</i>	The hydrophobic excipient matrix is designed to trap the active ingredient, making it difficult for abusers to extract the opioid.
	<i>High Melting Point</i>	Melting the waxy composition of the microspheres results in quick solidification when heat is removed, clogging a syringe.
Snorting	<i>Matrix Composition</i>	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.

**DETERx Pipeline**

We have applied our DETERx platform technology to Xtampza as well as other product candidates in our pipeline. We have an extended-release, abuse-deterrent oxycodone program for which we have filed an investigational new drug application, or IND. This program has received a grant from the National Institute on Drug Abuse, a constituent institute of NIH, and has been granted Fast Track status by the FDA. We also have other extended-release, abuse-deterrent product candidates that have completed preliminary preclinical studies, including hydrocodone and morphine for pain, and methylphenidate for the treatment of attention deficit hyperactivity disorder, or ADHD. We are targeting to begin clinical trials with our second product candidate in the first quarter of 2016. 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 our product candidates.

Product	Active	Preclinical	IND	Clinical Development	NDA
Xtampza ER	Oxycodone				
COL-172	Oxymorphone				
COL-195	Hydrocodone				
COL-196	Morphine				
COL-171	Methylphenidate				

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 lead product candidate, Xtampza, is an abuse-deterrent, extended-release, oral formulation of oxycodone in development for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The active ingredient in Xtampza is oxycodone, which is approved by the FDA and other regulators around the world in a number of both immediate-release and extended-release drug products. We developed Xtampza using our proprietary, DETERx abuse-deterrent technology to address common methods of abuse, including chewing, crushing and/or dissolving, and then taking it orally or snorting or injecting Xtampza. Xtampza has received Fast Track status from the FDA. Our NDA filing for Xtampza was accepted by the FDA on February 10, 2015. On February 25, 2015, the FDA set a PDUFA goal date of October 12, 2015 for completion of its review of the Xtampza NDA.

We are seeking approval of Xtampza through the FDA's Section 505(b)(2) regulatory approval pathway using OxyContin OP as our listed drug, with the goal of obtaining abuse-deterrent claims in our product label based on three categories of our completed abuse-deterrence studies. In July 2014, we completed our pivotal Phase 3 efficacy and safety clinical trial for Xtampza in patients with moderate-to-severe chronic low back pain, which met efficacy and safety endpoints. We also completed Category 1, Category 2 and Category 3 abuse-deterrent studies and clinical trials designed to follow the January 2013 FDA draft guidance on abuse-deterrent opioids, and which we believe to be consistent with the April 2015 final FDA guidance, as well as direct guidance received from the FDA in numerous meetings and written communications, including a pre-NDA meeting in April 2014.

Based on the results of our Category 1, 2 and 3 abuse-deterrent studies and clinical trial program and recent feedback from the FDA, we believe that Xtampza will be eligible for abuse-deterrence claims in its label based on all three categories of our completed abuse-deterrence studies, which would provide significant differentiation as compared to other marketed extended-release opioids.

We also conducted an alternative dosing clinical trial to assess the feasibility of administering Xtampza by sprinkling the microspheres onto applesauce. This clinical trial demonstrated that Xtampza microspheres retain their abuse-deterrent and extended-release properties even after being removed from the capsule and mixed with soft food. If approved, we have performed what we believe to be all of the required preclinical

studies and clinical trials to obtain FDA product labeling for sprinkling Xtampza microspheres directly in the mouth or on food, as well as administering the microspheres through a gastric or nasogastric feeding tube. If approved with such labeling, Xtampza would be the only abuse-deterrent extended-release oxycodone product addressing patients with CPD.

### **Market Opportunity**

We believe that, if approved, Xtampza can capture a significant share of the \$6 billion U.S. extended-release opioid market, including a portion of the existing \$2.5 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

Until recently, no product that uses oxycodone as its active ingredient had been permitted to make label claims describing the abuse-deterrent characteristics of its product. 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 label to include certain abuse-deterrent claims. Since the launch of OxyContin OP, there has been a reduction in the overall abuse of OxyContin, primarily in the snorted and injected routes of administration.

The FDA also concluded that the benefits of the previously-approved non-abuse-deterrent OxyContin no longer outweighed its risks and removed it from the list of drugs eligible to serve as a reference product for future generic or Section 505(b)(2) approvals. As a result, we expect that all extended-release oxycodone products, including generic products, will now be required to have abuse-deterrent claims as part of the FDA approval process. We believe this change in FDA policy creates a significant opportunity for Xtampza, if approved, to capture a portion of the extended-release oxycodone market.

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 2014, there are approximately 23 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 would offer 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, if approved, 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. None of the currently approved abuse-deterrent opioid drugs has an FDA product label that permits the sprinkling of the product on food, 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 they will be an effective pain-management solution for patients with CPD. An external marketing study performed for us in 2013 estimated that Xtampza, if approved, has a peak revenue potential for U.S. patients with CPD in excess of \$700 million annually.

#### **Clinical Development**

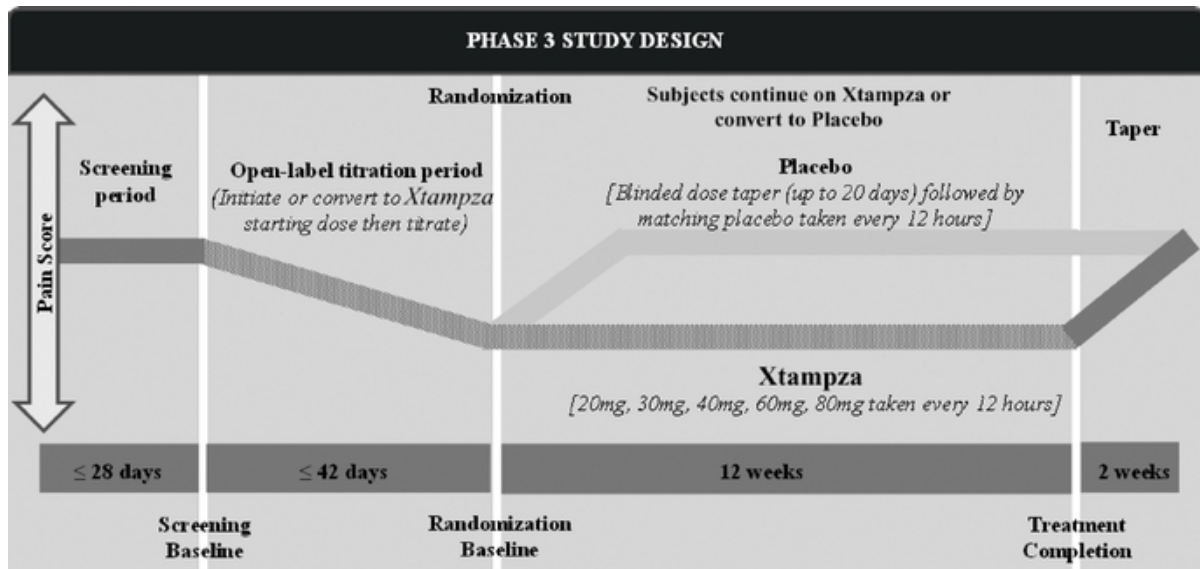
We have completed numerous studies and clinical trials on Xtampza. We submitted an NDA for Xtampza to the FDA on December 12, 2014. Xtampza has received Fast Track status from the FDA. We are seeking approval of Xtampza through the FDA's Section 505(b)(2) regulatory approval pathway using OxyContin OP as our listed drug with the goal of obtaining abuse-deterrent claims in our product label based on all three categories of our completed abuse-deterrence studies. To date, we have completed bioequivalence and bioavailability studies, a pivotal Phase 3 clinical trial of Xtampza in patients with moderate-to-severe chronic low back pain, which met safety and efficacy endpoints, as well as Category 1, Category 2 and Category 3 abuse deterrence studies and clinical trials based on the January 2013 FDA draft guidance regarding abuse-deterrent opioids.

#### *Evaluation of Safety and Efficacy*

#### Phase 3 Clinical Trial

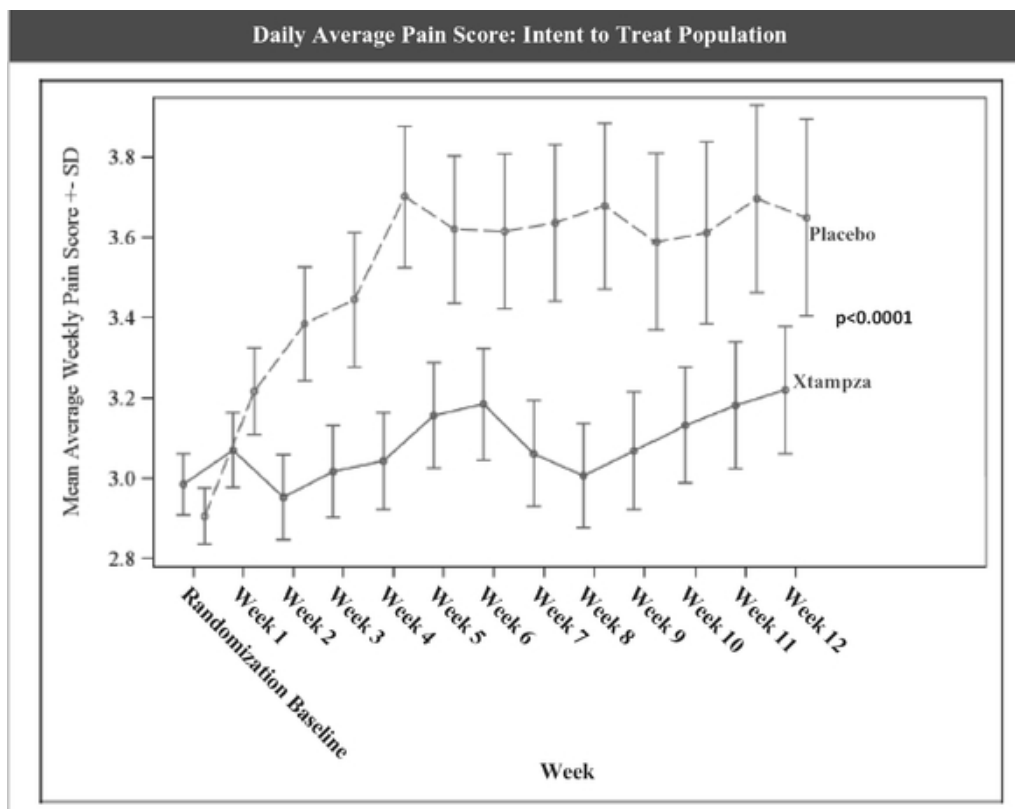
After discussions with the FDA, we conducted a single pivotal Phase 3 clinical trial designed to show safety and efficacy of Xtampza in a chronic pain population. The Phase 3 clinical trial was a multi-center, prospective, double-blind, enriched enrollment, randomized withdrawal, placebo-controlled clinical trial that examined the safety, tolerability, and efficacy of Xtampza versus placebo in opioid-experienced and opioid-naïve patients with moderate-to-severe chronic low back pain. This study was designed with acetaminophen

as the rescue medication in order to avoid the potential issue of immediate-release opioid rescue medication use confounding the effect of the study drug. The trial design is depicted in the figure below.



Of the 740 patients enrolled in the initial open-label titration portion of the clinical trial, 389 patients met the criteria for randomization, which included stable and effective pain scores, ability to tolerate the drug at the dose at which effective pain relief was achieved and compliance with all other aspects of the clinical trial protocol. These 389 patients were randomized into a 12-week, double-blind maintenance phase in which they were either maintained on their current dose regimen of Xtampza or were tapered to a placebo. The primary efficacy endpoint of the clinical trial was the change in average pain intensity from baseline to week 12; pain was measured using an 11-point pain intensity numerical rating scale. Sensitivity analyses were performed to evaluate the primary endpoint. Secondary endpoints in the clinical trial included

evaluation of safety and tolerability, quality of life, physical disability, and global impression of change. The graph below shows the daily average pain score in the randomized, intent to treat, or ITT, population.



The clinical trial demonstrated that the estimated marginal mean change in average pain score from Randomization Baseline to Week 12 was greater for the placebo treatment group (1.85) than for the Xtampza treatment group (0.29). The clinical trial successfully met the primary efficacy endpoint by showing that the difference between treatment groups in the estimated marginal mean change in average pain score was statistically significant ( $p < 0.0001$ ). All sensitivity analyses showed statistically significant results (with p values ranging from 0.0002 to  $< 0.0001$ ) supporting the primary endpoint analysis favoring Xtampza compared to placebo. All secondary endpoints were achieved. The p-value, or probability value, is a measure of statistical significance reflecting the likelihood that an observed result occurred by chance. Generally, p-values less than or equal to 0.05 are considered to indicate statistical significance.

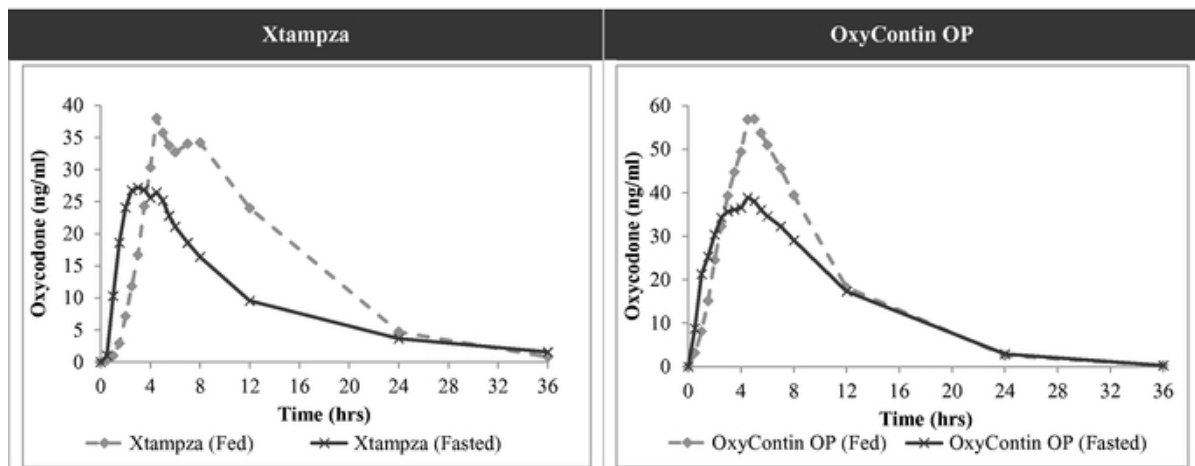
Xtampza was well-tolerated in this study. No new safety concerns were identified. The most common adverse events, or AEs, ( $>5\%$ ) reported by patients in the Phase 3 clinical trial during the titration phase were nausea, headache, constipation, drowsiness, itching, vomiting and dizziness. Each of these AEs declined in frequency with continued treatment. The most common adverse reactions ( $>5\%$ ) reported by patients in the Phase 3 clinical trial comparing Xtampza with placebo are shown in the table below. One subject was hospitalized for a serious adverse event moderate in severity of gastroesophageal reflux and

subsequently discharged upon resolution of the event. The investigator at the clinical trial site assessed this event as possibly related to study drug, but no action was taken with the study drug due to this event.

Adverse Reaction	Titration Period	Maintenance Period	
	Xtampza (n = 740) (%)	Xtampza (n = 193) (%)	Placebo (n = 196) (%)
Nausea	16.6	10.9	4.6
Headache	13.9	6.2	11.7
Constipation	13.0	5.2	0.5
Somnolence	8.8	<1	<1
Pruritus	7.4	2.6	1.5
Vomiting	6.4	4.1	1.5
Dizziness	5.7	1.6	0

Phase 1 Clinical Trials

We performed two Phase 1 bioequivalence and bioavailability clinical trials to compare the blood levels obtained after administration of Xtampza versus OxyContin OP. The first, in which we enrolled 48 patients, compared the pharmacokinetics, or PK, of Xtampza with OxyContin OP in fasted and fed states following single dose administration, with results shown in the figure below.



The single-dose PK profiles for Xtampza and OxyContin OP were similar. However, in the fasted state, the total amount of absorption, known as area under the curve, or AUC, was lower when compared with the fed state for Xtampza, suggesting a larger food effect than OxyContin OP. As a result, if approved, Xtampza is likely to be labeled to be taken with food.

We performed a second phase 1 clinical trial to assess the safety and PK of Xtampza and OxyContin OP in fed and fasted states following multiple-dose administration. In this clinical trial, which enrolled 45 patients, as shown in the figure below, both products were taken with food twice per day for five days, and the PK profiles — which were assessed based on two variables, peak plasma level of the drug, or  $C_{max}$ , and AUC — were bioequivalent.

**Day 5, All Doses Fed (CP-OXYDET-18)**

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	<u>C<sub>max</sub> (ng/ml)</u>	<u>AUC (hr*ng/ml)</u>
Xtampza	77.7	511
OxyContin OP	77.1	531
Xtampza : OxyContin OP % Ratio (90% Confidence Interval)	99.60 (93.60-105.97)	95.63 (92.73-98.61)

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**Evaluation of Abuse-Deterrence of Xtampza**

Xtampza was developed and evaluated in a manner consistent with recommendations described in the January 2013 draft FDA guidance on the evaluation and labeling of abuse-deterrent opioids. We believe our development program is consistent with the April 2015 final FDA guidance. Listed below is an overview of the studies and clinical trials needed for FDA abuse-deterrent labeling.

**FDA Guidance Pre and Post-marketing Study Categories**

<u>Category</u>	<u>Study Type</u>	<u>Objective</u>	<u>Claim Example</u>
1 — Pre-market	Laboratory Manipulation and Extraction Studies	§ Evaluate ease with which abuse-deterrent properties of formulation can be defeated or compromised	§ Category 1: The product is formulated with psychochemical barriers that are expected to deter intravenous abuse.
2 — Pre-market	PK Studies	§ Understand in vivo properties of formulation by comparing PK profiles of manipulated formulation with intact formulation	§ Category 2: The product is formulated with psychochemical properties that are expected to deter oral and nasal abuse.
3 — Pre-market	Clinical Human Abuse Potential Clinical Trials (Drug Likability)	§ Assess impact of the potentially abuse-deterrent formulation on measures that predict how probable it is the formulation will be attractive to abusers ("liked")	§ Category 3: The results from the oral and intranasal clinical abuse potential studies indicate that the medication has properties expected to deter abuse via oral, intranasal and intravenous routes.
4 — Post-market	Post-marketing Epidemiologic Studies	§ Conduct epidemiologic studies capable of detecting a change in the occurrence of abuse and abuse-related outcomes	§ Category 4: There was a demonstrated reduction in abuse of this medication in the community setting compared to the levels of abuse, overdose and death that occurred when only formulations of the same opioid without abuse-deterrent properties were available.

Our development program consisted of in vitro studies and clinical trials, the results of which indicate that Xtampza may result in reduced abuse by manipulation followed by oral ingestion, snorting or attempted intravenous injection. The table below summarizes the abuse deterrence studies and clinical trials we conducted for Xtampza.



**Abuse-deterrent Assessment Strategy**

	<u>Description</u>	<u>Collegium Studies and Clinical Trials</u>
<b>Category 1</b>	Laboratory based in vitro manipulation and extraction studies	Numerous physical, chemical manipulation and route specific studies (IV injection, smoking)
<b>Category 2</b>	PK clinical trials	Oral Crushed/Chewed PK Clinical Trial (CP-OXYDET-17) Intranasal PK Clinical Trial (CP-OXYDET-19) Comparative Crushing/Tampering PK Clinical Trial (CP-OXYDET-25) Intranasal PK and human abuse potential, or HAP, Clinical Trial (CP-OXYDET-21) Oral Chewed PK and HAP Clinical Trial (CP-OXYDET-24)
<b>Category 3</b>	Human abuse potential (drug likeability) clinical trials	Intranasal PK and HAP Clinical Trial (CP-OXYDET-21) Oral Chewed PK and HAP Clinical Trial (CP-OXYDET-24)

Category 1: In Vitro Studies

We demonstrated abuse-deterrent properties of Xtampza in each mode of physical, chemical and route specific manipulations.

*Physical Manipulations*

One of the key objectives of our Category 1 studies was to determine the most effective tool to crush Xtampza microspheres and OxyContin OP tablets as part of a particle size reduction, or PSR, study. The results of this PSR study informed the design of our PK clinical trials. A range of household tools was selected based upon the review of the literature and researching the internet for common methods used by abusers. Based upon this, 10 tools were selected that cut, broke, ground and crushed the Xtampza microspheres and/or OxyContin OP tablets. For OxyContin OP, five of these tools were effective in laboratory tests at substantially increasing the rate of drug release, resulting in "dose dumping" of the active ingredient. For Xtampza, none of these tools was effective at causing dose dumping. A subset of these tools were also applied to the Xtampza microspheres after pre-treatment by freezing or heating, but were still unable to cause dose dumping. Consistent with FDA guidance, results of the physical manipulation study were replicated by an independent third party analytical laboratory registered with the FDA.

*Chemical Extraction*

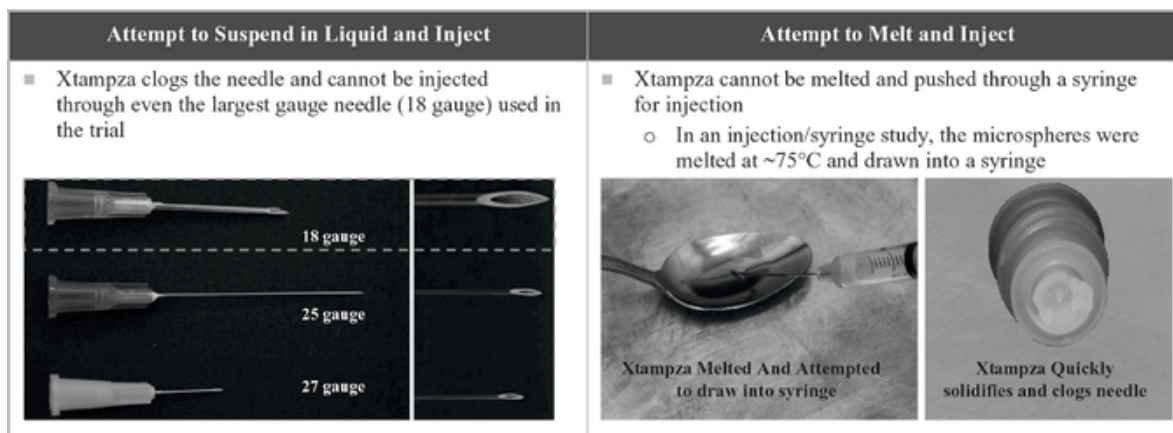
Our chemical extraction studies were completed using the optimal method of crushing for Xtampza and OxyContin OP as identified in the above Category 1 study. We conducted a series of laboratory-based Category 1 chemical manipulation studies to investigate simple and complex extraction methods and dissolution of Xtampza and OxyContin OP in a variety of commonly used beverages, solvents, and soft foods. Results from these studies show that Xtampza microspheres resist extraction of the oxycodone active ingredient into a usable non-toxic form that could be abused. By contrast, after crushing, the active ingredient was readily extracted from OxyContin OP. Results from these studies show that Xtampza has a greater resistance to a wide variety of solvents used for extraction than OxyContin OP.

*Route Specific — Injection*

To assess the ability for abusers to inject Xtampza, the microspheres were crushed, suspended in water and the resulting suspension was attempted to be expelled with needles and syringes. Only negligible amounts of the microspheres were able to pass through any size needle, including an 18 gauge needle (which was the largest needle size tested). By contrast, crushing OxyContin OP and mixing it in water resulted in a gel where a substantial amount, up to 54% of the active ingredient, could be passed through an 18 gauge needle, as well as smaller 25 and 27 gauge needles.

The Xtampza microspheres were then melted at approximately 75°C and the resulting molten material was attempted to be drawn through a needle into a syringe and then expelled through the needle. As the liquid was drawn into the syringe, it immediately solidified, making injection impossible. A comparable procedure on OxyContin OP was not performed because a substantial portion of the crushed and dissolved OxyContin OP mixture, without melting, could be passed through an 18 gauge needle.

Finally, attempts were made to extract the active drug from Xtampza microspheres and OxyContin OP in injectable amounts of water. Both drugs were subjected to three manipulation techniques prior to extraction in water, consisting of crushing alone, crushing and heating them on a hot plate, and crushing and microwaving them. For Xtampza, less than 10% of the oxycodone could be extracted for injection regardless of the manipulation applied. By contrast, the amount of oxycodone extracted from OxyContin OP ranged from 17-84%, depending on the method. Approximately 17% of oxycodone was extracted when crushed, 68% was extracted when crushed and subjected to pretreatment on a heating plate and 84% was extracted when crushed and subjected to heating in a microwave.



*Route Specific — Smoking*

Studies have shown that less than 5% of OxyContin OP abuse is by smoking. We conducted a study comparing the ability to vaporize Xtampza, OxyContin OP, and a marketed immediate-release form of oxycodone. The average amount of oxycodone recovered from vapor after 3 minutes, as a percentage of the total available in the smoked capsule or pill, was approximately 17% for Xtampza, 23% for OxyContin OP and 30% for the marketed immediate-release oxycodone suggesting that Xtampza is unlikely to be abused by smoking more often than existing oxycodone products. In addition, when Xtampza is heated in order to vaporize the oxycodone, inactive excipients are also vaporized, which may be unpleasant to an abuser.

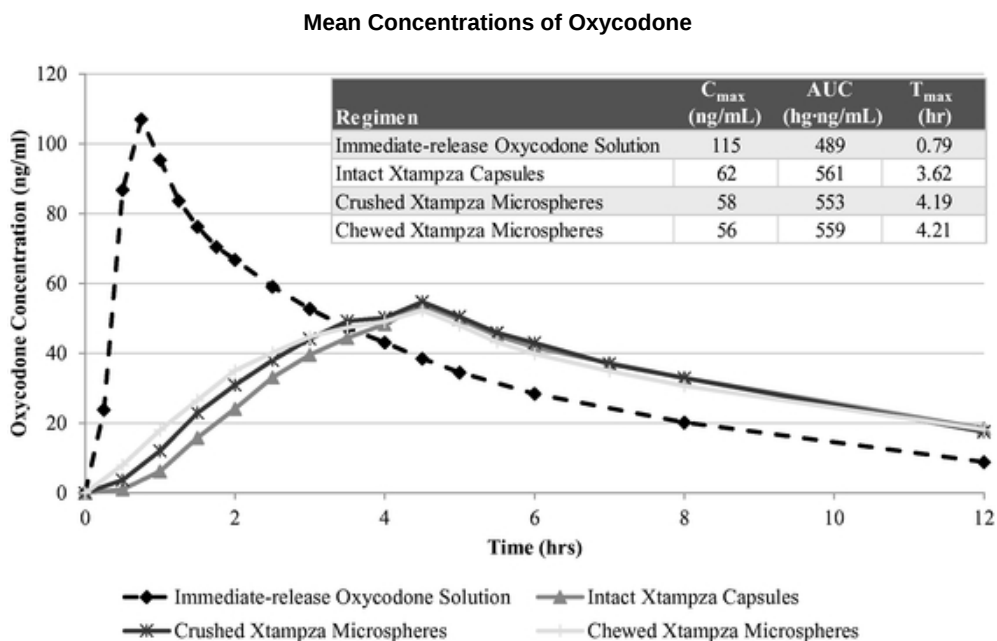
Category 2: Oral PK Clinical Trials

To support oral abuse-deterrent labeling for Xtampza we performed five separate PK clinical trials, three by the oral route of administration and two by the nasal route. The oral clinical trials were as follows:

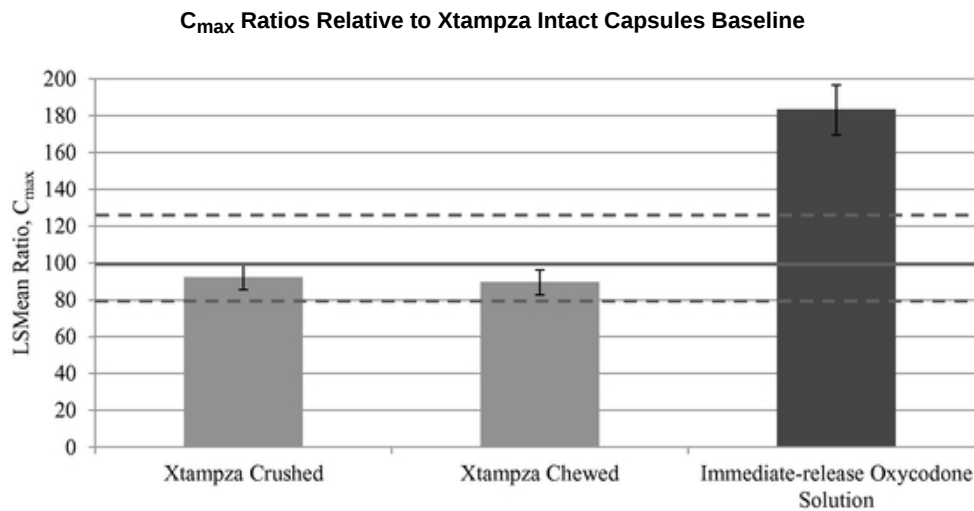
<u>Trial &amp; Category</u>	<u>Subjects</u>	<u>Comparator(s)</u>	<u>Key Objective</u>
<b>Oral Crushed/Chewed PK Clinical Trial (CP-OXYDET-17)</b> <i>Category 2</i>	n = 44	Immediate-release oxycodone solution	§ Assess the safety and PK of Xtampza intact, chewed and crushed
<b>Oral Chewed PK and HAP Clinical Trial (CP-OXYDET-24)</b> <i>Categories 2 &amp; 3</i>	n = 36	Crushed immediate-release oxycodone tablets	§ Assess the PK (Category 2) and drug-likeability (Category 3) of Xtampza, intact and chewed
<b>Comparative Crushing/Tampering PK Clinical Trial (CP-OXYDET-25)</b> <i>Category 2</i>	n = 36	OxyContin OP (intact and crushed) and crushed immediate-release oxycodone tablets	§ Assess the safety and PK of Xtampza, intact and crushed

*Oral Crushed/Chewed PK Clinical Trial (CP-OXYDET-17)*

Our oral crushed/chewed PK clinical trial (CP-OXYDET-17) was an open-label, randomized, active-controlled, crossover clinical trial to evaluate the effect of tampering (crushing and chewing) on Xtampza microspheres compared with immediate-release oxycodone solution. The clinical trial had seven treatment arms, consisting of three fasted-state treatment arms and four fed-state treatment arms. Because Xtampza has a mild food effect, we expect that Xtampza, if approved, will include a label that it should be taken with food. Accordingly, the graph below provides only the results of the clinical trial for the fed-state treatment arms.

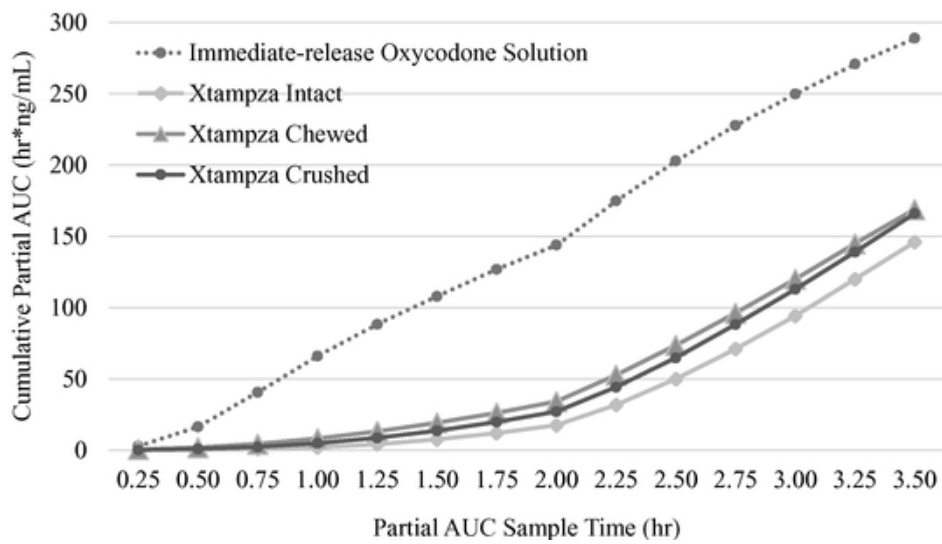


As demonstrated above, crushing or chewing Xtampza did not increase its  $C_{max}$  as compared to the intact Xtampza capsules. All treatment groups had substantially lower peak plasma levels and longer time to peak plasma level, or  $T_{max}$ , than the immediate-release oxycodone solution. The absorption of oxycodone, as measured by AUC, was substantially equivalent among the crushed, chewed and intact Xtampza treatment groups. In all Xtampza treatment groups, the extended-release properties remained intact and there was no evidence of dose dumping.



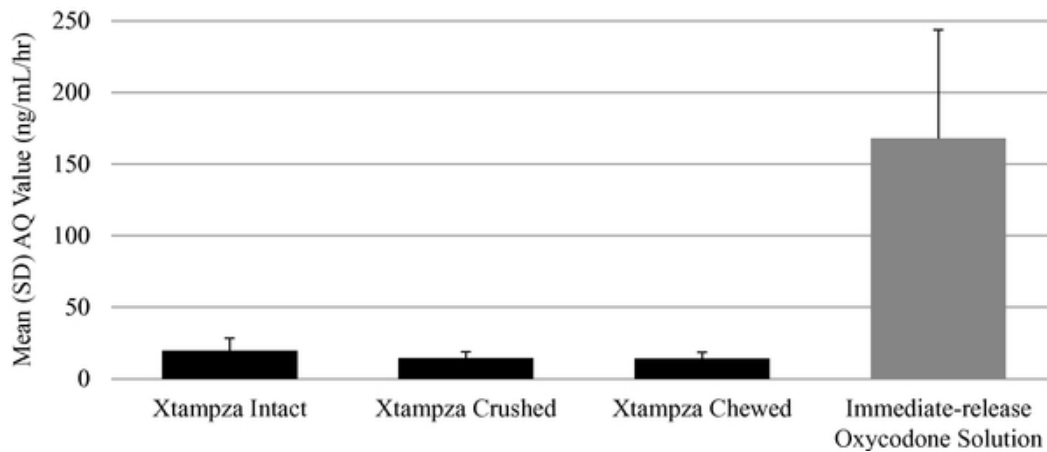
Substantial early increases in plasma concentrations after crushing or chewing, compared to intact capsules are indicative of dose dumping. As a result, the labels for all currently available orally administered extended-release opioids include a black box warning instructing patients that "crushing, dissolving or chewing the tablet can cause rapid release and absorption of a potential fatal dose" of the respective opioid. The results of the clinical trial shown in the graph below demonstrate that crushing and chewing, two common methods of manipulation used by abusers, did not increase the early plasma concentration of Xtampza when taken orally.

**Graphical Display of Mean Oxycodone Partial AUC Values from 0.25 to 3.5 hours**



Another measure used to assess the potential "likability" of a drug for abusers is the "abuse quotient," or AQ, which characterizes the rate at which the peak plasma rises after ingestion and is calculated by dividing  $C_{max}$  by  $T_{max}$ . By manipulating a formulation, an abuser seeks to create euphoria by maximizing AQ. As shown in the graph below, the AQ values for Xtampza after crushing or chewing were the same as taking the product intact and meaningfully lower than for the immediate-release oxycodone solution.

**Mean AQ Values for Each Treatment**



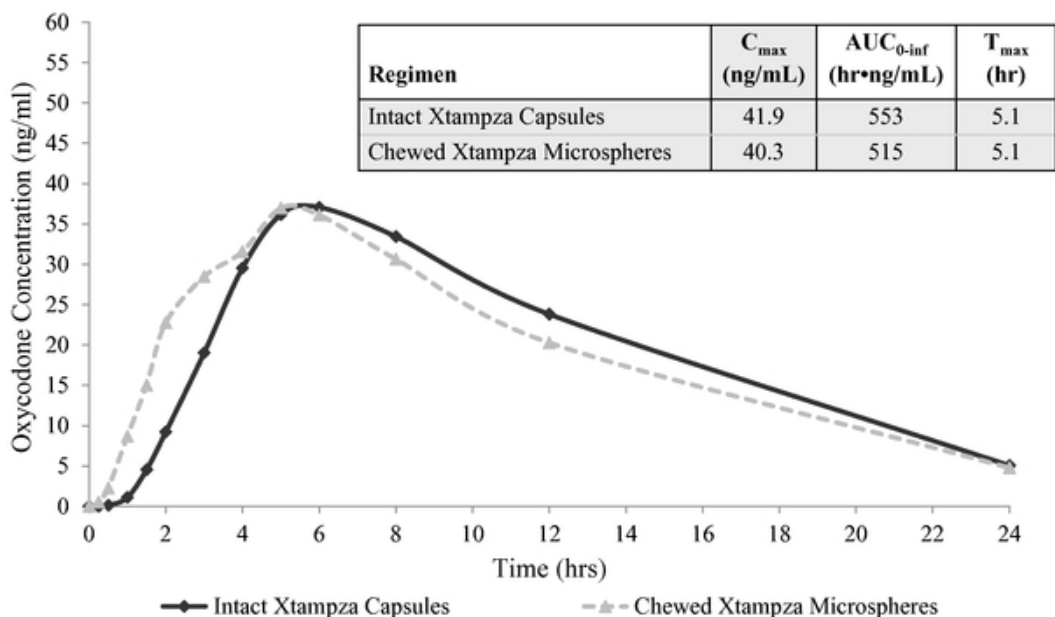
In summary, in this clinical trial, manipulation of Xtampza microspheres by crushing or chewing did not alter the extended-release properties of the Xtampza formulation in the fed-state treatment arms.

*Oral Chewed PK and HAP Clinical Trial (CP-OXYDET-24)*

Our oral chewed PK and HAP clinical trial was designed to assess the PK of Xtampza following chewing as compared to taking the product candidate intact and also as compared to crushing an immediate-release oxycodone tablet. The clinical trial design was consistent with FDA guidance.

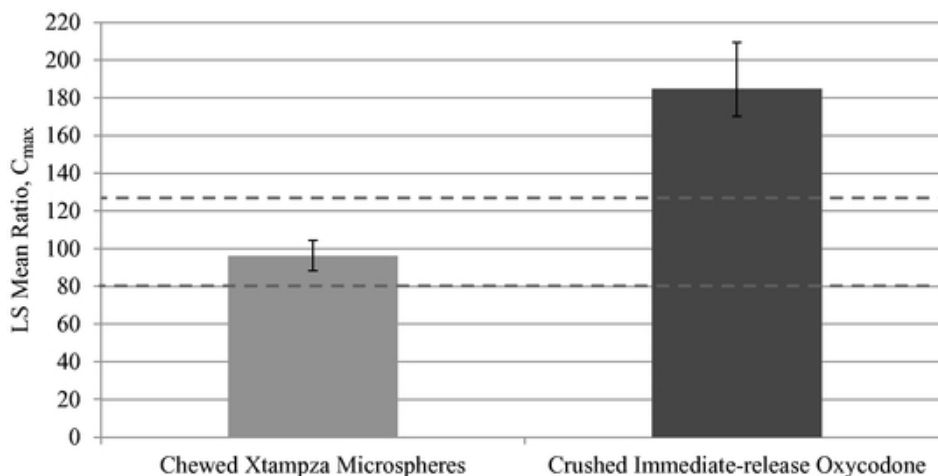
The results shown in the figure below indicate that for  $C_{max}$  and AUC, Xtampza intact and Xtampza chewed are bioequivalent with equivalent  $T_{max}$ . These results indicate that chewing Xtampza does not affect the peak and overall exposure to oxycodone.

**Mean Concentrations of Oxycodone**



The figure below further demonstrates that chewing Xtampza does not affect  $C_{max}$  relative to intact Xtampza capsules. Ratios below 100% indicate chewing does not increase peak plasma exposure versus baseline (taking Xtampza intact).

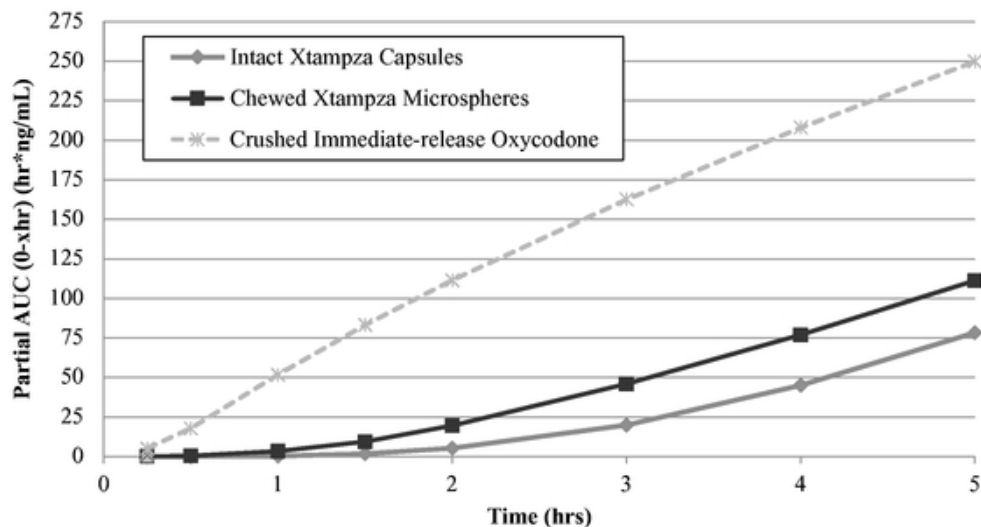
**$C_{max}$  Ratios Relative to Intact Xtampza Capsules**



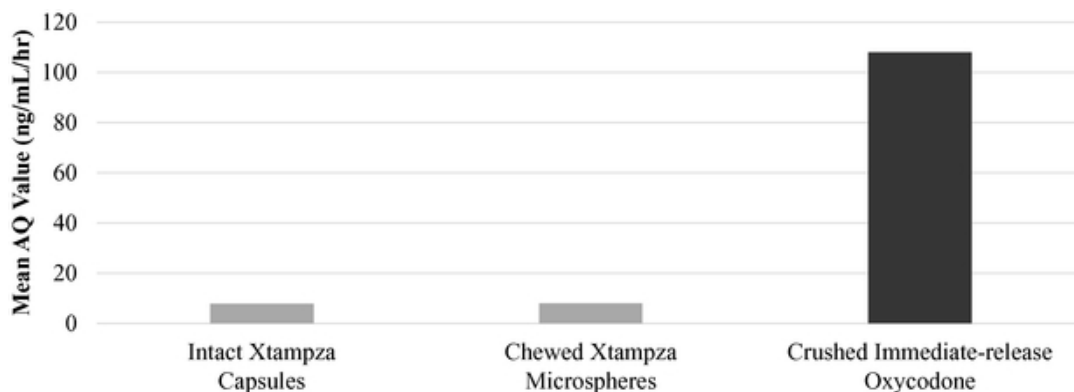
To better characterize early plasma exposure, partial area under the curve, or PAUC (which measures cumulative absorption over an initial period, in this case five hours, after dosage), and AQ values were calculated for each treatment arm. Over the timeframe of the first sampling time to five hours after dosing,

the PAUC values for all Xtampza treatments were substantially lower than the immediate-release oxycodone crushed solution PAUC values. The small increase in PAUC for the manipulated Xtampza capsules relative to intact capsules was anticipated because the microspheres were removed from the capsules prior to oral administration and were therefore more rapidly exposed to the gastric environment for absorption. As shown in the figures below, the mean PAUC and AQ values for all Xtampza treatments were substantially lower than the immediate-release oxycodone crushed solution AQ.

**Graphical Display of Mean Oxycodone Partial AUC Values over the First 5 hours**



**Mean AQ Values for Each Treatment**



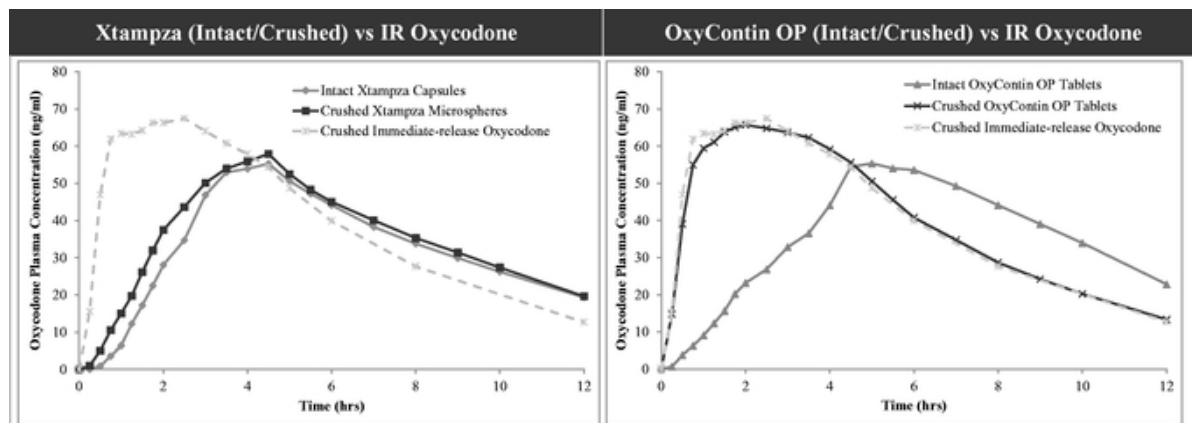
In summary, the PK data from this clinical trial indicate that there is no material increase in plasma exposure or dose dumping when Xtampza is administered after chewing, when compared to intact Xtampza. Similar to our oral crushed/chewed PK clinical trial, our oral chewed PK and HAP clinical trial demonstrated that intact and manipulated Xtampza are bioequivalent to each other.

Comparative Crushing/Tampering PK Clinical Trial (CP-OXYDET-25)

Our comparative crushing/tampering PK clinical trial was an open-label, randomized, active-controlled, cross-over, single-dose clinical trial that evaluated the effect of crushing Xtampza, OxyContin OP and immediate-release oxycodone tablets.

The figure on the left below indicates that crushing does not materially increase the  $C_{max}$  or materially change the AUC of Xtampza compared with the intact product, which retains its oral extended-release properties when crushed, confirming observations from our oral crushed/chewed PK clinical trial. By contrast, the OxyContin OP data in the figure on the right below show that OxyContin OP exhibits a higher  $C_{max}$  and shorter  $T_{max}$  when administered orally in the crushed state, as compared with the intact state, essentially converting OxyContin OP from an extended-release to an immediate-release formulation. This in vivo observation is consistent with in vitro studies on OxyContin OP, which showed that the amount of drug released in one hour increased from 17% in the intact state to 77% following crushing.

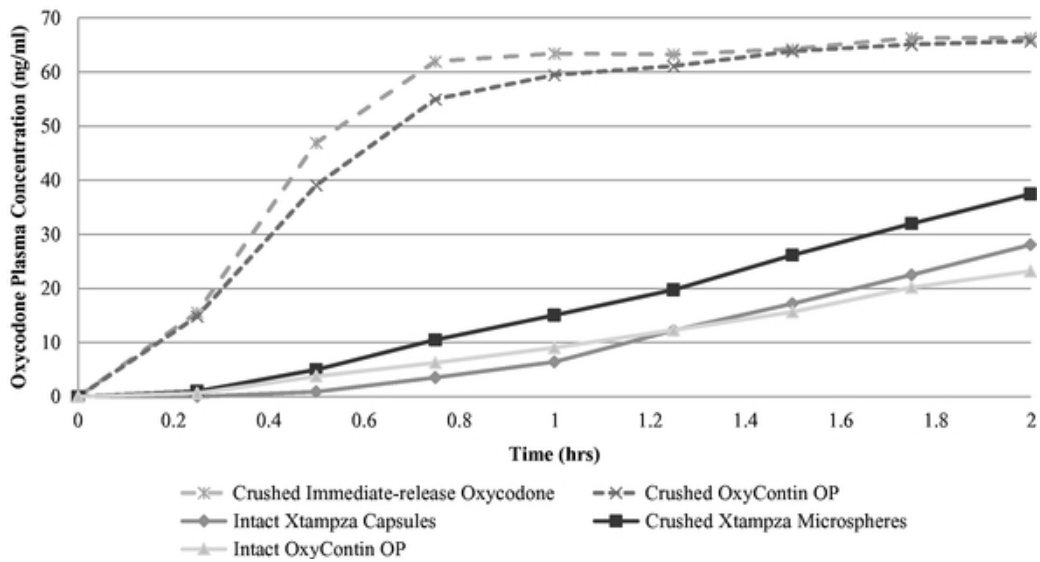
Mean Concentrations of Oxycodone



The figure below shows the mean PAUC values from the first sampling time to two hours for all treatments. Over the first two hours after dosing, the PAUC values for intact and crushed Xtampza, as well as intact OxyContin OP, treatments were substantially lower than the corresponding crushed immediate-release oxycodone values. Over this same timeframe, the PAUC values for crushed OxyContin OP overlapped with those of crushed immediate-release oxycodone. The small increase in PAUC for the crushed Xtampza treatment relative to intact Xtampza was anticipated because the microspheres were removed from the capsules prior to oral administration and were therefore more rapidly exposed to the gastric environment for absorption.

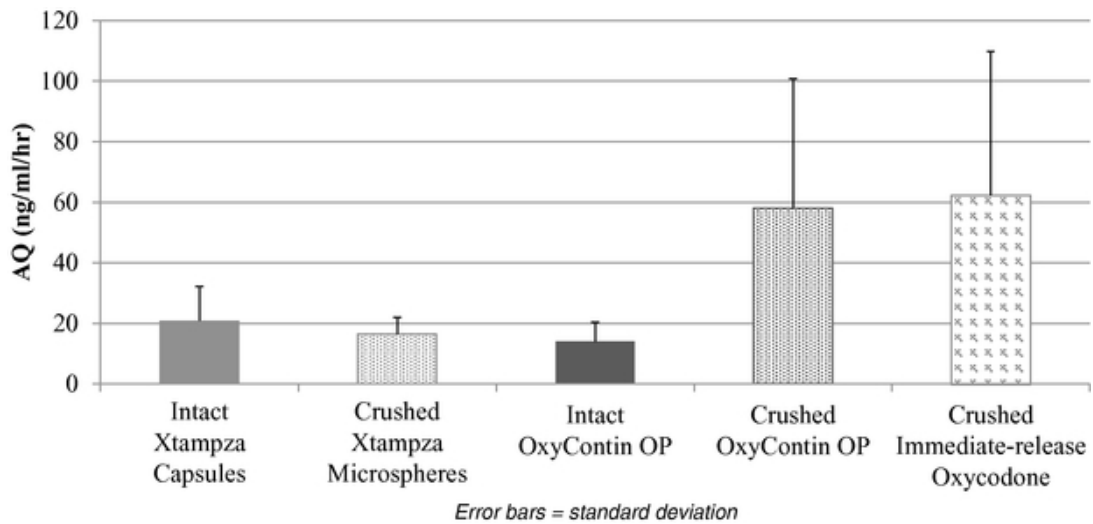


**Graphical Display of Mean Oxycodone Partial AUC Values from 0.25 to 2 hours**



As shown in the figure below, mean AQ values were comparable for crushed and intact Xtampza treatments and substantially lower than crushed immediate-release oxycodone. In contrast to Xtampza, crushing OxyContin OP compromises its extended-release profile such that the AQ value of crushed OxyContin OP increases by nearly four times and is similar to that of immediate-release oxycodone.

**Graphical Display of Mean (SD) AQ Values for Each Treatment**



In summary, crushing Xtampza microspheres does not materially change the extended-release properties of the product. By contrast, crushing OxyContin OP with common household tools causes it to completely lose its extended-release properties, turning it into an immediate-release and readily abuseable formulation. The data in this clinical trial confirm and extend the findings from previous studies, demonstrating that crushing or chewing Xtampza should not lead to a potentially fatal rapid release of oxycodone via "dose dumping" should a patient or a drug abuser crush, break or grind Xtampza.

Category 2: Intranasal PK Clinical Trials

We completed two intranasal PK clinical trials to support abuse-deterrent labeling for Xtampza.

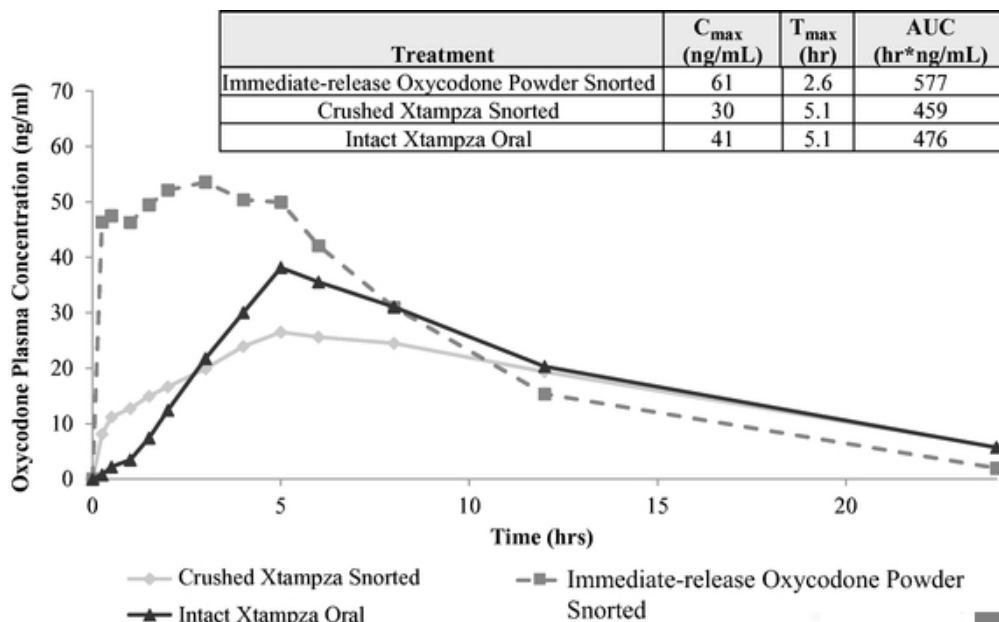
<u>Trial &amp; Category</u>	<u>Subjects</u>	<u>Comparator(s)</u>	<u>Key Objective</u>
<b>Intranasal PK Clinical Trial (CP-OXYDET-19)</b> <i>Category 2</i>	n = 15	Oxycodone powder	§ Compare the safety and PK of crushed and intact Xtampza following intranasal administration.
<b>Intranasal PK and HAP Clinical Trial (CP-OXYDET-24)</b> <i>Categories 2 &amp; 3</i>	n = 36	Crushed immediate-release oxycodone tablets	§ Evaluate the PK (Category 2) and abuse potential (Category 3) of crushed and intact Xtampza following snorting and oral administration.

*Intranasal PK Clinical Trial (CP-OXYDET-19)*

Our intranasal PK clinical trial was a randomized, open-label, active-controlled, cross-over comparison trial. The primary objective was to compare the safety and PK of crushed and snorted Xtampza, intact Xtampza capsules taken orally, and snorted immediate-release oxycodone powder.

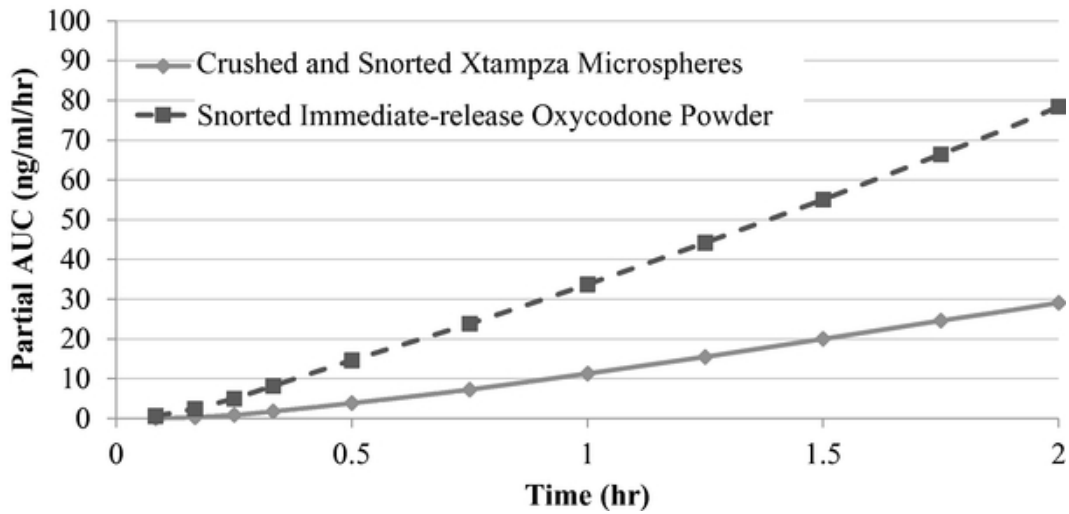
Data from this clinical trial demonstrated that administration of crushed and snorted Xtampza resulted in a lower  $C_{max}$  than both intact Xtampza taken orally and snorted immediate-release oxycodone powder; the  $C_{max}$  for crushed and snorted Xtampza was approximately 80% of intact Xtampza taken orally and 60% of snorted immediate-release oxycodone powder. The median  $T_{max}$  following crushed and snorted Xtampza was equivalent to the median  $T_{max}$  for intact Xtampza taken orally, and both demonstrated longer median  $T_{max}$  values than snorted immediate-release oxycodone powder. Crushed and snorted Xtampza, intact Xtampza taken orally, and snorted immediate-release oxycodone powder were all bioequivalent with respect to AUC parameters.

**Mean Concentrations of Oxycodone**



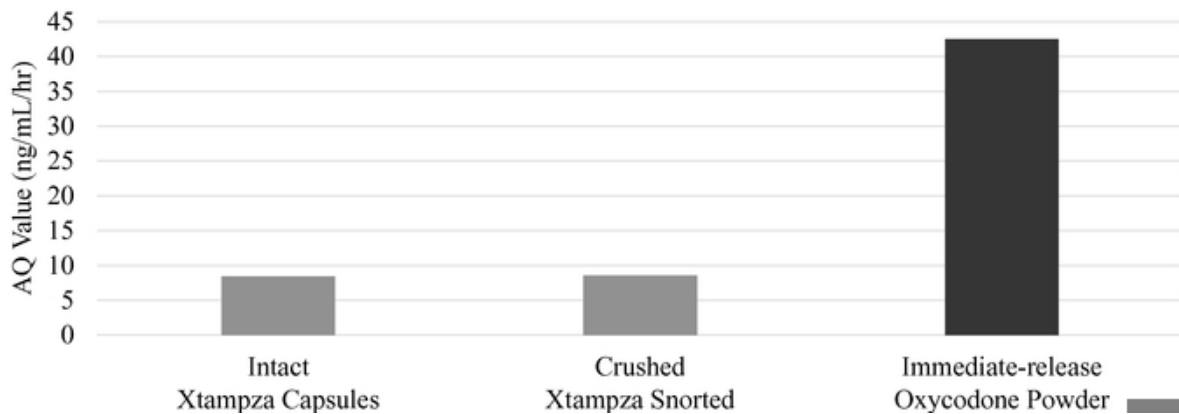
The figure below shows the mean PAUC values from the first sampling time to two hours for two treatments. Over the first two hours after dosing, the PAUC values for crushed and snorted Xtampza treatments were substantially lower than the crushed and snorted immediate-release oxycodone powder values.

**Graphical Display of Mean Oxycodone Partial AUC Values from 0.1 to 2 hours**



As shown in the figure below, the mean AQ values for crushed and snorted Xtampza and intact Xtampza taken orally were comparable. In this clinical trial, no increase in AQ was observed with crushed and snorted Xtampza relative to intact Xtampza taken orally. In contrast, the AQ value for snorted immediate-release oxycodone powder was approximately five-fold higher, on average, than that for crushed and snorted Xtampza.

**Mean AQ Values for Each Treatment**



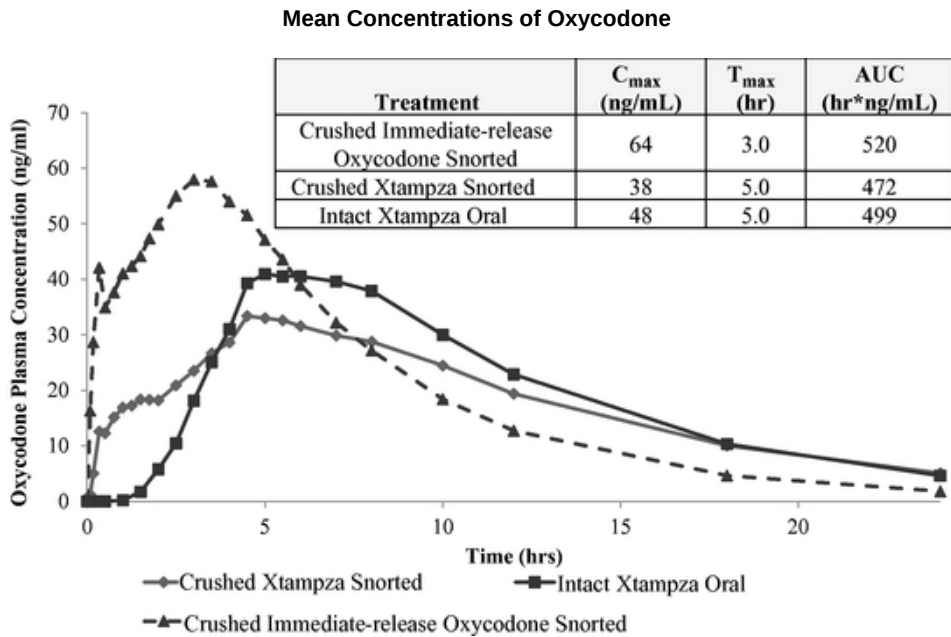
In summary, crushed and snorted Xtampza microspheres demonstrated a lower  $C_{max}$  and an equivalent  $T_{max}$  compared to taking the intact product orally as directed. The  $C_{max}$  of both crushed and snorted Xtampza and intact Xtampza taken orally are substantially lower than the  $C_{max}$  of snorted immediate-release oxycodone powder. Crushing and snorting Xtampza microspheres did not produce the rapid, high plasma concentrations that abusers might seek for euphoria. Additionally, crushed and snorted Xtampza produced a higher

percentage of mild respiratory AEs (e.g., nasal discomfort and congestion) and associated transient nasal events including burning, and facial pain/pressure compared with the immediate-release comparator.

*Intranasal PK and HAP Clinical Trial (CP-OXYDET-24)*

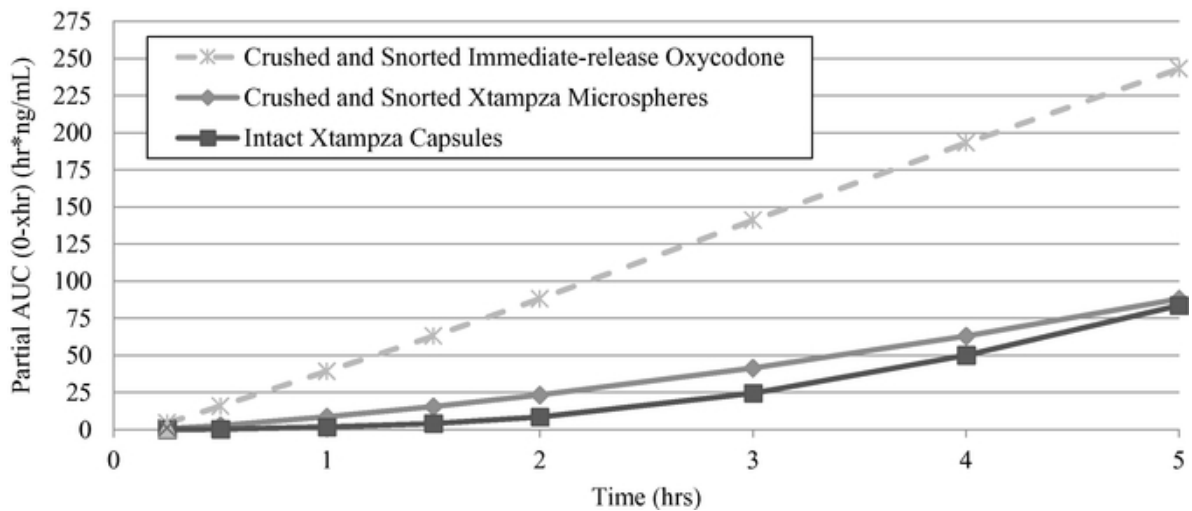
Our intranasal PK and HAP clinical trial was a randomized, open-label, active-controlled, cross-over comparison clinical trial. The primary objective was to compare the safety and PK of crushed and snorted Xtampza, intact Xtampza capsules taken orally, and snorted crushed immediate-release oxycodone tablets.

The PK results from our intranasal PK and HAP clinical trial are similar to those observed in our intranasal PK clinical trial. With respect to AUC, crushed and snorted Xtampza was bioequivalent to intact Xtampza taken orally. However, crushed and snorted Xtampza microspheres resulted in approximately 70% of the peak exposure of intact Xtampza taken orally and approximately 50% of the peak exposure of crushed and snorted immediate-release oxycodone. Median  $T_{max}$  was equivalent when comparing crushed and snorted Xtampza relative to intact Xtampza taken orally. Both Xtampza treatments had substantially longer median  $T_{max}$  values in comparison to crushed and snorted immediate-release oxycodone.



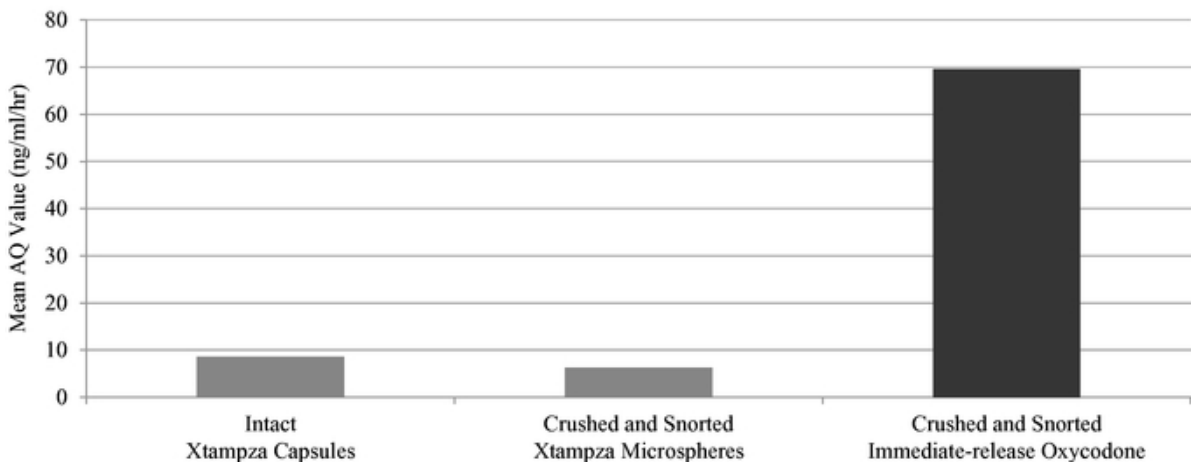
The figure below shows the mean PAUC values from the first sampling time to five hours for all three treatment arms. Over the first five hours after dosing, the PAUC values for intact Xtampza and crushed and snorted Xtampza treatments were substantially lower than those of the crushed and snorted immediate-release oxycodone treatment.

**Graphical Display of Mean Oxycodone Partial AUC Values from 0.25 to 5 hours**



The mean AQ value for crushed and snorted Xtampza was similar to (and slightly lower than) that of intact Xtampza taken orally. By contrast, the mean AQ value for the crushed and snorted immediate-release oxycodone treatment was approximately 11-fold greater than that of crushed and snorted Xtampza. These data indicate that crushed and snorted Xtampza may potentially be less desirable to (i.e., less liked by) drug abusers seeking to achieve a rapid, euphoric effect.

**Mean AQ Values for Each Treatment**



In summary, data from our intranasal PK and HAP clinical trial corroborate the findings from our intranasal PK clinical trial. Both clinical trials indicate that crushed and snorted Xtampza microspheres do not produce the rapid rise in peak plasma drug concentrations that abusers might seek for euphoria when manipulating and administering dosage forms by the nasal route. Additionally, crushed and snorted Xtampza produced a higher percentage of mild respiratory AEs (e.g., nasal discomfort, nasal congestion and nose bleeds) and associated transient nasal events including irritation, burning, and facial pain compared with the immediate-release comparator. The AEs following crushed and snorting Xtampza microspheres, without

the addition of potentially harmful antagonist or aversive agents, may serve as a nuisance to an abuser who wants to snort Xtampza.

Category 3: Human Abuse Potential Clinical Trials

We conducted two clinical trials — our intranasal and oral PK and HAP clinical trial and our oral chewed PK and HAP clinical trial — to evaluate the HAP of crushed Xtampza microspheres taken orally and snorted, as described in the table below.

*Summary of Category 3 Human Abuse Potential Clinical Trials*

<u>Trial &amp; Category</u>	<u>Subjects</u>	<u>Trial Type</u>	<u>Comparator(s)</u>	<u>Key Objective</u>
<b>Intranasal PK and HAP Clinical Trial (CP-OXYDET-21)</b> <i>Category 2 &amp; 3</i>	n = 36	Intranasal PK and human abuse potential clinical trial	Crushed immediate-release oxycodone tablets	§ Evaluate the PK (Category 2) and human abuse potential (Category 3) of crushed and intact Xtampza following intranasal and oral administration.
<b>Oral Chewed PK and HAP Clinical Trial (CP-OXYDET-24)</b> <i>Categories 2 &amp; 3</i>	n = 36	Oral chewed PK and human abuse potential clinical trial	Crushed immediate-release oxycodone tablets in solutions	§ Assess the PK (Category 2) and human abuse potential (Category 3) of Xtampza, intact and chewed

*Intranasal PK and HAP Clinical Trial (CP-OXYDET-21)*

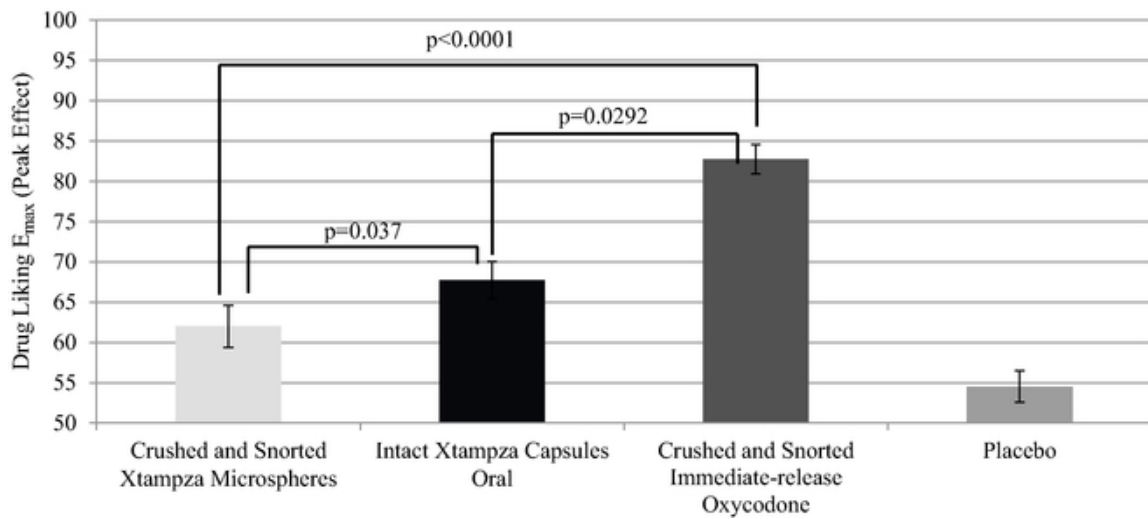
Our intranasal PK and HAP clinical trial assessed the human abuse potential of crushing and snorting Xtampza compared with taking intact Xtampza orally and with crushed and snorting immediate-release oxycodone tablets.

HAP trials are clinical trials that determine the intrinsic potential for abuse of a drug formulation. These clinical trials are conducted in a non-dependent, recreational drug abuser population and are designed to predict how probable it is that a particular drug formulation will be attractive to abusers (i.e., "liked").

This clinical trial measured drug liking, by which a drug abuser assesses how much he or she likes taking a drug using a visual analogue scale, or VAS, measured from 0 to 100, where 0 means the abuser significantly dislikes the drug, 50 means neutral, and 100 means the abuser significantly likes the drug. The primary endpoint of this clinical trial was maximum effect, or Drug Liking  $E_{max}$ , which is the maximum VAS score recorded over the 24-hour period following administration.

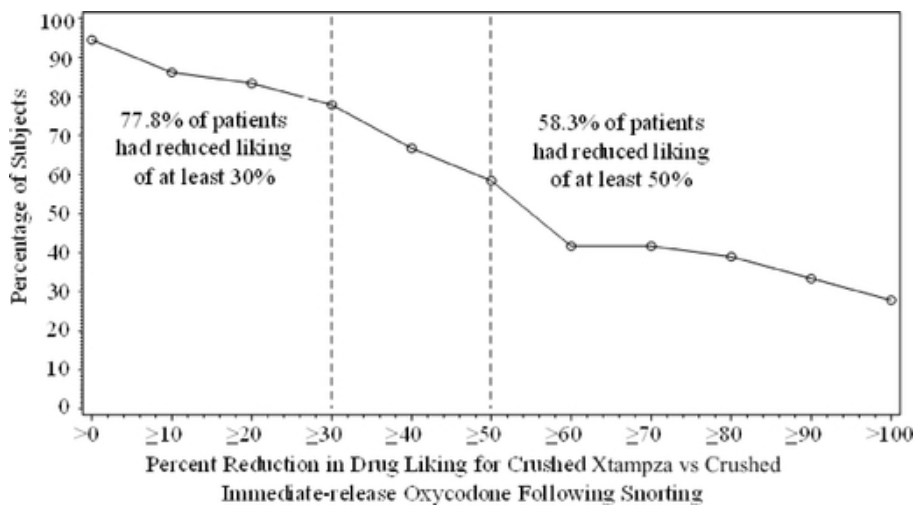
Results of the primary analysis for the Xtampza treatments (crushed and snorted Xtampza compared to intact Xtampza taken orally) were both significantly lower Drug Liking  $E_{max}$  when compared with the control, crushed and snorted immediate-release oxycodone ( $p < 0.0001$  and  $p = 0.0292$ , respectively). Additionally, a statistically significant reduction in Drug Liking  $E_{max}$  was also found when comparing crushed and snorted Xtampza microspheres with intact Xtampza capsules taken orally ( $p = 0.037$ ).

**Mean Drug Liking  $E_{max}$  (Peak Effect)**



As demonstrated in the figure below, analysis of the percentage reduction in Drug Liking  $E_{max}$  score for crushed and snorted Xtampza relative to crushed and snorted immediate-release oxycodone demonstrated a significant response for individual patients, with approximately 58% of patients showing at least a 50% reduction in Drug Liking  $E_{max}$  and approximately 78% of patients showing at least a 30% reduction in Drug Liking  $E_{max}$ .

**Percentage of Subjects Showing Reduced Drug Liking of Crushed and Snorted Xtampza Relative to Crushed and Snorted Immediate-Release Oxycodone**



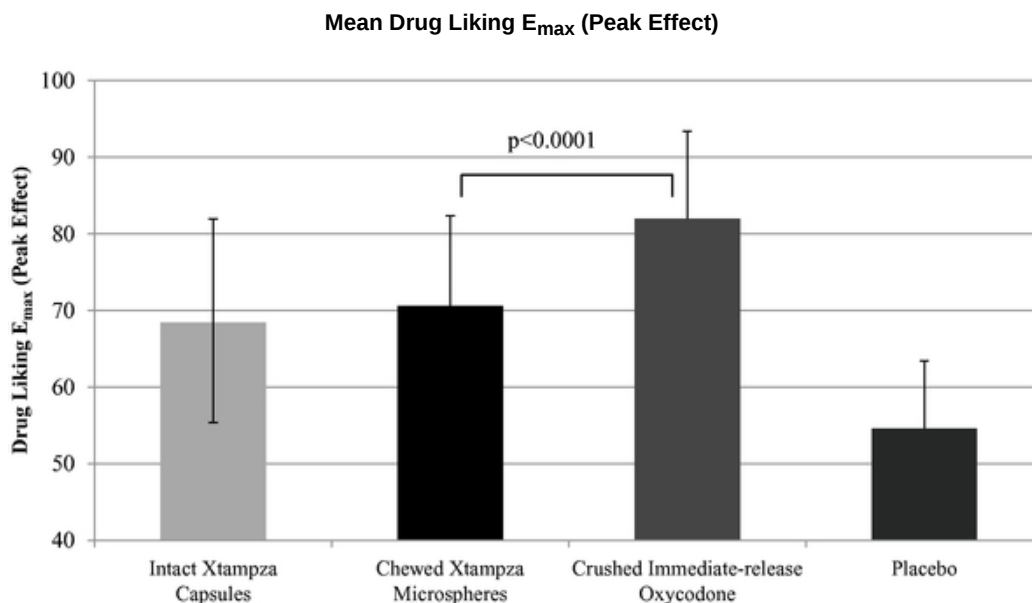
In summary, drug abusers liked crushed and snorted Xtampza microspheres significantly less than swallowing intact Xtampza capsules ( $p=0.037$ ), and they liked swallowing intact Xtampza capsules significantly less than snorting immediate-release oxycodone powder ( $p=0.0292$ ). Furthermore, crushing and snorting Xtampza was associated with the increased incidence of mild respiratory adverse events and

associated transient nasal events including irritation, burning, and facial pain among patients who crushed and snorted Xtampza microspheres. These AEs following snorting Xtampza microspheres, without the addition of potentially harmful antagonist or aversive agents, may serve as a nuisance to an abuser who attempts snorting the drug.

*Oral Chewed PK and HAP Clinical Trial (CP-OXYDET-24)*

Our oral chewed PK and HAP clinical trial assessed the HAP of chewing Xtampza capsule contents compared with taking the intact Xtampza orally and with taking crushed immediate-release oxycodone tablets orally.

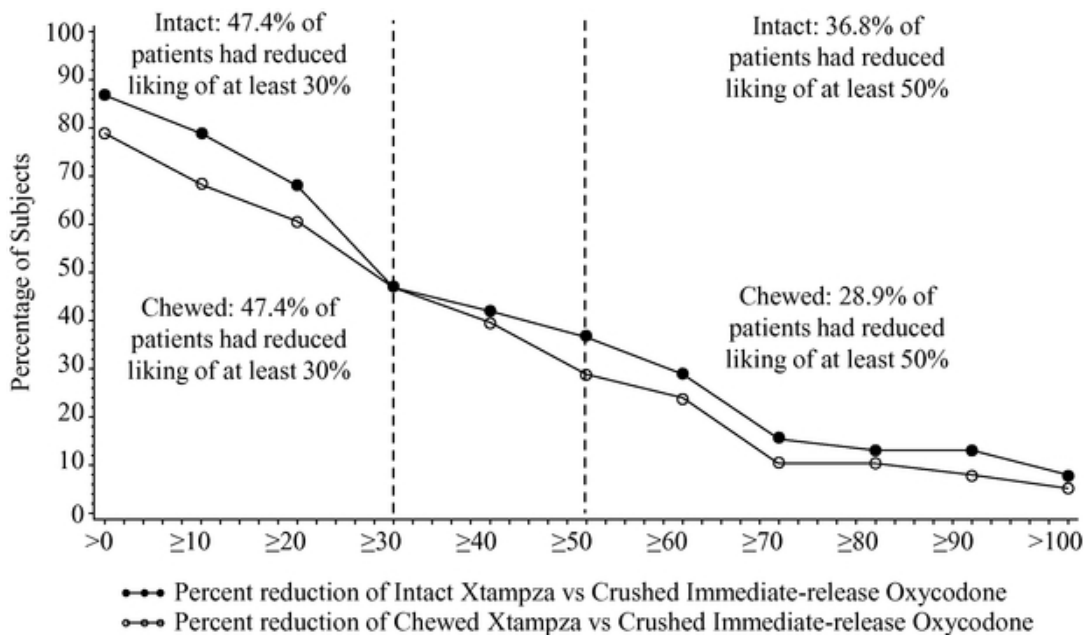
Similar to our intranasal and PK and HAP clinical trial, the primary endpoint for this clinical trial was Drug Liking  $E_{max}$  over the 24-hour period after dosing. Results of the primary analysis demonstrated that chewed Xtampza had significantly lower peak Drug Liking  $E_{max}$  when compared with crushed immediate-release oxycodone ( $p < 0.0001$ ). Similarly, Drug Liking  $E_{max}$  was significantly lower for intact Xtampza when compared with crushed immediate-release oxycodone ( $p < 0.0001$ ).



The percentage reduction for intact and chewed Xtampza relative to crushed immediate-release oxycodone as measured by Drug Liking  $E_{max}$  is presented below. This figure shows that relative to crushed immediate-release oxycodone, chewing Xtampza does not markedly impact reduction in Drug Liking  $E_{max}$  compared with swallowing Xtampza intact. For both Xtampza treatments (intact and chewed), approximately 29-37% of patients showed at least a 50% reduction in Drug Liking  $E_{max}$  relative to crushed immediate-release oxycodone, and approximately 48% of patients showed at least a 30% reduction in Drug Liking  $E_{max}$  relative to crushed immediate-release oxycodone.



**Percentage Reduction for Xtampza Intact and Chewed, Relative to Crushed Immediate-Release Oxycodone for Drug Liking VAS**

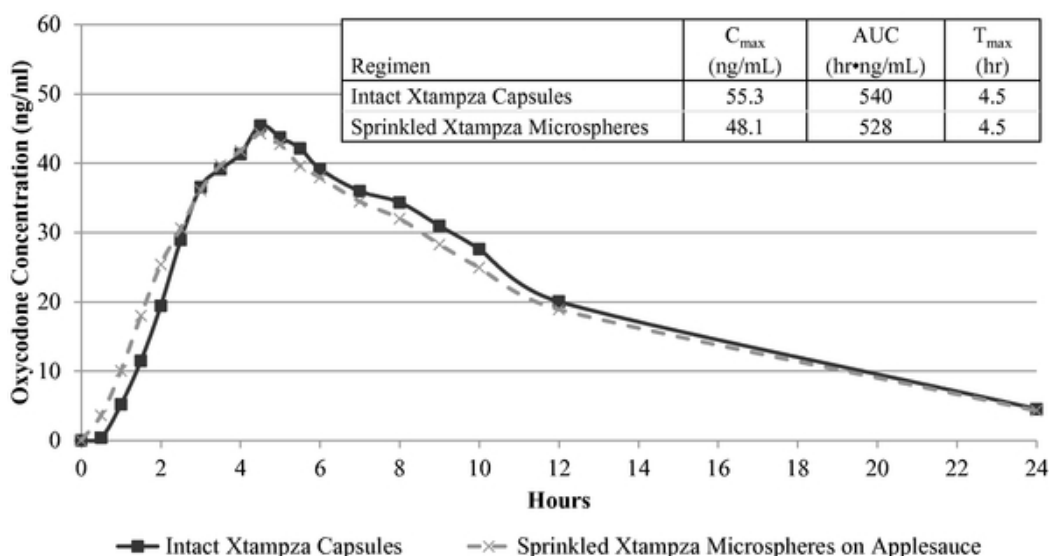


This clinical trial demonstrated that administration of chewed Xtampza resulted in lower Drug Liking  $E_{max}$  than swallowing crushed immediate-release oxycodone. Similarly, swallowing intact Xtampza resulted in lower Drug Liking  $E_{max}$  than swallowing crushed immediate-release oxycodone. This decrease in Drug Liking  $E_{max}$  for both chewed and intact oral administration of Xtampza suggests that the relative abuse potential of Xtampza is significantly lower than that of a non-abuse-deterrent formulation of crushed immediate-release oxycodone ( $p < 0.0001$ ).

In conclusion, data from these Category 3 human abuse potential clinical trials demonstrated that Xtampza resulted in reduced Drug Liking when the drug product is chewed prior to oral administration, or when Xtampza is crushed and snorted, relative to immediate-release oxycodone administered by the same routes. Based on these findings, Xtampza may result in reduced abuse by oral or nasal routes of administration, both of which are the most common abuse routes for oxycodone.

### Alternative Dosing PK Clinical Trial (CP-OXYDET-27)

CP-OXYDET-27 was an open-label, randomized, single-dose, cross-over comparison clinical trial designed to assess the safety and PK profile of Xtampza administered by sprinkling the Xtampza microspheres onto applesauce compared with administration of intact Xtampza. As shown in the graph below, the administration of Xtampza microspheres sprinkled onto applesauce did not lead to any change in their PK profile compared to intact Xtampza.



## Manufacturing

### Overview

Our product candidates 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 manufactured three registration batches of Xtampza and have 24 months of stability data to support a proposed two-year shelf life.

To date, we have produced Xtampza for use in our clinical trials, abuse-deterrence studies and clinical trials, and our preclinical studies at our contract manufacturing organization, Patheon. The existing Patheon facility has the capacity to support production of commercial quantities of Xtampza during the first several years after commercial launch. We are currently conducting a commercial validation program in preparation for commercial launch of Xtampza. As needed, we anticipate working with Patheon to build additional and 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 commercial supply agreement with a U.S.-based manufacturer and expect to continue to do so as we scale up production in anticipation of commercialization. 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. We expect that Xtampza and our other 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 intend to commercialize Xtampza and our other product candidates in the United States, if approved, with a direct sales force. We plan to out-license 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 will lead the commercialization of Xtampza, if approved, have substantial experience in pharmaceutical sales and marketing. If Xtampza is approved for marketing in the United States, we intend to hire or contract for a dedicated field sales force, initially consisting of approximately 100 sales professionals, to target the approximately 10,000 physicians who write more than 50% of the branded extended-release oral opioid prescriptions in the United States, with a primary focus on pain specialists. In addition, we plan to deploy a focused sales force to call on institutions where patients require extended-release opioids, such as skilled nursing or hospice facilities. In addition, we expect to employ medical sales liaisons, or MSLs, to respond to clinician inquiries about Xtampza. We also plan to employ a market-access team to support our formulary approval and payor contracting.

We are continuing to develop our commercialization strategy with the input of key opinion leaders in the field of pain management, as well as healthcare practitioners. Internally, we have begun pre-commercialization activities for Xtampza, such as developing positioning and messaging campaigns, a publication strategy, initiatives with payor organizations, and distribution and national accounts strategies. Our marketing strategy is expected to include increasing awareness of differences between Xtampza and OxyContin OP, the hazards of opioids that are not abuse-deterrent, and increasing awareness of solutions for patients with CPD who require or would benefit from extended-release opioids.

## **Intellectual Property**

We regard the protection of patents, designs, trademarks and other proprietary rights that we own or license as critical to our success and competitive position. Our patent portfolio directed toward Xtampza and our DETERx technology consists of six issued patents in the United States (four of which claim compositions of matter, one of which claims both compositions of matter and methods of use, and one of which claims methods of use), two pending applications in the European Union and one issued patent in each of Canada, Japan and Australia. In addition, we have six patent applications pending in the United States, and two pending foreign patent applications (excluding Europe), in Japan and Canada. Our issued U.S. patents are projected to expire in 2023 and 2025, and our pending patent applications in the United States, if issued, would be projected to expire in 2023 and 2030. 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 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.

### Patent Litigation Strategy

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. Under the Hatch-Waxman Act of 1984, 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 (all of which stand invalidated, subject to a pending appeal by Purdue) and a non-Orange Book-listed patent, and, accordingly, received a stay of up to 30 months before the FDA can issue a final approval for Xtampza, unless the stay is earlier terminated. The 30-month stay only applies to Orange Book-listed patents. On March 26, 2015, Purdue filed a second suit against us in the District of Massachusetts asserting infringement of the same four patents. On April 6, 2015, in the District of Delaware case, we filed a motion to dismiss for lack of personal jurisdiction or, in the alternative, to transfer venue to the Southern District of New York where three of the patents have already been invalidated. Purdue's opposition to our motion was filed on April 23, 2015 and our reply in support of the motion is due on May 4, 2015. The complaint in the District of Massachusetts case has not yet been served.

In order to commercialize Xtampza, we will need both FDA approval and to dispose of the lawsuits filed by Purdue (or wait until the expiration of the 30-month stay imposed by such litigation). We do not believe we infringe Purdue's patents and intend to vigorously defend the suit.

The FDA is entitled to give Xtampza a tentative approval before the 30-month stay has expired, which means the product is approved, subject to the expiration of the 30-month period or termination of the stay. If we receive a court order that the listed patents are invalid or not infringed, or if we settle the Purdue litigation before the 30-month period expires, the FDA can then provide final approval of Xtampza prior to the expiration of the 30-month period, at which point the product can be marketed. Our certification letter to Purdue and the other Orange Book-listed patent owners documents why Xtampza does not infringe any of the Orange Book-listed patents for OxyContin OP, or the OxyContin Patents, which fall into three general categories, as follows:

- § *High molecular weight poly(ethylene oxide)/polymer patents:* Some of the OxyContin Patents describe a formulation containing a significant amount of high molecular weight poly(ethylene oxide) or polyalkylene oxide, which creates a hard tablet that is difficult to crush. Some of these OxyContin Patents claim specific manufacturing methods and curing conditions that are intended to create hard tablets. The formulation described in our NDA for Xtampza does not contain any high molecular

weight component and is manufactured under different conditions from those claimed by the OxyContin Patents.

- § *Oxycodone HCl or preferential removal of 14-hydroxycodeinone patents:* Some of the OxyContin Patents describe oxycodone compositions, formulations and manufacturing processes that use oxycodone HCl as the active ingredient and thus require preferential removal of the toxic intermediary 14-hydroxycodeinone. The formulation described in our NDA uses an oxycodone base rather than oxycodone HCl, and does not require the preferential removal of 14-hydroxycodeinone.
- § *Viscosity-increasing patents:* Some of the OxyContin Patents describe the addition of viscosity-increasing agents as a method of abuse deterrence. The formulation described in our NDA does not contain any viscosity-increasing agent and, unlike OxyContin OP, does not form a gel when placed in an aqueous liquid.

Our certification letter to Purdue also noted that five of the 11 Orange Book-listed patents for OxyContin OP stand invalidated by the Federal District Court for the Southern District of New York, subject to a pending appeal.

Because we anticipated that Purdue would sue us for patent infringement as a possible means to delay the launch of Xtampza, we have engaged experienced litigation counsel, who worked carefully with us to construct a strategy to prevail in any litigation that arises as expeditiously as possible. We are now in the process of implementing this litigation strategy and plan to take all steps necessary to vigorously defend ourselves against these claims.

## **Our Strategy**

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

- § *Establish our leadership position by obtaining approval to market Xtampza with a best-in-class abuse-deterrent label.* If approved, we expect to receive differentiated abuse-deterrent claims in the Xtampza label compared to other approved abuse-deterrent opioids, which will allow us to detail Xtampza to physicians and highlight its unique abuse-deterrent characteristics.
- § *Commercialize Xtampza in the United States ourselves.* We are currently preparing for a potential U.S. commercial launch of Xtampza, if approved, in the first quarter of 2016. Our management team has extensive experience commercializing pharmaceutical products, and we intend to establish sales, marketing and reimbursement functions to commercialize Xtampza in the United States. Initially, we plan to detail Xtampza to approximately 10,000 physicians who write more than 50% of the branded extended-release oral opioid prescriptions in the United States with a sales team of approximately 100 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 plan to deploy a separate, focused sales team to detail Xtampza to nursing homes, hospices, and other institutions treating large populations of the elderly and other patients who need chronic pain relief and have difficulty swallowing.
- § *Establish Xtampza as the treatment of choice for patients with CPD.* In addition to positioning Xtampza as the superior abuse-deterrent, extended-release formulation of oxycodone, we intend to position Xtampza as the treatment of choice for patients with CPD. There are currently no approved, abuse-deterrent, extended-release products designed for this patient segment consisting of over 11 million patients in the United States. If approved with product labeling for sprinkling Xtampza microspheres directly in the mouth or on food, as well as administering the microspheres through feeding tubes, Xtampza would be the only abuse-deterrent, extended-release product designed to be suitable for this patient group.

- § *Establish strategic collaborations to accelerate and maximize the potential of our product candidates worldwide.* We intend to seek strategic collaborations with other pharmaceutical companies to commercialize our product candidates outside the United States and to develop certain of our product candidates that are outside of our core therapeutic focus. We believe that we are an attractive collaborator for pharmaceutical companies due to the strength of our abuse-deterrent technology.
- § *Advance other product candidates that incorporate our DETERx platform technology.* We have multiple opioid product candidates at different stages of development. We have an IND application on file for COL-172, an abuse-deterrent, extended-release oxycodone for the treatment of chronic pain, which has been granted Fast Track status by the FDA. We have also begun advancing our development program for COL-195, an abuse-deterrent, extended-release hydrocodone for the treatment of chronic pain. We target beginning clinical trials for our second product candidate by the first quarter of 2016. In addition, we have COL-171, a proprietary preclinical DETERx extended-release, abuse-deterrent methylphenidate formulation for the treatment of attention deficit hyperactive disorder, which we plan to advance with a collaborator.
- § *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.

We are continuing to develop our commercialization strategy with the input of key opinion leaders in the field of pain management, as well as healthcare practitioners and quality improvement organizations. Internally, we have begun pre-commercialization initiatives for Xtampza, such as developing positioning and messaging campaigns, a publication strategy, initiatives with payor organizations, and distribution and national accounts strategies.

## Competition

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

Currently, the only opioid drugs on the market for chronic pain relief that have an abuse-deterrent label are OxyContin OP and Hysingla®, both of which are marketed by Purdue, and Embeda, which is marketed by Pfizer. In addition, there is one other approved extended-release opioid that has abuse-deterrent labeling — Targiniq from Purdue — which is not currently on the market. Hysingla is a once a day hydrocodone extended-release product. Embeda is a combination of morphine and naltrexone, an opioid antagonist that can be sprinkled on soft food but contains 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 drug." Also, according to the warning labels of Oxycontin OP and other extended-release opioids, administration of the active ingredients by injection may result in necrosis, infection and increased risk of heart disease. Targiniq is a combination of oxycodone and naloxone, an opioid antagonist. In 2014, sales of extended-release opioids in the United States were \$6 billion, consisting of a number of large and small companies, including Purdue, Pfizer, Actavis, Endo Pharmaceuticals, Zogenix, Janssen Pharmaceuticals, Mallinckrodt and several generic drug companies. A number of other large and small companies are developing abuse-deterrent drugs for chronic pain, including Teva Pharmaceutical Industries Ltd., Endo Health Solutions Inc., Nektar Therapeutics, Egalet Corporation, Inspirion Delivery Technologies, LLC, and KemPharm, Inc.

We believe the key competitive factors that will affect the development and commercial success of our 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, oxycodone and methadone, as well as opioids that are currently in clinical development.

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

Additionally, we are aware of companies in late-stage development of abuse-deterrent oxycodone product candidates, including Pain Therapeutics' Remoxy®, a formulation of oxycodone, and Pfizer's ALO-02, a formulation of oxycodone and naltrexone. If these products are successfully developed and approved for marketing, they could represent significant competition for Xtampza. It is also possible that a company that has developed an abuse-deterrent technology could initiate an abuse-deterrent oxycodone program at any time.

## **Government Regulation**

### ***FDA Approval Process***

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

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

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

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

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

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

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

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

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap or be combined. In Phase 1, the drug is initially introduced into healthy human subjects or patients, and is tested to assess safety, dose tolerance, absorption, metabolism, PK, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common AEs and safety risks. Multiple Phase 2 trials may be conducted by the sponsor to obtain information prior to beginning larger and more extensive Phase 3 clinical trials. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of subjects, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the clinical trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible. Sponsors of clinical trials generally must register and report key parameters of certain clinical trials at the NIH-maintained website [ClinicalTrials.gov](http://ClinicalTrials.gov).

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to



the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently set at \$2,335,200, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees, currently set at \$110,370 per product and \$569,200 per establishment. These fees are typically increased annually.

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

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee — typically a panel that includes clinicians and other experts — for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. In addition, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMP is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

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

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

#### **REMS**

The FDA has the authority to require a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of the approval of an NDA or after approval to ensure that the benefits of a drug outweigh its risks. In determining whether a REMS is necessary, the FDA must consider the size of the population likely to use the drug, the seriousness of the disease or condition to be treated, the expected benefit of the drug, the

duration of treatment, the seriousness of known or potential adverse events, and whether the drug is a new molecular entity. If the FDA determines a REMS is necessary for a new drug, the drug sponsor must submit a proposed REMS plan as part of its NDA prior to approval. The FDA may also impose a REMS requirement on a drug already on the market if the FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug's benefits continue to outweigh its risks. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. In addition, the REMS must include a timetable to periodically assess the strategy, at a minimum, at 18 months, three years, and seven years after the REMS approval. The requirement for a REMS can materially affect the potential market and profitability of a drug.

In February 2009, the FDA informed manufacturers of certain opioid products that it would require a REMS for their opioid drug products. Subsequently, the FDA initiated efforts to develop a new standardized REMS for these opioid medications to ensure their safe use, and in July 2012, approved a class-wide REMS for extended-release and long-acting opioid products. Extended-release formulations of oxycodone, morphine, hydrocodone and hydromorphone, for example, are required to have a REMS. Manufacturers subject to this class-wide REMS must work together to implement the REMS as part of a single shared system to reduce the burden of the REMS on the healthcare system. The central component of the extended release/long acting opioid REMS program is an education program for prescribers and patients. Specifically, the REMS includes a Medication Guide available for distribution to patients who are dispensed the drug, as well as a number of ETASU. These ETASU include training for healthcare professionals who prescribe the drug; information provided to prescribers that they can use to educate patients in the safe use, storage, and disposal of opioids; and information provided to prescribers of the existence of the REMS and the need to successfully complete the necessary training. Prescriber training required as part of the REMS is conducted by accredited, independent continuing education providers, without cost to healthcare professionals, under unrestricted grants funded by the opioid analgesic manufacturers. Moreover, REMS assessments must be submitted on an annual basis to assess the extent to which the ETASU are meeting the goals of the REMS and whether the goals or elements should be modified.

### ***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 U.S. Department of Health and Human Services, or 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. 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 lead product candidate, Xtampza, if approved, will be 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."

We expect that Xtampza, an abuse-deterrent oral formulation of oxycodone, will be listed by the DEA as a Schedule II controlled substance under the CSA. Consequently, the manufacturing, shipping, storing, selling and using of the products will be 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 expected to be regulated as a Schedule II controlled substance, it will be subject to the DEA's production and procurement quota scheme. The DEA establishes annually an aggregate quota for how much oxycodone may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. The limited aggregate amount of opioids that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. We and our contract manufacturers must receive an annual quota from the DEA in order to produce or procure any Schedule I or Schedule II substance, including oxycodone base for use in manufacturing Xtampza. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments.

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

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

## ***International Regulation***

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

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

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

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

## ***Other Healthcare Laws and Compliance Requirements***

In the United States, the research, manufacturing, distribution, sale and promotion of drug products and medical devices are subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of HHS (e.g., the Office of Inspector General), the DOJ, state Attorneys General and other state and local government agencies. For example, sales, marketing and scientific/educational grant programs must comply with fraud and abuse laws such as the federal Anti-Kickback Statute, the federal False Claims Act, as amended and similar state laws. In order to participate in the Medicaid program, existing federal law requires pharmaceutical manufacturers to pay rebates to state governments, based on a statutory formula, on covered outpatient drugs reimbursed by the Medicaid program as a condition of having their drugs paid for by Medicaid. Manufacturers are required to report AMP and best price for each of their covered outpatient drugs to the government on a regular basis. Additionally, some state Medicaid programs have imposed a requirement for supplemental rebates over and above the formula set forth in federal law, as a condition for coverage. In addition to the Medicaid Rebate Program, federal law also requires that if a pharmaceutical manufacturer wishes to have its outpatient drugs covered under Medicaid as well as under Medicare Part B, it must sign a "Master Agreement" obligating it to provide a formulaic discount that results in a federal ceiling price, or maximum price that participating manufacturers may charge for covered drugs sold to the U.S. Departments of Defense (including the TRICARE retail pharmacy program), Veterans Affairs, the Public Health Service and the Coast Guard, and also provide discounts through a drug pricing agreement meeting the requirements of Section 340B of the Public Health Service Act, for outpatient drugs sold to certain specified eligible health



care organizations. The formula for determining the discounted purchase price under the 340B drug pricing program is defined by statute and is based on the AMP and rebate amount for a particular product as calculated under the Medicaid Drug Rebate Program, discussed above.

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

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



healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, we may be subject to, or our marketing activities in the future may be limited by, data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA and its implementing regulations established uniform standards for certain "covered entities," which are healthcare providers, health plans and healthcare clearinghouses, governing the conduct of specified electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included expansion of HIPAA's privacy and security standards through the Health Information Technology for Economic and Clinical Health Act, or 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, new requirements under the federal Open Payments program, created under Section 6002 of the Affordable Care Act and its implementing regulations, require that manufacturers of drugs for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to HHS 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 that manufacturers and applicable group purchasing organizations report annually to the HHS ownership and investment interests held by physicians (as defined above) and their immediate family members, with data collection required beginning August 1, 2013 and reporting to the Centers for Medicare & Medicaid Services, or CMS, required beginning March 31, 2014 and by the 90th day following the end of each subsequent calendar year, and disclosure of such information to be made 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 our product candidates, if and when 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 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 2% per fiscal year, and went into effect in April 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and, accordingly, our financial operations.

### **Other Regulatory Requirements**

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

### **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 former subsidiary, Onset Therapeutics, LLC to PreCision Dermatology, Inc. Since then, 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 and the creation and protection of related intellectual property. 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.

### **Legal Proceedings**

From time to time we face legal claims or actions in the normal course of business.

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 Pharma, L.P., or 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 stand invalidated by the Federal District Court for the Southern District of New York, subject to a pending appeal. 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 can issue a final approval for Xtampza, unless the stay is 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 (all of which stand invalidated subject to a pending appeal by Purdue) and a non-Orange Book-listed patent, and accordingly, received a stay of up to 30 months before the FDA can issue a final approval for Xtampza, unless the stay is earlier terminated. On March 26, 2015, Purdue filed a second suit against us in the District of Massachusetts asserting infringement of the same four patents. We have engaged experienced litigation counsel who worked carefully with us to construct a strategy to prevail in such litigation as expeditiously as possible. On April 6, 2015, in the District of

Delaware case, we filed a motion to dismiss for lack of personal jurisdiction or, in the alternative, to transfer venue to the Southern District of New York where three of the patents have already been invalidated. Purdue's opposition to our motion was filed on April 23, 2015 and our reply in support of the motion is due May 4, 2015. The complaint in the District of Massachusetts case has not yet been served. We do not believe we infringe Purdue's patents and intend to vigorously defend ourselves against these claims.

### **Facilities**

Our corporate headquarters are located in Canton, Massachusetts, where we lease 9,675 square feet of office space (including chemistry and pilot/formulation laboratories) under a lease agreement that was amended in March 2015 to expand the premises to include an additional 9,660 square feet of space for a total of 19,335 square feet. In addition, the lease term has been extended and now terminates on the date that is five years following the date, which has not yet been determined, on which the landlord delivers to us the expansion space with certain improvements substantially completed. The lease term may be extended for an additional five-year term at our election.

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

### **Employees**

As of April 2, 2015, we had a total of 24 full-time employees. Of these, 18 are engaged in full-time research and development activities. All of our employees are located in Canton, Massachusetts. None of our employees are represented by a labor organization or under any collective-bargaining arrangements. We consider our employee relations to be good.

**MANAGEMENT****Executive Officers and Directors**

The following table provides information regarding our executive officers and directors:

<b>Name</b>	<b>Age</b>	<b>Position(s)</b>
<i>Executive Officers:</i>		
Michael T. Heffernan, R.Ph.	50	Chairman, President and Chief Executive Officer
Paul Brannelly	42	Executive Vice President and Chief Financial Officer
Barry S. Duke	56	Executive Vice President and Chief Commercial Officer
Ernest A. Kopecky, Ph.D.	48	Vice President, Clinical Development and Head of Neuroscience
Douglas R. Carlson	36	Vice President, Corporate Development
Alison B. Fleming, Ph.D.	40	Vice President, Product Development
Said Saim, Ph.D.	57	Vice President, Pharmaceutical Development
<i>Non-Employee Directors:</i>		
Garen G. Bohlin	67	Director
John G. Freund, M.D.	61	Director
Patrick Heron	44	Director
David Hirsch, M.D., Ph.D.	44	Director
Eran Nadav, Ph.D.	45	Director
Gino Santini	58	Director

**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. 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., or PhyMatrix, 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. Since 2012, Mr. Heffernan has served on the board of directors of Ocata Therapeutics, Inc. (NASDAQ: OCAT) and currently serves as its Chairman. He also serves on the board of directors of Veloxis Pharmaceuticals A/S (CPH: VELO) (March 2015 to present). Mr. Heffernan previously served on the board of directors of Cornerstone Therapeutics Inc. (now known as Chiesi USA, Inc.) (NASDAQ: CRTX) and two privately held companies. Mr. Heffernan graduated from the University of Connecticut with a B.S. in Pharmacy in 1987 and is a Registered Pharmacist.

We believe that Mr. Heffernan's perspective and experience as a senior executive in the pharmaceutical industry, as well as the depth of his operations and board experience, provide him with the qualifications and skills to serve as a director.

**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), or Karyopharm, 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), or Verastem, 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., or Sirtris, 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, most recently as Vice President, Finance and Treasurer, where he led Zalucus through the initial public offering process. Mr. Brannelly graduated from the University of Massachusetts at Amherst with a B.B.A. in Accounting in 1995.

**Barry S. Duke, Executive Vice President and Chief Commercial Officer.** Mr. Duke has served as our Executive Vice President and Chief Commercial Officer since March 2015. Prior to joining us, Mr. Duke was Vice President of Sales and Marketing — U.S. Biosurgery at Sanofi, Inc. (formerly Genzyme Corporation), or Sanofi, from October 2011 to September 2014. From September 2014 to March 2015, Mr. Duke served as a sales and marketing consulting in the biopharmaceutical industry. Mr. Duke joined Sanofi in March 2005 as an area sales director and was promoted to Vice President of Sales — U.S. Biosurgery in November 2007, a position he held until September 2011, when he was promoted to Vice President of Sales and Marketing — U.S. Biosurgery. Prior to Sanofi, Mr. Duke was Senior Director of National Sales at Enzon Pharmaceuticals, Inc. (NASDAQ: ENZN), or Enzon, from November 2002 to March 2005. Prior to Enzon, Mr. Duke was Regional Sales Director at Élan Corporation, plc (now known as Élan Corporation Ltd) from March 2001 to November 2002. Over the course of his career, Mr. Duke has also held various sales positions at The Liposome Company, Inc., Astra USA, Inc., Centocor, Inc. and The Upjohn Company. Mr. Duke graduated from University of Virginia with a B.A. in Biology in 1981.

**Ernest A. Kopecky, Ph.D., Vice President, Clinical Development and Head of Neuroscience.** Dr. Kopecky has served as our Vice President, Clinical Development and Head of the Neuroscience Therapeutic Area since June 2012. Prior to joining us, Dr. Kopecky served as Senior Director of Clinical Research and Head of the Pain and Neuroscience Therapeutic Area at Endo Pharmaceuticals Holdings Inc., or Endo, from 2006 to June 2012. Prior to joining Endo, Dr. Kopecky held several positions in the pharmaceutical industry, including Global Medical Director at Bayer HealthCare AG, Senior Clinical Research Scientist at Purdue Pharma L.P., and Manager of the Clinical Drug Development Unit at SCIREX Corporation. He also held the academic title of Research Fellow at the Hospital for Sick Children, Division of Clinical Pharmacology and Toxicology, Toronto, Canada. Dr. Kopecky has served as a member of the IMMPACT Steering Committee and the FDA ACTION Executive Committee, Subteam Lead on the PhRMA Neonatal and Pediatric LDKITs, and Faculty at the Pharmaceutical Education Research Institute. Dr. Kopecky graduated from the University of Toronto with a B.S. in Human Biology in 1991, a Ph.D. in Pediatric Clinical Pharmacology in 1999 and an M.S. in Clinical Pharmacology in 2005. He also received an M.B.A. from the University of Connecticut in 2005.

**Douglas R. Carlson, Vice President, Corporate Development.** Mr. Carlson has served as our Vice President, Business Development since March 2013, and in January 2014, Mr. Carlson assumed responsibility for Corporate and Business Development. Mr. Carlson has a multi-disciplinary background in M&A, venture capital, corporate finance and business development with both large and emerging growth healthcare companies. Prior to joining us, Mr. Carlson was Senior Director of Business Development at BTG International Inc., or BTG, where he was responsible for global specialty pharmaceutical M&A and licensing from August 2011 to March 2013. Prior to BTG, Mr. Carlson was Senior Director and Head of Business



Development for Lundbeck Inc., or Lundbeck, the U.S. Headquarters of H. Lundbeck A/S, from December 2009 to August 2011. Prior to Lundbeck, Mr. Carlson was Director of Corporate Development and M&A at Ovation Pharmaceuticals, Inc., or Ovation where he played an integral role in the sale of Ovation to H. Lundbeck A/S in 2009. Prior to Ovation, Mr. Carlson was an Associate in the healthcare group at Pequot Ventures, the venture capital arm of Pequot Capital Management, Inc. Mr. Carlson began his career in the healthcare investing banking group of SG Cowen & Co. Mr. Carlson graduated from Trinity College in Hartford, CT with a B.A. in American Studies in 2001.

**Alison B. Fleming, Ph.D., Vice President, Product Development.** Dr. Fleming has served as our Vice President, Product Development and has led our development team 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.

**Said Saim, Ph.D., Vice President, Pharmaceutical Development.** Dr. Saim has served as our Vice President, Pharmaceutical Development since April 2012. Dr. Saim joined us in August 2008 as a Senior Director of Pharmaceutical Development, a position he held until April 2012. Prior to joining us, Dr. Saim was a Senior Principal Scientist at Boehringer Ingelheim Pharmaceuticals, Inc. or BIPI, where he led a team of engineers and scientists in charge of process development, scale up and technology transfer of North American products. Prior to BIPI, Dr. Saim was an Assistant Research Professor at the Higuchi BioSciences Center for Drug Delivery Research in Lawrence, Kansas. Dr. Saim graduated from the National Polytechnic School, Algeria with a B.S. in Chemical Engineering in 1983 and received an M.S. and Ph.D. in Chemical Engineering from the University of Kansas in 1987 and 1990, respectively.

#### Non-Employee Directors

**Garen G. Bohlin, Director.** Mr. Bohlin has served as a member of our board of directors since January 2015. Mr. Bohlin has almost thirty years' experience serving in executive roles at several biotechnology companies, including Constellation Pharmaceuticals, Inc., where he served as an Executive Vice President from January 2010 to his retirement in May 2012. Prior to that, Mr. Bohlin served as Chief Operating Officer at Sirtris Pharmaceuticals, Inc., or Sirtris, which was acquired by GlaxoSmithKline plc. Prior to joining Sirtris, Mr. Bohlin served as President and Chief Executive Officer of Syntonix Pharmaceuticals, Inc., or Syntonix, which was acquired by Biogen Idec in 2006. Mr. Bohlin spent 14 years in executive management at Genetics Institute, Inc., or Genetics Institute, which was acquired by Wyeth. Prior to Mr. Bohlin's tenure at Genetics Institute, he was a partner at Arthur Andersen & Co., where he spent 13 years.

Since his retirement, Mr. Bohlin has served on the boards of directors of several companies. Mr. Bohlin currently serves on the board of directors of Tetrphase Pharmaceuticals, Inc. (NASDAQ: TTPH) (2010 to Present), Karyopharm Therapeutics, Inc. (NASDAQ GS: KPTI) (2013 to Present), and Proteon Therapeutics, Inc. (NASDAQ: PRTO) (2014 to Present). Previously, he served on the board of directors of Acusphere, Inc. (OTC: ACUS) (2005 to 2015) and two other privately held companies. Mr. Bohlin graduated from the University of Illinois with a B.S. in Accounting and Finance in 1970.

We believe that Mr. Bohlin's perspective and experience as a senior executive in our industry, as well as his board and audit committee experience with publicly traded and privately held biotechnology companies, provide him with the qualifications and skills to serve as a director.

**John G. Freund, M.D., Director.** Dr. Freund has served as a member of our board of directors since February 2014. Dr. Freund co-founded Skyline Management LLC, or Skyline, in 1997 and has served as



Managing Director at Skyline since its founding. Prior to joining Skyline, Dr. Freund served as Managing Director in the private equity group of Chancellor Capital Management, LLC. In 1995, Dr. Freund co-founded Intuitive Surgical, Inc. and served on its board of directors until 2000. From 1988 to 1994, Dr. Freund served in various positions at Acuson Corporation, or Acuson, most recently as Executive Vice President. Prior to joining Acuson, Dr. Freund was a General Partner of Morgan Stanley Venture Partners from 1987 to 1988. From 1982 to 1988, Dr. Freund was a general partner at Morgan Stanley & Co., where he co-founded the Healthcare Group in the Corporate Finance Department in 1983.

Dr. Freund currently serves on the board of directors of XenoPort, Inc. (NASDAQ: XNOT) (1999 to Present), Tetrphase Pharmaceuticals, Inc. (NASDAQ: TTPH) (2012 to Present), Concert Pharmaceuticals, Inc. (NASDAQ: CNCE) (2014 to Present) and Proteon Therapeutics, Inc. (NASDAQ GS: PRTO) (2014 to Present). Dr. Freund also serves on the board of directors of two privately held companies and three U.S. registered investment funds managed by The Capital Group Companies. He also previously served on the board of directors of several publicly traded companies: Hansen Medical Inc. (NASDAQ: HNSN) (2002 to 2010), MAP Pharmaceuticals, Inc. (NASDAQ: MAPP) (2004 to 2011), and MAKO Surgical Corp. (NASDAQ: MAKO) (2008 to 2013). Dr. Freund is a member of the Advisory Board for the Harvard Business School Healthcare Initiative, and is a member of the Therapeutics Advisory Council of Harvard Medical School. Dr. Freund graduated from Harvard College with a B.A. in History in 1976 and received an M.D. from Harvard Medical School in 1980 and an M.B.A. from Harvard Business School in 1982.

We believe that Dr. Freund's extensive finance and investment experience, his experience as an executive, and his service on the board of directors of numerous public and privately held companies in our industry provide him with the qualifications and skills to serve as a director.

**Patrick Heron, Director.** Mr. Heron has served as a member of our board of directors since September 2008. Mr. Heron is a General Partner of Frazier Management, LLC, or Frazier, a position he has held since September 1999. Mr. Heron has been active in company formations and initial investments in various biotechnology companies, including Marcadia Biotech Inc., Calixa Therapeutics, Inc. and VentiRx Pharmaceuticals, Inc. Mr. Heron also led Frazier's involvement in MedPointe Inc. Prior to joining Frazier, Mr. Heron helped develop McKinsey & Co.'s west coast biotechnology consulting practice. His projects included mergers and acquisitions, product launch, sales force optimization, corporate partnering and research prioritization. Mr. Heron graduated from the University of North Carolina at Chapel Hill with a B.A. in Political Science in 1992 and received an M.B.A. from Harvard Business School in 1996.

We believe that Mr. Heron's extensive business experience and his experience in venture capital and the life science industry provide him with the qualifications and skills to serve as a director.

**David Hirsch, M.D., Ph.D., Director.** Dr. Hirsch has served as a member of our board of directors since February 2012. Since 2007, Dr. Hirsch has served as a Founder and Managing Director at Longitude Capital Management Co., LLC, or Longitude, where he focuses on investments in biotechnology. From 2005 to 2006, Dr. Hirsch was Vice President of Pequot Capital Management, or Pequot, where he worked in the life sciences practice. Prior to Pequot, Dr. Hirsch was an Engagement Manager in the pharmaceutical practice of McKinsey & Co. While at McKinsey & Co., he worked with many large pharmaceutical companies across a range of projects including clinical and commercial strategies, M&A evaluations, portfolio prioritization and managed care strategy.

Dr. Hirsch currently serves on the board of directors of Rapid Micro Biosystems, Inc. and previously served on Civitas Therapeutics, Inc. and Precision Therapeutics, Inc. Dr. Hirsch graduated from Johns Hopkins University with a B.S. in Biology in 1991 and, in 2001, received an M.D. from Harvard Medical School as well as a Ph.D. in Biology from Massachusetts Institute of Technology.

We believe that Dr. Hirsch's perspective and experience as an investor and board member in the life sciences industry, as well as his strong medical and scientific background, provide him with the qualifications and skills to serve as a director.

**Eran Nadav, Ph.D., Director.** Dr. Nadav has served as a member of our board of directors since March 2015. Dr. Nadav is a Partner and Managing Director at TPG Biotech, the life science venture investment arm of TPG, a global private investment firm. Dr. Nadav joined TPG in 2007 with a focus on global pharmaceuticals and biotechnology investments. Prior to TPG, Dr. Nadav served as Business Development Director at Eisai, a pharmaceutical company, from September 2003 to August 2007 and also as a manager at Johnson & Johnson Development Corporation, the venture capital arm of Johnson & Johnson, a healthcare company, from November 1999 until July 2002. Dr. Nadav served on the board of directors of Eden Springs Ltd., a European provider of drinking water solutions for the workplace, from July 2010 until August 2011. Dr. Nadav served on the board of directors of MacroGenics, Inc. (NASDAQ: MGNX) (June 2013 to June 2014). Dr. Nadav currently serves on the board of directors of Ultragenyx Pharmaceutical Inc. (NASDAQ: RARE) (2011 to Present), and has served as the Chairman of the board of directors of Ultragenyx Pharmaceutical Inc. since January 2012. Dr. Nadav received a B.Sc. magna cum laude in Life Sciences, an M.Sc. magna cum laude and Ph.D. in Biochemistry, as well as an M.B.A., from Tel Aviv University.

We believe that Dr. Nadav is qualified to serve on our board of directors due to his experience in the venture capital industry and his years of analyzing development opportunities in the life sciences sector.

**Gino Santini, Director.** Mr. Santini has served as a member of our board of directors since July 2012. Since December 2010, Mr. Santini has been a senior advisor providing financing and business consulting services to venture capital, pharmaceutical and biotechnology companies. Previously, Mr. Santini held various positions at Eli Lilly and Company, or Lilly, from 1983 until his retirement from Lilly in December 2010, most recently as Senior Vice President of Corporate Strategy and Business Development, a position he held since 2007. Mr. Santini also served as a member of Lilly's Executive Committee from January 2004 to his retirement and as President of U.S. Operations. He joined Eli Lilly and Company in 1983 as a financial planning associate in Italy.

Mr. Santini currently serves on the board of directors of Sorin S.p.A., a company traded on the Italian Stock Exchange (2012 to Present), AMAG Pharmaceuticals Inc. (NASDAQ: AMAG) (2012 to Present), Horizon Pharma plc (NASDAQ: HZNP) (2012 to Present) and Vitae Pharmaceuticals, Inc. (NASDAQ GS: VTAE) (2014 to Present), as well as several privately held companies. He graduated from the University of Bologna, Italy with a B.S. in Mechanical Engineering in 1981 and received an M.B.A. from the Simon School of Business at the University of Rochester in 1983.

We believe that Mr. Santini's perspective and experience as a senior executive at Lilly, as well as his extensive domestic and international commercial, corporate strategy, business development and transaction experience, provide him with the qualifications and skills to serve as a director.

## **Board Composition**

Our business and affairs are managed under the direction of our board of directors, which currently consists of seven members.

Upon the closing of this offering, our amended and restated articles of incorporation and amended bylaws will provide that our board of directors will consist of a number of directors to be fixed exclusively by resolution of the board of directors. Under our amended and restated articles of incorporation, our board of directors will be divided into three classes, each serving three-year terms and until each director's successors are duly elected and qualified. The election of the classes will be staggered, such that only approximately one third of our board of directors will be up for election in any given year. Our amended and restated articles of incorporation do not provide for cumulative voting in the election of directors.

## **Role of the Board in Risk Oversight**

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including adopting guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

## **Board Committees**

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Each committee will operate under a charter that has been approved by our board of directors and will be available on our website, [www.collegiumpharma.com](http://www.collegiumpharma.com), under the "Investor Relations" section, upon the effective date of this offering. The information contained in, or that can be accessed through, our website is not part of this prospectus.

### ***Audit Committee***

Our audit committee consists of Messrs. Bohlin, Freund and Nadav, and is chaired by Mr. Bohlin. The primary purpose of our audit committee is to assist the board of directors in the oversight of our accounting and financial reporting processes, the audit and integrity of our financial statements, and the qualifications and independence of our independent auditor and to prepare any reports required of the audit committee under the rules of the SEC. The audit committee has the following responsibilities, among other things, as set forth in the audit committee charter that will be effective upon the closing of this offering:

- § hiring our independent registered public accounting firm and pre-approving the audit and permitted non-audit and tax services to be performed by our independent registered public accounting firm;
- § reviewing and approving the planned scope of the annual audit and the results of the annual audit;
- § reviewing the significant accounting and reporting principles to understand their impact on our financial statements;
- § reviewing quarterly with management its assessment of the effectiveness and adequacy of our internal control structure and procedures for financial reporting and reviewing annually with our independent registered public accounting firm the attestation to and report on the assessment made by management;
- § reviewing with management and our independent registered public accounting firm, as appropriate, our financial reports, earnings announcements and our compliance with legal and regulatory requirements;
- § establishing procedures for the treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters and confidential submissions by our employees of concerns regarding questionable accounting or auditing matters;
- § preparing for adoption by our board of directors a Code of Ethics and periodically reviewing and recommending appropriate changes thereto;
- § reviewing and approving related-party transactions; and
- § reviewing and evaluating, at least annually, our audit committee's charter.

Our audit committee will review related-party transactions for potential conflicts of interests or other improprieties in accordance with our related party transactions policy. See "Certain Relationships and Related Party Transactions — Policies and Procedures for Related Party Transactions."

The financial literacy requirements of the SEC require that each member of our audit committee be able to read and understand fundamental financial statements. In addition, our board of directors has determined that Mr. Bohlin qualifies as an audit committee financial expert, as defined in Item 407(d) (5) of Regulation S-K promulgated under the Securities Act, and has financial sophistication in accordance with the NASDAQ Stock Market Rules.

Both our independent registered public accounting firm and management periodically will meet privately with our audit committee.

### **Compensation Committee**

Our compensation committee consists of Messrs. Heron, Hirsch and Santini, and is chaired by Dr. Hirsch. The primary purpose of our compensation committee is to review the performance and development of our management in achieving corporate goals and objectives and to assure that our executive officers are compensated effectively in a manner consistent with the strategy of our company, competitive practice, sound corporate governance principles and shareholder interests. In carrying out these responsibilities, this committee oversees, reviews and administers all of our compensation, equity and employee benefit plans and programs. The functions of our compensation committee include, among other things:

- § reviewing and approving the corporate goals and objectives relevant to executive compensation, evaluating performance in light of those goals and objectives and setting the compensation for our executive officers;
- § reviewing and recommending the terms of employment agreements and other employment-related arrangements with our executive officers;
- § reviewing and approving our compensation strategy for our employees;
- § overseeing and periodically reviewing the operation of all of our employee benefit plans;
- § reviewing and recommending to our board of directors the compensation of our directors;
- § administering our equity incentive plans and benefit plans and approving the grant of equity awards to our employees and directors under these plans;
- § when required, reviewing and discussing with management our Compensation Discussion and Analysis and recommending to the full board its inclusion in our periodic reports and proxy statement to be filed with the SEC;
- § when required, preparing the report of the compensation committee to be included in our annual proxy statement;
- § engaging compensation consultants or other advisors it deems appropriate to assist with its duties; and
- § reviewing and evaluating, at least annually, our compensation committee's charter.

### **Nominating and Corporate Governance Committee**

Our nominating and corporate governance committee consists of Messrs. Heffernan and Santini, and is chaired by Mr. Santini. The primary purpose of our nominating and corporate governance committee is to assist our board of directors by identifying individuals qualified to become members of our board of directors, recommending a slate of nominees to be proposed by our board of directors to shareholders for election to our board of directors, developing and recommending corporate governance principles and guidelines of our company and monitoring compliance therewith and to recommend directors to serve on the committees of our board of directors. The functions of our nominating and corporate governance committee include, among other things:

- § assisting our board of directors in identifying prospective director nominees and recommending nominees for each annual meeting of shareholders to our board of directors;

- § reviewing developments in corporate governance practices and developing and recommending governance principles applicable to our board of directors;
- § reviewing independence of the board of directors;
- § evaluating and making recommendations as to the size and composition of the board of directors;
- § recommending members for each board committee of our board of directors;
- § determining qualifications for service on our board;
- § developing, as appropriate, a set of corporate governance principles and guidelines, and reviewing and recommending to our board any changes to such guidelines;
- § reviewing the adequacy of our articles of incorporation and bylaws and recommending to our board of directors, as conditions dictate, amendments for consideration by our shareholders; and
- § periodically reviewing and evaluating, at least annually, our nominating and corporate governance committee's charter.

### **Code of Ethics**

Our board of directors has adopted a Code of Ethics, which will be effective upon the closing of this offering, applicable to all of our employees, executive officers and directors. The Code of Ethics will be available on our website at [www.collegiumpharma.com](http://www.collegiumpharma.com) upon the listing of our common stock on NASDAQ. Our board of directors will be responsible for overseeing 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 disclosed on our website. The information contained in, or that can be accessed through, our website is not part of this prospectus.

### **Compensation Committee Interlocks and Insider Participation**

On March 30, 2015, our board of directors appointed Messrs. Heron, Hirsch and Santini to be members of the compensation committee. Each of Messrs. Heron and Hirsch has relationships with us that require disclosure under Item 404 of Regulation S-K under the Exchange Act. See "Certain Relationships and Related Party Transactions" for more information.

No member of our compensation committee has ever been an executive officer or employee of ours. None of our officers currently serves, or has served during the last completed year, on the board of directors, compensation committee or other committee serving an equivalent function, of any other entity that has one or more officers serving as a member of our board of directors or compensation committee.

### **Director Independence**

The NASDAQ Stock Market Rules require that each committee of our board of directors has at least one independent director on the listing date of our common stock, has a majority of independent directors no later than 90 days after such date and be fully independent within one year after such date. The composition of our audit, compensation and nominating and corporate governance committees will satisfy these independence requirements in accordance with the phase-in schedule allowed by the NASDAQ Stock Market Rules.

Our board of directors will observe all applicable criteria for independence established by the NASDAQ Stock Market Rules and other governing laws and applicable regulations. No director will be deemed to be independent unless our board of directors determines that the director has no relationship which would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Our board of directors has determined that each of our directors, with the exception of Michael T. Heffernan, is independent as defined under the corporate governance rules of the NASDAQ Stock Market Rules.

**EXECUTIVE AND DIRECTOR COMPENSATION****Summary Compensation Table**

The following table shows the annual compensation paid to or earned by Michael T. Heffernan, our President and Chief Executive Officer, and Ernest A. Kopecky and Douglas R. Carlson, our two other most highly compensated executive officers (together our "named executive officers"), for the fiscal year ended December 31, 2014:

<b>Name and Principal Position</b>	<b>Year</b>	<b>Salary (\$)</b>	<b>Bonus (\$)</b>	<b>Stock Awards (\$)</b>	<b>Option Awards (\$)<sup>(1)</sup></b>	<b>Non-Equity Incentive Plan Compensation (\$)<sup>(2)</sup></b>	<b>All Other Compensation (\$)<sup>(3)</sup></b>	<b>Total (\$)</b>
Michael T. Heffernan, R.Ph. President and Chief Executive Officer	2014	380,380	—	—	—	130,851	7,570	518,801
Ernest A. Kopecky, Ph.D. Vice President, Clinical Development	2014	288,915	—	—	54,730	78,180	—	421,825
Douglas R. Carlson Vice President, Corporate Development	2014	231,750	15,000 <sup>(4)</sup>	—	67,612	69,641	4,619	388,622

<sup>(1)</sup> The amounts reflect the aggregate grant date fair value of option awards computed in accordance with FASB ASC Topic 718. Assumptions used in the calculation of these amounts are included in Note 11 to our financial statements.

<sup>(2)</sup> Represents annual bonus amounts calculated and paid pursuant to the named executive officers' respective employment agreements. For more information, see "— Non-Equity Incentive Plan Compensation."

<sup>(3)</sup> This amount reflects our contributions to the Company's 401(k) Plan on behalf of each named executive officer.

<sup>(4)</sup> Pursuant to the terms of his employment agreement, Mr. Carlson was paid a supplemental bonus of \$15,000 on April 11, 2014.

**Employment Agreements**

We have employment and other service agreements with all of our named executive officers. The following is a summary of the material terms of each employment agreement. For complete terms, please see the respective employment and service agreements attached as exhibits to the registration statement of which this prospectus forms a part.

*Michael T. Heffernan, R.Ph.*

On June 13, 2012, we entered into an amended and restated employment agreement with Michael T. Heffernan, our President and Chief Executive Officer. The principal terms of Mr. Heffernan's employment agreement are as follows:

- § base salary of \$350,000 per year, subject to annual adjustments (currently \$380,380 per year);
- § annual incentive bonus opportunity in an amount up to 40% of base salary based upon the achievement of certain bonus eligibility criteria; and
- § an award of restricted shares as described below under the heading "— Outstanding Equity Awards at Fiscal Year-End."

Upon a termination of Mr. Heffernan's employment by us without cause or by Mr. Heffernan for good reason, as defined in his employment agreement, prior to a sale of the Company, Mr. Heffernan is eligible to receive (i) continuation of his base salary for twelve months, or the Heffernan Severance Period, (ii) a lump sum payment equal to 40% of his then current base salary, (iii) continuation of his health insurance benefits at our expense for the duration of the Heffernan Severance Period, and (iv) immediate vesting of all unvested restricted stock and stock options awarded to him, subject to his execution of and non-revocation of a general release of claims. Upon a termination of Mr. Heffernan's employment by us without cause or by Mr. Heffernan for good reason within thirteen months following a sale of the Company, Mr. Heffernan is eligible to receive (i) continuation of his base salary for the Heffernan Severance Period and (ii) continuation of his health insurance benefits for the Heffernan Severance Period, subject to his execution of and non-revocation of a general release of claims. Upon a termination of Mr. Heffernan's employment with us due to his death or disability, he will become immediately vested in all unvested restricted stock and stock options awarded to him.

Upon a termination of Mr. Heffernan's employment by us with cause or by Mr. Heffernan without good reason, all compensation and benefits payable to Mr. Heffernan under his employment agreement shall terminate.

Mr. Heffernan is entitled to participate in all of our employee benefit plans, subject to the terms and conditions applicable to such plans. Further, Mr. Heffernan has executed a Noncompetition, Confidentiality and Inventions Agreement which contains customary non-solicitation and non-competition covenants, which covenants remain in effect for one year following any cessation of employment with respect to Mr. Heffernan.

*Ernest A. Kopecky, Ph.D.*

On May 30, 2012, we entered into an employment agreement with Ernest A. Kopecky, our Vice President, Clinical Development. The principal terms of Dr. Kopecky's employment agreement are as follows:

- § base salary of \$275,000 per year, subject to annual adjustments (currently \$288,915 per year);
- § annual incentive bonus opportunity in an amount up to 30% of base salary based upon the achievement of certain bonus eligibility criteria; and
- § stock option awards as described below under the heading "— Outstanding Equity Awards at Fiscal Year-End."

Upon a termination of Dr. Kopecky's employment by us without cause, Dr. Kopecky is eligible to receive continuation of his base salary and continuation of his health insurance benefits at our expense for six months, subject to his execution of and non-revocation of a general release of claims. Upon a termination of Dr. Kopecky's employment by us with cause or Dr. Kopecky's resignation, all compensation and benefits payable to Dr. Kopecky under his employment agreement shall terminate.

Dr. Kopecky is entitled to participate in all of our employee benefit plans, subject to the terms and conditions applicable to such plans. Further, Dr. Kopecky has executed a Confidentiality and Inventions Agreement which contains customary non-solicitation covenants, which covenants remain in effect for two years following any cessation of employment with respect to Dr. Kopecky.

*Douglas R. Carlson*

On March 13, 2013, we entered into an employment agreement with Douglas R. Carlson, our Vice President, Corporate Development. The principal terms of Mr. Carlson's employment agreement are as follows:

- § base salary of \$225,000 per year, subject to annual adjustments (currently \$231,750 per year);
- § annual incentive bonus opportunity in an amount up to 25% of base salary based upon the achievement of certain bonus eligibility criteria;
- § supplemental bonus of \$15,000 after three months of employment with the Company and an additional bonus of \$15,000 after twelve months of employment; and

§ stock option awards as described below under the heading "— Outstanding Equity Awards at Fiscal Year-End."

Upon a termination of Mr. Carlson's employment by us without cause, Mr. Carlson is eligible to receive continuation of his base salary and continuation of his health insurance benefits at our expense for six months, subject to his execution of and non-revocation of a general release of claims. Upon a termination of Mr. Carlson's employment by us with cause or Mr. Carlson's resignation, all compensation and benefits payable to Mr. Carlson under his employment agreement shall terminate.

Mr. Carlson is entitled to participate in all of our employee benefit plans, subject to the terms and conditions applicable to such plans. Further, Mr. Carlson has executed a Confidentiality and Inventions Agreement which contains customary non-solicitation covenants, which covenants remain in effect for two years following any cessation of employment with respect to Mr. Carlson.

#### *Potential Payments Upon a Termination or Change in Control*

Each of our named executive officers is entitled to severance in the event of a termination by the Company without cause or, in Mr. Heffernan's case, a resignation by him for good reason. The details of such severance arrangements are described above in the section titled "— Employment Agreements."

Additionally, certain unvested equity grants awarded to Mr. Heffernan will become fully vested (and exercisable as applicable) in connection with certain termination of employment events. The details of such accelerated vesting are described above in the section titled "— Employment Agreements" and below in the section titled "— Outstanding Equity Awards at Fiscal Year-End."

#### *Non-Equity Incentive Plan Compensation*

For the fiscal year ended December 31, 2014, each of Messrs. Heffernan, Kopecky and Carlson were eligible to earn a cash bonus, of which 70% of such bonuses were determined based on achievement of corporate performance goals and 30% of such bonuses were determined based on achievement of certain individual performance goals. The target amount of the annual bonuses for Messrs. Heffernan, Kopecky and Carlson were 40% of base salary, 30% of base salary and 25% of base salary, respectively. The applicable corporate performance goals were achieved at 86% of target with the applicable individual performance goals for Messrs. Heffernan, Kopecky and Carlson achieved at 86% of target, 100% of target and 200% of target, respectively. Thus, Messrs. Heffernan, Kopecky and Carlson each earned annual bonuses at 86% of target, 90.2% of target and 120.2% of target, respectively. The amounts shown above for each named executive officer in the column titled "—Non-Equity Incentive Plan Compensation" represent the actual annual performance bonuses payable for the fiscal year ended December 31, 2014 to each named executive officer.

#### *Option Awards During Fiscal Year Ended December 31, 2014*

On March 5, 2014, we awarded Messrs. Kopecky and Carlson stock options to purchase 19,299 and 23,841 shares of our common stock, respectively, with an aggregate grant date fair value computed in accordance with FASB ASC Topic 718 equal to \$54,730 and \$67,612, respectively. The options have an exercise price of \$0.28 and are subject to time-based vesting conditions as described below in the section titled "— Outstanding Equity Awards at Fiscal Year-End."

#### **Outstanding Equity Awards at Fiscal Year-End**

The following table provides information regarding equity awards held by each of our named executive officers that were outstanding as of December 31, 2014. Dollar values are based on the independent valuation of our common stock of \$6.07 per share as of December 31, 2014.



Name	Option Awards					Stock Awards	
	Number of Securities Underlying Unexercised Options (#) (Exercisable)	Number of Securities Underlying Unexercised Options (#) (Unexercisable)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)
Michael T. Heffernan, R.Ph. Chief Executive Officer	22,101 7,246 9,673 7,246 <sup>(1)</sup>	— — — 7,246 <sup>(1)</sup>	— — — —	\$ 0.90 \$ 0.90 \$ 3.31 \$ 0.48	10/24/2018 2/26/2020 11/11/2020 01/30/2023	— — — — 6,873 <sup>(2)</sup>	— — — — 41,735
Ernest A. Kopecky, Ph.D. Vice President, Clinical Development	23,400 <sup>(3)</sup> 905 <sup>(4)</sup> 3,618 <sup>(5)</sup>	12,831 <sup>(3)</sup> 906 <sup>(4)</sup> 15,681 <sup>(5)</sup>	— — —	\$ 0.48 \$ 0.48 \$ 0.28	06/13/2022 01/30/2023 03/05/2024	— — —	— — —
Douglas R. Carlson Vice President, Corporate Development	11,096 <sup>(6)</sup> — 3,790 <sup>(8)</sup> —	14,266 <sup>(6)</sup> — 16,427 <sup>(8)</sup> 3,623 <sup>(9)</sup>	— — — —	\$ 0.48 \$ 0.48 \$ 0.28 \$ 0.28	05/30/2023 05/30/2023 03/05/2024 03/05/2024	— — — —	— — — —

(1) A stock option to purchase 28,984 shares of our common stock was granted to Mr. Heffernan on January 24, 2013. The option was adjusted to an option to purchase 14,492 shares of our common stock in connection with the December 4, 2013 reverse stock split. As of December 31, 2014, 7,246 option shares were not exercisable. The option vests and becomes exercisable monthly over the four-year period following the grant date. Pursuant to Mr. Heffernan's employment agreement, the option will immediately become fully vested and exercisable upon a termination of Mr. Heffernan's employment without cause or due to Mr. Heffernan's death or disability, or upon a resignation by Mr. Heffernan for good reason.

(2) Mr. Heffernan was awarded 247,436 shares of restricted common stock on June 13, 2012. The restricted stock award was adjusted to an award of 123,718 shares of restricted common stock in connection with the December 4, 2013 reverse stock split. The restricted shares vest and become non-forfeitable monthly over the three-year period beginning on February 10, 2012 and became fully vested on February 10, 2015. Pursuant to Mr. Heffernan's employment agreement, the shares will immediately become fully vested upon a termination of Mr. Heffernan's employment without cause or due to Mr. Heffernan's death or disability, or upon a resignation by Mr. Heffernan for good reason. Additionally, pursuant to Mr. Heffernan's employment agreement, the shares will immediately become fully vested upon the occurrence of a "Sale Event" (as defined in the employment agreement).

(3) A stock option to purchase 72,462 shares of our common stock was granted to Dr. Kopecky on June 13, 2012. The option was adjusted to an option to purchase 36,231 shares of our common stock in connection with the December 4, 2013 reverse stock split. As of December 31, 2014, 12,831 of the option shares were not exercisable. The option vests and becomes exercisable over the four-year period following the grant date, with 25% of the option vesting and becoming exercisable on the first anniversary of Dr. Kopecky's date of hire and 1/48th of the option vesting and becoming exercisable at the end of each monthly period thereafter.

(4) A stock option to purchase 3,622 shares of our common stock was granted to Dr. Kopecky on January 24, 2013. The option was adjusted to an option to purchase 1,811 shares of our common stock in connection with the December 4, 2013 reverse stock split. As of December 31, 2014, 905 option shares were not exercisable. The option vests and becomes exercisable monthly over the four-year period following the grant date.

(5) A stock option to purchase 19,299 shares of our common stock was granted to Dr. Kopecky on March 5, 2014. As of December 31, 2014, 15,681 of the option shares were not exercisable. The option vests and becomes exercisable as to 1/48th of the option of the original number of option shares at the end of each monthly period following the grant date until the fourth anniversary of the grant date.

(6) A stock option to purchase 50,724 shares of our common stock was granted to Mr. Carlson on May 30, 2013. The option was adjusted to an option to purchase 25,362 shares of our common stock in connection with the December 4, 2013 reverse stock split. As of December 31, 2014, 14,266 option shares were not exercisable. The option vests and becomes exercisable over the four-year period following the grant date, with 25% of the option vesting and becoming exercisable on April 3, 2014, and 1/48<sup>th</sup> of the option vesting and becoming exercisable monthly thereafter.

(7) A stock option to purchase 28,984 shares of our common stock was granted to Mr. Carlson on May 30, 2013. The option was adjusted to an option to purchase 14,492 shares of our common stock in connection with the December 4, 2013 reverse stock split. The option vests and becomes exercisable upon the closing of a Sale Event (as defined in the employment agreement) or a strategic partnership with a third party relating to the development, manufacturing, sale and/or distribution of one or more of our products that occurs before April 3, 2017. If the total consideration received from such strategic partnership exceeds \$200 million but is less than \$300 million, then 50% of the option will vest. If the total consideration from the strategic partnership exceeds \$300 million, then 100% of the option will vest.

(8) A stock option to purchase 20,218 shares of our common stock was granted to Mr. Carlson on March 5, 2014. As of December 31, 2014, 16,427 of the option shares were not exercisable. The option vests and becomes exercisable as to 1/48th of the option of the original number of option shares at the end of each monthly period following the grant date until the fourth anniversary of the grant date.

(9) A stock option to purchase 3,623 shares of our common stock was granted to Mr. Carlson on March 5, 2014. As of December 31, 2014, 100% of the option shares were not exercisable. The option vests and becomes exercisable over the four-year period commencing on the grant date, with 25% of the option shares becoming vested on the first anniversary of the grant date and the balance of the option shares vesting in monthly installments over the remaining three years of the vesting term.

## Equity Incentive Plans

### ***Amended and Restated 2014 Stock Incentive Plan***

All of our outstanding equity awards are governed by the Collegium Pharmaceutical, Inc. Amended and Restated 2014 Stock Incentive Plan, or the Plan. We adopted the Plan, as amended and restated, on April 23, 2015, and it will become effective immediately prior to the closing of this offering. The Plan was adopted to enhance our ability to attract, retain and motivate persons who make important contributions to us and by providing such persons with equity ownership opportunities and performance-based incentives that are intended to better align the interests of such persons with those of our shareholders. The material terms of the Plan are described below.

The Plan permits the grant of (i) options, (ii) restricted stock awards, (iii) restricted stock units, or RSUs and (iv) performance awards, which we refer to collectively as Awards, as more fully described below.

Prior to this offering, options to purchase common stock and awards of restricted stock were granted to various participants under the Plan.

All Awards granted under the Plan are governed by award agreements, between us and the participants. No Awards may be granted after the tenth anniversary of the Plan's adoption by our shareholders, although Awards granted before that time will remain valid in accordance with their terms.

The compensation committee of our board of directors will administer the Plan. The compensation committee will designate each eligible individual to whom an Award is to be granted. Any of our employees, consultants, officers or other service providers, or those of our affiliates, are eligible to participate in the Plan if selected by the compensation committee. In its discretion, the compensation committee may delegate all or part of its authority and duties with respect to granting Awards to one or more individuals, provided applicable law so permits.

Subject to certain adjustments, the maximum number of shares of common stock that may be issued under the Plan in connection with Awards is (i) 2,700,000 shares (inclusive of shares subject to Awards issued under the Plan prior to its restatement that remain outstanding as of the effective date of the Plan), plus (ii) an annual increase to be added on the first day of each fiscal year beginning with the fiscal year ending December 31, 2016, and on each anniversary thereof until the expiration of the Plan equal to 4% of the outstanding shares of our common stock on December 31<sup>st</sup> of the immediately preceding fiscal year (or such lesser number of shares of common stock as determined by the board of directors). In the event of any stock dividend, recapitalization, forward stock split or reverse stock split, reorganization, division, merger, consolidation, spin-off, combination, repurchase or share exchange, extraordinary or unusual cash distribution or other similar corporate transaction or event that affects our common stock, the compensation committee shall make appropriate adjustment in the number and kind of shares authorized by the Plan and covered under outstanding Awards as it determines appropriate and equitable. Shares of our common stock subject to Awards under the Plan that expire unexercised or are otherwise forfeited shall again be available for Awards under the Plan (as amended and restated).

An option entitles the holder to purchase from us a stated number of shares of common stock. An incentive stock option, or ISO, may only be granted to an employee of ours or our affiliates (provided applicable law so permits). The aggregate maximum number of shares that may be issued pursuant to the exercise of ISOs will be 8,100,000 shares. The compensation committee will specify the number of shares of common stock subject to each option and the exercise price for such option, provided that the exercise price may not be less than the fair market value of a share of common stock on the date the option is granted. Notwithstanding the foregoing, if ISOs are granted to any 10% shareholder, the exercise price shall not be less than 110% of the fair market value of common stock on the date the option is granted. Generally, all or part of the exercise price may be paid (i) in cash, (ii) with the proceeds received from a broker-dealer whom the holder has authorized to sell all or a portion of the common stock covered by the option, (iii) with the consent of the compensation committee, in whole or in part in common stock held by the holder and valued at fair market value on the date of exercise, or (iv) by any combination of such methods. The

compensation committee may, in its sole discretion, permit payment of the exercise price of an option in the form of previously acquired shares based on the fair market value of the shares on the date the option is exercised or through means of "net settlement."

All options shall be exercisable in accordance with the terms of the applicable award agreement. The maximum term of an option shall be determined by the compensation committee on the date of grant but shall not exceed 10 years (5 years in the case of ISOs granted to any 10% shareholder). In the case of ISOs, the aggregate fair market value (determined as of the date of grant) of common stock with respect to which such ISOs become exercisable for the first time during any calendar year cannot exceed \$100,000. ISOs granted in excess of this limitation will be treated as NQOs.

Unless otherwise provided in an award agreement, if a participant terminates employment with us (or our affiliates) due to death or disability, the participant's unexercised options may be exercised, to the extent they were exercisable on the termination date, for a period of twelve months from the termination date or until the expiration of the original option term, if shorter. If the participant terminates employment with us (or our affiliates) for cause (as defined in the Plan), all unexercised options (whether vested or unvested) shall terminate and be forfeited on the termination date. If the participant's employment terminates for any other reason, any vested but unexercised options may be exercised by the participant, to the extent exercisable at the time of termination, for a period of ninety days from the termination date (or such time as specified by the compensation committee at the time of grant) or until the expiration of the original option term, whichever period is shorter. Unless otherwise provided by the compensation committee, any options that are not exercisable at the time of termination of employment shall terminate and be forfeited on the termination date.

A restricted stock award is a grant of shares of common stock, which may or may not be subject to forfeiture restrictions during a restriction period. The compensation committee will determine the price, if any, to be paid by the participant for each share of common stock subject to a restricted stock award. The compensation committee may condition the expiration of the restriction period, if any, upon: (i) the participant's continued service over a period of time with us or our affiliates; (ii) the achievement by the participant, us or our affiliates of any other performance goals set by the compensation committee; or (iii) any combination of the above conditions as specified in the award agreement. If the specified conditions are not attained, the participant will forfeit the portion of the restricted stock award with respect to which those conditions are not attained, and the underlying common stock will be forfeited to us. At the end of the restriction period, if the conditions, if any, have been satisfied, the restrictions imposed will lapse with respect to the applicable number of shares. During the restriction period, a participant will have the right to vote the shares underlying the restricted stock, however, unless otherwise provided by the compensation committee, all dividends will remain subject to restriction until the stock with respect to which the dividend was issued lapses. The compensation committee may, in its discretion, accelerate the vesting and delivery of shares of restricted stock.

RSUs are granted in reference to a specified number of shares of common stock and entitle the holder to receive, on achievement of specific performance goals established by the compensation committee, after a period of continued service or any combination of the above as set forth in the applicable award agreement, one share of common stock for each such share of common stock covered by the RSU. The compensation committee may, in its discretion, accelerate the vesting of RSUs.

The compensation committee may grant performance awards in accordance with the Plan. Performance awards may be denominated as a number of shares or specified number of other Awards (such as restricted stock or RSUs), which may be earned upon achievement or satisfaction of such performance goals as may be specified by the compensation committee. Performance goals may be linked to a variety of factors including the participant's completion of a specified period of employment or service with us or an affiliated company. Additionally, performance goals can include objectives stated with respect to us, an affiliated company or a business unit and are limited to one or more of the following: (i) specified levels of or increases in pre-tax earnings, return on capital, equity measures/ratios (on a gross, net, pre-tax or post tax

basis), including basic earnings per share, diluted earnings per share, total earnings (including total earnings as adjusted by the compensation committee at the time of the Award), operating earnings, earnings growth, earnings before interest and taxes, or EBIT, and earnings before interest, taxes, depreciation and amortization, or EBITDA (including EBIT or EBITDA as adjusted by the Committee at the time of the Award); (ii) total sales or sales growth; (iii) gross margin; (iv) customer service levels; (v) employee recruiting and development; (vi) advertising effectiveness; (vii) development of new markets; (viii) financial ratios; (ix) strategic initiatives; (x) improvement in or attainment of operating expense levels; (xi) improvement in or attainment of capital expense levels; (xii) the attainment of certain target levels of, or a specified increase in, operational cash flow; (xiii) the achievement of a certain level of, reduction of, or other specified objectives with regard to limiting the level of increase in, all or a portion of, our bank debt or other long-term or short-term public or private debt or other similar financial obligations of ours, which may be calculated net of such cash balances and/or other specified offsets; (xiv) appreciation in and/or maintenance of certain target levels in the fair market value; (xv) the attainment of a certain level of, reduction of, or other specified objectives with regard to limiting the level of or rate of increase in all or a portion of specified expenses (xvi) individual objectives; and (xvii) any combination of the foregoing.

The compensation committee may impose restrictions on the grant, exercise or payment of an Award as it determines appropriate. Generally, Awards granted under the Plan shall be nontransferable except by will or by the laws of descent and distribution. No participant shall have any rights as a shareholder with respect to shares covered by options or RSUs, unless and until such Awards are settled in shares of common stock.

No option shall be exercisable, no shares of common stock shall be issued, no certificates for shares of common stock shall be delivered and no payment shall be made under the Plan except in compliance with all applicable laws.

The board of directors may amend, suspend or terminate the Plan and the compensation committee may amend any outstanding Award at any time; provided, however, that no such amendment or termination may adversely affect Awards then outstanding without the holder's permission.

In the event of a change in control (as defined in the Plan), the compensation committee may, on a participant-by-participant basis: (i) cause any or all outstanding Awards to become vested and immediately exercisable (as applicable), in whole or in part; (ii) cause any outstanding option to become fully vested and immediately exercisable for a reasonable period in advance of the change in control and, to the extent not exercised prior to that change in control, cancel that option upon closing of the change in control; (iii) cancel any unvested Award or unvested portion thereof, with or without consideration; (iv) cancel any Award in exchange for a substitute award; (v) redeem any restricted stock or RSU for cash and/or other substitute consideration with value equal to fair market value of an unrestricted share on the date of the change in control; (vi) cancel any outstanding options with respect to all common stock for which the Award remains unexercised for a cash payment equal to the excess (if any) of the fair market value of the shares subject to the option over the exercise price of the option; (vii) take such other action as the compensation committee shall determine to be reasonable under the circumstances; and/or (viii) in the case of any Award subject to Section 409A of the Code, such Award shall vest and be distributed only in accordance with the terms of the applicable award agreement and the compensation committee shall only be permitted to use discretion to the extent that such discretion would be permitted under Section 409A of the Code.

Neither the board of directors nor the compensation committee may, without obtaining prior approval of our shareholders: (i) implement any cancellation/re-grant program pursuant to which outstanding options under the Plan are cancelled and new options are granted in replacement with a lower exercise per share, (ii) cancel outstanding options under the Plan with an exercise price per share in excess of the then current fair market value per share for consideration payable in our equity securities or (iii) otherwise directly reduce the exercise price in effect for outstanding options under the Plan.

### **2015 Employee Stock Purchase Plan**

On April 23, 2015, we adopted the 2015 Employee Stock Purchase Plan, or the 2015 ESPP, which shall be effective immediately prior to the closing of this offering. The 2015 ESPP will be administered by our board of directors or by a committee appointed by our board of directors. The 2015 ESPP will initially provide participating employees with the opportunity to purchase an aggregate of 200,000 shares of our common stock. The number of shares of our common stock reserved for issuance under the 2015 ESPP will automatically increase on the first day of each fiscal year, commencing on January 1, 2016 and ending on December 31, 2025, in an amount equal to the least of (i) 400,000 shares of our common stock, (ii) 1.0% of the total number of shares of our common stock outstanding on the first day of the applicable year, and (iii) an amount determined by our board of directors.

All of our employees are eligible to participate in the 2015 ESPP, provided that:

- § such person is customarily employed by us for more than 20 hours a week and for more than five months in a calendar year;
- § such person has been employed by us or by a designated subsidiary for at least 21 days prior to enrolling in the 2015 ESPP; and
- § such person was our employee on the first day of the applicable offering period under the 2015 ESPP.

No employee may purchase shares of our common stock under the 2015 ESPP and any of our other employee stock purchase plans in excess of \$25,000 of the fair market value of our common stock (as of the date of the option grant) in any calendar year. In addition, no employee may purchase shares of our common stock under the 2015 ESPP that would result in the employee owning 5% or more of the total combined voting power or value of our stock.

We expect to make one or more offerings to our eligible employees to purchase stock under the 2015 ESPP beginning at such time as our board of directors may determine. Each offering will consist of a six-month offering period during which payroll deductions will be made and held for the purchase of our common stock at the end of the offering period. Our board of directors may, at its discretion, choose a different period of not more than 12 months for offerings.

On the commencement date of each offering period, each eligible employee may authorize up to a maximum of 15% of his or her compensation to be deducted by us during the offering period. Each employee who continues to be a participant in the 2015 ESPP on the last business day of the offering period will be deemed to have exercised an option to purchase from us the number of whole shares of our common stock that his or her accumulated payroll deductions on such date will pay for, not in excess of the maximum numbers set forth above. Under the terms of the 2015 ESPP, the purchase price shall be determined by our board of directors or compensation committee for each offering period and will be at least 85% of the applicable closing price of our common stock. If our board of directors does not make a determination of the purchase price, the purchase price will be 85% of the lesser of the closing price of our common stock on the first business day of the offering period or on the last business day of the offering period.

An employee may for any reason withdraw from participation in an offering no later than 21 days prior to the end of an offering period and permanently draw out the balance accumulated in the employee's account. If an employee elects to discontinue his or her payroll deductions during an offering period but does not elect to withdraw his or her funds, funds previously deducted will be applied to the purchase of common stock at the end of the offering period. If a participating employee's employment ends before the last business day of an offering period, no additional payroll deductions will be made and the balance in the employee's account will be paid to the employee.

We will be required to make equitable adjustments to the number and class of securities available under the 2015 ESPP, the share limitations under the 2015 ESPP and the purchase price for an offering period

under the 2015 ESPP to reflect stock splits, reverse stock splits, stock dividends, recapitalizations, combinations of shares, reclassifications of shares, spin-offs and other similar changes in capitalization or events or any dividends or distributions to holders of our common stock other than ordinary cash dividends. The number of shares of common stock available for any offerings under the 2015 ESPP shall be adjusted if the number of our outstanding shares is increased or reduced by split up, reclassification, stock dividend or the like.

Our board of directors may at any time, and from time to time, terminate, amend or suspend the 2015 ESPP or any portion thereof. We will obtain shareholder approval for any amendment if such approval is required by Section 423 of the Code. The 2015 ESPP will also terminate upon the occurrence of a change in control (defined with reference to the Plan). Upon termination, we will refund all amounts in the accounts of participating employees.

## **Non-Equity Incentive Compensation**

### ***Performance Bonus Plan***

On April 23, 2015, we adopted the Performance Bonus Plan, which will be effective immediately prior to the closing of the offering. The Performance Bonus Plan will be administered by the compensation committee. The purpose of the Performance Bonus Plan is to benefit and advance our interests, by rewarding selected employees of ours and our affiliates for their contributions to our success and thereby motivate them to continue to make such contributions in the future by granting performance-based awards. The material terms of such plan are summarized below.

*Background.* Our board of directors believes that it is in our best interests and those of our shareholders to enhance our ability to attract and retain qualified personnel through performance based incentives, while at the same time obtaining the highest level of deductibility of compensation paid to employees. Section 162(m) of the Code disallows a deduction to us for any compensation paid to certain executive officers in excess of \$1.0 million per year, subject to certain exceptions. Among other exceptions, the deduction limit does not apply to compensation that meets the specified requirements for "performance-based compensation." In general, those requirements include the establishment of objective performance goals for the payment of such compensation by a committee of the board of directors composed solely of two or more outside directors, shareholder approval of the material terms of such compensation, and certification by the compensation committee that the performance goals for the payment of such compensation have been achieved.

*Administration.* Subject to the other provisions of the Performance Bonus Plan, the compensation committee has the authority to administer and interpret the Performance Bonus Plan, including the authority to select the employees (including employees who are directors) to participate in the Performance Bonus Plan, to establish the performance goals, to determine the amount of incentive compensation bonus payable to any participant, to determine the terms and conditions of any such incentive opportunity; to make all determinations and take all other actions necessary or appropriate for proper administration and operation of the Performance Bonus Plan and to establish and amend rules and regulations relating to the Performance Bonus Plan.

The compensation committee may also delegate to one or more of our executive officers the authority to administer the Performance Bonus Plan with respect to any participants who are not subject to Section 162(m) of the Code.

*Eligibility.* The named executive officers and such other of our employees as selected by the compensation committee are eligible to participate in the Performance Bonus Plan. The maximum amount of the incentive compensation bonuses payable to any participant under the Performance Bonus Plan in, or in respect of, any single fiscal year shall not exceed \$5.0 million. All incentive compensation bonuses paid pursuant to the Performance Bonus Plan will be paid in cash.

*Bonus Opportunity and Performance Goals.* Bonuses may be payable to a participant as a result of the satisfaction of performance goals in respect of any performance period determined by the compensation committee; provided that, to the extent a participant would be subject to Section 162(m) of the Code, the performance goals will be set in accordance with the regulations under Section 162(m) of the Code. Performance goals, which may vary among and between participants, may include objectives stated with respect to us, an affiliated company or a business unit and such objectives are limited to one or more of the following: (i) specified levels of or increases in pre-tax earnings, return on capital, equity measures/ratios (on a gross, net, pre-tax or post tax basis), including basic earnings per share, diluted earnings per share, total earnings (including total earnings as adjusted by the compensation committee at the time of the Award), operating earnings, earnings growth, EBIT and EBITDA (including EBIT or EBITDA as adjusted by the compensation committee at the time of the Award); (ii) total sales or sales growth; (iii) gross margin; (iv) customer service levels; (v) employee recruiting and development; (vi) advertising effectiveness; (vii) development of new markets; (viii) financial ratios; (ix) strategic initiatives; (x) improvement in or attainment of operating expense levels; (xi) improvement in or attainment of capital expense levels; (xii) the attainment of certain target levels of, or a specified increase in, operational cash flow; (xiii) the achievement of a certain level of, reduction of, or other specified objectives with regard to limiting the level of increase in, all or a portion of, the Company's bank debt or other long-term or short-term public or private debt or other similar financial obligations of the Company, which may be calculated net of such cash balances and/or other specified offsets; (xiv) appreciation in and/or maintenance of certain target levels in the fair market value; (xv) the attainment of a certain level of, reduction of, or other specified objectives with regard to limiting the level of or rate of increase in all or a portion of specified expenses (xvi) individual objectives; and (xvii) any combination of the foregoing.

The compensation committee shall provide a threshold level of performance below which no incentive compensation bonus will be paid, as well as a maximum level of performance above which no additional incentive compensation bonus will be paid. It also may provide for the payment of differing amounts for different levels of performance, determined with regard either to a fixed monetary amount or a percentage of the participant's base salary. The compensation committee shall make such adjustments, to the extent it deems appropriate, to established performance goals and performance thresholds to compensate for, or to reflect, any material changes which may have occurred due to an "extraordinary event"; provided, however, that no such adjustment may be made unless such adjustment would be permissible under Section 162(m) of the Code. An "extraordinary event" under the Performance Bonus Plan is defined as follows:

- § material changes in accounting practices, tax laws, other laws or regulations,
- § material changes in our financial structure,
- § an acquisition or disposition of one of our subsidiaries or divisions, or
- § unusual circumstances outside of our management's control which, in the sole judgment of the compensation committee, alters or affects the computation of such established performance goals and performance thresholds, our performance or the performance of a relevant subsidiary or division.

As soon as practicable after the end of each performance period, but before any incentive compensation bonuses are paid to the participants under the Performance Bonus Plan, the compensation committee will certify in writing (i) whether the performance goal(s) were attained and (ii) the amount of the incentive compensation bonus payable to each participant based upon the attainment of such specified performance goals. The compensation committee also may reduce, eliminate, or, with respect only to participants who are not subject to Section 162(m) of the Code, increase the amount of any incentive compensation bonus of any participant at any time prior to payment thereof, based on such criteria as the compensation committee shall determine, including but not limited to individual merit and attainment of, or the failure to attain, specified personal goals established by the compensation committee. Under no circumstances, however, may the compensation committee, with respect solely to a participant who is subject to Section 162(m) of the Code, (i) increase the amount of the incentive compensation otherwise payable to such participant beyond the amount originally established by the compensation committee, (ii) waive the attainment of the performance goals established and applicable to such participant's incentive



compensation or (iii) otherwise exercise its discretion so as to cause any incentive compensation bonus payable to such participant to not qualify as "performance-based compensation" under Section 162(m) of the Code.

All amounts due under the Performance Bonus Plan shall be paid within two and one-half months of the end of the year in which such incentive compensation is no longer subject to a risk of forfeiture. The compensation committee, without the consent of any participant, may amend or terminate the Performance Bonus Plan at any time. However, no amendment that would require the consent of the shareholders pursuant to Section 162(m) of the Code shall be effective without such consent.

### Retirement Benefits

We maintain a section 401(k) retirement plan for all employees after three months of consecutive employment who are 21 years of age or older. Employees can contribute up to 100% of their eligible pay, subject to maximum amounts allowed under law. The Company provides matching and profit sharing contributions under the 401(k) retirement plan. The total amount of Company matching contributions under the 401(k) retirement plan for 2014 was \$35,000.

### Compensation of Non-Employee Directors

The following table sets forth in summary form information concerning the compensation that we paid or awarded during the fiscal year ended December 31, 2014 to our non-employee director. Dollar values are based on the independent valuation of our common stock of \$6.07 per share as of December 31, 2014.

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<u>Name</u>	<u>Fees earned or paid in cash (\$)</u>	<u>Stock awards (\$)</u>	<u>Total (\$)</u>
Gino Santini	40,000	66,000	106,000

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(1) Mr. Santini was awarded 10,869 shares of restricted common stock on March 5, 2014. Of the 10,869 shares of restricted common stock, 5,434 shares were subject to forfeiture until vested. The restricted shares vest and become non-forfeitable as follows: 1,811 of the restricted shares vested on April 1, 2014, and thereafter an additional 1,811 vest at the end of each quarterly period following April 1, 2014. Pursuant to Mr. Santini's restricted stock award agreement, the shares will immediately become fully vested upon the occurrence of a "Sale Event" (as defined in the restricted stock award agreement).

With the exception of Gino Santini, we did not pay compensation or grant any equity awards to any of our other non-employee directors for serving on our board during 2014. The compensation earned by Mr. Heffernan, as President and Chief Executive Officer, for 2014 is included in the "— Summary Compensation Table" and his outstanding stock and option awards are included under "— Outstanding Equity Awards at Fiscal Year-End" above. Other than Mr. Heffernan and Mr. Santini, no other directors held directly any outstanding equity awards as of December 31, 2014. In March 2015, we granted a non-statutory stock option for the purchase of up to 28,985 shares of common stock at an exercise price of \$5.73 per share to Garen Bohlin, one of our non-employee directors for board of director services.

We intend to put in place a formal director compensation policy for all of our non-employee directors following the completion of this offering.



## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2012 to which we have been a party, in which the amount involved in the transaction exceeded \$120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive and Director Compensation."

### Series B Convertible Preferred Stock Financing

In February 2012, we entered into a Series B Convertible Preferred Stock Purchase Agreement, pursuant to which we issued and sold to investors an aggregate of 27,324,237 shares of our Series B Convertible Preferred Stock at a purchase price of \$0.84 per share, for aggregate consideration of \$23.0 million. In connection with the Series B Convertible Preferred Stock financing, all issued and outstanding shares of previously issued Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock, Series C-2 Preferred Stock and Series D-1 Preferred Stock were converted into 18,464,674 shares of Series A Convertible Preferred Stock.

### Series C Convertible Preferred Stock Financing

In August 2013, we entered into a Series C Convertible Preferred Stock Purchase Agreement, or the Series C Purchase Agreement, pursuant to which we issued and sold to investors an aggregate of 2,220,670 shares of our Series C Convertible Preferred Stock at a purchase price of \$1.386 per share, for aggregate consideration of \$3.1 million. In September 2013, at an additional closing pursuant to the Series C Purchase Agreement, we issued and sold to investors an aggregate of 665,334 shares of our Series C Convertible Preferred Stock at a purchase price of \$1.386 per share, for aggregate consideration of \$922,000. In December 2013, those investors who participated in the closings in August and September 2013 exercised their option under the Series C Purchase Agreement to purchase an additional pro rata portion of an aggregate of 5,772,004 shares of our Series C Convertible Preferred Stock at a purchase price of \$1.386 per share, for aggregate consideration of \$8.0 million.

### Series D Convertible Preferred Stock Financing

In March 2015, we entered into a Series D Convertible Preferred Stock Purchase Agreement pursuant to which we issued and sold to investors an aggregate of 41,666,667 shares of our Series D Convertible Preferred Stock at a purchase price of \$1.20 per share, for aggregate consideration of \$50.0 million. This financing was led by TPG Biotechnology Partners IV, L.P., which was joined by RA Capital Management, Adage Capital Management, Rock Springs Capital, EcoR1 Capital, Eventide Asset Management and Aperture Venture Partners. Entities affiliated with Longitude Capital Partners, LLC, Skyline Ventures Partners V, L.P., Frazier Healthcare VI, L.P. and Boston Millennia Partners also participated in the financing. In connection with the Series D Convertible Preferred Stock financing, convertible notes with related parties in the aggregate principal amount of \$5 million automatically converted to an aggregate of 4,166,667 shares of Series D Convertible Preferred Stock.

All outstanding convertible preferred stock will be converted into common stock upon the closing of this offering.

The participants in the convertible preferred stock financings described above included the following directors, executive officers and/or holders of more than 5% of our capital stock or entities affiliated with them. The following table presents the number of shares issued to these related parties in these financings:

Participants <sup>(1)</sup>	Shares of Series A Convertible Preferred Stock	Series A Convertible Preferred Stock Aggregate Purchase Price	Shares of Series B Convertible Preferred Stock	Series B Convertible Preferred Stock Aggregate Purchase Price	Shares of Series C Convertible Preferred Stock	Series C Convertible Preferred Stock Aggregate Purchase Price	Shares of Series D Convertible Preferred Stock	Series D Convertible Preferred Stock Aggregate Purchase Price
<b>5% or greater shareholders</b>								
Entities affiliated with Boston Millennia Partners <sup>(2)</sup>	4,881,801 <sup>(8)</sup>	\$ 5,988,017	1,862,481	\$ 1,564,484	—	\$ —	712,357	\$ 854,828
Frazier Healthcare VI, L.P. <sup>(3)</sup>	4,019,183 <sup>(8)</sup>	\$ 4,929,930	1,533,399	\$ 1,288,055	2,705,585	\$ 3,749,941	3,676,078	\$ 4,411,294
Entities affiliated with Longitude Capital Partners, LLC <sup>(4)</sup>	—	\$ —	13,095,238	\$ 11,000,000	3,224,261	\$ 4,468,826	5,146,509	\$ 6,175,811
Skyline Venture Partners V, L.P. <sup>(5)</sup>	—	\$ —	10,714,286	\$ 9,000,000	2,638,030	\$ 3,656,310	5,881,724	\$ 7,058,068
TPG Biotechnology Partners IV, L.P. <sup>(6)</sup>	—	—	—	—	—	—	8,333,333	\$ 10,000,000
RA Capital Healthcare Fund, LP <sup>(7)</sup>	—	—	—	—	—	—	5,833,333	\$ 7,000,000

<sup>(1)</sup> Additional details regarding these shareholders and their equity holdings are provided in "Principal Shareholders."

<sup>(2)</sup> Represents shares held, in the aggregate, by Boston Millennia Partners II Limited Partnership, Boston Millennia Partners II-A Limited Partnership, Boston Millennia Partners GmbH and Co. KG ("BMP KG"), Boston Millennia Associates II Partnership, and Strategic Advisors Fund Limited Partnership, or collectively, the Boston Millennia Funds. Robert Jevon, a former member of our board of directors, is an affiliate of Glen Partners II Limited Partnership, which is the special limited partner of BMP KG, and the general partner of the other Boston Millennia Funds.

<sup>(3)</sup> The general partner of Frazier Healthcare VI, L.P. is a limited partnership, the general partner of which is FHM VI, LLC. Patrick Heron, a member of our board of directors, is a member of FHM VI, LLC.

<sup>(4)</sup> Represents shares held, in the aggregate, by Longitude Venture Partners, L.P. and Longitude Capital Associates, L.P. or, collectively, the Longitude Funds. Longitude Capital Partners, LLC is the general partner of the Longitude Funds. David Hirsch, a member of our board of directors, is a member of Longitude Capital Partners, LLC.

<sup>(5)</sup> The general partner of Skyline Venture Partners V, L.P. is Skyline Venture Management V, LLC. John G. Freund, a member of our board of directors, is a manager of Skyline Venture Management V, LLC.

<sup>(6)</sup> The general partner of TPG Biotechnology Partners IV, L.P. is TPG Biotechnology GenPar IV, L.P., a Delaware limited partnership, whose general partner is TPG Biotechnology GenPar IV Advisors, LLC, a Delaware limited liability company, whose sole member is TPG Holdings I, L.P., a Delaware limited partnership, whose general partner is TPG Holdings I-A, LLC, a Delaware limited liability company, whose sole member is TPG Group Holdings (SBS), L.P., a Delaware limited partnership, whose general partner is TPG Group Holdings (SBS) Advisors, Inc., or Group Advisors, a Delaware corporation. Messrs. David Bonderman and James G. Coulter are officers and sole shareholders of Group Advisors and may therefore be deemed to be the beneficial owners of the shares held by TPG Biotechnology Partners IV, L.P. Each of Messrs. Bonderman and Coulter expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein. The address for Messrs. Bonderman and Coulter and TPG Biotechnology Partners IV, L.P. is c/o TPG Global, LLC, 301 Commerce Street, Suite 3300, Fort Worth, TX 76102.

<sup>(7)</sup> The investment adviser and sole general partner of RA Capital Healthcare Fund, LP is RA Capital Management, LLC. Peter Kolchinsky is the sole managing member of RA Capital Management, LLC and has the power to vote or dispose of the shares held by RA Capital Healthcare Fund, LP. The address for Dr. Kolchinsky and RA Capital Healthcare Fund, LP is 20 Park Plaza, Suite 1200, Boston, MA 02116

<sup>(8)</sup> These amounts reflect the December 2013 reverse stock split pursuant to which every two issued and outstanding shares of Series A Convertible Preferred Stock were reclassified and combined into one share of Series A Convertible Preferred Stock.

## Convertible Note Financing

In November and December 2014, we entered into a Convertible Note Purchase Agreement, pursuant to which we issued and sold to investors convertible promissory notes in the aggregate principal amount of \$5 million, or the 2014 Convertible Note Financing. Pursuant to the Convertible Note Purchase Agreement, the convertible notes bore interest at a rate per annum of 6.0% and mature on the earlier of (i) November 14, 2015, (ii) immediately prior to a liquidation of the company, or (iii) upon an event of default. In connection with the Series D Convertible Preferred Stock financing, the notes automatically converted into an aggregate of 4,166,667 shares of Series D Convertible Preferred Stock. The participants in the 2014 Convertible Notes Financing included the following directors, executive officers and/or holders of more than 5% of our capital

stock or entities affiliated with them. The following table presents the amount of the notes issued to these related parties in this financing:

Participants <sup>(1)</sup>	Amount of Notes Purchased
<b>5% or greater shareholders</b>	
Entities affiliated with Boston Millennia Partners <sup>(2)</sup>	\$ 754,829
Frazier Healthcare VI, L.P. <sup>(3)</sup>	\$ 924,264
Entities affiliated with Longitude Capital Partners, LLC <sup>(4)</sup>	\$ 1,826,499
Skyline Venture Partners V, L.P. <sup>(5)</sup>	\$ 1,494,408

<sup>(1)</sup> Additional details regarding these shareholders and their equity holdings are provided in "Principal Shareholders."

<sup>(2)</sup> Represents shares held, in the aggregate, by the Boston Millennia Funds. Robert Jevon, a former member of our board of directors, is an affiliate of Glen Partners II Limited Partnership, which is the special limited partner of BMP KG, and the general partner of the other Boston Millennia Funds.

<sup>(3)</sup> The general partner of Frazier Healthcare VI, L.P. is a limited partnership, the general partner of which is FHM VI, LLC. Patrick Heron, a member of our board of directors, is a member of FHM VI, LLC.

<sup>(4)</sup> Represents shares held, in the aggregate, by the Longitude Funds. Longitude Capital Partners, LLC is the general partner of the Longitude Funds. David Hirsch, a member of our board of directors, is a member of Longitude Capital Partners, LLC.

<sup>(5)</sup> The general partner of Skyline Venture Partners V, L.P. is Skyline Venture Management V, LLC. John G. Freund, a member of our board of directors, is a manager of Skyline Venture Management V, LLC.

In connection with the 2014 Convertible Note Financing, we entered into a Preferred Shareholder Agreement with the Boston Millennia Funds, the Longitude Funds, Skyline Venture Partners V, L.P. and Frazier Healthcare VI, L.P., pursuant to which the Longitude Funds, Skyline Venture Partners V, L.P. and Frazier Healthcare VI, L.P. agreed to vote their shares to waive, with respect to the Boston Millennia Funds, application of a mandatory conversion provision in our Articles of Incorporation, as amended, and other similar conversion provisions or other devices or mechanisms that may be adopted that are intended to incentivize the continued investment in the Company by existing holders of our preferred stock, subject to certain conditions described in the Preferred Shareholder Agreement. The Preferred Shareholder Agreement terminated by its terms upon the closing of the Series D Convertible Preferred Stock financing.

#### Seventh Amended and Restated Stockholders Agreement

In connection with the Series D Convertible Preferred Stock financing in March 2015, we entered into the Seventh Amended and Restated Stockholders Agreement, or the Stockholders Agreement, with certain of our shareholders, including Island View Investors, LLC, a limited liability company of which our President and Chief Executive Officer, Michael T. Heffernan, is the sole member, the Longitude Funds, the Boston Millennia Funds, Frazier Healthcare VI, L.P., Skyline Venture Partners V, L.P., TPG Biotechnology Partners IV, L.P. and RA Capital Healthcare Fund, LP. The Stockholders Agreement, among other things:

- § imposes restrictions on the transfer of capital stock;
- § grants holders of our outstanding convertible preferred stock certain rights of first refusal, co-sale and put rights with respect to certain proposed transfers of our securities by shareholders other than holders of Series D Convertible Preferred Stock;
- § grants us certain rights of first refusal with respect to certain proposed transfers of our securities by shareholders other than holders of Series D Convertible Preferred Stock;
- § imposes "drag along" obligations on our shareholders, and permits "tag along" by holders of our preferred stock in certain sale transactions that are approved by our board of directors and certain of our preferred shareholders;

- § sets forth voting obligations with respect to the constituency and size of our board of directors, and provides for the designation of our directors by certain of our preferred shareholders; and
- § requires shareholders to enter into a 180-day lock-up period upon an initial public offering.

The Stockholders Agreement will terminate automatically upon completion of this offering.

#### **Eighth Amended and Restated Investor Rights Agreement**

In connection with the Series D Convertible Preferred Stock financing in March 2015, we entered into the Eighth Amended and Restated Investor Rights Agreement, or the Investor Right Agreement, with certain of our investors, including the Longitude Funds, the Boston Millennia Funds, Frazier Healthcare VI, L.P., Skyline Venture Partners V, L.P., TPG Biotechnology Partners IV, L.P. and RA Capital Healthcare Fund, LP The Investor Rights Agreement, among other things:

- § imposes restrictions on the transfer of capital stock;
- § grants holders of our outstanding convertible preferred stock certain registration rights following an initial public offering;
- § grants holders of our outstanding convertible preferred stock certain pre-emptive rights with respect to certain issuances of our securities;
- § imposes certain affirmative and negative covenants on us, including an obligation for us to deliver periodic financial statements and budgets to any holder of at least 1 million shares of our preferred stock;
- § grants board observer rights to the Longitude Funds, Skyline Venture Partners V, L.P., Boston Millennia Partners and TPG Biotechnology Partners IV, L.P. so long as such investors hold at least 2 million shares of our preferred stock;
- § requires us to prepare and submit to the SEC a registration statement on Form S-1 for an initial public offering of our common stock and to use our best efforts to cause the registration statement to be declared effective; and
- § requires shareholders to enter into a 180-day lock-up period upon an initial public offering.

The provisions in the Investor Rights Agreement granting certain pre-emptive rights will terminate automatically upon completion of this offering.

#### **Participation in this Offering**

Certain of our existing stockholders, or their affiliates, have indicated an interest in purchasing up to an aggregate of approximately \$30.0 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these investors, and any of these investors may determine to purchase more, less or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these investors as they will on any other shares sold to the public in this offering.

#### **Management Rights Letters**

We entered into management rights letters with certain of our shareholders, including the Boston Millennia Funds, the Longitude Funds, Frazier Healthcare VI, L.P., Skyline Venture Partners V, L.P. and Aperture Venture Partners III, L.P. The management rights letters grant certain management rights in the event that such shareholder is not represented on our Board of Directors, as well as certain inspection rights. The management rights letters will terminate automatically upon completion of this offering.

#### **Employment Agreements**

We have entered into employment agreements with certain of our named executive officers that provide for salary, bonus and severance compensation. For more information regarding these employment agreements, see "Executive and Director Compensation — Employment Agreements" and "Executive and Director Compensation — Potential Payments Upon a Termination or Change of Control."

## **Equity Issued to Executive Officers and Directors**

We have granted common stock and/or stock options to our named executive officers and directors, as more fully described in "Executive and Director Compensation — Employment Agreements," "Executive and Director Compensation — Option Awards During Fiscal Year Ended December 31, 2014" and "Executive and Director Compensation — Compensation of Non-Employee Directors."

## **Indemnification Agreements with our Directors and Officers**

We have or will enter into, and intend to continue to enter into, indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our amended and restated articles of incorporation and our amended and restated bylaws. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors and/or executive officers or any other company or enterprise to which the person provides services at our request. Furthermore, the indemnification agreements with our directors who are designated by the Boston Millennia Funds, the Longitude Funds, Frazier Healthcare VI, L.P., Skyline Venture Partners V, L.P. and TPG Biotechnology Partners IV, L.P. require us to indemnify these shareholders for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by them in any action or proceeding arising by reason of the fact that such shareholders have the ability to appoint directors to our board. We believe that these charter and bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated articles of incorporation and amended and restated bylaws may discourage shareholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our shareholders. A shareholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

## **Policies and Procedures for Transactions with Related Persons**

Upon the closing of this offering, our board of directors will adopt a related party transactions policy for us. Pursuant to the related party transactions policy, we will review all transactions with a dollar value in excess of \$120,000 involving us in which any of our directors, director nominees, significant shareholders and executive officers and their immediate family members will be participants, to determine whether such person has a direct or indirect material interest in the transaction. This policy was not in effect when we entered into the transactions described above. All directors, director nominees and executive officers will be required to promptly notify our chief financial officer of any proposed transaction involving us in which such person has a direct or indirect material interest. Such proposed transaction will then be reviewed by the audit committee to determine whether the proposed transaction is a related party transaction under our policy. In reviewing any related party transaction, the audit committee will determine whether or not to approve or ratify the transaction based on all relevant facts and circumstances, including the following:

- § the materiality and character of the related person's interest in the transaction;
- § the commercial reasonableness of the terms of the transaction;
- § the benefit and perceived benefit, or lack thereof, to us;
- § the opportunity costs of alternate transactions; and
- § the actual or apparent conflict of interest of the related person.

In the event that any member of the audit committee is not a disinterested member with respect to the related person transaction under review, that member will be excluded from the review and approval or rejection of such related party transaction and another director may be designated to join the committee for purposes of such review. Whenever practicable, the reporting, review and approval will occur prior to entering into the transaction. If advance review and approval is not practicable, the audit committee will review and may, in its discretion, ratify the related party transaction. After any such review, the audit committee will approve or ratify the transaction only if it determines that the transaction is in, or not inconsistent with, the best interests of us and our shareholders. Our related party transaction policy will be available on our website, [www.collegiumpharma.com](http://www.collegiumpharma.com), under the "Investor Relations" section, upon the effective date of this offering. The information contained in, or that can be accessed through, our website is not part of this prospectus.

## PRINCIPAL SHAREHOLDERS

The following table sets forth certain information regarding the beneficial ownership of our capital stock outstanding as of April 2, 2015 by:

- § each person, or group of affiliated persons, known by us to beneficially own more than 5% of our shares of common stock;
- § each of our directors;
- § each of our named executive officers; and
- § all of our directors and executive officers as a group.

The percentage ownership information under the column entitled "Before offering" is based on 13,907,935 shares of common stock outstanding as of April 2, 2015, which assumes the conversion of all outstanding shares of our convertible preferred stock into 12,591,456 shares of common stock upon the closing of this offering. The percentage ownership information under the column entitled "After offering" is based on the sale of shares of common stock to be outstanding after this offering and gives effect to the conversion of all outstanding shares of our convertible preferred stock into 12,591,456 shares of common stock upon the closing of this offering.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common stock. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. The table below assumes that the underwriters do not exercise their option to purchase additional shares from us. In addition, the rules attribute beneficial ownership of securities as of a particular date to persons who hold options or warrants to purchase shares of common stock and that are exercisable within 60 days of such date. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for each person or entity listed in the table is c/o Collegium Pharmaceutical, Inc., 780 Dedham Street, Suite 800, Canton, MA 02021. The table below does not reflect any shares of our common stock that our directors, executive officers, 5% shareholders or their affiliated entities may purchase in this offering, including any of the reserved shares, as described in the "Underwriting" section of this prospectus.

Certain of our existing stockholders, or their affiliates, have indicated an interest in purchasing up to an aggregate of approximately \$30.0 million in shares of our common stock in this offering at the initial public offering price. The information set forth in the table below does not reflect the potential purchase of any shares in this offering by these stockholders.

Name and Address of Beneficial Owner	Number of shares beneficially owned	Percentage of shares beneficially owned	
		Before offering	After offering
<b>5% or greater shareholders:</b>			
Entities affiliated with Longitude Capital Partners, LLC <sup>(1)</sup>	3,111,014	22.37%	15.79%
Skyline Venture Partners V, L.P. <sup>(2)</sup>	2,787,541	20.04%	14.14%
Frazier Healthcare VI, L.P. <sup>(3)</sup>	1,729,598	12.44%	8.78%
TPG Biotechnology Partners IV, L.P. <sup>(4)</sup>	1,207,729	8.68%	6.13%
Entities affiliated with Boston Millennia Partners <sup>(5)</sup>	1,080,663	7.77%	5.48%
RA Capital Healthcare Fund, LP <sup>(6)</sup>	845,410	6.08%	4.29%
<b>Directors and Named Executive Officers:</b>			
Michael T. Heffernan, R. Ph. <sup>(7)</sup>	558,121	3.97%	2.83%
Ernest A. Kopecky Ph.D. <sup>(8)</sup>	34,872	*	*
Douglas R. Carlson <sup>(9)</sup>	21,776	*	*
Garen G. Bohlin <sup>(10)</sup>	2,415	*	*
John G. Freund, M.D. <sup>(11)</sup>	2,787,541	20.04%	14.14%
Patrick Heron <sup>(12)</sup>	1,729,598	12.44%	8.78%
David Hirsch, M.D., Ph.D. <sup>(13)</sup>	3,111,014	22.37%	15.79%
Eran Nadav, Ph.D. <sup>(14)</sup>	1,207,729	8.68%	6.13%
Gino Santini	23,188	*	*
<b>All current executive officers and directors as a group (13 persons)<sup>(15)</sup></b>	<b>9,595,479</b>	<b>68.28%</b>	<b>48.33%</b>

\* Represents beneficial ownership of less than one percent (1%) of the outstanding shares of our common stock.

- (1) Includes (a) 3,049,886 shares of common stock issuable upon conversion of convertible preferred stock held by Longitude Venture Partners, L.P. and (b) 61,128 shares of common stock issuable upon conversion of convertible preferred stock held by Longitude Capital Associates, L.P. Longitude Capital Partners, LLC is the general partner of the Longitude Funds and may be deemed to have sole voting investment and dispositive power over the shares held by the Longitude Funds. Patrick G. Enright and Juliet Tammenoms Bakker are managing members and in their capacity as such, may be deemed to exercise shared voting and investment power over the shares held by the reporting persons. David Hirsch, a member of our board of directors, is a member of Longitude Capital Partners, LLC. Each of these individuals disclaims beneficial ownership of such shares except to the extent of his or her pecuniary interest therein.
- (2) Represents shares of common stock issuable upon conversion of convertible preferred stock held by Skyline Venture Partners V, L.P. The general partner of Skyline Venture Partners V, L.P. is Skyline Venture Management V, LLC. John G. Freund and Yasunori Kaneko are managers of Skyline Venture Management V, LLC. These individuals share voting and investment power over the shares held by Skyline Venture Management, LLC. Each of these individuals disclaims beneficial ownership of all the shares held by Skyline Venture Partners V, L.P. except to the extent of his proportionate pecuniary interest therein.
- (3) Represents shares of common stock issuable upon conversion of convertible preferred stock held by Frazier Healthcare VI, L.P. The general partner of Frazier Healthcare VI, L.P. is a limited partnership, the general partner of which is FHM VI, LLC. The members of FHM VI, LLC are Dr. Nathan Every, Alan Frazier, Nader Naini, Patrick Heron, a member of our board of directors, and Dr. James Topper. These individuals share voting and investment power over the shares held by Frazier Healthcare VI, L.P. Each of these individuals disclaims beneficial ownership of such shares, except to the extent of his pecuniary interest.
- (4) Represents shares of common stock issuable upon conversion of convertible preferred stock held by TPG Biotechnology Partners IV, L.P. The general partner of TPG Biotechnology Partners IV, L.P. is TPG Biotechnology GenPar IV, L.P., a Delaware limited partnership, whose general partner is TPG Biotechnology GenPar IV Advisors, LLC, a Delaware limited liability company, whose sole member is TPG Holdings I, L.P., a Delaware limited partnership, whose general partner is TPG Holdings I-A, LLC, a Delaware limited liability company, whose sole member is TPG Group Holdings (SBS), L.P., a Delaware limited partnership, whose general partner is TPG Group Holdings (SBS) Advisors, Inc., or Group Advisors, a Delaware corporation. Messrs. David Bonderman and James G. Coulter are officers and sole shareholders of Group Advisors and may therefore be deemed to be the beneficial owners of the shares held by TPG Biotechnology Partners IV, L.P. Each of Messrs. Bonderman and Coulter expressly disclaims



beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein. The address for Messrs. Bonderman and Coulter and TPG Biotechnology Partners IV, L.P. is c/o TPG Global, LLC, 301 Commerce Street, Suite 3300, Fort Worth, TX 76102.

- (5) Includes (a) 4,660 shares of common stock issuable upon conversion of convertible preferred stock held by Boston Millennia Associates II Partnership, (b) 8,066 shares of common stock issuable upon conversion of convertible preferred stock held by Strategic Advisors Fund Limited Partnership, (c) 127,760 shares of common stock issuable upon conversion of convertible preferred stock held by Boston Millennia Partners GmbH & Co. KG, (d) 42,976 shares of common stock issuable upon conversion of convertible preferred stock held by Boston Millennia Partners II-A Limited Partnership, and (e) 897,201 shares of common stock issuable upon conversion of convertible preferred stock held by Boston Millennia Partners II Limited Partnership. Robert Jevon, a former member of our board of directors, is an affiliate of Glen Partners II Limited Partnership which is the special limited partner of BMP KG, and the general partner of the other Boston Millennia Funds. A. Dana Callow Jr., Martin J. Herson, and Robert S. Sherman are general partners of Glen Partners II Limited Partnership, exercise shared voting and investment power over the shares held by the Boston Millennia Funds, and may be deemed to have beneficial ownership of these shares.
- (6) Represents shares of common stock issuable upon conversion of convertible preferred stock held by RA Capital Healthcare Fund, LP. The investment adviser and sole general partner of RA Capital Healthcare Fund, LP is RA Capital Management, LLC. Peter Kolchinsky is the sole managing member of RA Capital Management, LLC and has the power to vote or dispose of the shares held by RA Capital Healthcare Fund, LP. The address for Dr. Kolchinsky and RA Capital Healthcare Fund, LP is 20 Park Plaza, Suite 1200, Boston, MA 02116
- (7) Includes 39,769 shares of our common stock subject to options exercisable within 60 days of April 2, 2015 and 163,043 shares of common stock held by Island View Investors LLC, of which Mr. Heffernan, our President and Chief Executive Officer, is the sole member.
- (8) Includes 34,872 shares of our common stock subject to options exercisable within 60 days of April 2, 2015.
- (9) Includes 21,776 shares of our common stock subject to options exercisable within 60 days of April 2, 2015.
- (10) Includes 2,415 shares of our common stock subject to options exercisable within 60 days of April 2, 2015.
- (11) Dr. Freund is a member of a group of persons who exercise voting and investment power over the shares of common stock beneficially owned by Skyline Venture Partners V, L.P. and may be deemed to beneficially own the shares held by Skyline Venture Partners V, L.P. Dr. Freund's address is c/o Skyline Venture Partners V, L.P., 525 University Ave., Palo Alto, CA 94301.
- (12) Mr. Heron is a member of a group of persons who exercise voting and investment power over the shares of common stock beneficially owned by Frazier Healthcare VI, L.P. and may be deemed to beneficially own the shares held by Frazier Healthcare VI, L.P. Mr. Heron's address is c/o Frazier Healthcare VI, L.P., 601 Union Street, Suite 3200, Seattle, WA 98101.
- (13) Dr. Hirsch is a member of a group of persons who exercise voting and investment power over the shares of common stock beneficially owned by the Longitude Funds and may be deemed to beneficially own the shares held by the Longitude Funds. Dr. Hirsch disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein. Dr. Hirsch's address is c/o Longitude Capital Partners, LLC, 800 El Camino Real, Ste. 220, Menlo Park, CA 94024.
- (14) Dr. Nadav is an affiliate of a group of persons who exercise voting and investment power over the shares of common stock beneficially owned by TPG Biotechnology Partners IV, L.P. and may be deemed to beneficially own the shares held by TPG Biotechnology Partners IV, L.P. Dr. Nadav's address is c/o TPG Biotech, 345 California Street, Suite 3300, San Francisco, CA 94104.
- (15) Includes 145,594 shares of common stock which the directors and executive officers have the right to acquire upon the exercise of stock options that were exercisable as of April 2, 2015, or that will become exercisable within 60 days after that date.

## DESCRIPTION OF CAPITAL STOCK

The following description summarizes information about our capital stock. This information does not purport to be complete and is subject to, and qualified in its entirety by reference to, the terms of our amended and restated articles of incorporation and amended and restated bylaws, which are included as exhibits to the registration statement of which this prospectus forms a part, and the applicable provisions of Virginia law, the state in which we are incorporated. You are encouraged to read our amended and restated articles of incorporation and amended and restated bylaws for greater detail with respect to these provisions.

As of April 2, 2015 our capital stock was held of record by 78 shareholders. Upon the closing of this offering, our authorized capital stock will consist of 105,000,000 shares, 100,000,000 of which are designated as common stock with a par value of \$0.001 per share and 5,000,000 of which are designated as preferred stock with a par value of \$0.001.

### Common Stock

Shares of our common stock have the following rights, preferences and privileges:

*Voting Rights.* The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the shareholders. With certain exceptions, a majority of the votes cast at a shareholder meeting at which a quorum is present must approve all shareholder matters. Our amended and restated articles of incorporation provide that an amendment to our amended and restated articles of incorporation, a merger, share exchange, domestication, entity conversion, sale of assets that requires shareholder approval or our dissolution must be approved by a majority of all the votes entitled to be cast at a shareholder meeting. Our amended and restated articles of incorporation provide that an amendment to our bylaws by the shareholders must be approved by more than two thirds of all the votes entitled to be cast. Our amended and restated bylaws also provide that our directors are elected by a plurality of the votes cast.

*Dividends.* Subject to the preferences applicable to any shares of preferred stock outstanding at any time, holders of our common stock are entitled to receive dividends when and as declared by our board of directors from assets or funds legally available therefor. The timing, declaration, amount and payment of future dividends will depend on our financial condition, earnings, capital requirements and debt service obligations, as well as legal requirements, regulatory constraints, industry practice and other factors that our board of directors deems relevant. Our board of directors will make all decisions regarding our payment of dividends from time to time in accordance with applicable law.

*Liquidation.* Subject to any preferential liquidation rights of holders of preferred stock that may be outstanding, upon our dissolution, the holders of our common stock will be entitled to share ratably in our assets legally available for distribution to our shareholders.

*No Preemptive or Similar Rights.* The holders of our common stock do not have any preemptive rights or preferential rights to subscribe for shares of our capital stock or any other securities. Our common stock is not subject to any redemption or sinking fund provisions.

### Preferred Stock

Immediately prior to the consummation of this offering, all outstanding shares of preferred stock will be converted into an aggregate of 12,591,456 shares of common stock. Under our amended and restated articles of incorporation, our board of directors may issue preferred stock in one or more series, with preferences, limitations and rights as authorized by our board of directors, to the extent permitted by Virginia law.

## **Stock Options**

As of December 31, 2014, we had outstanding options to purchase 281,029 shares of our common stock at a weighted-average price of \$0.69 per share, pursuant to our 2014 Stock Incentive Plan. Since December 31, 2014, we have awarded stock options to purchase an aggregate of 638,095 shares of common stock at a weighted-average exercise price of \$5.73 per share.

## **Restricted Common Stock**

As of December 31, 2014, we had 15,387 shares of restricted common stock issued and outstanding. In April 2015, we granted an additional 97,347 shares of restricted common stock to our President and Chief Executive Officer.

## **Warrants**

In October 2010, we issued a warrant to Comerica Bank, which warrant was immediately exercisable for 33,746 shares of our then outstanding Series D-1 Convertible Preferred Stock at an exercise price of \$1.778 per share. In connection with the Series B Convertible Preferred Stock financing, all issued and outstanding shares of previously issued preferred stock, including Series D-1 Preferred Stock, were converted into shares of Series A Convertible Preferred Stock. Additionally, pursuant to the December 2013 reverse stock split, the number of shares underlying the warrant was adjusted to 16,873 shares of Series A Preferred Stock. The shares underlying the warrant are entitled to the piggyback registration rights set forth in the Investor Rights Agreement described below. The warrant expires on October 28, 2017 but will be extended until the third anniversary of the effective date of this offering. Upon the completion of this offering, the warrant will be converted into a warrant to purchase 2,445 shares of common stock.

In August 2012, in connection with the closing of the Original Term Loan, we issued a warrant to SVB, which warrant was immediately exercisable for 3,450 shares of our common stock at an exercise price of \$0.48 per share. Pursuant to the December 2013 reverse stock split, the number of shares underlying this warrant was adjusted to 1,725 shares of common stock. This warrant expires on January 30, 2024. In January 2014, in connection with the closing of Amendment No. 1 to the Original Term Loan, we issued an additional warrant to SVB, which warrant was immediately exercisable for 2,091 shares of our common stock at an exercise price of \$0.35 per share. Pursuant to an adjustment mechanism included in this warrant, it automatically became exercisable for an additional 12,547 shares of our common stock. This warrant expires on January 30, 2024. Both SVB warrants are subject to cashless exercise. Upon the completion of this offering, the SVB warrants will represent the right to purchase an aggregate of 16,364 shares of common stock.

## **Convertible Notes**

In November 2014, we entered into a Convertible Note Purchase Agreement, pursuant to which we issued and sold to investors convertible promissory notes in the aggregate principal amount of \$5.0 million. Pursuant to the Convertible Note Purchase Agreement, the convertible notes bore interest at a rate per annum of 6.0% and mature on the earlier of (i) November 14, 2015, (ii) immediately prior to a liquidation of the company, or (iii) upon an event of default. In connection with the Series D Convertible Preferred Stock financing, the notes automatically converted into an aggregate of 4,166,667 shares of Series D Convertible Preferred Stock.

## **Registration Rights**

Pursuant to the Investor Rights Agreement, certain holders of shares of our common stock will have registration rights and certain holders of shares of our preferred stock will have registration rights with respect to the shares of common stock issuable upon conversion as further described below. After registration of these shares of common stock pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. These holders may also be able to sell shares without

registration pursuant to Rule 144 as described in this prospectus. See "Shares Eligible for Future Sale — Rule 144."

### ***Demand Registration Rights***

Beginning six months after this offering and subject to specified limitations set forth in the Investor Rights Agreement, (i) holders holding a majority of the registrable shares issued or issuable upon the conversion of Series D Convertible Preferred Stock, (ii) holders holding a majority of the registrable shares issued or issuable upon the conversion of Preferred Stock, or (iii) a lesser percentage of holders of registrable shares if the anticipated aggregate offering price to the public, net of underwriting discounts and commissions, is not less than \$10 million, may demand in writing that we register all or a portion of the registrable shares under the Securities Act pursuant to the filing of a Registration Statement on Form S-1. We are not obligated to file a registration statement pursuant to this provision on more than two occasions in any 12-month period, provided, however, that such obligation shall be deemed satisfied only when (i) a registration statement covering no less than 70% of the number of registrable shares specified in a notice received for sale in accordance with the method of disposition specified by the requesting holders shall have become effective or if such registration statement has been withdrawn prior to the consummation of the offering at the request of the holders of a majority of the registrable shares requested to be included in the offering, and (ii) if such method of disposition is a firm commitment, underwritten public offering, all such shares were sold pursuant thereto.

In addition, subject to specified limitations set forth in the Investor Rights Agreement, at any time after we become eligible to file a registration statement on Form S-3, a holder or holders of the registrable shares then outstanding may request that we register their registrable securities on Form S-3 for purposes of a public offering if the total shares registered have an aggregate offering price of at least \$1 million. We are not obligated to file a registration statement pursuant to this provision on more than two occasions in any 12-month period.

### ***Piggyback Registration Rights***

If, at any time, we propose to file a registration statement to register any of our securities under the Securities Act, either for our own account or for the account of any of our shareholders, the holders of our registrable securities are entitled to notice of registration and, subject to specified exceptions, we will be required upon the holder's request to use our best efforts to register their then-held registrable securities. The underwriters of any underwritten offering will have the right to limit the number of shares having registration rights to be included in the registration statement, but not below 30% of the total amount of securities included in such registration, unless such offering is the Initial Public Offering and such registration does not include shares of any other selling shareholders, in which event any or all of the registrable shares of the holders may be excluded pursuant to the terms of the Investor Rights Agreement. In addition, pursuant to the Investor Rights Agreement, in no event will shares of any other selling shareholder be included in such registration that would reduce the number of shares which may be included by holders without the written consent of holders of at least 60% of the registrable shares held by all holders.

### ***Other Provisions***

The Investor Rights Agreement provides that, in connection with this offering and upon the managing underwriters' request, holders of registrable securities will be subject to a "lock-up" provision prohibiting the sale or other disposition of our securities for up to 180 days.

We will pay registration expenses other than the underwriting discount, selling commissions and the fees and expenses of the selling shareholders' own counsel (other than the counsel selected to represent all of the selling shareholders), related to any demand registration. The Investor Rights Agreement contains customary cross-indemnification provisions, pursuant to which we are obligated to indemnify the selling shareholders in the event of material misstatements or omissions in the registration statement attributable

to us, and they are obligated to indemnify us for material misstatements or omissions in the registration statement attributable to them.

### **Anti-Takeover Effects of Provisions of our Articles of Incorporation, our Bylaws and Virginia Law**

Various provisions contained in our amended and restated articles of incorporation, our amended and restated bylaws and Virginia law could delay, deter or discourage some transactions involving an actual or potential change in control of the Company. Provisions in our amended and restated articles of incorporation and our amended and restated bylaws include:

- § a provision allowing our board of directors to establish one or more series or classes of undesignated preferred stock, the terms of which can be determined by the board of directors at the time of issuance;
- § 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;
- § 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
- § a prohibition on shareholders acting by less-than-unanimous written consent.

### **Articles of Incorporation and Bylaws**

#### *Preferred stock*

Our amended and restated articles of incorporation authorize our board of directors to establish one or more series of preferred stock and to determine, with respect to any series of preferred stock, the preferences, rights and other terms of such series. See "—Preferred Stock" for additional information. Under this authority, our board of directors could create and issue a series of preferred stock with rights, preferences or restrictions that have the effect of discriminating against an existing or prospective holder of our capital stock as a result of such holder beneficially owning or commencing a tender or exchange offer for a substantial amount of our common stock. One of the effects of authorized but unissued and unreserved shares of preferred stock may be to render it more difficult for, or to discourage an attempt by, a potential acquiror to obtain control of us by means of a merger, tender or exchange offer, proxy contest or otherwise, and thereby protect the continuity of our management. The issuance of shares of preferred stock may have the effect of delaying, deferring or preventing a change in control of our Company without any action by our shareholders.

#### *Qualification and election of directors*

Our amended and restated bylaws provide that to be eligible to be nominated by a shareholder for election to our board of directors, a person must submit a written questionnaire regarding his or her background and qualifications and must agree to other representations as set forth in our amended and restated bylaws.

Under our amended and restated articles of incorporation, our board of directors will be divided into three classes, each serving three-year terms and until each director's successors are duly elected and qualified. The election of the classes will be staggered, such that only approximately one third of our board of directors will be up for election in any given year. Our amended and restated articles of incorporation do not provide for cumulative voting in the election of directors.

*Board vacancies; removal*

Our amended and restated articles of incorporation provide that any vacancy occurring on our board of directors will be filled by a majority of directors then in office, even if less than a quorum. Our amended and restated articles of incorporation also provide that our directors can only be removed for cause upon the vote of more than two thirds of the votes entitled to be cast by holders of common stock.

*Special meetings of shareholders*

Our amended and restated articles of incorporation provide that only the board of directors, the chairman of the board of directors or the president may call a special meeting of the shareholders.

*Advance notification of shareholder nominations and proposals*

Our amended and restated bylaws establish advance notice procedures with respect to shareholder proposals and the nomination of persons for election as directors, other than nominations made by or at the direction of our board of directors.

**Virginia Anti-Takeover Statutes**

*Affiliated transactions statute*

Virginia law contains provisions governing certain material transactions, or affiliated transactions, between the Company and any holder of more than 10% of any class of its outstanding voting shares, or an interested shareholder. In general, these provisions prohibit a Virginia corporation from engaging in an affiliated transaction with an interested shareholder for a period of three years following the date such person became an interested shareholder, unless (i) a majority of the disinterested directors and the holders of at least two-thirds of the voting shares, other than those beneficially owned by the interested shareholder, approved the affiliated transaction, or (ii) before the date that the person became an interested shareholder, a majority of the disinterested directors approved the transaction that resulted in the person becoming an interested shareholder. After three years, any such transaction must be at a "fair price," as statutorily defined, or must be approved by the holders of at least two-thirds of the voting shares, other than those beneficially owned by the interested shareholder. Affiliated transactions subject to this approval requirement include mergers, share exchanges, material dispositions of corporate assets not in the ordinary course of business, the sale of shares of the corporation or any of its subsidiaries to an interested shareholder having an aggregate fair market value of greater than 5% of the aggregate fair market value of the corporation's outstanding shares, any dissolution of the Company proposed by or on behalf of an interested shareholder or any reclassification, including reverse stock splits, recapitalization or merger of the Company with its subsidiaries, if any, that increases the percentage of voting shares beneficially owned by an interested shareholder by more than 5%.

The shareholders of a Virginia corporation may adopt an amendment to the corporation's articles of incorporation or bylaws opting out of the provisions of Virginia law governing affiliated transactions but such amendment shall not be effective until 18 months after its adoption. Neither our amended and restated articles of incorporation nor our amended and restated bylaws contain a provision opting out of the provisions of Virginia law governing affiliated transactions.

*Control share acquisitions statute*

Virginia law also contains provisions relating to control share acquisitions, which are transactions causing the voting strength of any person acquiring beneficial ownership of shares of a Virginia public corporation to meet or exceed certain threshold percentages (20%, 33<sup>1</sup>/<sub>3</sub>% or 50%) of the total votes entitled to be cast for the election of directors. Shares acquired in a control share acquisition have no voting rights unless (i) the voting rights are granted by a majority vote of all outstanding shares other than those held by the acquiring person or any officer or employee director of the corporation or (ii) the articles of incorporation or bylaws of the corporation provide that these Virginia law provisions do not apply to acquisitions of its shares. The acquiring person may require that a special meeting of the shareholders be held to consider the grant of voting rights to the shares acquired in the control share acquisition.

As permitted by Virginia law, our amended and restated articles of incorporation contain a provision opting out of the Virginia anti-takeover law regulating control share acquisitions.

*Indemnification and limitation of directors' and officers' liability*

We are a Virginia corporation. As permitted by Virginia law, our amended and restated articles of incorporation provide that no director or officer shall be liable in any proceeding brought by or in the right of us or our shareholders for monetary damages arising out of any transaction, occurrence or other course of conduct, except for liability resulting from willful misconduct or a knowing violation of criminal law or of any federal or state securities laws.

Our amended and restated articles of incorporation require us to indemnify any director or officer who was or is a party to a proceeding, including a proceeding brought by or in the right of the Company, due to his or her status as our director or officer unless he or she engaged in willful misconduct or a knowing violation of criminal law. Our amended and restated articles of incorporation also require us to advance expenses to such person prior to the final disposition of any such proceeding.

We have obtained policies that insure our directors and officers against certain liabilities they may incur in their capacity as directors and officers.

We have or plan to enter into indemnification agreements with our directors and officers who also serve as directors. These agreements contain provisions that may require us, among other things, to advance expenses to and indemnify these directors and officers against certain liabilities that may arise because of their status or service as directors or officers of us.

***Transfer Agent and Registrar***

The transfer agent and registrar for our common stock will be Computershare Trust Company, N.A.

***Listing***

We expect to receive approval to list our common stock on NASDAQ under the symbol "COLL."

## SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of common stock in the public market could adversely affect prevailing market prices. Furthermore, since only a limited number of shares will be available for sale shortly after this offering because of contractual and legal restrictions on resale described below, sales of substantial amounts of common stock in the public market after the restrictions lapse could adversely affect the prevailing market price for our common stock as well as our ability to raise equity capital in the future.

Based on the number of shares of common stock outstanding as of December 31, 2014, upon the closing of this offering, 19,707,935 shares of common stock will be outstanding, assuming no exercise of the underwriters' option to purchase additional shares from us and no exercise of options. All of the shares sold in this offering will be freely tradable unless held by an affiliate of ours. Except as set forth below, the remaining shares of common stock outstanding after this offering will be restricted as a result of securities laws or lock-up agreements. These remaining shares will be eligible for sale under Rule 144 or Rule 701 of the Securities Act upon expiration of lock-up agreements at least 180 days after the date of this offering.

### Rule 144

In general, under Rule 144 as currently in effect, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, any person who is not an affiliate of ours and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell shares without restriction, provided current public information about us is available. In addition, under Rule 144, any person who is not an affiliate of ours and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available. Beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of restricted shares within any three-month period that does not exceed the greater of:

- § 1% of the number of shares of our common stock then outstanding, which will equal approximately 197,079 shares immediately after this offering; and
- § the average weekly trading volume of our common stock on NASDAQ during the four calendar weeks preceding the filing of a notice on Form 144 pursuant to Rule 144 with respect to the sale.

Sales of restricted shares under Rule 144 held by our affiliates are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us. Rule 144 also provides that affiliates relying on Rule 144 to sell shares of our common stock that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted shares have entered into lock-up agreements as described below and their restricted shares will become eligible for sale at the expiration of the restrictions set forth in those agreements.

### Rule 701

Under Rule 701 of the Securities Act, or Rule 701, shares of our common stock acquired upon the exercise of currently outstanding options or pursuant to other rights granted under our stock plans may be resold by:

- § persons other than affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject only to the manner-of-sale provisions of Rule 144; and



§ our affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject to the manner-of-sale and volume limitations, current public information and filing requirements of Rule 144, in each case, without compliance with the six-month holding period requirement of Rule 144.

As of December 31, 2014, options to purchase a total of 281,029 shares of common stock were outstanding. In March 2015, we awarded options to purchase an additional 638,095 shares of our common stock. Of the total number of shares of our common stock issuable under these options, substantially all are subject to contractual lock-up agreements with us or the underwriters described below under "Underwriting" and will become eligible for sale at the expiration of those agreements unless held by an affiliate of ours.

#### **Lock-Up Agreements**

We, along with our directors, executive officers and all or substantially all of our other shareholders and optionholders, have agreed that for a period of 180 days after the date of this prospectus, subject to specified exceptions, we or they will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock. Upon expiration of the "lock-up" period, certain of our shareholders will have the right to require us to register their shares under the Securities Act. See "—Registration Rights" below.

#### **Registration Rights**

Upon the closing of this offering, the holders of 12,787,524 shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up arrangement described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates, immediately upon the effectiveness of the registration. Any sales of securities by these shareholders could have a material adverse effect on the trading price of our common stock. See "Description of Capital Stock — Registration Rights."

#### **Equity Incentive Plans**

We intend to file with the SEC a registration statement on Form S-8 under the Securities Act covering the shares of common stock reserved for issuance under the Amended and Restated 2014 Stock Incentive Plan and 2015 Employee Stock Purchase Plan. The registration statement is expected to be filed and become effective as soon as practicable after the closing of this offering. Accordingly, shares registered under the registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable. See "Executive and Director Compensation."

**MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES  
TO NON-U.S. HOLDERS OF OUR COMMON STOCK**

The following is a general discussion of material U.S. federal income and estate tax considerations relating to the ownership and disposition of our common stock by a non-U.S. holder. For purposes of this discussion, the term "non-U.S. holder" means a beneficial owner of our common stock that is not and is not treated as, for U.S. federal income tax purposes:

- § an individual who is a citizen or resident of the United States;
- § a corporation, or other entity treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States or of any political subdivision of the United States;
- § an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- § a trust, if (i) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (ii) if the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

An individual may be treated as a resident instead of a nonresident of the United States in any calendar year for U.S. federal income tax purposes if the individual was present in the United States for at least 31 days in that calendar year and for an aggregate of at least 183 days during the three-year period ending with that calendar year. For purposes of this calculation, all of the days present in the tested year, one-third of the days present in the immediately preceding year and one-sixth of the days present in the second preceding year are counted. Residents are taxed for U.S. federal income tax purposes as if they were U.S. citizens.

This discussion is based on current provisions of the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus. In addition, the Internal Revenue Service, or the IRS, could challenge one or more of the tax consequences described in this discussion.

We assume in this discussion that each non-U.S. holder holds shares of our common stock as a capital asset within the meaning of the Code (generally, property held for investment). This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address any aspects of state, local or non-U.S. taxes. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder, including the alternative minimum tax and the Medicare contribution tax on net investment income, and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- § insurance companies;
- § tax-exempt organizations or tax-qualified retirement plans;
- § governmental organizations;
- § financial institutions;
- § brokers, dealers or traders in securities or currencies;
- § real estate investment trusts or regulated investment companies;
- § pension plans;
- § controlled foreign corporations;
- § passive foreign investment companies;

- § persons deemed to sell our common stock under the constructive sale provisions of the Code;
- § persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- § owners that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and
- § certain U.S. expatriates.

In addition, this discussion does not address the tax treatment of partnerships or persons who hold their common stock through partnerships or other entities that are pass-through entities for U.S. federal income tax purposes.

**This summary is general information only. It is not tax advice. We urge each prospective non-U.S. Holder to consult their tax advisor concerning the particular U.S. federal, state, local and non-U.S. income, estate and other tax consequences of the purchase, ownership and disposition of our common stock.**

## Dividends

If we pay distributions on our common stock, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such non-U.S. holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described in this prospectus under the heading "— Gain on Disposition of Common Stock." Any such distribution will also be subject to the discussion in this prospectus under the heading "— Withholding and Information Reporting Requirements — FATCA."

Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax on the gross amount of the dividends at a 30.0% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence. If we determine, at a time reasonably close to the date of payment of a distribution on our common stock, that the distribution will not constitute a dividend because we do not anticipate having current or accumulated earnings and profits, we may elect not to withhold U.S. federal income tax from such distribution as permitted by U.S. Treasury Regulations.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) and satisfy applicable certification and other requirements.

A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States, and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30.0% withholding tax if the non-U.S. holder provides a properly executed IRS Form W-8ECI (or successor form). However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to "United States persons" (within the meaning of the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30.0% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such non-U.S. holder's country of residence.

## Gain on Disposition of Common Stock

Subject to the discussion below regarding backup withholding and the Foreign Account Tax Compliance Act, or FATCA, a non-U.S. holder generally will not be subject to U.S. federal income tax on gain recognized on a disposition of our common stock unless:

- § the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States, and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States; in these cases, the non-U.S. holder will be taxed on a net income basis at the regular graduated rates and in the manner applicable to United States persons, and, if the non-U.S. holder is a foreign corporation, an additional branch profits tax at a rate of 30.0%, or a lower rate as may be specified by an applicable income tax treaty, may also apply;
- § the non-U.S. holder is an individual present in the United States for 183 days or more in the taxable year of the disposition and certain other requirements are met (in which case the non-U.S. holder will be subject to a 30.0% tax, or such lower rate as may be specified by an applicable income tax treaty, on the net gain derived from the disposition, which may be offset by U.S.-source capital losses of the non-U.S. holder, if any); or
- § we are or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter) a "United States real property holding corporation" within the meaning of the Code, unless during such applicable period our common stock is regularly traded on an established securities market and the non-U.S. holder held no more than 5.0% of our outstanding common stock, actually or constructively. Generally, a corporation is a "United States real property holding corporation" if the fair market value of its "United States real property interests" equals or exceeds 50.0% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we believe that we are not currently, and we do not anticipate becoming, a "United States real property holding corporation" for U.S. federal income tax purposes. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rule described above.

## Information Reporting and Backup Withholding

The gross amount of the distributions on our common stock paid to each non-U.S. holder and the tax withheld, if any, with respect to such distributions must be reported annually to the IRS. Non-U.S. holders may have to comply with specific certification procedures to establish that they are not "United States persons" (within the meaning of the Code) in order to avoid backup withholding at the applicable rate, currently 28.0%, with respect to dividends on our common stock. Generally, a non-U.S. holder will comply with such procedures if it provides a properly executed IRS Form W-8BEN, W-8BEN-E or W-8ECI or otherwise meets documentary evidence requirements for establishing that it is a non-U.S. holder, or otherwise establishes an exemption. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above under the heading "Dividends," will generally be exempt from backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through a U.S. office of any broker, United States or foreign, unless the holder certifies its status as a non-U.S. holder (such as by providing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI) and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

#### **Withholding and Information Reporting Requirements — FATCA**

Legislation known as the Foreign Account Tax Compliance Act, or FATCA, imposes U.S. federal withholding tax of 30.0% on payments of dividends on, and (to the extent described below) on gross proceeds from the sale or disposition of, our common stock if paid to a foreign entity unless (i) in the case of a foreign entity that is a "foreign financial institution" (within the meaning of the Code), the foreign entity undertakes certain due diligence, reporting, withholding and certification obligations, (ii) in the case of a foreign entity that is not a foreign financial institution, the foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or identifies each substantial United States owner or (iii) the foreign entity is otherwise exempt under FATCA. Withholding under FATCA will only apply (1) to payments of dividends on our common stock and (2) to payments of gross proceeds from a sale or other disposition of our common stock made after December 31, 2016. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of such taxes.

#### **Federal Estate Tax**

Common stock owned or treated as owned by an individual (including by reason of holding interests in certain entities) who is not a citizen or resident of the United States (as specially determined for U.S. federal estate tax purposes) at the time of death will be included in the individual's gross estate for U.S. federal estate tax purposes and, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax or other treaty provides otherwise.

**THE PRECEDING DISCUSSION OF MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSIDERATIONS IS FOR GENERAL INFORMATION ONLY. IT IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL, STATE, LOCAL AND NON-U.S. TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK (DIRECTLY OR THROUGH ENTITIES), INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGES IN APPLICABLE LAWS.**

## UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, among us and Jefferies LLC and Piper Jaffray & Co., as the representatives of the underwriters named below and the joint book-running managers of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common stock shown opposite its name below:

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<b>Underwriter</b>	<b>Number of Shares</b>
Jefferies LLC	
Piper Jaffray & Co.	
Wells Fargo Securities, LLC	
Needham & Company, LLC	
Total	<u>5,800,000</u>

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The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

### Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of \$ \_\_\_\_\_ per share of common stock. The underwriters may allow, and certain dealers may reallow, a discount from the concession not in excess of \$ \_\_\_\_\_ per share of common stock to certain brokers and dealers. After the offering, the initial public offering price, concession and reallowance to dealers may be reduced by the representatives. No

such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

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	Per Share		Total	
	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares
Public offering price	\$	\$	\$	\$
Underwriting discounts and commissions paid by us	\$	\$	\$	\$
Proceeds to us, before expenses	\$	\$	\$	\$

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Needham & Company, LLC, one of the underwriters of this offering, owns, through its parent company, a limited partnership interest in Boston Millennia Partners II Limited Partnership, one of the entities affiliated with Boston Millennia Partners that acquired shares of our Series D convertible preferred stock in March 2015. Under the rules of the Financial Industry Regulatory Authority (FINRA), the indirect beneficial interest of Needham & Company, LLC in 6,298 shares of our common stock is regarded as additional compensation to the underwriters of this offering.

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$2,600,000. We have also agreed to reimburse the underwriters for certain of their expenses in an amount up to \$50,000, incurred in connection with review by the Financial Industry Regulatory Authority, Inc. of the terms of this offering, as set forth in the underwriting agreement.

#### Determination of Offering Price

Prior to this offering, there has not been a public market for our common stock. Consequently, the initial public offering price for our common stock will be determined by negotiations between us and the representatives. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the common stock will trade in the public market subsequent to the offering or that an active trading market for the common stock will develop and continue after the offering.

#### Listing

We expect to receive approval to list our common stock on NASDAQ under the trading symbol "COLL."

## Stamp Taxes

If you purchase shares of common stock offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

## Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of 870,000 shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus.

## No Sales of Similar Securities

We, our officers, directors and holders of all or substantially all our outstanding capital stock and other securities have agreed, subject to specified exceptions, not to directly or indirectly:

- § sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-1(h) under the Exchange Act, or
- § otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially, or
- § publicly announce an intention to do any of the foregoing for a period of 180 days after the date of this prospectus without the prior written consent of Jefferies LLC and Piper Jaffray & Co.

This restriction terminates after the close of trading of the common stock on and including the 180<sup>th</sup> day after the date of this prospectus.

Jefferies LLC and Piper Jaffray & Co. may, in their sole discretion and at any time or from time to time before the termination of the 180-day period release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our shareholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

## Stabilization

The underwriters have advised us that they, pursuant to Regulation M under the Exchange Act, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.



"Naked" short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter's purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we, nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

### **Electronic Distribution**

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

### **Directed Share Program**

At our request, the underwriters have reserved for sale at the initial public offering price up to approximately 5% of the shares of our common stock for employees, directors and other persons associated with us who have expressed an interest in purchasing shares in the offering. The number of shares of common stock available for sale to the general public in the offering will be reduced to the extent these persons purchase the directed shares in the program. Any directed shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares. Except for certain participants who have entered into lock-up agreements as contemplated above, each person buying shares through the directed share program has agreed that, for a period of 180 days from and including the date of this prospectus, he or she will not, without the prior written consent of Jefferies LLC and Piper Jaffray & Co., dispose of or hedge any shares of common stock or any securities convertible into or exchangeable for shares of common stock with respect to shares purchased in the program. For those participants who have entered into lock-up agreements as contemplated above, the lock-up agreements contemplated therein shall govern with respect to their purchases of shares of common stock in the program. Jefferies LLC and Piper Jaffray & Co. in their sole discretion may release any of the securities subject to these lock-up agreements at any time. We have agreed to indemnify the underwriters against

certain liabilities and expenses, including liabilities under the Securities Act, in connection with sales of the directed shares.

## **Other Activities and Relationships**

The underwriter and certain of its affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriter and certain of its affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriter and certain of its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

## **Disclaimers About Non-U.S. Jurisdictions**

### ***Australia***

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- § a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- § a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the Company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
- § a person associated with the Company under Section 708(12) of the Corporations Act; or
- § a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the securities issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

## **European Economic Area**

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State"), an offer to the public of any common stock which is the subject of the offering contemplated by this prospectus may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- § to any legal entity which is a "qualified investor" as defined in the Prospectus Directive;
- § to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the underwriters or the underwriters nominated by us for any such offer; or
- § in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of common stock shall require us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer common stock to the public" in relation to the common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the common stock to be offered so as to enable an investor to decide to purchase or subscribe to the common stock, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

## **Hong Kong**

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong ("SFO") and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong ("CO") or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he, she or it is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he, she or it is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

## **Japan**

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the underwriters will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

## **Singapore**

This prospectus has not been and will not be lodged or registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- § a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- § a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

- § to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- § where no consideration is or will be given for the transfer;
- § where the transfer is by operation of law;
- § as specified in Section 276(7) of the SFA; or
- § as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

## **Switzerland**

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the Company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be

authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

**United Kingdom**

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated (each such person being referred to as a "relevant person").

Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

## LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Pepper Hamilton LLP. Latham & Watkins LLP is counsel for the underwriters in connection with this offering.

## EXPERTS

The financial statements of Collegium Pharmaceutical, Inc. included in this prospectus and elsewhere in the registration statement have been so included in reliance upon the report of Grant Thornton LLP, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at [www.sec.gov](http://www.sec.gov). You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, NE, Washington, DC 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, NE, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. You may also request a copy of these filings, at no cost, by writing us at 780 Dedham Street, Suite 800, Canton, MA 02021 or telephoning us at (781) 713-3699.

Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We also maintain a website at [www.collegiumpharma.com](http://www.collegiumpharma.com), at which, following the closing of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is incorporated by reference in, and is not part of, this prospectus.

**COLLEGIUM PHARMACEUTICAL, INC.**  
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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Shareholders  
Collegium Pharmaceutical, Inc.

We have audited the accompanying balance sheets of Collegium Pharmaceutical, Inc. (a Virginia corporation) (the "Company") as of December 31, 2013 and 2014, and the related statements of operations, convertible redeemable preferred stock and shareholders' deficit, and cash flows for each of the two years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Collegium Pharmaceutical, Inc. as of December 31, 2013 and 2014, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2014 in conformity with accounting principles generally accepted in the United States of America.

/s/ Grant Thornton LLP

Boston, Massachusetts  
April 27, 2015



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

	<u>December 31,</u>		<u>Pro Forma</u>
	<u>2013</u>	<u>2014</u>	<u>December 31,</u>
			<u>2014</u>
			<u>(unaudited)</u>
<b>ASSETS</b>			
Current assets:			
Cash and cash equivalents	\$ 7,551	\$ 1,634	\$ 1,634
Refundable PDUFA fee	—	2,335	2,335
Prepaid expenses and other current assets	710	527	527
Total current assets	8,261	4,496	4,496
Property and equipment, net	693	514	514
Restricted cash	80	80	80
Total assets	<u>\$ 9,034</u>	<u>\$ 5,090</u>	<u>\$ 5,090</u>
<b>LIABILITIES, CONVERTIBLE REDEEMABLE PREFERRED STOCK AND SHAREHOLDERS' DEFICIT</b>			
Current liabilities:			
Accounts payable	\$ 1,217	\$ 2,208	\$ 2,208
Accrued expenses	1,013	1,956	1,956
Current portion of deferred rent and lease note payable	55	59	59
Current portion of term loan payable	333	1,194	1,194
Convertible bridge notes with related parties	—	5,000	5,000
Total current liabilities	2,618	10,417	10,417
Deferred rent and lease note payable, long-term	59	—	—
Lease incentive obligation	135	101	101
Term loan payable, long-term	640	6,813	6,813
Total liabilities	3,452	17,331	17,331
Commitments and contingencies (See Note 7)			
Convertible redeemable preferred stock (See Note 10):			
Series A convertible redeemable preferred stock, \$0.001 par value; authorized shares — 18,498,419 at December 31, 2013, December 31, 2014 and at December 31, 2014 pro forma (unaudited); issued and outstanding shares — 9,232,334 at December 31, 2013 and December 31, 2014 and no shares at December 31, 2014 pro forma (unaudited); liquidation preference of \$12,277 at December 31, 2013, \$12,781 at December 31, 2014 and \$0 at December 31, 2014 pro forma (unaudited)	12,277	12,781	—
Series B convertible redeemable preferred stock, \$0.001 par value; authorized shares — 27,324,237 at December 31, 2013, December 31, 2014 and at December 31, 2014 pro forma (unaudited); issued and outstanding shares — 27,324,237 at December 31, 2013, December 31, 2014 and no shares at December 31, 2014 pro forma (unaudited); liquidation preference of \$49,376 at December 31, 2013, \$51,212 at December 31, 2014 and \$0 at December 31, 2014 pro forma (unaudited)	49,376	51,212	—
Series C convertible redeemable preferred stock, \$0.001 par value; authorized shares — 8,658,344 at December 31, 2013, December 31, 2014 and at December 31, 2014 pro forma (unaudited); issued and outstanding shares — 8,658,008 at December 31, 2013, December 31, 2014 and no shares at December 31, 2014 pro forma (unaudited); liquidation preference of \$12,154 at December 31, 2013, \$13,114 at December 31, 2014 and \$0 at December 31, 2014 pro forma (unaudited)	12,154	13,114	—
Shareholders' deficit:			
Common stock, \$0.001 par value; authorized shares — 72,000,000 at December 31, 2013, December 31, 2014 and at December 31, 2014 pro forma (unaudited); issued and outstanding shares — 962,960 at December 31, 2013, 1,006,219 at December 31, 2014; and 7,559,035 at December 31, 2014 pro forma (unaudited)	1	1	8
Additional paid-in capital	12,313	12,407	89,507
Accumulated deficit	(80,536)	(101,753)	(101,753)
Treasury stock	(3)	(3)	(3)
Total shareholders' deficit	(68,225)	(89,348)	(12,241)
Total liabilities, convertible redeemable preferred stock and shareholders' deficit	<u>\$ 9,034</u>	<u>\$ 5,090</u>	<u>\$ 5,090</u>

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

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

	<u>Year Ended December 31,</u>	
	<u>2013</u>	<u>2014</u>
Operating expenses:		
Research and development	\$ 14,157	\$ 14,959
General and administrative	1,885	2,706
Total operating expenses	<u>16,042</u>	<u>17,665</u>
Loss from operations	(16,042)	(17,665)
Other expense:		
Interest expense, net	76	252
Change in fair value of derivative liability	79	—
Total other expense, net	<u>155</u>	<u>252</u>
Net loss	\$ (16,197)	\$ (17,917)
Basic and diluted net loss per common share (See Note 3)	\$ (4.06)	\$ (22.72)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share (See Note 3)	<u>1,697,044</u>	<u>933,997</u>
Pro forma net loss per common share, basic and diluted (unaudited)		\$ (2.84)
Weighted-average shares used to compute pro forma net loss per common share (unaudited)		<u>7,471,303</u>

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

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

	Series A Convertible Redeemable Preferred Stock		Series B Convertible Redeemable Preferred Stock		Series C Convertible Redeemable Preferred Stock		Common Stock		Additional Paid-In Capital	Treasury Stock, at cost	Accumulated Deficit	Total Shareholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at January 1, 2013	18,464,674	\$ 23,546	27,324,237	\$ 47,540	—	\$ —	1,924,845	\$ 2	11	\$ (3)	(61,414)	\$ (61,404)
Issuance of new Series C convertible redeemable preferred stock, net of issuance costs of \$45	—	—	—	—	8,658,008	12,034	—	—	—	—	—	—
Accruals of dividends and accretion to redemption value	—	970	—	1,836	—	120	—	—	(1)	—	(2,925)	(2,926)
Performance Adjustment of Series A	(9,232,340)	(12,239)	—	—	—	—	(962,962)	(1)	12,240	—	—	12,239
Stock-based compensation expense	—	—	—	—	—	—	—	—	62	—	—	62
Exercise of common stock options	—	—	—	—	—	—	1,077	—	1	—	—	1
Net loss	—	—	—	—	—	—	—	—	—	—	(16,197)	(16,197)
Balance at December 31, 2013	9,232,334	12,277	27,324,237	49,376	8,658,008	12,154	962,960	1	12,313	(3)	(80,536)	(68,225)
Accruals of dividends and accretion to redemption value	—	504	—	1,836	—	960	—	—	—	—	(3,300)	(3,300)
Issuance of restricted stock awards to employees	—	—	—	—	—	—	10,869	—	—	—	—	—
Exercise of common stock options	—	—	—	—	—	—	32,390	—	72	—	—	72
Stock-based compensation expense	—	—	—	—	—	—	—	—	22	—	—	22
Net loss	—	—	—	—	—	—	—	—	—	—	(17,917)	(17,917)
Balance at December 31, 2014	9,232,334	\$ 12,781	27,324,237	\$ 51,212	8,658,008	\$ 13,114	1,006,219	\$ 1	12,407	\$ (3)	(101,753)	(89,348)

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

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

	Years Ended	
	December 31,	
	2013	2014
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (16,197)	\$ (17,917)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	169	187
Lease incentive	(34)	(34)
Stock-based compensation	62	22
Non cash interest expense	12	7
Accrual of back end fees related to note payable	13	7
Change in fair value of derivative liability	79	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(11)	183
Refundable PDUFA fee	—	(2,335)
Accounts payable	(822)	990
Accrued expenses	199	943
Net cash used in operating activities	<u>(16,530)</u>	<u>(17,947)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	<u>(206)</u>	<u>(8)</u>
Net cash used in investing activities	<u>(206)</u>	<u>(8)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of convertible bridge note	—	5,000
Proceeds from notes payable, net of original note payoff	500	7,056
Proceeds from issuance of Series C preferred stock, net of issuance costs of \$45	11,955	—
Repayment of term note borrowings	(43)	(28)
Repayment of lease note payable	(62)	(62)
Proceeds from the exercise of common stock options	1	72
Net cash provided by financing activities	<u>12,351</u>	<u>12,038</u>
Net decrease in cash and cash equivalents	<u>(4,385)</u>	<u>(5,917)</u>
Cash and cash equivalents—Beginning of period	11,936	7,551
Cash and cash equivalents—End of period	<u>\$ 7,551</u>	<u>\$ 1,634</u>
<b>Supplemental disclosure of noncash activities</b>		
Accruals of dividends and accretion to redemption value	\$ 2,926	\$ 3,300
Performance Adjustment to Series A and common shares	\$ 12,239	\$ —
Repayment of term note with proceeds of notes payable	\$ —	\$ 944
Cash paid for interest	\$ 73	\$ 181
Cash paid for taxes	\$ 14	\$ —

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

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS**

(in thousands, except share and per share data)

**1. NATURE OF BUSINESS**

**Organization**

Collegium Pharmaceutical, Inc. (the "Company") was incorporated in Delaware in April 2002 and then reincorporated in Virginia in July 2014. The Company has its principal operations in Canton, Massachusetts. The Company is a specialty pharmaceutical company developing and planning to commercialize next-generation abuse-deterrent products that incorporate the Company's patented DETERx® platform technology for the treatment of chronic pain and other diseases. The Company's lead product candidate, Xtampza ER™, or Xtampza, is an abuse-deterrent, extended-release, oral formulation of oxycodone, a widely prescribed opioid medication. Xtampza has received Fast Track status from the U.S. Food and Drug Administration ("FDA"). The Company's new drug application ("NDA") filing for Xtampza was accepted by the FDA on February 10, 2015.

The Company's operations are subject to certain risks and uncertainties. The risks include negative outcome of clinical trials, inability or delay in completing clinical trials or obtaining regulatory approvals, changing market conditions for products being developed by the Company, 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.

**Basis of Accounting**

The financial statements include the accounts of the Company and are prepared in conformity with accounting principles generally accepted in the United States of America.

**Liquidity**

The Company has experienced net losses and negative cash flows from operating activities since its inception, and as of December 31, 2013 and December 31, 2014, had a deficit accumulated of \$80,536 and \$101,753, respectively. The Company expects to continue to incur net losses in the foreseeable future. A successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company's cost structure.

On March 6, 2015, the Company received aggregate consideration of \$50,000 from the issuance of Series D Preferred Stock, comprised of \$45,000 in cash and \$5,000 in convertible notes from related parties.

The Company expects to continue to incur losses for the foreseeable future. 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. The Company believes that it will have sufficient cash to fund operations and future growth initiatives through December 31, 2015; however, there can be no assurance that the Company will be successful in achieving its projections, reducing costs, or raising additional funds with terms acceptable to the Company. 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.

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(in thousands, except share and per share data)

**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 the valuation of equity awards, fair value estimates of warrants, estimated useful lives of fixed assets, asset retirement obligations and accruals related to clinical trials. 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.

**Unaudited Pro Forma Balance Sheet and Net Loss per Share Information**

The unaudited pro forma balance sheet information as of December 31, 2014 assumes the conversion of all outstanding shares of convertible redeemable preferred stock into shares of the Company's common stock.

Unaudited pro forma net loss per share applicable to common shareholders is computed using the weighted-average number of common shares outstanding after giving effect to the conversion of all the outstanding convertible redeemable preferred stock into shares of common stock as if such conversion had occurred at the beginning of the period presented, or the date of original issuance, if later, and excludes the gain on extinguishment of preferred stock and the accretion of dividends.

**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 and accrued liabilities approximate their respective fair values because of the short-term nature of these accounts.

Fair Value Measurements and Disclosures describes 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** Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities. The Company's Level 1 assets and liabilities consist of money market investments.

**Level 2** Quoted prices for similar assets, or inputs that are observable, either directly or indirectly, for substantially the full term through corroboration with observable market data. Level 2 includes investments valued at quoted prices adjusted for legal or contractual restrictions specific to the security. The Company does not have Level 2 assets or liabilities.

**Level 3** Pricing inputs are unobservable for the assets or liabilities, that is, inputs that reflect the reporting entity's own assumptions about the assumptions market participants would use in pricing the assets. Level 3 includes private investments that are supported by little or no market activity. The Company does not have Level 3 assets or liabilities.

**COLLEGIUM PHARMACEUTICAL, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

(in thousands, except share and per share data)

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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, 2013 and 2014.

**Concentration of Credit Risk**

Financial instruments, which potentially subject the Company to significant concentration of credit risk, consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the financial institutions in which those deposits are held. The Company has no financial instruments with off-balance sheet risk of loss.

**Cash and Cash Equivalents**

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

The Company's cash equivalents, which consist of money market funds, are measured at fair value on a recurring basis. As of December 31, 2013 and 2014, the carrying amount of cash and cash equivalents was \$7,551 and \$1,634, 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.

**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:

<u>Asset Category</u>	<u>Estimated Useful Life</u>
Machinery and equipment	5 years
Computers and office equipment	5 years
Furniture and fixtures	7 years
Leasehold improvements	5 years

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.

**Impairment of Long-Lived Assets**

Long-lived assets consist of property and equipment. When impairment indicators exist, the Company's management evaluates long-lived assets for potential impairment. An impairment loss is recorded if and when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. While the Company's current and historical operating losses and negative cash flows are indicators of impairment,

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(in thousands, except share and per share data)

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

management believes that future cash flows to be received support the carrying value of its long-lived assets and, accordingly, has not recognized any impairment losses since inception.

Impairment losses, if any, are recognized in earnings. An impairment loss would be recognized in an amount equal to the excess of the carrying amount over the undiscounted expected future cash flows.

**Initial Public Offering Costs**

The Company defers direct incremental costs attributable to the initial public offering ("IPO") of its common stock. These costs represent legal, accounting and other direct costs related to the Company's efforts to raise capital through a public sale of its common stock. Future costs will be deferred until the completion of the IPO, at which time they will be reclassified to additional paid-in capital as a reduction of the IPO proceeds. If the Company terminates its plan for an IPO or delays such plan for more than 90 days, any costs deferred will be expensed immediately. As of December 31, 2014, IPO costs were \$233 and are included in prepaid expenses and other assets in the balance sheet.

**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.

**Deferred Rent**

Deferred rent consists of the difference between cash payments and the recognition of rent expense on a straight-line basis for the facilities the Company occupies. The Company's lease for its facility provides for fixed increases in minimum annual rental payments and for additional rent in the form of maintenance and operating costs during the lease term. The total amount of rental payments due over the lease term is being charged to rent expense ratably over the life of the lease.

**Convertible Redeemable Preferred Stock**

The Company classifies convertible redeemable preferred stock that is redeemable outside of the Company's control outside of permanent equity. The Company recorded such redeemable preferred stock at fair value upon issuance, net of any issuance costs or discounts, and the carrying value is being increased by periodic accretion to its redemption value at each balance sheet date as if the redeemable preferred stock was redeemable at that date. In the absence of retained earnings these accretion charges are recorded against additional paid-in capital, if any, and then to accumulated deficit.

**Research and Development Costs**

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



**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(in thousands, except share and per share data)

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

other expenses including allocated expenses for rent and maintenance of facilities. Government grants are recognized as a reduction of the qualifying cost being reimbursed.

**Patent Costs**

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

**Stock-Based Compensation**

The Company accounts for grants of stock options and restricted stock to employees 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 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 at year end. Stock-based compensation expense recognized in the financial statements is based on awards that are ultimately expected to vest.

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

The Company accounts for stock options and restricted stock awards to non-employees using the fair value approach. Stock options and restricted stock awards to non-employees are subject to periodic revaluation over their vesting terms. There were no non-employee grants in 2013 and 2014.

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(in thousands, except share and per share data)

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

**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 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, 2013 and 2014, 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 twelve months ended December 31, 2013 and 2014, diluted net loss per common share is the same as basic net loss per common share for those periods.

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

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(in thousands, except share and per share data)

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

**Recently Issued Accounting Pronouncements**

In July 2013, the Financial Accounting Standards Board ("FASB") issued ASU No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exist*. ASU 2013-11 amends the presentation requirements of ASC 740 and requires an unrecognized tax benefit to be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, similar tax loss, or a tax credit carryforward. To the extent the tax benefit is not available at the reporting date under the governing tax law or if the entity does not intend to use the deferred tax asset for such purpose, the unrecognized tax benefit should be presented as a liability and not combined with deferred tax assets. This ASU is effective for annual periods, and interim periods within those years, beginning after December 15, 2013, which is fiscal 2014 for the Company. The amendments are to be applied to all unrecognized tax benefits that exist as of the effective date and may be applied retrospectively to each prior reporting period presented. The adoption of ASU 2013-11 did not have a material impact on the Company's financial position or results of operations.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*. This ASU is a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services. This ASU is effective for annual reporting periods beginning after December 15, 2016 and early adoption is not permitted. Accordingly, the Company will adopt this ASU on January 1, 2017. Management does not believe the adoption of this ASU will have a material impact on the Company's financial condition, results of operations or cash flows.

In June 2014, the FASB issued ASU No. 2014-12, *Compensation — Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period*. ASU 2014-12 applies to all reporting entities that grant their employees share-based payments in which the terms of the award provide that a performance target that affects vesting could be achieved after the requisite service period. That is the case when an employee is eligible to retire or otherwise terminate employment before the end of the period in which a performance target (for example, an initial public offering or a profitability target) could be achieved and still be eligible to vest in the award if and when the performance target is achieved. The standard is required to be adopted by public business entities in annual periods beginning on or after December 15, 2015 and interim periods within those annual periods. The Company plans to implement this standard in the first quarter of fiscal year 2016 and is currently evaluating the potential impact of this new guidance on its financial statements.

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

In November 2014, the FASB issued ASU No. 2014-16, *Derivatives and Hedging (Topic 815) — Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share is More Akin to Debt or to Equity*. This ASU was issued to clarify how current U.S. generally accepted

## COLLEGIUM PHARMACEUTICAL, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

(in thousands, except share and per share data)

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

accounting principles should be interpreted in evaluating the economic characteristics and risk of a host contract in a hybrid financial instrument that is issued in the form of a share. In addition, this ASU was issued to clarify that in evaluating the nature of a host contract, an entity should assess the substance of the relevant terms and features (that is, the relative strength of the debt-like or equity-like terms and features given the facts and circumstances) when considering how to weight those terms and features. The effects of initially adopting this ASU should be applied on a modified retrospective basis to existing hybrid financial instruments issued in a form of a share as of the beginning of the fiscal year for which the amendments are effective. Retrospective application is permitted to all relevant prior periods. This ASU is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. Early adoption in an interim period is permitted. The Company is currently evaluating the impact of the adoption of this ASU on its financial statements.

## 3. NET LOSS PER COMMON SHARE

Basic net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. 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. Stock options, warrants, convertible preferred stock and unvested restricted stock are considered to be potentially dilutive securities and are only included in the calculation of diluted net loss per share when their effect is dilutive. For the twelve months ended December 31, 2013 and December 31, 2014, these securities were anti-dilutive due to the net losses in those periods and, therefore, the number of shares used to compute basic and diluted earnings per share are the same for those periods.

In connection with the Company's recalculation of loss per common share to reflect the reverse stock split, the Company identified an immaterial error in its weighted-average shares calculation for the years ended December 31, 2013 and 2014. The impact of the errors was to reduce basic and diluted net loss per common share from \$(4.24) to \$(4.06) for 2013 and from \$(25.63) to \$(22.72) for 2014 and have been corrected in the periods in which they originated.

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

	<u>Years Ended December 31,</u>		<u>Pro Forma Year</u>
	<u>2013</u>	<u>2014</u>	<u>Ended</u>
			<u>December 31,</u>
			<u>2014</u>
			<u>(unaudited)</u>
Net loss	\$ (16,197)	\$ (17,917)	\$ (17,917)
Performance Adjustment of Series A	12,239	—	—
Accruals of dividends and accretion to redemption value of preferred stock	(2,925)	(3,300)	(3,300)
Loss attributable to common shareholders — basic and diluted	<u>\$ (6,883)</u>	<u>\$ (21,217)</u>	<u>\$ (21,217)</u>
Weighted-average shares used in computing basic and diluted net loss per common share	<u>1,697,044</u>	<u>933,997</u>	<u>7,471,303</u>
Basic and diluted net loss per common share	<u>\$ (4.06)</u>	<u>\$ (22.72)</u>	<u>\$ (2.84)</u>

## COLLEGIUM PHARMACEUTICAL, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

(in thousands, except share and per share data)

## 3. NET LOSS PER COMMON SHARE (Continued)

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,		Pro Forma Year
	2013	2014	Ended December 31, 2014 (unaudited)
Stock Options	229,791	281,029	281,029
Warrants	4,170	18,809	18,809
Redeemable convertible preferred stock	6,552,820	6,552,820	—
Unvested restricted stock	55,298	15,387	15,387

## 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	As of December 31,	
	2013	2014
Other current assets	\$ —	\$ 253
Initial public offering costs	—	233
Employee advances	21	33
Prepaid expenses	33	8
Prepaid development costs	656	—
Prepaid expenses and other current assets	<u>\$ 710</u>	<u>\$ 527</u>

## 5. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	As of December 31,	
	2013	2014
Machinery and equipment	\$ 741	\$ 741
Computers and office equipment	26	26
Furniture and fixtures	36	44
Leasehold improvements	606	606
Total property and equipment	1,409	1,417
Less: accumulated depreciation	(716)	(903)
Property and equipment, net	<u>\$ 693</u>	<u>\$ 514</u>

Depreciation expense related to property and equipment amounted to \$169 and \$187 for the years ended December 31, 2013 and 2014, respectively.

## COLLEGIUM PHARMACEUTICAL, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

(in thousands, except share and per share data)

## 6. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of December 31,	
	2013	2014
Accrued development costs	\$ 520	\$ 970
Accrued compensation	449	635
Accrued audit and legal	12	249
Accrued interest	—	71
Accrued other	32	31
Total accrued expenses	<u>\$ 1,013</u>	<u>\$ 1,956</u>

## 7. COMMITMENTS AND CONTINGENCIES

## Legal Proceedings

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

The Company's NDA filing for Xtampza is a 505(b)(2) application, which allows the Company to reference data from an approved drug listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book"), in this case OxyContin OP. In connection with the 505(b)(2) process, the Company certified to the FDA and notified Purdue Pharma, L.P. ("Purdue"), as the holder of the NDA and any other Orange Book-listed patent owners, that the Company does not infringe any of the patents listed for OxyContin OP in the Orange Book. Under the Hatch-Waxman Act of 1984 (the "Hatch-Waxman Act"), Purdue can elect to sue the Company for infringement, and if they do, receive a stay of up to 30 months before the FDA can issue a final approval for Xtampza, unless the stay is earlier terminated. Purdue has not yet brought such litigation, but it is possible that they will do so. At this time the Company is unable to provide meaningful quantification of how this potential litigation may impact its future financial condition, results of operations, or cash flows.

## Operating Leases

The Company leases its office and research facility under a non-cancellable operating lease, which expires in December 2017. 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. Aggregate minimum annual lease commitments of the Company under its non-cancellable operating lease as of December 31, 2014 are as follows:

Year Ending December 31,	
2015	\$ 106
2016	111
2017	116
Total minimum lease payments	<u>\$ 333</u>

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(in thousands, except share and per share data)

**7. COMMITMENTS AND CONTINGENCIES (Continued)**

Rent expense under the operating lease agreement amounted to approximately \$69 for the years ended December 31, 2013 and 2014, respectively. In addition, the Company maintained a stand-by letter of credit in connection with the Canton facility lease of \$80 at December 31, 2013 and December 31, 2014. This amount is classified as restricted cash in the balance sheets.

As an inducement to enter into its Canton facility lease, the lessor agreed to provide the Company with an improvement allowance of up to \$174 towards leasehold improvements. In addition the lessor provided the Company with a reimbursable allowance of \$164 which is to be amortized and repaid by the Company at an 8% interest rate over the initial term of 36 months. Amounts provided by the lessor related to tenant improvements are considered inducements to enter into the lease. The Company has recorded these costs in the balance sheet as leasehold improvements, with the corresponding liabilities as deferred lease incentive and lease note payable. These liabilities are amortized on a straight-line basis over the term of the lease.

**8. DEBT**

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 23,810 shares of common stock at an exercise price of \$0.07 per share (See Note 9).

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 9).

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 9).

In September 2014, the Original Term Loan was further amended ("Amendment No. 3") to extend the loan draw period through the earlier to occur of September 30, 2014 and an Event of Default.

**COLLEGIUM PHARMACEUTICAL, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

(in thousands, except share and per share data)

**8. DEBT (Continued)**

The Company capitalized deferred financing costs of approximately \$38 in entering into the Original Term Loan, of which approximately \$16 was repaid at the time of Amendment No. 1 with the remaining approximately \$22 being amortized to interest expense over the term of the debt. The balance of deferred financing costs was approximately \$15 and \$7 at December 31, 2013 and December 31, 2014 respectively. The total outstanding amount of the loans was \$958 and \$8,000 at December 31, 2013 and December 31, 2014 respectively. Interest expense on these notes payable totaled \$62 and \$208 for the years ended December 31, 2013 and December 31, 2014.

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. All notes become due and payable at the earlier to occur of a qualified financing, a deemed liquidation event and November 2015.

As of December 31, 2014, future payments under the Company's debt agreements are as follows:

2015	\$ 6,194
2016	2,667
2017	2,667
2018	1,479
Balance as of December 31, 2014	<u>\$ 13,007</u>

**9. WARRANTS**

In November 2010, the Company issued to Comerica Bank a warrant to purchase 33,746 shares of a series of then outstanding preferred stock with an exercise price of \$1.778 per share through October 28, 2017. In February 2012, all outstanding shares of Preferred Stock were converted to shares of Series A Preferred Stock. As such the warrant was amended to be exercisable into 33,746 shares of Series A Preferred Stock. In December 2013, a Performance Adjustment (See Note 10) occurred, pursuant to which the Series A Preferred Stock and common stock were subject to modification such that every two shares of issued and outstanding Series A Preferred Stock and common stock became one share of each class respectively, resulting in the warrant being adjusted to represent the right to purchase 16,873 shares of Series A Preferred Stock. The shares of Series A Preferred Stock have certain mandatorily redeemable features resulting in the warrant being recorded as a liability and re-measured at each period at fair value. The fair value of the warrant was *de minimis* at December 31, 2013 and December 31, 2014.

In connection with the issuance of the Original Term Loan (See Note 8), in August 2012, the Company issued to SVB a warrant to purchase 3,450 shares of common stock with an exercise price of \$0.48 per share through August 27, 2022.

This Performance Adjustment resulted in the number of common shares issuable upon exercise of the warrant being adjusted to 1,725.

In connection with the execution of Amendment No. 1 to the Original Term Loan in January 2014, the Company issued an additional warrant to the lending financial institution. In January 2014, the Company issued a warrant to purchase 2,091 shares of common stock with an exercise price of \$0.35 per share through January 31, 2024. The warrant agreement provides for additional warrant shares to be issued and



**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(in thousands, except share and per share data)

**9. WARRANTS (Continued)**

immediately exercisable upon additional borrowings by the Company. Additional borrowings are contingent upon meeting certain performance measures for the Company's lead product candidate. The Company met the performance measures and in August 2014 additional financing was extended. Based on the terms of the warrant agreement an additional 12,548 shares were granted. The fair value of these warrants was *de minimis* at December 31, 2013 and December 31, 2014.

**10. EQUITY**

As of December 31, 2013, the authorized capital stock of the Company included 72,000,000 shares of common stock, par value \$0.001 per share, 962,960 of which were issued and outstanding. As of December 31, 2013, 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.

As of December 31, 2014, the authorized capital stock of the Company included 72,000,000 shares of common stock, par value \$0.001 per share, 1,006,219 of which were issued and outstanding. 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.

**Common Stock**

*General*

The voting, dividend and liquidation rights of the holders of shares of common stock are subject to and qualified by the rights, powers and preferences of the holders of shares of preferred stock. Common stock has the characteristics described herein.

*Voting*

The holders of shares of common stock are entitled to one vote for each share of common stock held, may act by written consent in lieu of shareholder's meetings in accordance with the Company's articles of incorporation, and shall be entitled to notice of shareholder's meetings.

*Dividends*

The Company shall not declare, pay or set aside any dividends on shares of common stock (other than dividends on shares of common stock payable in shares of common stock) unless in addition to obtaining any consents required by law and/or the Company's articles of incorporation, the holders of Series A, Series B and Series C Preferred Stock then outstanding receive a dividend payment as specified in the Company's articles of incorporation.

**COLLEGIUM PHARMACEUTICAL, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

(in thousands, except share and per share data)

**10. EQUITY (Continued)***Liquidation*

After payment of all preferential amounts required to be paid to the holders of shares of Preferred Stock, the remaining assets of the Company available for distribution to the shareholders shall be distributed among the holders of shares of Preferred Stock and common stock pro rata based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to common stock pursuant to the terms of the Company's articles of incorporation immediately prior to such dissolution, liquidation or winding up or deemed liquidation event of the Company.

*Reserved for future issuance*

The Company has reserved for future issuance the following number of shares of common stock:

	<b>As of December 31, 2014</b>
Conversion of Series A Preferred	18,498,419
Conversion of Series B Preferred	27,324,237
Conversion of Series C Preferred	8,658,344
Options to purchase common stock	3,412,685
<b>Total</b>	<b>57,893,685</b>

**Convertible Redeemable Preferred Stock****Series A, B and Series C Redeemable Convertible Preferred Stock**

In February 2012, the Company exchanged all previously outstanding preferred stock into 18,464,674 shares of Series A Preferred Stock ("Series A"), par value \$0.001. On the same date, the Company issued 27,324,237 shares of Series B Preferred Stock ("Series B"), par value \$0.001 for \$0.84 per share, which resulted in gross proceeds of \$20,050. Closing costs associated with the issuance of the Series B amounted to \$147. These costs were recorded as a reduction of the carrying amount of the Series B and are being accreted to the carrying value of the applicable preferred stock. During 2013, the Company issued 8,658,008 shares of Series C Preferred Stock ("Series C") in exchange for \$12,000 in a series of tranches. Costs incurred in connection with the issuance of Series C amounted to \$45 and have been recorded as a reduction to the carrying amount of Series C and were accreted to the carrying value of the applicable preferred stock. In accordance with the terms of the Series C Preferred Stock Purchase Agreement, the Company authorized the sale and issuance of up to 8,658,008 shares of Series C for total gross proceeds of \$12,000. Closing costs associated with the issuance of Series C amounted to \$45. The Series C financing was structured to close in two tranches. The Company determined the right of the investors to purchase shares of Series C in a future tranche met the definition of a freestanding financial instrument and was recognized as a liability at fair value. The Company adjusted the carrying value of the tranche obligations to its estimated fair value at each reporting date and upon closing of the second tranche in December 2013. Increases or decreases in the fair value of the tranche obligations were recorded as other expense, net, in the statements of operations.

The first tranche closed in August and September 2013 and resulted in the issuance of 2,886,004 shares of Series C for gross cash proceeds of \$4,000. Upon the first tranche closing, the Company recognized a liability of \$266 for the fair value of the future tranche obligations. The fair value of the freestanding

**COLLEGIUM PHARMACEUTICAL, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****(in thousands, except share and per share data)****10. EQUITY (Continued)**

instrument tranche obligations was determined using Black-Scholes option-pricing models on the date of the issuance using the following assumptions: fair value of Series C of \$1.30, expected life of 0.35 to 0.43 years and expected volatility of 53% to 60%.

The liability related to the tranche obligations was remeasured at fair value up to the date of the closing of the second tranche in December 2013. Upon the closing of the second tranche, the Company derecognized the tranche obligation, which resulted in a net increase in the proceeds allocated to the Series C shares of \$345. The fair value of the freestanding instrument tranche obligations was determined using Black-Scholes option-pricing models on the date of the issuance using the following assumptions: fair value of Series C of \$1.27, expected life of 0.16 years and expected volatility of 52%.

The valuation of the tranche obligation liability was determined to be a Level 3 valuation based upon the use of unobservable inputs. A roll-forward of the recurring fair value measurements of the tranche liability categorized with Level 3 inputs are as follows:

Balance — December 31, 2012	\$	—
Tranche liability upon issuance		266
Change in fair value		79
Tranche liability upon close of tranche		(345)
Balance — December 31, 2013	\$	<u>—</u>

The closing of the second tranche of Series C in December 2013 triggered the Performance Adjustment (described below) of the outstanding shares of Series A and common stock to which the Series A and common stock were subject to modification in which every two shares of issued and outstanding Series A and common shares became one share of each class respectively. In connection with the Performance Adjustment, the Company adjusted the carrying value of the outstanding shares of Series A to its redemption amount by recording a decrease of \$12,239.

As of December 31, 2014, the holders of Series A, Series B and Series C Preferred Stock had rights, preferences, privileges and restrictions as follows:

*Voting*

The holders of shares of Preferred Stock are entitled to the number of votes equal to the number of whole shares of common stock into which the shares of the applicable series of Preferred Stock held by such holder are convertible as of the record date. Except as provided by law or otherwise, the holders of shares of Preferred Stock vote together with the holders of shares of common stock as a single class. The holders of record of Series A exclusively and as a separate class are entitled to elect two directors of the Company. The holders of record of Series B and Series C exclusively and as a separate class are entitled to elect one director, respectively, of the Company. The Company cannot amend, alter or repeal the preferences, special rights or other powers of the Series A, Series B or Series C without the written consent or affirmative vote of not less than 66% of the then outstanding shares of the respective class.

*Dividends*

From and after the issuance of any shares of Series A, Series B and Series C cumulative non-compounding stock, dividends will accrue at a rate of 4.5%, 8.0% and 8.0% per annum respectively per share. In the

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(in thousands, except share and per share data)

**10. EQUITY (Continued)**

event a dividend is declared on common stock, Series A, Series B and Series C will receive a dividend equal to the equivalent number of common shares multiplied by the dividend payable on each class of stock. The Company has recorded cumulative accrued dividends for Series A, Series B and Series C of \$2,371, \$5,307 and \$1,114, respectively, as of December 31, 2013 and 2014.

*Conversion*

Each share of Series A, Series B and Series C is convertible at the option of the holder at any time into such number of fully paid and nonassessable shares of common stock as is determined by dividing the original issue price of each Series by its conversion price of \$8.46, \$5.80 and \$9.59 per share, respectively.

Conversion is mandatory for all Series upon an IPO with gross proceeds in excess of \$50,000 and a price per share of at least \$20.70.

*Special Mandatory Conversion*

Any holder of at least 1,000,000 shares of Preferred Stock who does not participate in a Qualified Financing by purchasing such holder's applicable portion of the shares of each Preferred Stock, within the time period specified by the Company, are automatically converted into shares of Common Stock at the applicable Conversion Price to that series of Preferred Stock concurrently with the Qualified Financing. A Qualified Financing is a financing or series of financings after the issuance date of the Series C involving the sale of additional shares of common stock (including pursuant to the conversion of debt) with gross proceeds of more than \$1,000.

*Liquidation Rights*

In the event of any voluntary or involuntary liquidation, dissolution or winding-up of the affairs of the Company or a Deemed Liquidation Event, the holders of Series B are entitled to be paid out an amount per share equal to two times the Series B original issue price of \$5.80 plus unpaid accrued dividends. The holders of Series A and Series C are entitled to be paid out an amount per share equal to one times the original issue price of \$8.46 and \$9.59, respectively, plus any unpaid accrued dividends. After the payment of all preferential amounts required to be paid to the holders of the Preferred Stock, all the remaining assets of the Company shall be distributed among the holders of the common and Preferred Stock pro rata based on the number of shares held.

*Participation*

In the event of liquidation, payment to the holders of Series C shall precede payment to the holders of Series B, which shall precede payment to the holders of Series A. Holders of Series C shall be paid at their Original Issuance Price plus any unpaid accrued dividends. In the event that the amount to be distributed to the shareholders is in excess of the Series A, Series B and Series C liquidation preferences, the preferred holders shall participate on an as-converted basis with the common stock holders in the distribution of the remaining assets.

*Redemption*

The Company shall require a redemption of Series A, Series B and Series C in the event of a deemed liquidation event, including (i) merger or consolidation, (ii) sale or transfer of substantially all of the Company's assets or (iii) sale or exchange or transfer by the Company's shareholders of a majority of the voting power of the Company unless the requisite holders (as defined in the Company's articles of incorporation) elect otherwise.

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(in thousands, except share and per share data)

**10. EQUITY (Continued)**

There is an optional redemption feature on or after August 27, 2019 for all series of Preferred Stock, upon a vote of at least 60% of the holders of the Preferred Stock voting as a single class. The payment is equal to the original issuance price for Series A and Series C and two (2) times the original issuance price for Series B, plus unpaid accrued dividends on the date of the redemption. Optional redemption shall be paid in three installments.

*Protective Provision*

At any time when there are shares of Series B and Series C outstanding the Company will not engage in certain activities (including enter into a liquidating event) without written consent of a majority of the Series B and Series C holders.

*Performance Adjustment*

The Company's articles of incorporation provided that if the Company raised additional capital in excess of \$4,000 after the initial closing of the Series C financing, that such additional financing would trigger a one-time modification of the Series A and common stock shares (the "Performance Adjustment"), such that every two shares of issued and outstanding Series A and common stock became one share of each class, respectively. The Performance Adjustment occurred in December 2013.

**11. STOCK-BASED COMPENSATION**

**Restricted Stock Awards and Stock Options**

In July 2014, the Company adopted the 2014 Stock Incentive Plan (the "Plan"), under which 525,700 shares of common stock are authorized for issuance to employees, officers, directors, consultants and advisors of the Company. As of December 31, 2014, 281,029 of the shares of common stock authorized for issuance pursuant to the Plan were outstanding. In connection with the Company's reincorporation into Virginia in July 2014, each outstanding option to purchase shares of common stock under the 2012 Stock Incentive Plan and 2002 Stock Plan, was automatically terminated and replaced with an option to purchase shares of common stock under the Plan having the same vesting terms and exercise price as the option that was replaced. 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.

In determining the exercise prices for options granted, the board of directors considered the fair value of the common stock as of the measurement date. The fair value of the common stock was determined by the board of directors based on a variety of factors, including valuations prepared by third parties, Company's financial position, the status of development efforts within the Company, the composition and ability of the current scientific and management teams, the current climate in the marketplace, the illiquid nature of the Company's common stock, arm's length sales of the Company's preferred stock, the effect of the rights and preferences of the preferred shareholders, and the prospects of a liquidity event, among others.

In connection with the Performance Adjustment which occurred on December 4, 2013 (See Note 10) the Company adjusted previously granted and then outstanding options such that for each option exercised, the

## COLLEGIUM PHARMACEUTICAL, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

(in thousands, except share and per share data)

## 11. STOCK-BASED COMPENSATION (Continued)

option holder would receive one share of common stock for every two shares of common stock underlying the grant.

Stock option activity under the Plan is summarized as follows:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2012	323,488	\$ 1.73	6.94	\$ 8
Granted	146,730	0.48		
Exercised	(1,077)	0.62		
Cancelled	(9,559)	2.76		
Modification	(229,791)	1.17		
Outstanding at December 31, 2013	229,791	1.17	7.02	117
Granted	89,641	0.28		
Exercised	(32,390)	2.21		—
Cancelled	(6,013)	4.42		
Outstanding at December 31, 2014	281,029	\$ 0.69	7.49	\$ 1,505
Vested and expected to vest at December 31, 2014	247,139	\$ 0.83	4.31	\$ 1,293
Exercisable at December 31, 2014	121,304	\$ 1.38	4.31	\$ 570

As of December 31, 2013 and 2014, the unrecognized compensation cost related to outstanding options was \$40 and \$215, respectively, and is expected to be recognized as expense over approximately 1.1 years and 1.0 years, respectively.

As of December 31, 2014, the weighted average fair value of vested options was \$1.93.

Additional information about the Company's stock option activity is as follows:

	As of December 31,	
	2013	2014
Weighted-average grant date fair value per share of employee option grants	\$ 0.28	\$ 0.76

## COLLEGIUM PHARMACEUTICAL, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

(in thousands, except share and per share data)

## 11. STOCK-BASED COMPENSATION (Continued)

Restricted stock awards under the Plan are summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2012	203,342	\$ 0.62
Vesting of restricted stock	(89,308)	0.55
Performance Adjustment	(58,736)	0.62
Unvested at December 31, 2013	55,298	0.69
Grant of restricted stock	10,869	1.24
Vesting of restricted stock	(50,780)	0.62
Unvested at December 31, 2014	<u>15,387</u>	<u>\$ 0.69</u>

As of December 31, 2013 and 2014, the unrecognized compensation cost related to restricted stock awards was \$73 and \$26, respectively, and is expected to be recognized as expense over approximately 1.2 years and 0.2 years, respectively.

**Stock-Based Compensation Expense**

The Company granted stock options to employees for the years ended December 31, 2013 and 2014. The Company estimates the fair value of stock options as of the date of grant using the Black-Scholes option pricing model and restricted stock 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 and restricted stock awards are reported within:

	Years Ended December 31,	
	2013	2014
Research and development	\$ 24	\$ 12
General and administrative	38	10
Total stock-based compensation expense	<u>\$ 62</u>	<u>\$ 22</u>

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

	Years Ended December 31,	
	2013	2014
Risk-free interest rate	1.09% – 1.22%	1.80%
Expected volatility	87.8%	77.1%
Expected term (in years)	6.25	6.25
Expected dividend yield	0.0%	0.0%

## COLLEGIUM PHARMACEUTICAL, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

(in thousands, except share and per share data)

## 11. STOCK-BASED COMPENSATION (Continued)

**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 medical device industries.

**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, 2014 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. In 2013, some of the stock option grants were in-the-money, based on the retrospective fair value determinations, so the Company determined the expected life using a risk-adjusted method, which adjusts the average of the contractual term of the option and its vesting period for risk, thereby reducing the expected life.

**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.

## 12. INCOME TAXES

For the years ended December 31, 2014 and 2013, the Company did not record a current or deferred income tax expense or (benefit) due to current and historical losses incurred by the Company. The Company's losses before income taxes consist solely of domestic losses.

A reconciliation of income tax expense (benefit) computed at the statutory federal income tax rate to income taxes as reflected in the financial statements is as follows:

	As of December 31,	
	2013	2014
Federal income tax (benefit) at statutory rate	34.00%	34.00%
(Increase) decrease income tax (benefit) resulting from:		
Expiration of state net operating losses	(12.11)	0.00
Permanent items	(0.01)	(0.17)
Research and experimental credits	4.19	3.74
Change in valuation allowance	(26.07)	(37.57)
Income tax expense (benefit)	<u>0.00%</u>	<u>0.00%</u>



## COLLEGIUM PHARMACEUTICAL, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

(in thousands, except share and per share data)

## 12. INCOME TAXES (Continued)

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,	
	2013	2014
Deferred tax assets:		
Net operating loss carryforwards	\$ 21,392	\$ 28,419
Depreciation and amortization	—	36
Research Credits	2,400	3,070
Deferred tax assets before valuation allowance	23,792	31,525
Valuation allowance	(23,788)	(31,525)
	4	—
Deferred tax liabilities:		
Depreciation and amortization	(4)	—
	(4)	—
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, 2014 and 2013, 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, 2014 and 2013. The valuation allowance increased \$7,737 during the year ended December 31, 2014, due primarily to net operating losses generated. The valuation allowance increased by \$5,081 during the year ended December 31, 2013, due primarily to net operating losses generated.

As of December 31, 2014 and 2013, the Company had U.S. federal net operating loss carryforwards of \$78,276 and \$60,380, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2034. As of December 31, 2014 and 2013, the Company also had U.S. state net operating loss carryforwards of \$34,184 and \$16,354, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2034.

Utilization of the NOL and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred or that could occur in the future, as required by Section 382 and Section 383 of the Internal Revenue Code of 1986, as amended (the "Code"), as well as similar state and foreign provisions. These ownership changes may limit the amount of net operating loss and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain shareholders. The Company has not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since its formation. The Company has not recorded net operating losses that, as a result of these restrictions, will expire unused.

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(in thousands, except share and per share data)

**12. INCOME TAXES (Continued)**

The Company files income tax returns in the United States and Massachusetts. The federal and Massachusetts income tax returns are generally subject to tax examinations for the tax years ended December 31, 2011 through December 31, 2013. 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 and state tax authorities to the extent utilized in a future period.

**13. EMPLOYEE BENEFITS**

The Company has a retirement savings plan, which is qualified under section 401(k) of the Code, for its employees. The plan allows eligible employees to defer, at the employee's discretion, pretax compensation up to the Internal Revenue Service annual limits. Employees become eligible to participate after completing 3 months of service. The Company is not required to contribute to this plan. Total expense for contributions made by the Company was \$31 for the year ended December 31, 2013 and \$35 for the year ended December 31, 2014.

**14. SUBSEQUENT EVENTS**

The Company has completed an evaluation of all subsequent events through April 27, 2015, the date these financial statements are available to be issued. The Company has concluded that no subsequent event has occurred that requires disclosure, except as noted below:

- (a) 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.
- (b) On March 24, 2015, Purdue sued the Company in the District of Delaware asserting infringement of four patents. On March 26, 2015, Purdue filed a second suit against the Company in the District of Massachusetts asserting infringement of the same four patents.
- (c) In March 2015, the Company granted a total of 638,095 stock options under the Plan to employees. The stock options were granted at fair market value on the date of grant, vest over approximately four years and expire ten years from the date of grant.
- (d) In March 2015, the Plan was amended to increase the maximum number authorized for issuance pursuant to the Plan to 1,087,005 shares.
- (e) 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 the date that is 5 years following the date, which has not yet been determined, on which the landlord delivers the expansion space with certain improvements substantially completed. At the Company's election, the lease term may be extended for an additional 5-year term.
- (f) In April 2015, the Company granted 194,694 shares of restricted stock to an employee. Pursuant to the grant, 97,347 shares vested upon grant, while the remaining 97,347 shares of restricted stock vest in monthly installments over a three-year period commencing as of the date of grant.
- (g) In April 2015, 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 our common stock, including reclassifying an amount equal to the reduction in par value to additional paid-in capital.

Through and including \_\_\_\_\_, 2015 (the 25<sup>th</sup> day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

**5,800,000 Shares**



**Collegium Pharmaceutical, Inc.**

**Common Stock**

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**PRELIMINARY PROSPECTUS**

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**Jefferies**

**Piper Jaffray**

**Wells Fargo Securities**

**Needham & Company**

, 2015

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**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth all expenses, other than underwriting discounts and commissions, paid or payable by us in connection with this offering. All amounts shown are estimates except for the SEC registration fee, the Financial Industry Regulatory Authority, or FINRA, filing fee and NASDAQ listing fee.

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	<u>Amount Paid or to be Paid</u>
SEC registration fee	\$ 10,851
FINRA filing fee	14,507
NASDAQ Global Market listing fee	125,000
Blue sky qualification fees and expenses, if any	20,000
Printing and engraving expenses	275,000
Legal fees and expenses	1,725,000
Accounting fees and expenses	375,000
Transfer agent and registrar fees and expenses	15,000
Miscellaneous expenses	39,642
Total	<u>\$ 2,600,000</u>

**Item 14. Indemnification of Directors and Officers.****Virginia Stock Corporation Act**

We are a Virginia corporation. The Virginia Stock Corporation Act, or the VSCA, permits indemnification of a corporation's directors and officers in a variety of circumstances, which may include indemnification for liabilities under the Securities Act. Sections 13.1-696 and 13.1-704 of the VSCA generally authorize a Virginia corporation to indemnify its directors and officers in civil or criminal actions if they acted in good faith and believed their conduct to be in the best interests of the corporation if acting in their official capacity with the corporation or, in all other cases, at least not opposed to its best interests, and, in the case of criminal actions, had no reasonable cause to believe that the conduct was unlawful. Additionally, Section 13.1-704 of the VSCA provides that a Virginia corporation has the power to make any further indemnity to any director or officer, including in a proceeding brought by or in the right of the corporation, if authorized by its articles of incorporation or any bylaw or resolution adopted by the shareholders, except an indemnity against his or her willful misconduct or a knowing violation of the criminal law. Our amended and restated articles of incorporation require us to indemnify our directors and officers to the full extent permitted by the VSCA.

Our amended and restated articles of incorporation also provide that, to the full extent that the VSCA permits the limitation or elimination of the liability of directors and officers, no director or officer of the Company shall be liable in any proceeding brought by or on behalf of the Company or its shareholders for monetary damages arising out of any transaction, occurrence or course of conduct. Section 13.1-692.1 of the VSCA permits the elimination of liability of directors and officers in any proceeding brought by or in the right of a corporation or brought by or on behalf of shareholders of a corporation, except for liability resulting from such persons having engaged in willful misconduct or a knowing violation of the criminal law or any federal or state securities law, including, without limitation, any unlawful insider trading or manipulation of the market for any security.

We have or will enter into indemnification agreements with each of our directors and officers pursuant to which we agree to indemnify, including advancing expenses to, each of them against any liabilities that he or she may incur as a result of his or her service as a director or officer of the Company to the fullest extent permitted by Virginia law and our amended and restated articles of incorporation.

We carry insurance on behalf of directors, officers, employees or agents that may cover liabilities under the Securities Act.

The form of underwriting agreement attached hereto as Exhibit 1.1 provides for indemnification by the underwriters named in this registration statement of our executive officers, directors and us, and by us of the underwriters named in the registration statement, for certain liabilities, including liabilities arising under the Securities Act, in connection with matters specifically provided in writing for inclusion in this registration statement.

**Item 15. Recent Sales of Unregistered Securities.**

During the three years preceding the filing of this registration statement, we (since our reincorporation in Virginia in July 2014) and our predecessor Delaware corporation (prior to such reincorporation), issued unregistered securities in the following transactions. None of these transactions involved underwriters, underwriting discounts or commissions, or any public offering, and we believe that each transaction was exempt from the registration requirements of the Securities Act, as described below.

(i) Issuances of Common Stock

- § In April 2015, we issued 194,694 shares of restricted common stock to Michael T. Heffernan. Pursuant to the grant, 97,347 of the shares of restricted common stock vested upon grant while the remaining 97,347 shares of restricted common stock vest in monthly installments over a three-year period commencing as of the date of the grant;
- § In connection with our reincorporation into Virginia in July 2014, each outstanding share of common stock was converted into one share of common stock of the new Virginia corporation.
- § In connection with the closing of the second tranche of our Series C Convertible Preferred Stock financing in December 2013, every two issued and outstanding shares of common stock were reclassified and combined into one share of common stock.
- § On June 13, 2012, we issued 247,437 restricted shares of common stock, which have since vested, to Michael T. Heffernan under the 2012 Stock Incentive Plan.

(ii) Issuances of Preferred Stock

- § In March 2015, we issued 41,666,667 shares of our Series D Convertible Preferred Stock to TPG Biotechnology Partners IV, L.P., RA Capital Healthcare Fund, LP, the Longitude Funds, Skyline Venture Partners V, L.P., Frazier Healthcare VI, L.P., the Boston Millennia Funds and certain other investors, at a purchase price of \$1.20 per share, for an aggregate purchase price of approximately \$50.0 million.
- § In connection with our reincorporation into Virginia in July 2014, each outstanding share of Series A Convertible Preferred Stock, Series B Convertible Preferred Stock and Series C Convertible Preferred Stock was converted into one share of Series A Convertible Preferred Stock, Series B Convertible Preferred Stock and Series C Convertible Preferred Stock, respectively, of the new Virginia corporation.
- § In connection with the closing of the second tranche of our Series C Convertible Preferred Stock financing in December 2013, every two issued and outstanding shares of Series A Convertible Preferred Stock were reclassified and combined into one share of Series A Convertible Preferred Stock.
- § In December 2013, those investors who participated in the closings in August and September 2013 exercised their option to purchase an additional pro rata portion of an aggregate of

5,772,004 shares of our Series C Convertible Preferred Stock, at a purchase price of \$1.386 per share, for an aggregate purchase price of approximately \$8 million.

§ On August 27, 2013, we issued 2,220,670 shares of our Series C Convertible Preferred Stock to the Longitude Funds, Skyline Venture Partners V, L.P., Frazier Healthcare VI, L.P. and certain other existing investors in the Company, at a purchase price of \$1.386 per share, for an aggregate purchase price of approximately \$3.1 million, or the Initial Tranche 1 Closing. On September 25, 2013, we issued and sold an additional 665,334 shares of Series C Convertible Preferred Stock to certain of our investors, some of whom did not participate in the Initial Tranche 1 Closing and who qualified as "accredited investors" under Regulation D of the Securities Act, at a purchase price of \$1.386 per share, for an aggregate purchase price of approximately \$922,000, or the Additional Tranche 1 Closing.

§ On February 10, 2012, we issued an aggregate of 27,324,237 shares of Series B Convertible Preferred Stock to the Longitude Funds, Skyline Venture Partners V, L.P., Frazier Healthcare VI, L.P., the Boston Millennia Funds and certain other investors, at a purchase price of \$0.84 per share, for an aggregate purchase price of approximately \$23.0 million.

§ On February 10, 2012, in connection with our Series B Convertible Preferred Stock financing, all issued and outstanding shares of previously issued Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock, Series C-2 Preferred Stock and Series D-1 Preferred Stock were converted into shares of Series A Convertible Preferred Stock. In connection with this financing, we issued an aggregate of 18,464,674 shares of Series A Convertible Preferred Stock.

(iii) Issuance of Convertible Notes

§ In November and December 2014, we entered into a Convertible Note Purchase Agreement, pursuant to which we issued and sold to investors convertible promissory notes in the aggregate principal amount of \$5 million. The participants in the convertible note financing described above included the Longitude Funds, Skyline Venture Partners V, L.P., Frazier Healthcare VI, L.P. and the Boston Millennia Funds. In connection with the Series D Convertible Stock financing, convertible notes in the aggregate principal amount of \$5 million automatically converted to an aggregate of 4,166,667 shares of Series D Convertible Preferred Stock.

(iv) Stock Option Grants

§ In March 2015, we granted options to purchase an aggregate of 638,095 shares of our common stock with an exercise price of \$5.73 per share to 24 employees and 1 director.

§ In connection with our reincorporation into Virginia in July 2014, each outstanding option to purchase shares of common stock under the 2012 Stock Incentive Plan, as amended, and the Amended and Restated 2002 Stock Option Plan, as amended, was automatically terminated and replaced with an option to purchase shares of common stock under the 2014 Stock Incentive Plan having the same vesting terms and exercise price as the option that was replaced.

§ On March 5, 2014, we granted options to purchase an aggregate of 89,641 shares of our common stock with an exercise price of \$0.28 per share to 16 employees.

§ On May 30, 2013, we granted options to purchase an aggregate of 79,778 shares of our common stock with an exercise price of \$0.48 per share to 2 employees.

§ On January 24, 2013, we granted options to purchase an aggregate of 66,952 shares of our common stock with an exercise price of \$0.48 per share to 14 employees.

§ On December 20, 2012, we granted options to purchase an aggregate of 724 shares of our common stock with an exercise price of \$0.48 per share to 1 employee.

§ On August 16, 2012, we granted options to purchase 72,462 shares of our common stock with an exercise price of \$0.48 per share to 1 employee.

§ On May 10, 2012, we granted options to purchase an aggregate of 39,275 shares of our common stock with an exercise price of \$0.48 per share to 9 employees.

(v) Warrants

§ In connection with our reincorporation into Virginia in July 2014, each warrant to purchase shares of Series A Convertible Preferred Stock and each warrant to purchase shares of our common stock was assumed by the new Virginia corporation.

§ On August 28, 2012, in connection with the closing of the Original Term Loan, we issued the First SVB Warrant, which warrant was immediately exercisable for 3,450 shares of our common stock at an exercise price of \$0.48 per share. Pursuant to the December 2013 reverse stock split, the number of shares underlying the First SVB Warrant was adjusted to 1,725 shares of common stock. On January 31, 2014, in connection with the closing of Amendment No. 1 to the Original Term Loan, we issued the Second SVB Warrant, which warrant was immediately exercisable for 2,091 shares of our common stock at an exercise price of \$0.35 per share. Pursuant to an adjustment mechanism included in the Second SVB Warrant, the Second SVB Warrant automatically became exercisable for an additional 12,548 shares of our common stock.

We believe these transactions, including the issuance of new securities in connection with our reincorporation in Virginia, were exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act, or Regulation D promulgated thereunder, or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about Collegium.

**Item 16. Exhibits and Financial Statement Schedules.**

**(a) Exhibits.**

See the Index to Exhibits attached to this registration statement, which is incorporated by reference herein.

**(b) Financial statement schedule.**

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or notes.

**Item 17. Undertakings.**

The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.



**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the Town of Canton, Commonwealth of Massachusetts, on the 27<sup>th</sup> day of April, 2015.

**COLLEGIUM PHARMACEUTICAL, INC.**By:                   /s/ MICHAEL T. HEFFERNAN, R.PH.

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

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated below:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ MICHAEL T. HEFFERNAN, R.PH.</u> Michael T. Heffernan, R.Ph.	President, Chief Executive Officer (Principal Executive Officer) and Director	April 27, 2015
<u>*</u> Paul Brannelly	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	April 27, 2015
<u>*</u> Garen G. Bohlin	Director	April 27, 2015
<u>*</u> John G. Freund, M.D.	Director	April 27, 2015
<u>*</u> Patrick Heron	Director	April 27, 2015
<u>*</u> David Hirsch, M.D., Ph.D.	Director	April 27, 2015
<u>*</u> Eran Nadav, Ph.D.	Director	April 27, 2015
<u>*</u> Gino Santini	Director	April 27, 2015
* <u>/s/ MICHAEL T. HEFFERNAN</u> Name: Michael T. Heffernan Title: Attorney-in-Fact		

**INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Exhibit Description</b>
1.1	Form of Underwriting Agreement.
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. <sup>(1)</sup>
3.1†	Amended and Restated Articles of Incorporation of Collegium Pharmaceutical, Inc., as currently in effect. <sup>(1)</sup>
3.2	Articles of Amendment to Amended and Restated Articles of Incorporation.
3.3	Form of Second Amended and Restated Articles of Incorporation of Collegium Pharmaceutical, Inc. to be effective upon the completion of this offering.
3.4†	Bylaws of Collegium Pharmaceutical, Inc., as currently in effect. <sup>(1)</sup>
3.5	Form of Amended and Restated Bylaws of Collegium Pharmaceutical, Inc. to be effective upon the completion of this offering.
4.1†	Form of Convertible Promissory Note. <sup>(1)</sup>
4.2†	Seventh Amended and Restated Stockholders Agreement, dated March 6, 2015, by and among Collegium Pharmaceutical, Inc. and certain of its shareholders. <sup>(1)</sup>
4.3†	Eighth Amended and Restated Investor Rights Agreement, dated March 6, 2015, by and among Collegium Pharmaceutical, Inc. and certain of its shareholders. <sup>(1)</sup>
4.4†	Preferred Shareholder Agreement, dated November 26, 2014, by and among Collegium Pharmaceutical, Inc., Boston Millennia Partners and certain of its preferred shareholders. <sup>(1)</sup>
4.5†	Warrant to Purchase Stock, dated October 28, 2010, issued by Collegium Pharmaceutical, Inc. to Comerica Bank. <sup>(1)</sup>
4.6†	Warrant to Purchase Stock, dated January 31, 2014, issued by Collegium Pharmaceutical, Inc. to Silicon Valley Bank. <sup>(1)</sup>
4.7†	Warrant to Purchase Stock, dated August 28, 2012, issued by Collegium Pharmaceutical, Inc. to Silicon Valley Bank. <sup>(1)</sup>
4.8†	Amendment No. 1 to the Sixth Amended and Restated Stockholders Agreement, dated January 29, 2015, by and among Collegium Pharmaceutical, Inc. and certain of its shareholders. <sup>(1)</sup>
5.1	Opinion of Pepper Hamilton LLP.
10.1†	Office Lease Agreement, dated August 28, 2012, by and between 780 Dedham Street Holdings, LLC and Collegium Pharmaceutical, Inc. <sup>(1)</sup>
10.2†	Loan and Security Agreement, dated August 28, 2012, by and between Silicon Valley Bank and Collegium Pharmaceutical, Inc. <sup>(1)</sup>
10.3†	First Amendment to Loan and Security Agreement, dated January 31, 2014, by and between Silicon Valley Bank and Collegium Pharmaceutical, Inc. <sup>(1)</sup>
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. <sup>(1)</sup>
10.5†	Third Amendment to Loan and Security Agreement, dated September 25, 2014, by and between Silicon Valley Bank and Collegium Pharmaceutical, Inc. <sup>(1)</sup>

<b>Exhibit Number</b>	<b>Exhibit Description</b>
10.6†	Fourth Amendment to Loan and Security Agreement, dated October 31, 2014, by and between Silicon Valley Bank and Collegium Pharmaceutical, Inc. <sup>(1)</sup>
10.7†	Series B Convertible Preferred Stock Purchase Agreement, dated February 10, 2012, by and among Collegium Pharmaceutical, Inc. and the purchasers thereto. <sup>(1)</sup>
10.8†	Series C Convertible Preferred Stock Purchase Agreement, dated August 27, 2013, by and among Collegium Pharmaceutical, Inc. and the purchasers thereto. <sup>(1)</sup>
10.9†	Amendment No. 1 to Series C Convertible Preferred Stock Purchase Agreement, dated September 24, 2013, by and among Collegium Pharmaceutical, Inc. and the purchasers thereto. <sup>(1)</sup>
10.10†	Convertible Note Purchase Agreement, dated November 14, 2014, by and among Collegium Pharmaceutical, Inc. and the purchasers thereto. <sup>(1)</sup>
10.11†	Subordination Agreement, dated November 14, 2014, by and among Collegium Pharmaceutical, Inc., Silicon Valley Bank and the creditors named therein. <sup>(1)</sup>
10.12†	Subordination Agreement, dated December 2, 2014, by and among Collegium Pharmaceutical, Inc., Silicon Valley Bank and the creditors named therein. <sup>(1)</sup>
10.13+†	Employment Agreement, dated June 13, 2012, by and between Collegium Pharmaceutical, Inc. and Michael T. Heffernan. <sup>(1)</sup>
10.14+†	Amendment to Employment Agreement, dated September 10, 2013, by and between Collegium Pharmaceutical, Inc. and Michael T. Heffernan. <sup>(1)</sup>
10.15+†	Restricted Stock Award Agreement, dated June 13, 2012, by and between Collegium Pharmaceutical, Inc. and Michael T. Heffernan. <sup>(1)</sup>
10.16+†	Employment Agreement, dated May 30, 2012, by and between Collegium Pharmaceutical, Inc. and Ernest A. Kopecky. <sup>(1)</sup>
10.17+†	Employment Agreement, dated March 13, 2013, by and between Collegium Pharmaceutical, Inc. and Douglas R. Carlson. <sup>(1)</sup>
10.18+†	Restricted Stock Award Agreement, dated July 18, 2012, by and between Collegium Pharmaceutical, Inc. and Gino Santini. <sup>(1)</sup>
10.19+†	Restricted Stock Award Agreement, dated March 5, 2014, by and between Collegium Pharmaceutical, Inc. and Gino Santini. <sup>(1)</sup>
10.20(A)+†	2014 Stock Incentive Plan. <sup>(1)</sup>
10.20(B)+†	Form of Incentive Stock Option Agreement Granted Under 2014 Stock Incentive Plan (Originally Granted under 2002 Stock Option Plan). <sup>(1)</sup>
10.20(C)+†	Form of Non-Statutory Stock Option Agreement Granted Under 2014 Stock Incentive Plan (Originally Granted under 2002 Stock Option Plan). <sup>(1)</sup>
10.20(D)+†	Form of Incentive Stock Option Agreement Granted Under 2014 Stock Incentive Plan (Originally Granted under 2012 Stock Option Plan). <sup>(1)</sup>
10.20(E)+†	Form of Non-Statutory Stock Option Agreement Granted Under 2014 Stock Incentive Plan (Originally Granted under 2012 Stock Option Plan). <sup>(1)</sup>
10.20(F)+†	Form of Incentive Stock Option Agreement Granted Under 2014 Stock Incentive Plan. <sup>(1)</sup>
10.20(G)+†	Form of Non-Statutory Stock Option Agreement Granted Under 2014 Stock Incentive Plan. <sup>(1)</sup>
10.21†	Form of Indemnification Agreement. <sup>(1)</sup>
10.22†	Form of Management Rights Agreement. <sup>(1)</sup>

<b>Exhibit Number</b>	<b>Exhibit Description</b>
10.23†	Form of Confidentiality and Inventions Agreement. <sup>(1)</sup>
10.24+†	Confidential Offer Letter, dated January 30, 2015, by and between Collegium Pharmaceutical, Inc. and Paul Brannelly. <sup>(1)</sup>
10.25+†	2014 Transaction Bonus Plan. <sup>(1)</sup>
10.26+†	Noncompetition, Confidentiality and Inventions Agreement, dated October 5, 2003, by and between Collegium Pharmaceutical, Inc. and Michael T. Heffernan. <sup>(1)</sup>
10.27+†	Offer Letter, dated June 26, 2002, by Collegium Pharmaceutical, Inc. to Alison B. Fleming. <sup>(1)</sup>
10.28+†	Offer Letter, dated June 6, 2008, by and between Collegium Pharmaceutical, Inc. and Said Saim. <sup>(1)</sup>
10.29+†	Offer Letter, dated January 29, 2015, by and between Collegium Pharmaceutical, Inc. and Garen Bohlin. <sup>(1)</sup>
10.30†	Series D Convertible Preferred Stock Purchase Agreement, dated March 6, 2015, by and among Collegium Pharmaceutical, Inc. and the purchasers thereto. <sup>(1)</sup>
10.31†	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. <sup>(1)</sup>
10.32+†	Confidential Offer Letter, dated March 23, 2015, by and between Collegium Pharmaceutical, Inc. and Barry Duke. <sup>(1)</sup>
10.33+	2015 Employee Stock Purchase Plan.
10.34+	Performance Bonus Plan.
10.35+	Amended and Restated 2014 Stock Incentive Plan.
10.36+	Restricted Stock Award Agreement, dated April 2, 2015, by and between Collegium Pharmaceutical, Inc. and Michael T. Heffernan.
10.37	Form of Indemnification Agreement to be effective upon the closing of this offering.
16.1†	Letter of Walter & Shuffain, P.C., as to change in accountant, dated February 25, 2015. <sup>(1)</sup>
23.1	Consent of Grant Thornton LLP.
23.2	Consent of Pepper Hamilton LLP (included in Exhibit 5.1).
24.1†	Power of Attorney (included on the signature page of the Registration Statement on Form S-1 (File No. 333-203208) filed with the Commission on April 2, 2015). <sup>(1)</sup>

† Previously filed.

+ Indicates management contract or compensatory plan.

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



[ · ]

## Collegium Pharmaceutical, Inc.

UNDERWRITING AGREEMENT(1)

[ · ], 2015

JEFFERIES LLC  
 PIPER JAFFRAY & CO.  
 As Representatives of the several Underwriters

c/o JEFFERIES LLC  
 520 Madison Avenue  
 New York, New York 10022

c/o PIPER JAFFRAY & CO.  
 800 Nicollet Mall  
 Minneapolis, MN 55402

Ladies and Gentlemen:

**Introductory.** Collegium Pharmaceutical, Inc., a Virginia corporation (the “**Company**”), proposes to issue and sell to the several underwriters named in Schedule A (the “**Underwriters**”) an aggregate of [ · ] shares of its common stock, par value \$0.001 per share (the “**Shares**”). The [ · ] Shares to be sold by the Company are called the “**Firm Shares**.” In addition, the Company has granted to the Underwriters an option to purchase up to an additional [ · ] Shares as provided in Section 2. The additional [ · ] Shares to be sold by the Company pursuant to such option are collectively called the “**Optional Shares**.” The Firm Shares and, if and to the extent such option is exercised, the Optional Shares are collectively called the “**Offered Shares**.” Jefferies LLC (“**Jefferies**”) and Piper Jaffray & Co. (“**Piper Jaffray**”) have agreed to act as representatives of the several Underwriters (in such capacity, the “**Representatives**”) in connection with the offering and sale of the Offered Shares. To the extent there are no additional underwriters listed on Schedule A, the term “**Representatives**” as used herein shall mean you, as Underwriters, and the term “**Underwriters**” shall mean either the singular or the plural, as the context requires.

Jefferies agrees that up to [ · ] of the Firm Shares to be purchased by the Underwriters (the “**Directed Shares**”) shall be reserved for sale to certain eligible directors, officers and employees of the Company and persons having business relationships with the Company (collectively, the “**Participants**”), as part of the distribution of the Offered Shares by the Underwriters (the “**Directed Share Program**”) subject to the terms of this Agreement, the applicable rules, regulations and interpretations of the Financial Industry Regulatory Authority, Inc. (“**FINRA**”) and all other applicable laws, rules and regulations. The Directed Share Program shall be administered by Jefferies. To the extent that the Directed Shares are not orally confirmed for purchase by the Participants by the end of the first business day after the date of this

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Agreement, such Directed Shares may be offered to the public by the Underwriters as part of the public offering contemplated hereby.

The Company has prepared and filed with the Securities and Exchange Commission (the “**Commission**”) a registration statement on Form S-1, File No. 333-203208 which contains a form of prospectus to be used in connection with the public offering and sale of the Offered Shares. Such registration statement, as amended, including the financial statements, exhibits and schedules thereto, in the form in which it became effective under the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder (collectively, the “**Securities Act**”), including any information deemed to be a part thereof at the time of effectiveness pursuant to Rule 430A under the Securities Act, is called the “**Registration Statement**.” Any registration statement filed by the Company pursuant to Rule 462(b) under the Securities Act in connection with the offer and sale of the Offered Shares is called the “**Rule 462(b) Registration Statement**,” and from and after the date and time of filing of any such Rule 462(b) Registration Statement the term “**Registration Statement**” shall include the Rule 462(b) Registration Statement. The prospectus, in the form first used by the Underwriters to confirm sales of the Offered Shares or in the form first made available to the Underwriters by the Company to meet requests of purchasers pursuant to Rule 173 under the Securities Act, is called the “**Prospectus**.” The preliminary prospectus dated April 27, 2015 describing the Offered Shares and the offering thereof is called the “**Preliminary Prospectus**,” and the Preliminary Prospectus and any other prospectus in preliminary form that describes the Offered Shares and the offering thereof and is used prior to the filing of the Prospectus is called a “**preliminary prospectus**.” As used herein, “**Applicable Time**” is [ · ]: [ · ] p.m. (New York City time) on [ · ], 2015. As used herein, “**free writing prospectus**” has the meaning set forth in Rule 405 under the Securities Act, and “**Time of Sale Prospectus**” means the Preliminary Prospectus together with the free writing prospectuses, if any, identified in Schedule B hereto. As used herein, “**Road Show**” means a “road show” (as defined in Rule 433 under the Securities Act) relating to the offering of the Offered Shares contemplated hereby that is a “written communication” (as defined in Rule 405 under the Securities Act). As used herein, “**Section 5(d) Written Communication**” means each written communication (within the meaning of Rule 405 under the Securities Act) that is made in reliance on Section 5(d) of the Securities Act by the Company or any person authorized to act on behalf of the Company to one or more potential investors that are qualified institutional buyers (“**QIBs**”) and/or institutions that are accredited investors (“**IAs**”), as such terms are respectively defined in Rule 144A and Rule 501(a) under the Securities Act, to determine whether such investors might have an interest in the offering of the Offered Shares; “**Section 5(d) Oral Communication**” means each oral communication, if any, made in reliance on Section 5(d) of the Securities Act by the Company or any person authorized to act on behalf of the Company made to one or more QIBs and/or one or more IAs to determine whether such investors might have an interest in the offering of the Offered Shares; “**Marketing Materials**” means any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Offered Shares, including any roadshow or investor presentations made to investors by the Company (whether in person or electronically); and “**Permitted Section 5(d) Communication**” means the Section 5(d) Written Communication(s) and Marketing Materials listed on Schedule C attached hereto.

All references in this Agreement to (i) the Registration Statement, any preliminary prospectus (including the Preliminary Prospectus), or the Prospectus, or any amendments or supplements to any of the foregoing, or any free writing prospectus, shall include any copy thereof filed with the Commission pursuant to its Electronic Data Gathering, Analysis and Retrieval System (“**EDGAR**”) and (ii) the Prospectus shall be deemed to include any “electronic Prospectus” provided for use in connection with the offering of the Offered Shares as contemplated by Section 3(o) of this Agreement.

The Company hereby confirms its agreements with the Underwriters as follows:

## Section 1. Representations and Warranties of the Company.

The Company hereby represents, warrants and covenants to each Underwriter, as of the date of this Agreement, as of the First Closing Date (as hereinafter defined) and as of each Option Closing Date (as hereinafter defined), if any, as follows:

(a) **Compliance with Registration Requirements.** The Registration Statement has become effective under the Securities Act. The Company has complied, to the Commission's satisfaction with all requests of the Commission for additional or supplemental information, if any. No stop order suspending the effectiveness of the Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the knowledge of the Company, are contemplated or threatened by the Commission.

(b) **Disclosure.** Each preliminary prospectus and the Prospectus when filed complied in all material respects with the Securities Act and, if filed by electronic transmission pursuant to EDGAR, was identical (except as may be permitted by Regulation S-T under the Securities Act) to the copy thereof delivered to the Underwriters for use in connection with the offer and sale of the Offered Shares. Each of the Registration Statement and any post-effective amendment thereto, at the time it became or becomes effective, complied and will comply in all material respects with the Securities Act and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. As of the Applicable Time, the Time of Sale Prospectus did not, and at the First Closing Date (as defined in Section 2) and at each applicable Option Closing Date (as defined in Section 2), as then amended or supplemented by the Company will not, contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Prospectus, as of its date, did not, and at the First Closing Date and at each applicable Option Closing Date, as then amended or supplemented by the Company will not, contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the three immediately preceding sentences do not apply to statements in or omissions from the Registration Statement or any post-effective amendment thereto, or the Prospectus or the Time of Sale Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with written information relating to any Underwriter furnished to the Company in writing by or on behalf of the Representatives expressly for use therein, it being understood and agreed that the only such information consists of the information described in Section 9(b) below. There are no contracts or other documents required to be described in the Time of Sale Prospectus or the Prospectus or to be filed as an exhibit to the Registration Statement which have not been described or filed as required.

(c) **Free Writing Prospectuses; Road Show.** As of the determination date referenced in Rule 164(h) under the Securities Act, the Company was not, is not or will not be (as applicable) an "ineligible issuer" in connection with the offering of the Offered Shares pursuant to Rules 164, 405 and 433 under the Securities Act. Each free writing prospectus that the Company is required to file pursuant to Rule 433(d) under the Securities Act has been, or will be, filed with the Commission in accordance with the requirements of the Securities Act. Each free writing prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act or that was prepared by or on behalf of or used or referred to by the Company complies or will comply in all material respects with the requirements of Rule 433 under the Securities Act, including timely filing with the Commission or retention where required and legending, and each such free writing prospectus, as of its issue date and at all subsequent times through the completion of the public offer and sale of the Offered Shares did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement, the Prospectus or any preliminary prospectus and not superseded or modified. The

representations and warranties set forth in the immediately preceding sentence do not apply to statements made in reliance upon and in conformity with written information relating to any Underwriters furnished to the Company in writing by the Representatives expressly for use therein, it being understood and agreed that the only such information consists of the information described in Section 9(b) below. Except for the free writing prospectuses, if any, identified in Schedule B, and electronic road shows, if any, furnished to the Representatives before first use, the Company has not prepared, used or referred to, and will not, without the prior written consent of the Representatives, prepare, use or refer to, any free writing prospectus. Each Road Show, when considered together with the Time of Sale Prospectus, did not, as of the Applicable Time, contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(d) **Directed Share Program.** (i) The Registration Statement, the Prospectus, the Time of Sale Prospectus and any preliminary prospectus comply, and any further amendments or supplements thereto will comply, with any applicable laws or regulations of foreign jurisdictions in which the Prospectus, Time of Sale Prospectus or any preliminary prospectus, as amended or supplemented, if applicable, are distributed in connection with the Directed Share Program, and (ii) no authorization, approval, consent, license, order registration or qualification of or with any government, governmental instrumentality or court, other than such as have been obtained, is necessary under the securities laws and regulations of foreign jurisdictions in which the Directed Shares are offered outside the United States. The Company has not offered, or caused the Underwriters to offer, any Offered Shares to any person pursuant to the Directed Share Program with the intent to unlawfully influence (i) a customer or supplier of the Company to alter the customer's or supplier's level or type of business with the Company or (ii) a trade journalist or publication to write or publish favorable information about the Company or its products.

(e) **Distribution of Offering Material By the Company.** Prior to the later of (i) the expiration or termination of the option granted to the several Underwriters in Section 2, (ii) the completion of the Underwriters' distribution of the Offered Shares and (iii) the expiration of 25 days after the date of the Prospectus, the Company has not distributed and will not distribute any offering material in connection with the offering and sale of the Offered Shares other than the Registration Statement, the Time of Sale Prospectus, the Prospectus or any free writing prospectus reviewed and consented to by the Representatives, the free writing prospectuses, if any, identified on Schedule B hereto and any Permitted Section 5(d) Communications.

(f) **The Underwriting Agreement.** This Agreement has been duly authorized, executed and delivered by the Company.

(g) **Authorization of the Offered Shares.** The Offered Shares have been duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company against payment therefor pursuant to this Agreement, will be validly issued, fully paid and nonassessable, and the issuance and sale of the Offered Shares is not subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase the Offered Shares.

(h) **No Applicable Registration or Other Similar Rights.** There are no persons with registration or other similar rights to have any equity or debt securities registered for sale under the Registration Statement or included in the offering contemplated by this Agreement except for such rights as have been duly

waived.

(i) **No Material Adverse Change.** Except as otherwise disclosed in the Registration Statement, the Time of Sale Prospectus and the Prospectus, subsequent to the respective dates as of which information is given in the Registration Statement, the Time of Sale Prospectus and the Prospectus:

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(i) there has been no material adverse change, or any development that would reasonably be expected to result in a material adverse change, in the condition, financial or otherwise, or in the earnings, business, properties, operations, assets, liabilities or prospects, whether or not arising from transactions in the ordinary course of business, of the Company (any such change being referred to herein as a “**Material Adverse Change**”); (ii) the Company has not incurred any material liability or obligation, indirect, direct or contingent, including without limitation any losses or interference with its business from fire, explosion, flood, earthquakes, accident or other calamity, whether or not covered by insurance, or from any strike, labor dispute or court or governmental action, order or decree, that are material, individually or in the aggregate, to the Company, or has entered into any material transactions not in the ordinary course of business; and (iii) there has not been any material decrease in the capital stock or any material increase in any short-term or long-term indebtedness of the Company and there has been no dividend or distribution of any kind declared, paid or made by the Company on any class of capital stock, or any repurchase or redemption by the Company of any class of capital stock.

(j) **Independent Accountants.** Grant Thornton LLP, which has expressed its opinion with respect to the financial statements (which term as used in this Agreement includes the related notes thereto) filed with the Commission as a part of the Registration Statement, the Time of Sale Prospectus and the Prospectus, is (i) an independent registered public accounting firm as required by the Securities Act, the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder (collectively, the “**Exchange Act**”), and the rules of the Public Company Accounting Oversight Board (“**PCAOB**”), (ii) in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X under the Securities Act and (iii) a registered public accounting firm as defined by the PCAOB whose registration has not been suspended or revoked and who has not requested such registration to be withdrawn.

(k) **Financial Statements.** The financial statements filed with the Commission as a part of the Registration Statement, the Time of Sale Prospectus and the Prospectus present fairly, in all material respects, the financial position of the Company as of the dates indicated and the results of its operations, changes in stockholders’ equity and cash flows for the periods specified. Such financial statements have been prepared in conformity with generally accepted accounting principles as applied in the United States on a consistent basis throughout the periods involved (“**GAAP**”), except as may be expressly stated in the related notes thereto. No other financial statements or supporting schedules are required to be included in the Registration Statement, the Time of Sale Prospectus or the Prospectus. The financial data set forth in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus under the captions “Prospectus Summary—Summary Selected Financial Data,” “Selected Financial Data” and “Capitalization” fairly present, in all material respects, the information set forth therein on a basis consistent with that of the audited financial statements contained in the Registration Statement, the Time of Sale Prospectus and the Prospectus. To the Company’s knowledge, no person who has been suspended or barred from being associated with a registered public accounting firm, or who has failed to comply with any sanction pursuant to Rule 5300 promulgated by the PCAOB, has participated in or otherwise aided the preparation of, or audited, the financial statements, supporting schedules or other financial data filed with the Commission as a part of the Registration Statement, the Time of Sale Prospectus and the Prospectus.

(l) **Company’s Accounting System.** The Company makes and keeps books and records that are accurate in all material respects and maintains a system of internal accounting controls designed to, and which the Company believes is sufficient to, provide reasonable assurance that: (i) transactions are executed in accordance with management’s general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management’s general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

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(m) **Disclosure Controls and Procedures; Deficiencies in or Changes to Internal Control Over Financial Reporting.** The Company has established and maintains disclosure controls and procedures (as defined in Rules 13a-15 and 15d-15 under the Exchange Act), which are designed to ensure that material information relating to the Company is made known to the Company’s principal executive officer and its principal financial officer by others within the Company, and such disclosure controls and procedures are effective in all material respects to perform the functions for which they were established. Except as set forth in the Registration Statement, the Prospectus, the Time of Sale Prospectus or any preliminary prospectus, since the end of the Company’s most recent audited fiscal year, there have been no significant deficiencies or material weakness in the Company’s internal control over financial reporting (whether or not remediated) and there has been no change in the Company’s internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting. The Company is not aware of any change in its internal control over financial reporting that has occurred during its most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting.

(n) **Incorporation and Good Standing of the Company.** The Company has been duly incorporated and is validly existing as a corporation in good standing under the laws of the jurisdiction of its incorporation and has the corporate power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus and to enter into and perform its obligations under this Agreement. The Company is duly qualified as a foreign corporation to transact business and is in good standing in the Commonwealth of Massachusetts and each other jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure to so qualify or to be in good standing would not reasonably be expected, individually or in the aggregate, to have a material adverse effect on the condition (financial or other), earnings, business, properties, operations, assets, liabilities or prospects of the Company (a “**Material Adverse Effect**”).

(o) **Subsidiaries.** The Company has no subsidiaries (as defined in Rule 405 under the Securities Act).

(p) **Capitalization and Other Capital Stock Matters.** The authorized, issued and outstanding capital stock of the Company is as set forth in the Registration Statement, the Time of Sale Prospectus and the Prospectus under the caption “Capitalization” (other than for subsequent issuances, if any, pursuant to employee benefit plans, or upon the exercise of outstanding options or warrants, in each case as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus). The Shares (including the Offered Shares) conform in all material respects to the description thereof contained in the Time of Sale Prospectus. All of the issued and outstanding Shares have been duly authorized and validly issued, are fully paid and nonassessable and have been issued in compliance with all federal and state securities laws. None of the outstanding Shares was issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities of the Company. There are no authorized or outstanding options, warrants, preemptive rights, rights of



first refusal or other rights to purchase, or equity or debt securities convertible into or exchangeable or exercisable for, any capital stock of the Company other than those described in the Registration Statement, the Time of Sale Prospectus and the Prospectus. The descriptions of the Company's stock option, stock bonus and other stock plans or arrangements, and the options or other rights granted thereunder, set forth in the Registration Statement, the Time of Sale Prospectus and the Prospectus accurately and fairly present, in all material respects, the information required to be shown with respect to such plans, arrangements, options and rights.

(q) **Stock Exchange Listing.** The Offered Shares have been approved for listing on The NASDAQ Global Market (the "NASDAQ"), subject only to official notice of issuance.

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(r) **Non-Contravention of Existing Instruments; No Further Authorizations or Approvals Required.** The Company is not in violation of its charter or by-laws, or in default (or, with the giving of notice or lapse of time, would be in default) ("Default") under any indenture, loan, credit agreement, note, lease, license agreement, contract, franchise or other instrument (including, without limitation, any pledge agreement, security agreement, mortgage or other instrument or agreement evidencing, guaranteeing, securing or relating to indebtedness) to which the Company is a party or by which it may be bound, or to which any of its properties or assets are subject (each, an "Existing Instrument"), except for such Defaults as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. The Company's execution, delivery and performance of this Agreement, consummation of the transactions contemplated hereby and by the Registration Statement, the Time of Sale Prospectus and the Prospectus and the issuance and sale of the Offered Shares (including the use of proceeds from the sale of the Offered Shares as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus under the caption "Use of Proceeds") (i) have been duly authorized by all necessary corporate action and will not result in any violation of the provisions of the charter or by-laws of the Company, (ii) will not conflict with or constitute a breach of, or Default or a Debt Repayment Triggering Event (as defined below) under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to, or require the consent of any other party to, any Existing Instrument and (iii) will not result in any violation of any law, administrative regulation or administrative or court decree applicable to the Company. No consent, approval, authorization or other order of, or registration or filing with, any court or other governmental or regulatory authority or agency, is required for the Company's execution, delivery and performance of this Agreement and consummation of the transactions contemplated hereby and by the Registration Statement, the Time of Sale Prospectus and the Prospectus, except (A) such as have been obtained or made by the Company and are in full force and effect under the Securities Act and such as may be required under applicable state securities or blue sky laws or FINRA and (B) such as have been obtained under the laws and regulations of jurisdictions outside of the United States in which Directed Shares are offered. As used herein, a "Debt Repayment Triggering Event" means any event or condition which gives, or with the giving of notice or lapse of time would give, the holder of any note, debenture or other evidence of indebtedness (or any person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company.

(s) **Compliance with Laws.** The Company has been and is in compliance with all applicable laws, rules and regulations, except where failure to be so in compliance would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

(t) **No Material Actions or Proceedings.** There is no action, suit, proceeding, inquiry or investigation brought by or before any governmental entity now pending or, to the knowledge of the Company, threatened, against or affecting the Company, which would reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect or materially and adversely affect the consummation of the transactions contemplated by this Agreement or the performance by the Company of its obligations hereunder; and the aggregate of all pending legal or governmental proceedings to which the Company is a party or of which any of its respective properties or assets is the subject, including ordinary routine litigation incidental to the business, if determined adversely to the Company, would not reasonably be expected to have a Material Adverse Effect. No material labor dispute with the employees of the Company, or with the employees of any principal supplier, manufacturer, or contractor of the Company, exists or, to the knowledge of the Company, is threatened or imminent, which would reasonably be expected to have a Material Adverse Effect.

(u) **Intellectual Property Rights.** The Company owns, or has obtained valid and enforceable licenses for, the inventions, patent applications, patents, trademarks, trade names, service names, copyrights, trade secrets and other intellectual property described in the Registration Statement, the Time

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of Sale Prospectus and the Prospectus as being owned or licensed by it or which are necessary for the conduct of its business as currently conducted or as currently proposed to be conducted in the Registration Statement, the Time of Sale Prospectus and the Prospectus (collectively, "Intellectual Property"). None of the Intellectual Property has been adjudged invalid or unenforceable in whole or in part, and the Company is unaware of any facts which would form a reasonable basis for a determination that any issued patent within the Intellectual Property is invalid or unenforceable. To the Company's knowledge, and except as would not reasonably be expected to, individually or in the aggregate, have a Material Adverse Effect: (i) there are no third parties who have rights to any Intellectual Property, except for customary reversionary rights of third-party licensors with respect to Intellectual Property that is disclosed in the Registration Statement, the Time of Sale Prospectus and the Prospectus as licensed to the Company; and (ii) there is no infringement by third parties of any Intellectual Property. Except as disclosed in the Registration Statements, the Time of Sale Prospectus and the Prospectus, there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others: (A) challenging the Company's rights in or to any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (B) challenging the validity, enforceability or scope of any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; or (C) asserting that the Company infringes, misappropriates or otherwise violates, or would, upon the commercialization of any product or service described in the Registration Statement, the Time of Sale Prospectus or the Prospectus as under development, infringe, misappropriate or otherwise violate, any patent, trademark, trade name, service name, copyright, trade secret or other proprietary rights of others, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim. None of the technology employed by the Company has been obtained or is being used by the Company in violation of any contractual obligation binding on the Company or, to the Company's knowledge, upon any officers, directors or employees of the Company, and the Company is not aware of any facts that would form a reasonable basis for a successful challenge that any of its employees are in or have ever been in violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where such violation relates to such employee's breach of a confidentiality obligation, obligation to assign intellectual property to an employer, or obligation not to use third-party intellectual property or other proprietary rights of a third party. The product candidates described in the Registration Statement, the Time of Sale Prospectus and the Prospectus as under development by the Company fall within the scope of the claims of one or more patents owned by, or exclusively licensed to, the Company.

(v) **All Necessary Permits, etc.** The Company possesses such valid and current certificates, authorizations or permits required by state, federal or foreign regulatory agencies or bodies to conduct its business as currently conducted and as described in the Registration Statement, the Time of Sale Prospectus or

the Prospectus (“**Permits**”). The Company is not in violation of, or in default under, any of the Permits and has not received any notice of proceedings relating to the revocation or modification of, or non-compliance with, any such Permit.

(w) **Title to Properties.** The Company does not own any real property. The Company has good and marketable title to all of the personal property and other assets reflected as owned in the financial statements referred to in Section 1(k) above (or elsewhere in the Registration Statement, the Time of Sale Prospectus or the Prospectus), in each case free and clear of any security interests, mortgages, liens, encumbrances, equities, adverse claims and other defects, except as would not reasonably be expected, individually or in the aggregate, to materially affect the value of such property or materially interfere with the use thereof. The real property, improvements, equipment and personal property held under lease by the Company are held under valid and enforceable leases, with such exceptions as are not material and do

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not materially interfere with the use made or proposed to be made of such real property, improvements, equipment or personal property by the Company.

(x) **Tax Law Compliance.** The Company has filed all necessary federal, state and foreign income and franchise tax returns or has properly requested extensions thereof, except insofar as the failure to file such returns would not reasonably be expected to have a Material Adverse Effect, and has paid all taxes required to be paid by it and, if due and payable, any related or similar assessment, fine or penalty levied against it except as may be being contested in good faith and by appropriate proceedings, and except where the failure to pay such taxes, assessments, fines or penalties would not reasonably be expected to have a Material Adverse Effect. The Company has made adequate charges, accruals and reserves in the applicable financial statements referred to in Section 1(k) above in respect of all federal, state and foreign income and franchise taxes for all periods as to which the tax liability of the Company has not been otherwise finally determined.

(y) **Insurance.** The Company is insured by recognized, financially sound and reputable institutions with policies in such amounts and with such deductibles and covering such risks as the Company reasonably believes are generally adequate and customary for its business including, but not limited to, policies covering real and personal property owned or leased by the Company against theft, damage, destruction, acts of vandalism and earthquakes and policies covering the Company for product liability claims and clinical trial liability claims. The Company has no reason to believe that it will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not reasonably be expected to have a Material Adverse Effect. The Company has not been denied any insurance coverage which it has sought or for which it has applied.

(z) **Compliance with Environmental Laws.** Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect: (i) the Company is not in violation of any federal, state, local or foreign statute, law, rule, regulation, ordinance, code, policy or rule of common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including, without limitation, laws and regulations relating to the release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products (collectively, “**Hazardous Materials**”) or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials (collectively, “**Environmental Laws**”); (ii) the Company has all permits, authorizations and approvals required under any applicable Environmental Laws and is in compliance with their requirements; (iii) there are no pending or, to the knowledge of the Company, threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigation or proceedings relating to any Environmental Law against the Company; and (iv) to the knowledge of the Company there are no events or circumstances that might reasonably be expected to form the basis of an order for clean-up or remediation, or an action, suit or proceeding by any private party or governmental body or agency, against or affecting the Company relating to Hazardous Materials or any Environmental Laws.

(aa) **ERISA Compliance.** The Company and any “employee benefit plan” (as defined under the Employee Retirement Income Security Act of 1974, as amended, and the regulations and published interpretations thereunder (collectively, “**ERISA**”)) established or maintained by the Company, or to the knowledge of the Company, its “ERISA Affiliates” (as defined below) are in compliance in all material respects with ERISA. “**ERISA Affiliate**” means, with respect to the Company, any member of any group of organizations described in Sections 414(b), (c), (m) or (o) of the Internal Revenue Code of 1986, as

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amended, and the regulations and published interpretations thereunder (the “**Code**”) of which the Company is a member. No “reportable event” (as defined under ERISA) has occurred or is reasonably expected to occur with respect to any “employee benefit plan” established or maintained by the Company or any of its ERISA Affiliates. No “employee benefit plan” established or maintained by the Company or its ERISA Affiliates, if such “employee benefit plan” were terminated, would have any “amount of unfunded benefit liabilities” (as defined under ERISA). Neither the Company nor any of its ERISA Affiliates has incurred or reasonably expects to incur any material liability under (i) Title IV of ERISA with respect to termination of, or withdrawal from, any “employee benefit plan” or (ii) Sections 412, 4971, 4975 or 4980B of the Code. Each employee benefit plan established or maintained by the Company or any of its ERISA Affiliates that is intended to be qualified under Section 401(a) of the Code is so qualified and nothing has occurred, whether by action or failure to act, which would reasonably be expected to cause the loss of such qualification.

(bb) **Company Not an “Investment Company.”** The Company is not, and will not be, either after receipt of payment for the Offered Shares or after the application of the proceeds therefrom as described under “Use of Proceeds” in the Registration Statement, the Time of Sale Prospectus or the Prospectus, required to register as an “investment company” under the Investment Company Act of 1940, as amended (the “**Investment Company Act**”).

(cc) **No Price Stabilization or Manipulation; Compliance with Regulation M.** The Company has not taken, directly or indirectly, without giving effect to activities by the Underwriters, any action designed to or that would reasonably be expected to cause or result in stabilization or manipulation of the price of the Shares or of any “reference security” (as defined in Rule 100 of Regulation M under the Exchange Act (“**Regulation M**”)) with respect to the Shares, whether to facilitate the sale or resale of the Offered Shares or otherwise, or any action which would directly or indirectly violate Regulation M.

(dd) **Related-Party Transactions.** There are no business relationships or related-party transactions involving the Company or any other person required to be described in the Registration Statement, the Time of Sale Prospectus or the Prospectus that have not been described as required.

(ee) **FINRA Matters.** All of the information provided to the Underwriters or to counsel for the Underwriters by the Company, its counsel, its officers and directors and, to the knowledge of the Company, the holders of any securities (debt or equity) or options to acquire any securities of the Company in

connection with the offering of the Offered Shares is true, complete, correct in all material respects and compliant with FINRA's rules and any letters, filings or other supplemental information provided to FINRA pursuant to FINRA Rules or NASD Conduct Rules is true, complete and correct in all material respects.

**(ff) Parties to Lock-Up Agreements.** The Company has furnished to the Underwriters a letter agreement in the form attached hereto as Exhibit A (the "**Lock-up Agreement**") from each director, officer and beneficial owner of the outstanding issued share capital of the Company. If any additional persons shall become directors or executive officers of the Company prior to the end of the Company Lock-up Period (as defined below), the Company shall cause each such person, prior to or contemporaneously with their appointment or election as a director or executive officer of the Company, to execute and deliver to the Representatives a Lock-up Agreement.

**(gg) Statistical and Market-Related Data.** All statistical, demographic and market-related data included in the Registration Statement, the Time of Sale Prospectus or the Prospectus are based on or derived from sources that the Company believes to be reliable and accurate. To the extent required, the Company has obtained the written consent to the use of such data from such sources.

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**(hh) No Unlawful Contributions or Other Payments.** Neither the Company nor, to the Company's knowledge, any employee or agent of the Company, has made any contribution or other payment to any official of, or candidate for, any federal, state or foreign office in violation of any law or of the character required to be disclosed in the Registration Statement, the Time of Sale Prospectus or the Prospectus.

**(ii) Foreign Corrupt Practices Act.** Neither the Company nor, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company has, in the course of its actions for, or on behalf of, the Company (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expenses relating to political activity; (ii) made any direct or indirect unlawful payment to any domestic government official, "foreign official" (as defined in the U.S. Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (collectively, the "**FCPA**") or employee from corporate funds; (iii) violated or is in violation of any provision of the FCPA or any applicable non-U.S. anti-bribery statute or regulation; or (iv) made any unlawful bribe, rebate, payoff, influence payment, kickback or other unlawful payment to any domestic government official, such foreign official or employee; and the Company and, to the knowledge of the Company, the Company's affiliates have conducted their respective businesses in compliance with the FCPA and have instituted and maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.

**(jj) Money Laundering Laws.** The operations of the Company are, and have been conducted at all times, in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar applicable rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "**Money Laundering Laws**") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

**(kk) OFAC.** Neither the Company nor, to the knowledge of the Company, after due inquiry, any director, officer, agent, employee, affiliate or person acting on behalf of the Company is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("**OFAC**"); and the Company will not directly or indirectly use the proceeds of this offering, or lend, contribute or otherwise make available such proceeds to any joint venture partner or other person or entity, for the purpose of financing the activities of or business with any person, or in any country or territory, that currently is the subject to any U.S. sanctions administered by OFAC or in any other manner that will result in a violation by any person (including any person participating in the transaction whether as underwriter, advisor, investor or otherwise) of U.S. sanctions administered by OFAC.

**(ll) Brokers.** Except pursuant to this Agreement, there is no broker, finder or other party that is entitled to receive from the Company any brokerage or finder's fee or other fee or commission as a result of any transactions contemplated by this Agreement.

**(mm) Forward-Looking Statements.** Each financial or operational projection or other "forward-looking statement" (as defined by Section 27A of the Securities Act or Section 21E of the Exchange Act) contained in the Registration Statement, the Time of Sale Prospectus or the Prospectus (i) was so included by the Company in good faith and with reasonable basis after due consideration by the Company of the underlying assumptions, estimates and other applicable facts and circumstances and (ii) is accompanied by meaningful cautionary statements identifying those factors that could cause actual results to differ materially from those in such forward-looking statement. No such statement was made with the knowledge of an executive officer or director of the Company that it was false or misleading.

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**(nn) Emerging Growth Company Status.** From the time of initial confidential submission of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged in any Section 5(d) Written Communication or any Section 5(d) Oral Communication) through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "**Emerging Growth Company**").

**(oo) Communications.** The Company (i) has not alone engaged in communications with potential investors in reliance on Section 5(d) of the Securities Act other than Permitted Section 5(d) Communications with the consent of the Representatives with entities that are QIBs or IAs and (ii) has not authorized anyone other than the Representatives to engage in such communications; the Company reconfirms that the Representatives have been authorized to act on its behalf in undertaking Marketing Materials, Section 5(d) Oral Communications and Section 5(d) Written Communications; as of the Applicable Time, each Permitted Section 5(d) Communication, if any, when considered together with the Time of Sale Prospectus, did not, as of the Applicable Time, include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; and each Permitted Section 5(d) Communication, if any, does not, as of the date hereof, conflict with the information contained in the Registration Statement, the Preliminary Prospectus and the Prospectus and the Company has filed publicly on EDGAR at least 21 calendar days prior to any "road show" (as defined in Rule 433 under the Securities Act), any confidentially submitted registration statement and registration statement amendments relating to the offer and sale of the Offered Shares.

**(pp) Clinical Data and Regulatory Compliance.** The preclinical studies and clinical trials (collectively, "studies") that are described in, or the results of which are referred to in, the Registration Statement, the Time of Sale Prospectus or the Prospectus were and, if still pending, are being conducted in all material respects in accordance with the protocols, procedures and controls designed and approved for such studies and with standard medical and scientific research procedures and all applicable laws and regulations, including, without limitation, 21 C.F.R. Parts 50, 54, 56, 58, and 312; each description of the results of such studies contained in the Registration Statements, the Time of Sale Prospectus and the Prospectus, is accurate and complete in all material respects and fairly

presents in all material respects the data derived from such studies, and the Company has no knowledge of any other studies the results of which are inconsistent with, or otherwise call into question, the results described or referred to in the Registration Statement, the Time of Sale Prospectuses or the Prospectus; the Company has made all such filings and obtained all such Permits as may be required by the Food and Drug Administration of the U.S. Department of Health and Human Services or any committee thereof or from any other U.S. or foreign government or drug or medical device regulatory agency, or health care facility Institutional Review Board (collectively, the “**Regulatory Agencies**”); the Company has not received any notice of, or correspondence from, any Regulatory Agency requiring the termination or suspension of any clinical trials; and the Company has operated and currently is in compliance in all material respects with all applicable rules, regulations and policies of the Regulatory Agencies.

**(qq) Compliance with Health Care Laws.** The Company has been and is in compliance in all material respects with all applicable Health Care Laws, except where failure to be so in compliance would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. For purposes of this Agreement, “**Health Care Laws**” means: (i) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 *et seq.*) and the regulations promulgated thereunder; (ii) all applicable federal, state, local and all applicable foreign health care related fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the U.S. Physician Payment Sunshine Act (42 U.S.C. § 1320a-7h), the U.S. Civil False Claims Act (31 U.S.C. Section 3729 *et seq.*), the criminal False Claims Law (42 U.S.C. § 1320a-7b(a)), all criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. Sections 286 and 287, and the health care fraud criminal provisions

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under the U.S. Health Insurance Portability and Accountability Act of 1996 (“**HIPAA**”) (42 U.S.C. Section 1320d *et seq.*), the exclusion laws (42 U.S.C. § 1320a-7), the civil monetary penalties law (42 U.S.C. § 1320a-7a), HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. Section 17921 *et seq.*), and the regulations promulgated pursuant to such statutes; (iii) Medicare (Title XVIII of the Social Security Act); (iv) Medicaid (Title XIX of the Social Security Act); (v) the Controlled Substances Act (21 U.S.C. §§ 801 *et seq.*) and the regulations promulgated thereunder; and (vi) any and all other applicable health care laws and regulations. The Company has not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any court or arbitrator or governmental or regulatory authority alleging that any product operation or activity is in material violation of any Health Care Laws, and, to the Company’s knowledge, no such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action is threatened against the Company. The Company is not a party to or has any ongoing reporting obligations pursuant to any corporate integrity agreements, deferred prosecution agreements, monitoring agreements, consent decrees, settlement orders, plans of correction or similar agreements with or imposed by any Regulatory Agency or other governmental or regulatory authority. Additionally, neither the Company nor any of its employees, officers or directors has been excluded, suspended or debarred from participation in any U.S. federal health care program or human clinical research or, to the knowledge of the Company, is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion.

**(rr) No Rights to Purchase Preferred Stock.** The issuance and sale of the Shares as contemplated hereby will not cause any holder of any shares of capital stock, securities convertible into or exchangeable or exercisable for capital stock or options, warrants or other rights to purchase capital stock or any other securities of the Company to have any right to acquire any shares of preferred stock of the Company.

Any certificate signed by any officer of the Company and delivered to any Underwriter or to counsel for the Underwriters in connection with the offering, or the purchase and sale, of the Offered Shares shall be deemed a representation and warranty by the Company to each Underwriter as to the matters covered thereby.

The Company has a reasonable basis for making each of the representations set forth in this Section 1. The Company acknowledges that the Underwriters and, for purposes of the opinions to be delivered pursuant to Section 6 hereof, counsel to the Company and counsel to the Underwriters, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

## **Section 2. Purchase, Sale and Delivery of the Offered Shares.**

**(a) The Firm Shares.** Upon the terms herein set forth, the Company agrees to issue and sell to the several Underwriters an aggregate of [ · ] Firm Shares. On the basis of the representations, warranties and agreements herein contained, and upon the terms but subject to the conditions herein set forth, the Underwriters agree, severally and not jointly, to purchase from the Company the respective number of Firm Shares set forth opposite their names on Schedule A. The purchase price per Firm Share to be paid by the several Underwriters to the Company shall be \$[ · ] per share.

**(b) The First Closing Date.** Delivery of certificates for the Firm Shares to be purchased by the Underwriters and payment therefor shall be made at the offices of Latham & Watkins LLP (or such other place as may be agreed to by the Company and the Representatives) at 9:00 a.m. New York City time, on [ · ], 2015, or such other time and date not later than 1:30 p.m. New York City time, on [ · ], 2015 as the Representatives shall designate by notice to the Company (the time and date of such closing

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are called the “**First Closing Date**”). The Company hereby acknowledges that circumstances under which the Representatives may provide notice to postpone the First Closing Date as originally scheduled include, but are not limited to, any determination by the Company or the Representatives to recirculate to the public copies of an amended or supplemented Prospectus or a delay as contemplated by the provisions of Section 11.

**(c) The Optional Shares; Option Closing Date.** In addition, on the basis of the representations, warranties and agreements herein contained, and upon the terms but subject to the conditions herein set forth, the Company hereby grants an option to the several Underwriters to purchase, severally and not jointly, up to an aggregate of [ · ] Optional Shares from the Company at the purchase price per share to be paid by the Underwriters for the Firm Shares. The option granted hereunder may be exercised at any time and from time to time in whole or in part upon notice by the Representatives to the Company, which notice may be given at any time within 30 days from the date of this Agreement. Such notice shall set forth (i) the aggregate number of Optional Shares as to which the Underwriters are exercising the option and (ii) the time, date and place at which certificates for the Optional Shares will be delivered (which time and date may be simultaneous with, but not earlier than, the First Closing Date; and in the event that such time and date are simultaneous with the First Closing Date, the term “**First Closing Date**” shall refer to the time and date of delivery of certificates for the Firm Shares and such Optional Shares). Any such time and date of delivery, if subsequent to the First Closing Date, is called an “**Option Closing Date**,” shall be determined by the Representatives and shall not be earlier than three or later than five full business days after delivery of such notice of exercise. If any Optional Shares are to be purchased, each Underwriter agrees, severally and not jointly, to purchase the number of Optional Shares (subject to such adjustments to eliminate fractional shares as the Representatives may determine) that bears the same proportion to the total number of Optional Shares to be purchased as the number of Firm Shares set forth on Schedule A opposite the name of such

Underwriter bears to the total number of Firm Shares. The Representatives may cancel the option at any time prior to its expiration by giving written notice of such cancellation to the Company.

**(d) Public Offering of the Offered Shares.** The Representatives hereby advise the Company that the Underwriters intend to offer for sale to the public, initially on the terms set forth in the Registration Statement, the Time of Sale Prospectus and the Prospectus, their respective portions of the Offered Shares as soon after this Agreement has been executed and the Registration Statement has been declared effective as the Representatives, in their sole judgment, have determined is advisable and practicable.

**(e) Payment for the Offered Shares.** (i) Payment for the Offered Shares shall be made at the First Closing Date (and, if applicable, at each Option Closing Date) by wire transfer of immediately available funds to the order of the Company.

(ii) It is understood that the Representatives have been authorized, for their own account and the accounts of the several Underwriters, to accept delivery of and receipt for, and make payment of the purchase price for, the Firm Shares and any Optional Shares the Underwriters have agreed to purchase. Each of Jefferies and Piper Jaffray, individually and not as the Representatives of the Underwriters, may (but shall not be obligated to) make payment for any Offered Shares to be purchased by any Underwriter whose funds shall not have been received by the Representatives by the First Closing Date or the applicable Option Closing Date, as the case may be, for the account of such Underwriter, but any such payment shall not relieve such Underwriter from any of its obligations under this Agreement.

**(f) Delivery of the Offered Shares.** The Company shall deliver, or cause to be delivered through the facilities of The Depository Trust Company (“DTC”) unless the Representatives shall otherwise instruct, to the Representatives for the accounts of the several Underwriters certificates for the Firm Shares at the First Closing Date, against release of a wire transfer of immediately available funds for

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the amount of the purchase price therefor. The Company shall also deliver, or cause to be delivered through the facilities of DTC unless the Representatives shall otherwise instruct, to the Representatives for the accounts of the several Underwriters, certificates for the Optional Shares the Underwriters have agreed to purchase at the First Closing Date or the applicable Option Closing Date, as the case may be, against the release of a wire transfer of immediately available funds for the amount of the purchase price therefor. The certificates for the Offered Shares shall be registered in such names and denominations as the Representatives shall have requested at least two full business days prior to the First Closing Date (or the applicable Option Closing Date, as the case may be) and shall be made available for inspection on the business day preceding the First Closing Date (or the applicable Option Closing Date, as the case may be) at a location in New York City as the Representatives may designate. Time shall be of the essence, and delivery at the time and place specified in this Agreement is a further condition to the obligations of the Underwriters.

### Section 3. Additional Covenants.

The Company further covenants and agrees with each Underwriter as follows:

**(a) Delivery of Registration Statement, Time of Sale Prospectus and Prospectus.** The Company shall furnish to you in New York City, without charge, prior to 10:00 a.m. New York City time on the second business day succeeding the date of this Agreement and during the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) in connection with sales of the Offered Shares, as many copies of the Time of Sale Prospectus, the Prospectus and any supplements and amendments thereto or to the Registration Statement as you may reasonably request.

**(b) Representatives’ Review of Proposed Amendments and Supplements.** During the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule), the Company (i) will furnish to the Representatives for review, a reasonable period of time prior to the proposed time of filing of any proposed amendment or supplement to the Registration Statement, a copy of each such amendment or supplement and (ii) will not amend or supplement the Registration Statement without the Representatives’ prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed. Prior to amending or supplementing any preliminary prospectus, the Time of Sale Prospectus or the Prospectus, the Company shall furnish to the Representatives for review, a reasonable amount of time prior to the time of filing or use of the proposed amendment or supplement, a copy of each such proposed amendment or supplement. The Company shall not file or use any such proposed amendment or supplement without the Representatives’ prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed. The Company shall file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.

**(c) Free Writing Prospectuses.** The Company shall furnish to the Representatives for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each proposed free writing prospectus or any amendment or supplement thereto prepared by or on behalf of, used by, or referred to by the Company, and the Company shall not file, use or refer to any proposed free writing prospectus or any amendment or supplement thereto without the Representatives’ prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed. The Company shall furnish to each Underwriter, without charge, as many copies of any free writing prospectus prepared by or on behalf of, used by or referred to by the Company as such Underwriter may reasonably request. If at any time when a prospectus is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) in connection with sales of the

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Offered Shares (but in any event if at any time through and including the First Closing Date) there occurred or occurs an event or development as a result of which any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company conflicted or would conflict with the information contained in the Registration Statement or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at such time, not misleading, the Company shall promptly amend or supplement such free writing prospectus to eliminate or correct such conflict so that the statements in such free writing prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at such time, not misleading, as the case may be; *provided, however*, that prior to amending or supplementing any such free writing prospectus, the Company shall furnish to the Representatives for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of such proposed amended or supplemented free writing prospectus, and the Company shall not file, use or refer to any such amended or supplemented free writing prospectus without the Representatives’ prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed.

(d) **Filing of Underwriter Free Writing Prospectuses.** The Company shall not take any action that would result in an Underwriter or the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of such Underwriter that such Underwriter otherwise would not have been required to file thereunder.

(e) **Amendments and Supplements to Time of Sale Prospectus.** If the Time of Sale Prospectus is being used to solicit offers to buy the Offered Shares at a time when the Prospectus is not yet available to prospective purchasers, and any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Time of Sale Prospectus so that the Time of Sale Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when delivered to a prospective purchaser, not misleading, or if any event shall occur or condition exist as a result of which the Time of Sale Prospectus conflicts with the information contained in the Registration Statement, or if, in the opinion of counsel for the Underwriters, it is necessary to amend or supplement the Time of Sale Prospectus to comply with applicable law, the Company shall (subject to Section 3(b) and Section 3(c) hereof) promptly prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to any dealer upon request, either amendments or supplements to the Time of Sale Prospectus so that the statements in the Time of Sale Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when delivered to a prospective purchaser, not misleading or so that the Time of Sale Prospectus, as amended or supplemented, will no longer conflict with the information contained in the Registration Statement, or so that the Time of Sale Prospectus, as amended or supplemented, will comply with applicable law.

(f) **Certain Notifications and Required Actions.** After the date of this Agreement and until such time as the Underwriters are no longer required to deliver a Prospectus in order to confirm sales of the Offered Shares, the Company shall promptly advise the Representatives in writing of: (i) the receipt of any comments of, or requests for additional or supplemental information from, the Commission relating to the Registration Statement; (ii) the time and date of any filing of any post-effective amendment to the Registration Statement or any amendment or supplement to any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus or the Prospectus; (iii) the time and date that any post-effective amendment to the Registration Statement becomes effective; and (iv) the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto or any amendment or supplement to any preliminary prospectus, the Time of Sale Prospectus or the

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Prospectus or of any order preventing or suspending the use of any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus or the Prospectus, or of any proceedings to remove, suspend or terminate from listing or quotation the Shares from any securities exchange upon which they are listed for trading or included or designated for quotation, or of the threatening or initiation of any proceedings for any of such purposes. If the Commission shall enter any such stop order at any time, the Company will use its best efforts to obtain the lifting of such order as soon as reasonably practicable. Additionally, the Company agrees that it shall comply with all applicable provisions of Rule 424(b), Rule 433 and Rule 430A under the Securities Act and will use its reasonable efforts to confirm that any filings made by the Company under Rule 424(b) or Rule 433 were received in a timely manner by the Commission.

(g) **Amendments and Supplements to the Prospectus and Other Securities Act Matters.** If any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus so that the Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) to a purchaser, not misleading, or if in the opinion of the Representatives or counsel for the Underwriters it is otherwise necessary to amend or supplement the Prospectus to comply with applicable law, the Company agrees (subject to Section 3(b) and Section 3(c) hereof) to promptly prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to any dealer upon request, amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) to a purchaser, not misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law. Neither the Representatives' consent to, nor delivery of, any such amendment or supplement shall constitute a waiver of any of the Company's obligations under Section 3(b) or Section 3(c).

(h) **Blue Sky Compliance.** The Company shall cooperate with the Representatives and counsel for the Underwriters to qualify or register the Offered Shares for sale under (or obtain exemptions from the application of) the state securities or blue sky laws or Canadian provincial securities laws of those jurisdictions designated by the Representatives, shall comply with such laws and shall continue such qualifications, registrations and exemptions in effect so long as required for the distribution of the Offered Shares. The Company shall not be required to qualify as a foreign corporation or to take any action that would subject it to general service of process in any such jurisdiction where it is not presently qualified or where it would be subject to taxation as a foreign corporation. The Company will advise the Representatives promptly of the suspension of the qualification or registration of (or any such exemption relating to) the Offered Shares for offering, sale or trading in any jurisdiction or any initiation or threat of any proceeding for any such purpose, and in the event of the issuance of any order suspending such qualification, registration or exemption, the Company shall use its best efforts to obtain the withdrawal thereof as soon as reasonably practicable.

(i) **Use of Proceeds.** The Company shall apply the net proceeds from the sale of the Offered Shares sold by it in the manner described under the caption "Use of Proceeds" in the Registration Statement, the Time of Sale Prospectus and the Prospectus.

(j) **Transfer Agent.** The Company shall engage and maintain, at its expense, a registrar and transfer agent for the Shares.

(k) **Earnings Statement.** The Company will make generally available to its security holders and to the Representatives as soon as practicable an earnings statement (which need not be audited)

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covering a period of at least twelve months beginning with the first fiscal quarter of the Company commencing after the date of this Agreement that will satisfy the provisions of Section 11(a) of the Securities Act and the rules and regulations of the Commission thereunder.

(l) **Continued Compliance with Securities Laws.** The Company will comply with the Securities Act and the Exchange Act so as to permit the completion of the distribution of the Offered Shares as contemplated by this Agreement, the Registration Statement, the Time of Sale Prospectus and the Prospectus. Without limiting the generality of the foregoing, the Company will, during the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule), file on a timely basis

with the Commission and the NASDAQ all reports and documents required to be filed under the Exchange Act. Additionally, the Company shall report the use of proceeds from the issuance of the Offered Shares as may be required under Rule 463 under the Securities Act.

(m) **Directed Share Program.** In connection with the Directed Share Program, the Company will ensure that the Directed Shares will be restricted to the extent required by FINRA or its rules from sale, transfer, assignment, pledge or hypothecation for a period of three months following the date of the effectiveness of the Registration Statement. Jefferies will notify the Company as to which Participants will need to be so restricted. The Company will direct the transfer agent to place stop transfer restrictions upon such securities for such period of time. Should the Company release, or seek to release, from such restrictions any of the Directed Shares, the Company agrees to reimburse the Underwriters for any reasonable expenses (including, without limitation, reasonable attorney's fees) they incur in connection with such release.

(n) **Listing.** The Company will use its best efforts to list, subject to notice of issuance, the Offered Shares on the NASDAQ.

(o) **Company to Provide Copy of the Prospectus in Form That May be Downloaded from the Internet.** If requested by the Representatives, the Company shall cause to be prepared and delivered, at its expense, within one business day from the effective date of this Agreement, to the Representatives an "electronic Prospectus" to be used by the Underwriters in connection with the offering and sale of the Offered Shares. As used herein, the term "electronic Prospectus" means a form of Time of Sale Prospectus, and any amendment or supplement thereto, that meets each of the following conditions: (i) it shall be encoded in an electronic format, satisfactory to the Representatives, that may be transmitted electronically by the Representatives and the other Underwriters to offerees and purchasers of the Offered Shares; (ii) it shall disclose the same information as the paper Time of Sale Prospectus, except to the extent that graphic and image material cannot be disseminated electronically, in which case such graphic and image material shall be replaced in the electronic Prospectus with a fair and accurate narrative description or tabular representation of such material, as appropriate; and (iii) it shall be in or convertible into a paper format or an electronic format, satisfactory to Jefferies, that will allow investors to store and have continuously ready access to the Time of Sale Prospectus at any future time, without charge to investors (other than any fee charged for subscription to the Internet as a whole and for on-line time). The Company hereby confirms that it has included or will include in the Prospectus filed pursuant to EDGAR or otherwise with the Commission and in the Registration Statement at the time it was declared effective an undertaking that, upon receipt of a request by an investor or his or her representative, the Company shall transmit or cause to be transmitted promptly, without charge, a paper copy of the Time of Sale Prospectus.

(p) **Agreement Not to Offer or Sell Additional Shares.** During the period commencing on and including the date hereof and continuing through and including the 180th day following the date of the Prospectus (such period, as extended as described below, being referred to herein as the "Lock-up Period"), the Company will not, without the prior written consent of the Representatives (which consent

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may be withheld in their sole discretion), directly or indirectly: (i) sell, offer to sell, contract to sell or lend any Shares or Related Securities (as defined below); (ii) effect any short sale, or establish or increase any "put equivalent position" (as defined in Rule 16a-1(h) under the Exchange Act) or liquidate or decrease any "call equivalent position" (as defined in Rule 16a-1(b) under the Exchange Act) of any Shares or Related Securities; (iii) pledge, hypothecate or grant any security interest in any Shares or Related Securities; (iv) in any other way transfer or dispose of any Shares or Related Securities; (v) enter into any swap, hedge or similar arrangement or agreement that transfers, in whole or in part, the economic risk of ownership of any Shares or Related Securities, regardless of whether any such transaction is to be settled in securities, in cash or otherwise; (vi) announce the offering of any Shares or Related Securities; (vii) file any registration statement under the Securities Act in respect of any Shares or Related Securities (other than as contemplated by this Agreement with respect to the Offered Shares); or (viii) publicly announce the intention to do any of the foregoing; *provided, however*, that the Company may (A) effect the transactions contemplated hereby; (B) issue Shares or options to purchase Shares, or issue Shares upon exercise of options, pursuant to any stock option, stock bonus or other stock plan or arrangement described in the Registration Statement, the Time of Sale Prospectus and the Prospectus, but only if the holders of such Shares or options have provided to the Representatives a signed Lock-Up Agreement in the form of Exhibit A hereto; (C) issue Shares pursuant to the conversion or exchange of any convertible or exchangeable securities outstanding on the date hereof, but only if the holders of such Shares or options have provided to the Representatives a signed Lock-Up Agreement in the form of Exhibit A hereto; (D) file a registration statement on Form S-8 to register Shares issuable pursuant to the terms of a stock option, stock bonus or other stock plan or arrangement described in the Registration Statement, the Time of Sale Prospectus and the Prospectus; and (E) issue Shares in connection with any joint venture, commercial or collaborative relationship or acquisition or license by the Company of the securities, property, business or other assets of another person or entity; *provided, however*, that in the case of clause (E), the sum of the aggregate number of shares of common stock of the Company so issued shall not exceed 5% of the total outstanding shares of common stock of the Company immediately following the completion of this offering of Offered Securities; and *provided further*, that the holders of such Shares or options have provided to the Representatives a signed Lock-Up Agreement in the form of Exhibit A hereto. For purposes of the foregoing, "Related Securities" shall mean any options or warrants or other rights to acquire Shares or any securities exchangeable or exercisable for or convertible into Shares, or to acquire other securities or rights ultimately exchangeable or exercisable for, or convertible into, Shares.

(q) **Future Reports to the Representatives.** During the period of five years hereafter, the Company will furnish to the Representatives, c/o Jefferies, at 520 Madison Avenue, New York, New York 10022, Attention: Global Head of Syndicate, and c/o Piper Jaffray, at 800 Nicollet Mall, Minneapolis, MN 55402: (i) as soon as practicable after the end of each fiscal year, copies of the Annual Report of the Company containing the balance sheet of the Company as of the close of such fiscal year and statements of income, stockholders' equity and cash flows for the year then ended and the opinion thereon of the Company's independent public or certified public accountants; (ii) as soon as practicable after the filing thereof, copies of each proxy statement, Annual Report on Form 10-K, Quarterly Report on Form 10-Q, Current Report on Form 8-K or other public report filed by the Company with the Commission or any securities exchange; and (iii) as soon as available, copies of any report or communication of the Company furnished or made available generally to holders of its capital stock; *provided, however*, that the requirements of this Section 3(q) shall be satisfied to the extent that such reports, statement, communications, financial statements or other documents are available on EDGAR.

(r) **Investment Limitation.** The Company shall not invest or otherwise use the proceeds received by the Company from its sale of the Offered Shares in such a manner as would require the Company to register as an investment company under the Investment Company Act.

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(s) **No Stabilization or Manipulation; Compliance with Regulation M.** The Company will not take, and will ensure that no affiliate of the Company will take, directly or indirectly, without giving effect to activities by the Underwriters, any action designed to or that might cause or result in stabilization or manipulation of the price of the Shares or any reference security with respect to the Shares, whether to facilitate the sale or resale of the Offered Shares or otherwise, and the Company will, and shall cause each of its affiliates to, comply with all applicable provisions of Regulation M.

(t) **Enforce Lock-Up Agreements.** During the Lock-up Period, the Company will enforce all agreements between the Company and any of its security holders that restrict or prohibit, expressly or in operation, the offer, sale or transfer of Shares or Related Securities or any of the other actions restricted or prohibited under the terms of the form of Lock-up Agreement. In addition, the Company will direct the transfer agent to place stop transfer restrictions upon any such securities of the Company that are bound by such “lock-up” agreements for the duration of the periods contemplated in such agreements, including, without limitation, “lock-up” agreements entered into by the Company’s officers and directors and stockholders pursuant to Section 6(j) hereof.

(u) **Company to Provide Interim Financial Statements.** Prior to the First Closing Date and each applicable Option Closing Date, the Company will furnish the Underwriters, as soon as reasonably practicable after they have been prepared by or are available to the Company, a copy of any unaudited interim financial statements of the Company for any period subsequent to the period covered by the most recent financial statements appearing in the Registration Statement and the Prospectus.

(v) **Amendments and Supplements to Permitted Section 5(d) Communications.** If at any time following the distribution of any Permitted Section 5(d) Communication, during the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule), there occurred or occurs an event or development as a result of which such Permitted Section 5(d) Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representatives and will promptly amend or supplement, at its own expense, such Permitted Section 5(d) Communication to eliminate or correct such untrue statement or omission.

(w) **Emerging Growth Company Status.** The Company will promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) the time when a prospectus relating to the Offered Shares is not required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) and (ii) the expiration of the Lock-Up Period (as defined herein).

The Representatives, on behalf of the several Underwriters, may, in their sole discretion, waive in writing the performance by the Company of any one or more of the foregoing covenants or extend the time for their performance.

**Section 4. Payment of Expenses.** The Company agrees to pay all costs, fees and expenses incurred in connection with the performance of its obligations hereunder and in connection with the transactions contemplated hereby, including without limitation (i) all expenses incident to the issuance and delivery of the Offered Shares (including all printing and engraving costs), (ii) all fees and expenses of the registrar and transfer agent of the Shares, (iii) all necessary issue, transfer and other stamp taxes in connection with the issuance and sale of the Offered Shares to the Underwriters, (iv) all fees and expenses of the Company’s counsel, independent public or certified public accountants and other advisors, (v) all costs and expenses incurred in connection with the preparation, printing, filing, shipping and distribution

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of the Registration Statement (including financial statements, exhibits, schedules, consents and certificates of experts), the Time of Sale Prospectus, the Prospectus, each free writing prospectus prepared by or on behalf of, used by, or referred to by the Company, and each preliminary prospectus, each Permitted Section 5(d) Communication, and all amendments and supplements thereto, and this Agreement, (vi) all filing fees, attorneys’ fees and expenses incurred by the Company or the Underwriters in connection with qualifying or registering (or obtaining exemptions from the qualification or registration of) all or any part of the Offered Shares for offer and sale under the state securities or blue sky laws or the provincial securities laws of Canada, and, if requested by the Representatives, preparing and printing a “Blue Sky Survey” or memorandum (such “Blue Sky Survey” or memorandum, fees and expenses of counsel not to exceed \$10,000) and a “Canadian wrapper”, and any supplements thereto, advising the Underwriters of such qualifications, registrations and exemptions, (vii) the costs, fees and expenses incurred by the Underwriters in connection with determining their compliance with the rules and regulations of FINRA related to the Underwriters’ participation in the offering and distribution of the Offered Shares, including any related filing fees and the legal fees of, and disbursements by, counsel to the Underwriters in an amount not to exceed \$50,000 (excluding filing fees), (viii) the costs and expenses of the Company relating to investor presentations on any “road show”, any Permitted Section 5(d) Communication or any Section 5(d) Oral Communication undertaken in connection with the offering of the Offered Shares, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the representatives, employees and officers of the Company and any such consultants, and 50% of the cost of any aircraft chartered in connection with the road show, the remaining 50% of the cost of such aircraft to be paid by the Underwriters, (ix) the fees and expenses associated with listing the Offered Shares on the NASDAQ, (x) all other fees, costs and expenses of the nature referred to in Item 13 of Part II of the Registration Statement and (xi) all costs and expenses of the Underwriters, including the fees and disbursements of counsel for the Underwriters, in connection with matters related to the Directed Shares which are designated by the Company for sale to Participants. Except as provided in this Section 4 or in Section 7, Section 9 or Section 10 hereof, the Underwriters shall pay their own expenses, including the fees and disbursements of their counsel.

**Section 5. Covenant of the Underwriters.** Each Underwriter severally and not jointly covenants with the Company not to take any action that would result in the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of such Underwriter that otherwise would not, but for such actions, be required to be filed by the Company under Rule 433(d).

**Section 6. Conditions of the Obligations of the Underwriters.** The respective obligations of the several Underwriters hereunder to purchase and pay for the Offered Shares as provided herein on the First Closing Date and, with respect to the Optional Shares, each Option Closing Date, shall be subject to the accuracy of the representations and warranties on the part of the Company set forth in Section 1 hereof as of the date hereof and as of the First Closing Date as though then made and, with respect to the Optional Shares, as of each Option Closing Date as though then made, to the timely performance by the Company of its covenants and other obligations hereunder, and to each of the following additional conditions:

(a) **Comfort Letter.** On the date hereof, the Representatives shall have received from Grant Thornton LLP, independent registered public accountants for the Company, a letter dated the date hereof addressed to the Underwriters, in form and substance satisfactory to the Representatives, containing statements and information of the type ordinarily included in accountant’s “comfort letters” to underwriters, delivered according to Statement of Auditing Standards No. 72 (or any successor bulletin),

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with respect to the audited and unaudited financial statements and certain financial information contained in the Registration Statement, the Time of Sale Prospectus, and each free writing prospectus, if any.



**(b) Compliance with Registration Requirements; No Stop Order; No Objection from FINRA.**

(i) The Company shall have filed the Prospectus with the Commission (including the information required by Rule 430A under the Securities Act) in the manner and within the time period required by Rule 424(b) under the Securities Act; or the Company shall have filed a post-effective amendment to the Registration Statement containing the information required by such Rule 430A, and such post-effective amendment shall have become effective.

(ii) No stop order suspending the effectiveness of the Registration Statement or any post-effective amendment to the Registration Statement shall be in effect, and no proceedings for such purpose shall have been instituted or threatened by the Commission.

(iii) FINRA shall have raised no objection to the fairness and reasonableness of the underwriting terms and arrangements.

**(c) No Material Adverse Change.** For the period from and after the date of this Agreement and through and including the First Closing Date and, with respect to any Optional Shares purchased after the First Closing Date, each Option Closing Date, in the judgment of the Representatives there shall not have occurred any Material Adverse Change.

**(d) Opinion of Counsel for the Company.** On each of the First Closing Date and each Option Closing Date the Representatives shall have received the opinion of Pepper Hamilton LLP, counsel for the Company, dated as of such date, in form and substance reasonably satisfactory to the Representatives.

**(e) Opinion of IP Counsel.** On each of the First Closing Date and each Option Closing Date, the Representatives shall have received the opinion of Cooley LLP, counsel for the Company with respect to intellectual property, dated as of such date, in form and substance reasonably satisfactory to the Representatives.

**(f) Opinion of Counsel for the Underwriters.** On each of the First Closing Date and each Option Closing Date the Representatives shall have received the opinion of Latham & Watkins LLP, counsel for the Underwriters in connection with the offer and sale of the Offered Shares, in form and substance satisfactory to the Underwriters, dated as of such date, with executed copies for each of the other Underwriters named on the Prospectus cover page.

**(g) Officers' Certificate.** On each of the First Closing Date and each Option Closing Date, the Representatives shall have received a certificate executed by the Chief Executive Officer of the Company and the Chief Financial Officer of the Company, dated as of such date, to the effect set forth in Section 6(b)(ii) and further to the effect that:

(i) for the period from and including the date of this Agreement through and including such date, there has not occurred any Material Adverse Change;

(ii) the representations, warranties and covenants of the Company set forth in Section 1 of this Agreement are true and correct with the same force and effect as though expressly made on and as of such date; and

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(iii) the Company has complied with all the agreements hereunder and satisfied all the conditions on its part to be performed or satisfied hereunder at or prior to such date.

**(h) Bring-down Comfort Letter.** On each of the First Closing Date and each Option Closing Date the Representatives shall have received from Grant Thornton LLP, independent registered public accountants for the Company, a letter dated such date, in form and substance satisfactory to the Representatives, which letter shall: (i) reaffirm the statements made in the letter furnished by them pursuant to Section 6(a), except that the specified date referred to therein for the carrying out of procedures shall be no more than three business days prior to the First Closing Date or the applicable Option Closing Date, as the case may be; and (ii) cover certain financial information contained in the Prospectus.

**(i) Lock-Up Agreements.** On or prior to the date hereof, the Company shall have furnished to the Representatives an agreement in the form of Exhibit A hereto from each director, officer and each beneficial owner of the outstanding issued share capital of the Company, and each such agreement shall be in full force and effect on each of the First Closing Date and each Option Closing Date.

**(j) Rule 462(b) Registration Statement.** In the event that a Rule 462(b) Registration Statement is filed in connection with the offering contemplated by this Agreement, such Rule 462(b) Registration Statement shall have been filed with the Commission on the date of this Agreement and shall have become effective automatically upon such filing.

**(k) Approval of Listing.** At the First Closing Date, the Offered Shares shall have been approved for listing on the NASDAQ, subject only to official notice of issuance.

**(l) Additional Documents.** On or before each of the First Closing Date and each Option Closing Date, the Representatives and counsel for the Underwriters shall have received such information, documents and opinions as they may reasonably request for the purposes of enabling them to pass upon the issuance and sale of the Offered Shares as contemplated herein, or in order to evidence the accuracy of any of the representations and warranties, or the satisfaction of any of the conditions or agreements, herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Offered Shares as contemplated herein and in connection with the other transactions contemplated by this Agreement shall be satisfactory in form and substance to the Representatives and counsel for the Underwriters.

If any condition specified in this Section 6 is not satisfied when and as required to be satisfied, this Agreement may be terminated by the Representatives by notice from the Representatives to the Company at any time on or prior to the First Closing Date and, with respect to the Optional Shares, at any time on or prior to the applicable Option Closing Date, which termination shall be without liability on the part of any party to any other party, except that Section 4, Section 7, Section 9 and Section 10 shall at all times be effective and shall survive such termination.

**Section 7. Reimbursement of Underwriters' Expenses.** If this Agreement is terminated by the Representatives pursuant to Section 6, Section 11 or Section 12, or if the sale to the Underwriters of the Offered Shares on the First Closing Date is not consummated because of any refusal, inability or failure on the part of the Company to perform any agreement herein or to comply with any provision hereof, the Company agrees to reimburse the Representatives and the other Underwriters (or such Underwriters as have terminated this Agreement with respect to themselves), severally, upon demand for all out-of-pocket expenses that shall have been reasonably incurred by the Representatives and the Underwriters in connection with the proposed purchase and the offering and sale

any such termination is effected after the First Closing Date but prior to any Option Closing Date with respect to the purchase of any Optional Shares, the Company shall only reimburse the Underwriters for all of their out of pocket expenses, including the reasonable fees and disbursements of counsel for the Underwriters, incurred after the First Closing Date in connection with the proposed purchase of any such Optional Shares.

**Section 8. Effectiveness of this Agreement.** This Agreement shall become effective upon the execution and delivery hereof by the parties hereto.

**Section 9. Indemnification.**

**(a) Indemnification of the Underwriters.** The Company agrees to indemnify and hold harmless each Underwriter, its affiliates, directors, officers, employees and agents, and each person, if any, who controls any Underwriter within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which such Underwriter or such affiliate, director, officer, employee, agent or controlling person may become subject, under the Securities Act, the Exchange Act, other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Offered Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of the Company), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, or the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged untrue statement of a material fact included in any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act, any Marketing Material, any Section 5(d) Written Communication or the Prospectus (or any amendment or supplement to the foregoing) or any prospectus wrapper material distributed in connection with the reservation and sale of Directed Shares to the Participants, or the omission or alleged omission to state therein a material fact necessary in order to make the statements, in the light of the circumstances under which they were made, not misleading; and to reimburse each Underwriter and each such affiliate, director, officer, employee, agent and controlling person for any and all expenses (including the fees and disbursements of counsel) as such expenses are incurred by such Underwriter or such affiliate, director, officer, employee, agent or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action; *provided, however*, that the foregoing indemnity agreement shall not apply to any loss, claim, damage, liability or expense to the extent, but only to the extent, arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with information relating to any Underwriter furnished to the Company by the Representatives in writing expressly for use in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, any such free writing prospectus, any Marketing Material, any Section 5(d) Written Communication or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information consists of the information described in Section 9(b) below. The indemnity agreement set forth in this Section 9(a) shall be in addition to any liabilities that the Company may otherwise have.

**(b) Indemnification of the Company, its Directors and Officers.** Each Underwriter agrees, severally and not jointly, to indemnify and hold harmless the Company, each of its directors, each of its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of the Securities Act or the Exchange Act, against any loss, claim, damage, liability or expense, as incurred, to which the Company, or any such director, officer or controlling person may become subject, under the Securities Act, the Exchange Act, or other federal or state statutory law or

regulation, or at common law or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of such Underwriter), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, or any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading or (ii) any untrue statement or alleged untrue statement of a material fact included in any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus, that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433 of the Securities Act, any Section 5(d) Written Communication or the Prospectus (or any such amendment or supplement) or the omission or alleged omission to state therein a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in the Registration Statement, such preliminary prospectus, the Time of Sale Prospectus, such free writing prospectus, such Section 5(d) Written Communication or the Prospectus (or any such amendment or supplement), in reliance upon and in conformity with information relating to such Underwriter furnished to the Company by the Representatives in writing expressly for use therein; and to reimburse the Company, or any such director, officer or controlling person for any and all expenses (including the fees and disbursements of counsel) as such expenses are incurred by the Company, or any such director, officer or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action. The Company hereby acknowledges that the only information that the Representatives have furnished to the Company expressly for use in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) of the Securities Act, any Section 5(d) Written Communication or the Prospectus (or any amendment or supplement to the foregoing) are the statements set forth in the first sentence of the third paragraph under the caption "Underwriting," the concession and reallowance amounts, if any, in the first paragraph under the caption "Underwriting—Commission and Expenses," the first sentence under the caption "Underwriting—Stabilization," and the first three sentences of the second paragraph under the caption "Underwriting—Other Activities and Relationships" in the Preliminary Prospectus and the Prospectus in the Preliminary Prospectus and the Prospectus. The indemnity agreement set forth in this Section 9(b) shall be in addition to any liabilities that each Underwriter may otherwise have.

**(c) Notifications and Other Indemnification Procedures.** Promptly after receipt by an indemnified party under this Section 9 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against an indemnifying party under this Section 9, notify the indemnifying party in writing of the commencement thereof, but the omission to so notify the indemnifying party will not relieve the indemnifying party from any liability which it may have to any indemnified party to the extent the indemnifying party is not materially prejudiced as a proximate result of such failure and shall not in any event relieve the indemnifying party from any liability that it may have other than on account of this indemnity agreement. In case any such action is brought against any indemnified party and such indemnified party seeks or intends to seek indemnity from an indemnifying party, the indemnifying party will be entitled to participate in, and, to the extent that it shall elect, jointly with all other indemnifying parties similarly notified, by written notice delivered to the indemnified party promptly after receiving the aforesaid notice from such indemnified party, to assume the defense thereof with counsel reasonably satisfactory to

such indemnified party; *provided, however*, that if the defendants in any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that a conflict may arise between the positions of the indemnifying party and the indemnified party in conducting the defense of any such action or that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, the indemnified party or parties shall have the right to select separate counsel to

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assume such legal defenses and to otherwise participate in the defense of such action on behalf of such indemnified party or parties. Upon receipt of notice from the indemnifying party to such indemnified party of such indemnifying party's election so to assume the defense of such action and approval by the indemnified party of counsel, the indemnifying party will not be liable to such indemnified party under this Section 9 for any reasonable and documented legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof unless (i) the indemnified party shall have employed separate counsel in accordance with the proviso to the preceding sentence (it being understood, however, that the indemnifying party shall not be liable for the fees and expenses of more than one separate counsel (together with local counsel), representing the indemnified parties who are parties to such action), which counsel (together with any local counsel) for the indemnified parties shall be selected by the Representatives (in the case of counsel for the indemnified parties referred to in Section 9(a) above) or by the Company (in the case of counsel for the indemnified parties referred to in Section 9(b) above) or (ii) the indemnifying party shall not have employed counsel reasonably satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of commencement of the action or (iii) the indemnifying party has authorized in writing the employment of counsel for the indemnified party at the expense of the indemnifying party, in each of which cases the fees and expenses of counsel shall be at the expense of the indemnifying party and shall be paid as they are incurred.

**(d) Settlements.** The indemnifying party under this Section 9 shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party against any loss, claim, damage, liability or expense by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by Section 9(c) hereof, the indemnifying party shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by such indemnifying party of the aforesaid request and (ii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is or could have been a party and indemnity was or could have been sought hereunder by such indemnified party, unless such settlement, compromise or consent includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such action, suit or proceeding and does not include an admission of fault or culpability or a failure to act by or on behalf of such indemnified party.

**(e) Indemnification for Directed Shares.** In connection with the offer and sale of the Directed Shares, the Company agrees, promptly upon a request in writing, to indemnify and hold harmless the Underwriters from and against any and all losses, liabilities, claims, damages and expenses incurred by any of them as a result of the failure of the Participants to pay for and accept delivery of Directed Shares which, by the end of the first business day following the date of this Agreement, were subject to a properly confirmed agreement to purchase. The Company agrees to indemnify and hold harmless the Underwriters and their respective affiliates, directors, officers, employees and agents, and each person, if any, who controls any of the Underwriters within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which the Underwriters or such controlling person may become subject, which is (i) caused by any untrue statement or alleged untrue statement of a material fact contained in any material prepared by or with the consent of the Company for distribution to Participants in connection with the Directed Share Program or caused by any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading; (ii) caused by the failure of any Participant to pay for and accept delivery of Directed Shares that such Participant agreed to purchase; or (iii) related to, arising out of, or in connection with the

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Directed Share Program; *provided, however*, that the foregoing indemnity agreement shall not apply to any loss, claim, damage, liability or expense to the extent arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with information relating to any Underwriter furnished to the Company by the Representatives in writing expressly for use in any material prepared by or with the consent of the Company for distribution to Participants in connection with the Directed Share Program, it being understood and agreed that the only such information consists of the information described in Section 9(b) above. The indemnity agreement set forth in this paragraph shall be in addition to any liabilities that the Company may otherwise have.

**Section 10. Contribution.** If the indemnification provided for in Section 9 is for any reason held to be unavailable to or otherwise insufficient to hold harmless an indemnified party in respect of any losses, claims, damages, liabilities or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount paid or payable by such indemnified party, as incurred, as a result of any losses, claims, damages, liabilities or expenses referred to therein (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, from the offering of the Offered Shares pursuant to this Agreement or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Underwriters, on the other hand, in connection with the statements or omissions which resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, in connection with the offering of the Offered Shares pursuant to this Agreement shall be deemed to be in the same respective proportions as the total proceeds from the offering of the Offered Shares pursuant to this Agreement (before deducting expenses) received by the Company, and the total underwriting discounts and commissions received by the Underwriters, in each case as set forth on the front cover page of the Prospectus, bear to the aggregate initial public offering price of the Offered Shares as set forth on such cover. The relative fault of the Company, on the one hand, and the Underwriters, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company, on the one hand, or the Underwriters, on the other hand, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The amount paid or payable by a party as a result of the losses, claims, damages, liabilities and expenses referred to above shall be deemed to include, subject to the limitations set forth in Section 9(c), any documented legal or other fees or expenses reasonably incurred by such party in connection with investigating or defending any action or claim. The provisions set forth in Section 9(c) with respect to notice of commencement of any action shall apply if a claim for contribution is to be made under this Section 10; *provided, however*, that no additional notice shall be required with respect to any action for which notice has been given under Section 9(c) for purposes of indemnification.

The Company and the Underwriters agree that it would not be just and equitable if contribution pursuant to this Section 10 were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to in this Section 10.

Notwithstanding the provisions of this Section 10, no Underwriter shall be required to contribute any amount in excess of the underwriting discounts and commissions received by such Underwriter in connection with the Offered Shares underwritten by it and distributed to the public. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters'

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obligations to contribute pursuant to this Section 10 are several, and not joint, in proportion to their respective underwriting commitments as set forth opposite their respective names on Schedule A. For purposes of this Section 10, each affiliate, director, officer, employee and agent of an Underwriter and each person, if any, who controls an Underwriter within the meaning of the Securities Act or the Exchange Act shall have the same rights to contribution as such Underwriter, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of the Securities Act and the Exchange Act shall have the same rights to contribution as the Company.

**Section 11. Default of One or More of the Several Underwriters.** If, on the First Closing Date or any Option Closing Date any one or more of the several Underwriters shall fail or refuse to purchase Offered Shares that it or they have agreed to purchase hereunder on such date, and the aggregate number of Offered Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase does not exceed 10% of the aggregate number of the Offered Shares to be purchased on such date, the Representatives may make arrangements satisfactory to the Company for the purchase of such Offered Shares by other persons, including any of the Underwriters, but if no such arrangements are made by such date, the other Underwriters shall be obligated, severally and not jointly, in the proportions that the number of Firm Shares set forth opposite their respective names on Schedule A bears to the aggregate number of Firm Shares set forth opposite the names of all such non-defaulting Underwriters, or in such other proportions as may be specified by the Representatives with the consent of the non-defaulting Underwriters, to purchase the Offered Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase on such date. If, on the First Closing Date or any Option Closing Date any one or more of the Underwriters shall fail or refuse to purchase Offered Shares and the aggregate number of Offered Shares with respect to which such default occurs exceeds 10% of the aggregate number of Offered Shares to be purchased on such date, and arrangements satisfactory to the Representatives and the Company for the purchase of such Offered Shares are not made within 48 hours after such default, this Agreement shall terminate without liability of any party to any other party except that the provisions of Section 4, Section 7, Section 9 and Section 10 shall at all times be effective and shall survive such termination. In any such case either the Representatives or the Company shall have the right to postpone the First Closing Date or the applicable Option Closing Date, as the case may be, but in no event for longer than seven days in order that the required changes, if any, to the Registration Statement and the Prospectus or any other documents or arrangements may be effected.

As used in this Agreement, the term "Underwriter" shall be deemed to include any person substituted for a defaulting Underwriter under this Section 11. Any action taken under this Section 11 shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

**Section 12. Termination of this Agreement.** Prior to the purchase of the Firm Shares by the Underwriters on the First Closing Date, this Agreement may be terminated by the Representatives by notice given to the Company if at any time: (i) trading or quotation in any of the Company's securities shall have been suspended or limited by the Commission or by the NASDAQ, or trading in securities generally on either the NASDAQ or the New York Stock Exchange shall have been suspended or limited, or minimum or maximum prices shall have been generally established on any of such stock exchanges; (ii) a general banking moratorium shall have been declared by any of federal, New York, or Virginia authorities; (iii) there shall have occurred any outbreak or escalation of national or international hostilities or any crisis or calamity, or any change in the United States or international financial markets, or any substantial change or development involving a prospective substantial change in United States' or international political, financial or economic conditions, as in the judgment of the Representatives is material and adverse and makes it impracticable to market the Offered Shares in the manner and on the terms described in the Time of Sale Prospectus or the Prospectus or to enforce contracts

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for the sale of securities; (iv) in the judgment of the Representatives there shall have occurred any Material Adverse Change; or (v) the Company shall have sustained a loss by strike, fire, flood, earthquake, accident or other calamity of such character as in the judgment of the Representatives may interfere materially with the conduct of the business and operations of the Company regardless of whether or not such loss shall have been insured. Any termination pursuant to this Section 12 shall be without liability on the part of (a) the Company to any Underwriter, except that the Company shall be obligated to reimburse the expenses of the Representatives and the Underwriters pursuant to Section 4 or Section 7 hereof or (b) any Underwriter to the Company; *provided, however*, that the provisions of Section 9 and Section 10 shall at all times be effective and shall survive such termination.

**Section 13. No Advisory or Fiduciary Relationship.** The Company acknowledges and agrees that (a) the purchase and sale of the Offered Shares pursuant to this Agreement, including the determination of the public offering price of the Offered Shares and any related discounts and commissions, is an arm's-length commercial transaction between the Company, on the one hand, and the several Underwriters, on the other hand, (b) in connection with the offering contemplated hereby and the process leading to such transaction, each Underwriter is and has been acting solely as a principal and is not the agent or fiduciary of the Company, or its stockholders, creditors, employees or any other party, (c) no Underwriter has assumed or will assume an advisory or fiduciary responsibility in favor of the Company with respect to the offering contemplated hereby or the process leading thereto (irrespective of whether such Underwriter has advised or is currently advising the Company on other matters) and no Underwriter has any obligation to the Company with respect to the offering contemplated hereby except the obligations expressly set forth in this Agreement, (d) the Underwriters and their respective affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, and (e) the Underwriters have not provided any legal, accounting, regulatory or tax advice with respect to the offering contemplated hereby and the Company has consulted its own legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.

**Section 14. Representations and Indemnities to Survive Delivery.** The respective indemnities, agreements, representations, warranties and other statements of the Company, of its officers and of the several Underwriters set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of any Underwriter or the Company or any of its or their partners, officers or directors or any controlling person, as the case may be, and, anything herein to the contrary notwithstanding, will survive delivery of and payment for the Offered Shares sold hereunder and any termination of this Agreement.

**Section 15.**

**Notices.** All communications hereunder shall be in writing and shall be mailed, hand delivered or telecopied and confirmed to the parties hereto as follows:

If to the Representatives:

Jefferies LLC  
520 Madison Avenue  
New York, New York 10022  
Facsimile: (646) 619-4437  
Attention: General Counsel

Piper Jaffray & Co.  
800 Nicollet Mall  
Minneapolis, MN 55402  
Facsimile: (612) 303-1070  
Attention: General Counsel

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with a copy to: Latham & Watkins LLP  
885 Third Avenue;  
New York, NY 10022,  
Attention: Peter Handrinos, Esq.

If to the Company: Collegium Pharmaceutical, Inc.  
780 Dedham Street, Suite 800  
Canton, MA 02021  
Facsimile: (781) 828-4697  
Attention: Michael Heffernan

with a copy to: Pepper Hamilton LLP  
3000 Two Logan Square  
Philadelphia, PA 19103  
Attention: Steven J. Abrams, Esq.

Any party hereto may change the address for receipt of communications by giving written notice to the others.

**Section 16.**

**Successors.** This Agreement will inure to the benefit of and be binding upon the parties hereto, including any substitute Underwriters pursuant to Section 11 hereof, and to the benefit of the affiliates, directors, officers, employees, agents and controlling persons referred to in Section 9 and Section 10, and in each case their respective successors, and no other person will have any right or obligation hereunder. The term “**successors**” shall not include any purchaser of the Offered Shares as such from any of the Underwriters merely by reason of such purchase.

**Section 17.**

**Partial Unenforceability.** The invalidity or unenforceability of any section, paragraph or provision of this Agreement shall not affect the validity or enforceability of any other section, paragraph or provision hereof. If any section, paragraph or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.

**Section 18.**

**Governing Law Provisions.** This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York applicable to agreements made and to be performed in such state. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby (“**Related Proceedings**”) may be instituted in the federal courts of the United States of America located in the Borough of Manhattan in the City of New York or the courts of the State of New York in each case located in the Borough of Manhattan in the City of New York (collectively, the “**Specified Courts**”), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court (a “**Related Judgment**”), as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party’s address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

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**Section 19.**

**General Provisions.** This Agreement constitutes the entire agreement of the parties to this Agreement and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof. This Agreement may be executed in two or more counterparts, each one of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument. This Agreement may not be amended or modified unless in writing by all of the parties hereto, and no condition herein (express or implied) may be waived unless waived in writing by each party whom the condition is meant to benefit. The section headings herein are for the convenience of the parties only and shall not affect the construction or interpretation of this Agreement.

Each of the parties hereto acknowledges that it is a sophisticated business person who was adequately represented by counsel during negotiations regarding the provisions hereof, including, without limitation, the indemnification provisions of Section 9 and the contribution provisions of Section 10, and is fully informed regarding said provisions. Each of the parties hereto further acknowledges that the provisions of Section 9 and Section 10 hereof fairly allocate the risks in light of the ability of the parties to investigate the Company, its affairs and its business in order to assure that adequate disclosure has been made in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, each free writing prospectus and the Prospectus (and any amendments and supplements to the foregoing), as contemplated by the Securities Act and the Exchange Act.

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If the foregoing is in accordance with your understanding of our agreement, kindly sign and return to the Company the enclosed copies hereof, whereupon this instrument, along with all counterparts hereof, shall become a binding agreement in accordance with its terms.

Very truly yours,

**COLLEGIUM PHARMACEUTICAL, INC.**

By: \_\_\_\_\_  
Name:  
Title:

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The foregoing Underwriting Agreement is hereby confirmed and accepted by the Representatives in New York, New York as of the date first above written.

**JEFFERIES LLC**  
**PIPER JAFFRAY & CO.**  
Acting individually and as Representatives  
of the several Underwriters named in  
the attached Schedule A.

**JEFFERIES LLC**

By: \_\_\_\_\_  
Name:  
Title:

**PIPER JAFFRAY & CO.**

By: \_\_\_\_\_  
Name:  
Title:

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**Schedule A**

<u>Underwriters</u>	<u>Number of Firm Shares to be Purchased</u>
Jefferies LLC	
Piper Jaffray & Co.	
Wells Fargo Securities, LLC	
Needham & Company, LLC	
Total	

**Schedule B**

**Free Writing Prospectuses Included in the Time of Sale Prospectus**

[To be added]

**Schedule C**

**Permitted Section 5(d) Communications**

[To be added]

Form of Lock-up Agreement

[ · ], 2015

JEFFERIES LLC  
 PIPER JAFFRAY & CO.  
 As Representatives of the several Underwriters

c/o JEFFERIES LLC  
 520 Madison Avenue  
 New York, New York 10022

c/o PIPER JAFFRAY & CO.  
 800 Nicollet Mall  
 Minneapolis, MN 55402

RE: Collegium Pharmaceutical, Inc. (the “**Company**”)

Ladies & Gentlemen:

The undersigned is an owner of shares of common stock, par value \$0.001 per share, of the Company (“**Shares**”) and/or Related Securities. The Company proposes to conduct a public offering of Shares (the “**Offering**”) for which Jefferies LLC (“**Jefferies**”) and Piper Jaffray & Co. (“**Piper Jaffray**”) will act as the representatives of the underwriters. The undersigned recognizes that the Offering will benefit each of the Company and the undersigned. The undersigned acknowledges that the underwriters are relying on the representations and agreements of the undersigned contained in this letter agreement in conducting the Offering and, at a subsequent date, in entering into an underwriting agreement (the “**Underwriting Agreement**”) and other underwriting arrangements with the Company with respect to the Offering.

Annex A sets forth definitions for capitalized terms used in this letter agreement that are not defined in the body of this agreement. Those definitions are a part of this agreement.

In consideration of the foregoing, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned hereby agrees that, during the Lock-up Period, subject to the exceptions set forth in this Agreement, the undersigned will not (and will cause any Family Member not to), without the prior written consent of Jefferies and Piper Jaffray, which may withhold their consent in their sole discretion:

- Sell or Offer to Sell any Shares or Related Securities currently or hereafter owned either of record or beneficially (as defined in Rule 13d-3 under the Exchange Act) by the undersigned or such Family Member,
- enter into any Swap,
- make any demand for, or exercise any right with respect to, the registration under the Securities Act of the offer and sale of any Shares or Related Securities, or cause to be filed a registration statement, prospectus or prospectus supplement (or an amendment or supplement thereto) with respect to any such registration, or

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- publicly announce any intention to do any of the foregoing.

The foregoing will not apply to the registration of the offer and sale of the Shares, and the sale of the Shares to the underwriters, in each case as contemplated by the Underwriting Agreement. In addition, the foregoing restrictions shall not apply to (i) the acquisition of Shares in open market transactions in or after the completion of Offering; provided that no filing under Section 16(a) of the Securities Exchange Act of 1934, as amended, shall be required or shall be voluntarily made in connection with subsequent sales of Shares acquired in such open market transactions; (ii) the transfer of Shares or Related Securities by gift, (iii) the transfer of Shares or Related Securities by will or intestate succession to the legal representative, heir or beneficiary of the undersigned, (iv) the transfer of Shares or Related Securities to a trust whose beneficiaries consist exclusively of one or more of the undersigned and/or a Family Member, (v) transfers or dispositions of the undersigned’s Shares or Related Securities to any corporation, partnership, limited liability company or other entity all of the beneficial ownership interests of which are held by the undersigned or any Family Member, (vi) distributions of the undersigned’s Shares or Related Securities to limited partners, general partners, members, stockholders or other equityholders of the undersigned, provided that any such transfer or distribution shall not involve a disposition for value, (vii) by operation of law, including pursuant to a domestic order or negotiated divorce settlement or (viii) if the undersigned is a corporation, partnership, limited liability company, trust or other business entity, the transfer of Shares or Related Securities to another corporation, partnership, limited liability company, trust or other business entity that is a direct or indirect affiliate (as defined in Rule 405 promulgated under the Securities Act of 1933, as amended) of the undersigned, provided that any such transfer or distribution shall not involve a disposition for value; *provided, however*, that in any such case, it shall be a condition to such transfer that:

- each transferee executes and delivers to Jefferies and Piper Jaffray an agreement in form and substance satisfactory to Jefferies and Piper Jaffray stating that such transferee is receiving and holding such Shares and/or Related Securities subject to the provisions of this letter agreement and agrees not to Sell or Offer to Sell such Shares and/or Related Securities, engage in any Swap or engage in any other activities restricted under this letter agreement except in accordance with this letter agreement (as if such transferee had been an original signatory hereto), and
- prior to the expiration of the Lock-up Period, no public disclosure or filing under the Exchange Act by any party to the transfer (donor, donee, transferor or transferee) shall be required, or made voluntarily, reporting a reduction in beneficial ownership of Shares or Related Securities in connection with such transfer.

Furthermore, notwithstanding the restrictions imposed by this letter agreement, the undersigned may (i) exercise an option to purchase Shares granted under any equity incentive plan or stock purchase plan of the Company existing as of the date hereof and described in the Prospectus, *provided* that the Shares issued upon such exercise shall continue to be subject to the restrictions on transfer set forth in this letter agreement, (ii) establish a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of Shares, *provided* that such plan does not provide for any transfers of Shares or Related Shares during the Lock-up Period and

the entry into such plan is not publicly disclosed, including in any filing under the Exchange Act, during the Lock-up Period or (iii) transfer Shares or Related Securities (A) as forfeitures to satisfy tax withholding obligations of the undersigned in connection with the vesting or exercise of equity awards by the undersigned pursuant to the Company's equity incentive plan existing as of the date hereof and described in the Prospectus, (B) pursuant to a net exercise or cashless exercise by the undersigned of outstanding equity awards pursuant to the Company's equity incentive plan existing as of the date hereof and described in the Prospectus, *provided* that any Shares acquired upon the net exercise or cashless exercise of equity awards described in this clause (B) shall be subject to the restrictions set forth in this letter agreement, (C) pursuant to a bona fide third-party tender offer for all outstanding shares of the Company, merger, consolidation or other similar transaction made to all holders of the Company's

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securities involving a change of control of the Company (including, without limitation, the entering into any lock-up, voting or similar agreement pursuant to which the undersigned may agree to transfer, sell, tender or otherwise dispose of common stock or other such securities in connection with such transaction, or vote any common stock or other such securities in favor of any such transaction), *provided* that in the event that such tender offer, merger, consolidation or other such transaction is not completed, such securities held by the undersigned shall remain subject to the provisions of this letter agreement, or (D) that may be deemed to have occurred as a result of the conversion of the outstanding preferred shares of the Company into shares of common stock or the exercise of warrants, *provided* that the restrictions set forth in this letter agreement shall apply to any of the undersigned's Shares or Related Securities issued upon such conversion or exercise; *provided* that, in the case of a transfer pursuant to clause (A) or (B) above, if the undersigned is required to make a filing under the Exchange Act reporting a reduction in beneficial ownership of Shares during the Lock-up Period, the undersigned shall include a statement in such report to the effect that the purpose of such transfer was to cover tax obligations of the undersigned in connection with such exercise.

If the undersigned is an officer or director of the Company, the undersigned further agrees that the foregoing provisions shall be equally applicable to any Company-directed Shares the undersigned may purchase or otherwise receive in the Offering (including pursuant to a directed share program).

In addition, if the undersigned is an officer or director of the Company, (i) Jefferies and Piper Jaffray agree that, at least three business days before the effective date of any release or waiver of the foregoing restrictions in connection with a transfer of Shares, Jefferies and Piper Jaffray will notify the Company of the impending release or waiver, and (ii) the Company (in accordance with the provisions of the Underwriting Agreement) will announce the impending release or waiver by press release through a major news service at least two business days before the effective date of the release or waiver. Any release or waiver granted by Jefferies and Piper Jaffray hereunder to any such officer or director shall only be effective two business days after the publication date of such press release. The provisions of this paragraph will not apply if both (a) the release or waiver is effected solely to permit a transfer not for consideration and (b) the transferee has agreed in writing to be bound by the same terms described in this letter agreement that are applicable to the transferor to the extent and for the duration that such terms remain in effect at the time of the transfer.

The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of Shares or Related Securities held by the undersigned and the undersigned's Family Members, if any, except in compliance with the foregoing restrictions.

With respect to the Offering only, the undersigned waives any registration rights relating to registration under the Securities Act of the offer and sale of any Shares and/or any Related Securities owned either of record or beneficially by the undersigned, including any rights to receive notice of the Offering.

The undersigned confirms that the undersigned has not, and has no knowledge that any Family Member has, directly or indirectly, taken any action designed to or that might reasonably be expected to cause or result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale of the Shares. The undersigned will not, and will cause any Family Member not to take, directly or indirectly, any such action.

Whether or not the Offering occurs as currently contemplated or at all depends on market conditions and other factors. The Offering will only be made pursuant to the Underwriting Agreement, the terms of which are subject to negotiation between the Company and the underwriters.

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The undersigned hereby represents and warrants that the undersigned has full power, capacity and authority to enter into this letter agreement. This letter agreement is irrevocable and will be binding on the undersigned and the successors, heirs, personal representatives and assigns of the undersigned.

Notwithstanding anything herein to the contrary, if (a) the closing of the Offering has not occurred prior to September 30, 2015, (b) after being executed, the Underwriting Agreement (other than the provisions thereof that survive termination) shall terminate or be terminated prior to payment for and delivery of the Shares to be sold thereunder or (c) the Company notifies the Underwriters in writing that it does not intend to proceed with the Offering, then the undersigned shall be released from all obligations under this letter agreement upon the earliest to occur of the events specified above.

This letter agreement shall be governed by, and construed in accordance with, the laws of the State of New York.

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\_\_\_\_\_  
Signature

\_\_\_\_\_  
Printed Name of Person Signing

*(Indicate capacity of person signing if signing as custodian or trustee, or on behalf of an entity)*

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**Certain Defined Terms  
Used in Lock-up Agreement**

For purposes of the letter agreement to which this Annex A is attached and of which it is made a part:

- “**Call Equivalent Position**” shall have the meaning set forth in Rule 16a-1(b) under the Exchange Act.
- “**Exchange Act**” shall mean the Securities Exchange Act of 1934, as amended.
- “**Family Member**” shall mean the spouse of the undersigned, an immediate family member of the undersigned or an immediate family member of the undersigned’s spouse, in each case living in the undersigned’s household or whose principal residence is the undersigned’s household (regardless of whether such spouse or family member may at the time be living elsewhere due to educational activities, health care treatment, military service, temporary internship or employment or otherwise). “**Immediate family member**” as used above shall have the meaning set forth in Rule 16a-1(e) under the Exchange Act.
- “**Lock-up Period**” shall mean the period beginning on the date hereof and continuing through the close of trading on the date that is 180 days after the date of the Prospectus (as defined in the Underwriting Agreement).
- “**Put Equivalent Position**” shall have the meaning set forth in Rule 16a-1(h) under the Exchange Act.
- “**Related Securities**” shall mean any options or warrants or other rights to acquire Shares or any securities exchangeable or exercisable for or convertible into Shares, or to acquire other securities or rights ultimately exchangeable or exercisable for or convertible into Shares.
- “**Securities Act**” shall mean the Securities Act of 1933, as amended.
- “**Sell or Offer to Sell**” shall mean to:
  - sell, offer to sell, contract to sell or lend,
  - effect any short sale or establish or increase a Put Equivalent Position or liquidate or decrease any Call Equivalent Position
  - pledge, hypothecate or grant any security interest in, or
  - in any other way transfer or dispose of,in each case whether effected directly or indirectly.
- “**Swap**” shall mean any swap, hedge or similar arrangement or agreement that transfers, in whole or in part, the economic risk of ownership of Shares or Related Securities, regardless of whether any such transaction is to be settled in securities, in cash or otherwise.

Capitalized terms not defined in this Annex A shall have the meanings given to them in the body of this lock-up agreement.

**ARTICLES OF AMENDMENT OF THE  
AMENDED AND RESTATED ARTICLES OF INCORPORATION OF  
COLLEGIUM PHARMACEUTICAL, INC.**

I.

The name of the corporation is Collegium Pharmaceutical, Inc. (the "Corporation").

II.

The amendment (the "Amendment") adopted is as follows:

The following is hereby added to the end of Paragraph A of Article IV of the Corporation's Amended and Restated Articles of Incorporation:

"Simultaneously with the effective time of this amendment (the "Effective Time"), subject to the treatment of fractional share interests as described below, each 6.9 shares of the Corporation's Common Stock issued and outstanding immediately prior to the Effective Time shall be combined and converted into one (1) validly issued, fully paid and non-assessable share of Common Stock (the "Reverse Stock Split"). There shall be no combination or conversion of the Series A Preferred Stock, the Series B Preferred, the Series C Preferred or the Series D Preferred Stock in connection with the Reverse Split.

The Reverse Stock Split will be effected on a holder-by-holder basis. In lieu of any fractional shares to which the holder would otherwise be entitled, the Corporation shall pay an amount of cash (without interest or deduction) equal to the product of (i) the fractional share to which the holder would otherwise be entitled and (ii) the fair value of such share as of the Effective Time as determined in good faith by the Board of Directors of the Corporation. The Reverse Stock Split shall occur automatically without any further action by the Corporation or the holders of the shares of Common Stock affected thereby. All rights, preferences and privileges of the Common Stock and the Preferred Stock as provided in these Restated Articles shall be adjusted to reflect the Reverse Stock Split (including the Conversion Prices of each series of the Preferred Stock, which shall be adjusted in accordance with Section 4.5 of Paragraph D of Article IV).

Each stock certificate representing shares of Common Stock immediately prior to the Effective Time shall, from and after the Effective Time, represent that number of shares of Common Stock into which such shares shall have been reclassified pursuant to the Reverse Stock Split, subject to the elimination of fractional share interests as described above.

III.

The Amendment was adopted by the Corporation's Board of Directors on April 23, 2015. The Amendment was proposed by the Corporation's Board of Directors and submitted to the

Corporation's shareholders in accordance with the provisions of Title 13.1, Chapter 9 of the Code of Virginia.

IV.

The designation, number of outstanding shares, and number of votes entitled to be cast by each voting group entitled to vote separately on the Amendment was:

<u>Designation</u>	<u>Number of Outstanding Shares</u>	<u>Number of Votes Entitled to be Cast</u>
Common Stock, \$0.001 par value per share; Preferred Stock, \$0.001 par value per share, Series A, Series B, Series C and Series D	95,965,129	95,965,129
Preferred Stock, \$0.001 par value per share, Series A, Series B, Series C and Series D	86,881,246	86,881,246

The total number of undisputed votes cast for the Amendment separately by each voting group was:

<u>Voting Group</u>	<u>Total Undisputed Votes "FOR"</u>
Common Stock, \$0.001 par value per share; Preferred Stock, \$0.001 par value per share, Series A, Series B, Series C and Series D	71,535,900
Preferred Stock, \$0.001 par value per share, Series A, Series B, Series C and Series D	68,424,265

The total number of votes cast for the Amendment by each voting group was sufficient for approval of the Amendment by such voting group.

V.

Pursuant to Section 13.1-606 of the Virginia Stock Corporation Act, the Amendment shall become effective at 3:00 p.m., Eastern Time, on April 24, 2015.

[Signature Page Follows]

**IN WITNESS WHEREOF**, the undersigned corporation has caused these Articles of Amendment to be executed by its duly authorized officer as of this 24<sup>th</sup> day of April, 2015.

**COLLEGIUM PHARMACEUTICAL, INC.**, a  
Virginia corporation

By: /s/ Paul Brannelly  
Name: Paul Brannelly  
Title: Executive Vice President and Chief  
Financial Officer

**AMENDED AND RESTATED  
ARTICLES OF INCORPORATION  
OF  
COLLEGIUM PHARMACEUTICAL, INC.**

ARTICLE I

The name of the corporation (the "Corporation") is Collegium Pharmaceutical, Inc.

ARTICLE II

The Corporation's purpose is to transact any or all lawful business not required to be specifically stated in these Articles.

ARTICLE III

The Corporation shall have the authority to issue 100,000,000 shares of Common Stock, par value \$0.001 per share ("Common Stock"), and 5,000,000 shares of Preferred Stock, par value \$0.001 per share ("Preferred Stock"). The rights, preferences voting powers and the qualifications, limitations and restrictions of the authorized stock shall be as follows:

**(A) Voting Powers**

1. Each share of Common Stock outstanding on any voting record date shall be entitled to one vote on any action of shareholders for which that voting record date was fixed. Except as otherwise required by the Virginia Stock Corporation Act (the "Act"), the exclusive general voting power for all purposes shall be vested in the Common Stock.

2. Except as otherwise required by these Articles, the Act or the Board of Directors acting pursuant to subsection B of Section 13.1-707 (or any successor provision) of the Act:

(i) the vote required to constitute any voting group's approval of any corporate action except the election of directors, an amendment of these Articles or the Bylaws, a plan of merger, share exchange, domestication or entity conversion, or a proposed sale or other disposition of the Corporation's property that requires shareholder approval pursuant to Section 13.1-724 of the Act (or any successor provision), or the dissolution of the Corporation, shall be a majority of all votes cast on the matter by such voting group;

(ii) the Bylaws shall set forth the vote required for the election of directors or, if not set forth in the Bylaws, the vote required shall be that set forth in the Act;

(iii) the vote required to constitute any voting group's approval of an amendment of these Articles, a plan of merger, share exchange, domestication or entity conversion, or a proposed sale or other disposition of the Corporation's property that requires shareholder approval pursuant to Section 13.1-724 of the Act (or any successor

provision), or the dissolution of the Corporation, shall be a majority of all votes entitled to be cast on the matter by such voting group; and

(iv) the vote required to constitute any voting group's approval of an adoption, amendment or repeal of the Bylaws shall be more than two-thirds of all votes entitled to be cast on the matter by such voting group.

**(B) Common Stock**

1. *Dividends*

Subject to the rights of the holders of Preferred Stock, holders of Common Stock shall be entitled to receive such dividends and other distributions as the Board of Directors may declare thereon from time to time out of assets or funds of the Corporation legally available therefor and shall share equally on a per share basis in all such dividends and other distributions.

2. *Dissolution*

In the event of the Corporation's dissolution, whether voluntary or involuntary, after payment in full of the amounts required to be paid to the holders of Preferred Stock, the remaining assets and funds of the Corporation shall be distributed pro rata to the holders of Common Stock. For purposes of this Article III(B)2, the voluntary sale, conveyance, lease, exchange or transfer (for cash, shares of stock, securities or other consideration) of all or substantially all of the assets of the Corporation or a merger or share exchange involving the Corporation and one or more other entity (whether or not the Corporation is the entity surviving such merger) shall not be deemed to be a dissolution of the Corporation.

**(C) Preferred Stock**

The Board of Directors, without shareholder action, may, by adopting an amendment of these Articles:

1. Classify any unissued shares into one or more classes or into one or more series within one or more classes;

2. Reclassify any unissued shares of any class into one or more classes or into one or more series within one or more classes; or

3. Reclassify any unissued shares of any series of any class into one or more classes or into one or more series within one or more classes.

The Board of Directors may determine the preferences, limitations and relative rights, to the extent permitted by the Act, of any class of shares of Preferred Stock before the issuance of any shares of that class, or of one or more series within a class before the issuance of any shares of that series. Each class or series shall be appropriately designated by a distinguishing designation prior to the issuance of any shares thereof. The Preferred Stock of all classes and series shall have preferences, limitations and relative rights identical with those of other shares of the same class or series. The preferences, limitations and relative rights of each series shall be

identical with those of shares of other series of the same class, except to the extent otherwise provided in the description of the series.

Prior to the issuance of any shares of a class or series of Preferred Stock, (1) the Board of Directors shall establish such class or series, without any action required by the shareholders, by adopting an amendment of these Articles and by filing with the State Corporation Commission of Virginia articles of amendment setting forth the designation and number of shares of the class or series and the preferences, limitations and relative rights thereof, and (2) the State Corporation Commission of Virginia shall have issued a certificate of amendment.

**(D) No Preemptive Rights**

No holder of any capital stock of the Corporation shall have any preemptive right to subscribe for, purchase or acquire (1) any shares of capital stock of the Corporation, (2) any securities convertible into or exchangeable for any such shares or (3) any options, warrants or rights to subscribe for, purchase or acquire any such shares or securities.

**ARTICLE IV**

The number of directors shall be fixed by or in accordance with the Bylaws. Commencing with the 2015 annual meeting of shareholders, the Board of Directors shall be divided into three classes, Class I, Class II and Class III, as nearly equal in number as possible. At the 2015 annual meeting of shareholders (or pursuant to written consent in lieu of such annual meeting), directors of the first class (Class I) shall be elected to hold office for a term expiring at the 2016 annual meeting of shareholders, directors of the second class (Class II) shall be elected to hold office for a term expiring at the 2017 annual meeting of shareholders and directors of the third class (Class III) shall be elected to hold office for a term expiring at the 2018 annual meeting of shareholders and, in each case, until such directors' successors are duly elected and qualified. At each annual meeting of shareholders after 2015, the successors to the class of directors whose terms then shall expire shall be identified as being of the same class as the directors they succeed and elected to hold office for a term expiring at the third succeeding annual meeting of shareholders and until such directors' successors are duly elected and qualified. When the number of directors is changed, any newly created directorships or any decrease in directorships shall be apportioned among the classes by the Board of Directors as to make all classes as nearly equal in number as possible.

Directors may be removed only for cause upon the affirmative vote of more than two-thirds of all votes entitled to be cast by holders of the Common Stock.

Any vacancy on the Board of Directors, including a vacancy resulting from an increase in the number of directors, shall be filled by the Board of Directors or, if the directors remaining in office constitute fewer than a quorum of the Board of Directors, then by the affirmative vote of a majority of such directors remaining in office.

To the full extent permitted by the Act, the Board of Directors is expressly empowered to adopt, amend and repeal the Bylaws.

**ARTICLE V**

**(A) Definitions**

For purposes of this Article V, the following terms shall have the meanings indicated:

1. "eligible person" means a person who is or was a director or officer of the Corporation or a person who, while a director or officer of the Corporation, is or was serving at the request of the Corporation as a director, trustee, partner or officer of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise. A person shall be considered to be serving an employee benefit plan at the Corporation's request if his or her duties to the Corporation also impose duties on, or otherwise involve services by, him or her to the plan or to participants in or beneficiaries of the plan;
2. "expenses" includes, without limitation, counsel fees and expenses;
3. "liability" means the obligation to pay a judgment, settlement, penalty, fine (including any excise tax assessed with respect to an employee benefit plan) or reasonable expenses incurred with respect to a proceeding;
4. "party" includes, without limitation, an individual who was, is or is threatened to be made a named defendant or respondent in a proceeding; and
5. "proceeding" means any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative and whether formal or informal.

**(B) Limitation of Liability**

To the full extent that the Act, as it exists on the effective date of these Articles or as hereafter amended, permits the limitation or elimination of the liability of directors and officers, no director or officer of the Corporation made a party to any proceeding brought by or in the right of the Corporation or brought by or on behalf of shareholders of the Corporation shall be liable to the Corporation or its shareholders for monetary damages arising out of any transaction, occurrence or course of conduct, whether occurring prior or subsequent to the effective date of this Article V.

**(C) Indemnification**

To the full extent permitted by the Act, as it exists on the date hereof or as hereafter amended, the Corporation shall indemnify and hold harmless any person who was or is a party to any proceeding, including a proceeding brought by or in the right of the Corporation or brought by or on behalf of shareholders of the Corporation, by reason of the fact that such person is or was an eligible person against any liability incurred by such person in connection with such proceeding, except for liability resulting from such person's having engaged in willful misconduct or a knowing violation of the criminal law.

**(D) Termination of Proceeding**

The termination of any proceeding by judgment, order, settlement, conviction or upon a plea of *nolo contendere* or its equivalent, shall not, of itself, create a presumption that the eligible person did not meet any standard of conduct that is a prerequisite to the limitation or elimination of liability provided in Article V(B) or to such person's entitlement to indemnification under Article V(C).

**(E) Determination of Availability**

The Corporation shall indemnify and hold harmless under Article V(C) any eligible person who entirely prevails in the defense of any proceeding. Any other indemnification under Article V(C) (unless ordered by a court) shall be made by the Corporation only as authorized in the specific case upon a determination that indemnification is proper in the circumstances because the eligible person has met any standard of conduct that is a prerequisite to his or her entitlement to indemnification under Article V(C).

The determination shall be made:

1. If there are two or more disinterested directors (as defined in the Act), by the Board of Directors by a majority vote of all the disinterested directors, a majority of whom shall for such purpose constitute a quorum, or by a majority of the members of a committee of two or more disinterested directors appointed by such a vote;
2. By special legal counsel:
  - (a) Selected in the manner prescribed in subdivision 1 of this subsection; or
  - (b) If there are fewer than two disinterested directors, selected by the Board of Directors, in which selection directors who do not qualify as disinterested directors may participate; or
3. By the shareholders, but shares owned by or voted under the control of a director who at the time does not qualify as a disinterested director may not be voted on the determination.

Notwithstanding the other provisions of this Article V(E), in the event there has been a change in the composition of a majority of the Board of Directors after the date of the alleged act or omission with respect to which indemnification is claimed other than through successor directors approved by the Board of Directors as it existed prior to such date, any determination as to such indemnification shall be made by special legal counsel agreed upon by the Board of Directors and the eligible person. If the Board of Directors and the eligible person are unable to agree upon such special legal counsel, the Board of Directors and the eligible person each shall select a nominee, and the nominees shall select such special legal counsel.

**(F) Advances**

To the full extent permitted by the Act, as it exists on the date hereof or as hereafter amended, the Corporation shall pay for or reimburse the reasonable expenses incurred by any eligible person who is a party to a proceeding in advance of final disposition of the proceeding or the making of any determination under Article V(C) if such eligible person furnishes the

Corporation a written undertaking, executed personally or on his or her behalf, to repay the advance if it is ultimately determined that he or she did not meet the requisite standard of conduct. The undertaking required by this Article V(F) shall be an unlimited general obligation but need not be secured and shall be accepted without reference to financial ability to make repayment.

**(G) Indemnification of Others**

The Corporation is empowered to indemnify and advance expenses to or contract to indemnify or advance expenses to any person not specified in Article V(C) or Article V(F) who was, is or may become a party to any proceeding, by reason of the fact that he or she is or was an employee or agent of the Corporation or is or was serving at the request of the Corporation as a director, trustee, partner or officer of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, to the same or a lesser extent as if such person were specified as one to whom indemnification or advancement of expenses is granted in Article V(C) or Article V(F).

**(H) Application; Amendment**

The provisions of this Article V shall be applicable to all proceedings commenced after it becomes effective arising from any act or omission, whether occurring before or after such effective date. No amendment or repeal of this Article V shall impair or otherwise diminish the rights provided under this Article V (including those created by contract) with respect to any act or omission occurring prior to such amendment or repeal. The Corporation shall promptly take all such actions and make all such determinations and authorizations as shall be necessary or appropriate to comply with its obligation to make any indemnity against liability, or to advance any expenses, under this Article V and shall promptly pay or reimburse all reasonable expenses incurred by any eligible person in connection with such actions and determinations or proceedings of any kind arising therefrom.

**(I) Insurance**

The Corporation may purchase and maintain insurance to indemnify it against the whole or any portion of the liability assumed by it in accordance with this Article and may also procure insurance, in such amounts as the Board of Directors may determine, on behalf of any eligible person (and for a person referred to in Article V(G)) against any liability asserted against or incurred by such person whether or not the Corporation would have power to indemnify such person against such liability under the provisions of this Article V or the Act.

**(J) Further Indemnity**

1. Every reference herein to directors, officers, trustees, partners, employees or agents shall include former directors, officers, trustees, partners, employees or agents and their respective heirs, executors and administrators. The indemnification hereby provided and provided hereafter pursuant to the power hereby conferred by this Article V shall not be exclusive of any other rights to which any person may be entitled, including any right under policies of insurance that may be purchased and maintained by the Corporation or others, with respect to claims, issues or

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matters in relation to which the Corporation would not have the power to indemnify such person under the provisions of this Article V.

2. Nothing herein shall prevent or restrict the power of the Corporation to make or provide for any further indemnity or advancement of expenses, or provisions for determining entitlement to indemnity or advancement of expenses, pursuant to one or more agreements, Bylaws, resolutions of directors or shareholders, or other arrangements (including, without limitation, creation of trust funds or security interests funded by letters of credit or other means); *provided, however*, that any provision of any such agreement, Bylaw, resolution or other arrangement shall not be effective if and to the extent that it is determined to be contrary to this Article or applicable laws of the Commonwealth of Virginia, but other provisions of any such agreement, Bylaw, resolution or other arrangement shall not be affected by any such determination.

**(K) Severability**

Each provision of this Article V shall be severable, and an adverse determination as to any such provision shall in no way affect the validity of any other provision.

ARTICLE VI

Article 14.1 of Chapter 9 of Title 13.1 of the Code of Virginia shall not apply to the Corporation.

ARTICLE VII

The Board of Directors may establish procedures and limitations regarding the submission by shareholders of nominations for director and proposals for consideration at meetings of the shareholders.

Special meetings of shareholders may be called by the Board of Directors, the Chairman of the Board of Directors or the President of the Corporation, and may not be called by any other person or entity.

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AMENDED AND RESTATED  
BYLAWS  
of  
COLLEGIUM PHARMACEUTICAL, INC.

ARTICLE I

Meetings of Shareholders

**Section 1. Annual Meetings.** - The annual meeting of the shareholders for the election of directors and for the transaction of such other business as may properly come before the meeting, and any postponement or adjournment thereof, shall be held on such date and at such time as the Board of Directors may in its discretion determine.

**Section 2. Special Meetings.** - Special meetings of the shareholders may be called by the chairman of the Board of Directors, the president of the Corporation or the Board of Directors.

**Section 3. Place of Meetings.** - All meetings of the shareholders shall be held at such place as from time to time may be fixed by the Board of Directors.

**Section 4. Notice of Meetings.**

(a) Notice, stating the place, day and time and, in the case of a special meeting, the purpose or purposes for which the meeting is called, shall be given not less than 10 nor more than 60 days before the date of the meeting (except as a different time is specified herein or by law), to each shareholder of record having voting power in respect of the business to be transacted thereat. Notice of a shareholders' meeting to act on an amendment or restatement of the Articles of Incorporation, a plan of merger, share exchange, domestication or entity conversion, a proposed sale or other disposition of the Corporation's property that requires shareholder approval or the dissolution of the Corporation shall be given not less than 25 nor more than 60 days before the date of the meeting. A record date fixed by the Board of Directors with respect to any meeting of the shareholders shall be the record date for determining shareholders entitled to notice of and to vote at such meeting, unless the Board of Directors, at the time it fixes the record date for shareholders entitled to notice of the meeting, fixes a later record date on or before the date of the meeting to determine the shareholders entitled to vote at the meeting. Notice may be given in any manner permitted by law. The Board of Directors may postpone any previously scheduled meeting.

(b) Notwithstanding Section 4(a) of this Article I, a written waiver of notice signed by the person or persons entitled to such notice, either before or after the time stated therein, shall be equivalent to the giving of such notice. A shareholder who attends a meeting shall be deemed to have (i) waived objection to lack of notice or defective notice of the meeting, unless at the beginning of the meeting such shareholder objects to holding the meeting or transacting business at the meeting, and (ii) waived objection to consideration of a particular

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matter at the meeting that is not within the purpose or purposes described in the meeting notice, unless such shareholder objects to considering the matter when it is presented.

**Section 5. Quorum and Vote Required.** - At all meetings of the shareholders, unless a greater number or voting by groups is required by law, a majority of the shares entitled to vote, represented in person or by proxy, shall constitute a quorum. Once a share is represented for any purpose at a meeting, it is present for quorum purposes for the remainder of the meeting and for any adjournment thereof unless a new record date is or must be set for that adjourned meeting.

If a quorum is present, action on a matter is approved if the votes cast favoring the action exceed the votes cast opposing the action, unless the vote of a greater number or voting by groups is required by law or the Articles of Incorporation, and except that directors shall be elected by a plurality of the votes cast. In the absence of a quorum, a majority of the votes cast may adjourn such meeting, provided that no business other than adjournment shall be conducted in the absence of a quorum.

**Section 6. Organization.** - At all meetings of the shareholders, the chairman of the Board of Directors or, in the chairman's absence, the chief executive officer or, in the chief executive officer's absence, such other person selected by the Board of Directors, shall act as chairman of the meeting. In the absence of the foregoing persons, a majority of the shares present and entitled to vote at such meeting may appoint any person to act as chairman. The secretary of the Corporation or, in the secretary's absence, an assistant secretary, shall act as secretary at each meeting of the shareholders. In the event that neither the secretary nor any assistant secretary is present, the chairman of the meeting may appoint any person to act as secretary of the meeting. The Board of Directors may adopt such rules, regulations and procedures for the conduct of any meeting of shareholders as it shall deem appropriate. Except to the extent inconsistent with such rules, regulations and procedures as adopted by the Board of Directors, the chairman of any meeting of shareholders shall have the right and authority to prescribe such rules, regulations and procedures and to do all such acts and things as, in the judgment of such person, are appropriate for the proper conduct of the meeting. Such rules, regulations and procedures, whether adopted by the Board of Directors or prescribed by the chairman of the meeting, may include, without limitation, the following: (a) the establishment of an agenda or order of business for the meeting; (b) rules and procedures for maintaining order at the meeting and the safety of those present; (c) limitations on attendance at or participation in the meeting to shareholders of record, their duly authorized and constituted proxies or such other persons as the chairman of the meeting shall permit; (d) restrictions on entry to the meeting after the time fixed for the commencement thereof; and (e) limitations on the time allotted to questions or comments by participants. The chairman of the meeting shall have the power to recess or adjourn any meeting.

**Section 7. Order of Business.**

(a) Annual Meeting of Shareholders. At any annual meeting of the shareholders, only such nominations of persons for election to the Board of Directors shall be made, and only such other business shall be conducted or considered, as shall have been properly

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brought before the meeting. For nominations to be properly made at an annual meeting, and proposals of other business to be properly brought before an annual meeting, nominations and proposals of other business must be (i) specified in the Corporation's notice of meeting (or any supplement thereto) given by or at the direction of the Board of Directors, (ii) otherwise properly made at the annual meeting, by or at the direction of the Board of Directors, or (iii) otherwise properly requested to be brought before the annual meeting by a shareholder of the Corporation in accordance with these Bylaws. For nominations of persons for election to the Board of Directors or proposals of other business to be properly requested by a shareholder to be made at an annual meeting, a shareholder must (x) be a shareholder of record at the time of giving of notice of such annual meeting by or at the direction of the Board of Directors, at the time the shareholder provides the notice required by Section 8 of Article I of these Bylaws and at the time of the annual meeting, (y) be entitled to vote at such annual meeting and (z) comply with the procedures set forth in these Bylaws as to such business or nomination. The immediately preceding sentence shall be the exclusive means for a shareholder to make nominations or other business proposals (other than matters properly brought under Rule 14a-8 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and included in the Corporation's notice of meeting) before an annual meeting of shareholders.

(b) Special Meeting of Shareholders. At any special meeting of the shareholders, only such business shall be conducted or considered as shall have been properly brought before the meeting pursuant to the Corporation's notice of meeting.

To be properly brought before a special meeting, proposals of business must be (i) specified in the Corporation's notice of meeting (or any supplement thereto) given by or at the direction of the Board of Directors or (ii) otherwise properly brought before the special meeting, by or at the direction of the Board of Directors. Nominations of persons for election to the Board of Directors may be made at a special meeting of shareholders at which directors are to be elected pursuant to the Corporation's notice of meeting (A) by or at the direction of the Board of Directors or (B) provided that the Board of Directors has determined that directors shall be elected at such meeting, by any shareholder of the Corporation who (x) is a shareholder of record at the time of giving of notice of such special meeting, at the time the shareholder provides the notice required by Section 8 of Article I of these Bylaws and at the time of the special meeting, (y) is entitled to vote at the meeting and (z) complies with the procedures set forth in these Bylaws as to such nomination. The immediately preceding sentence shall be the exclusive means for a shareholder to make nominations or other business proposals before a special meeting of shareholders (other than matters properly brought under Rule 14a-8 under the Exchange Act and included in the Corporation's notice of meeting).

(c) General. Except as otherwise provided by law, the Articles of Incorporation or these Bylaws, the chairman of the meeting shall have the power to determine whether a nomination or any other business proposed to be brought before the meeting was made or proposed, as the case may be, in accordance with these Bylaws and, if any proposed nomination or other business is not in compliance with these Bylaws, to declare that no action shall be taken on such nomination or other proposal and such nomination or other proposal shall be disregarded.

## **Section 8. Advance Notice of Shareholder Business and Nominations.**

(a) Annual Meeting of Shareholders. Without qualification or limitation, subject to Section 8(c)(iv) of Article I of these Bylaws, for any nominations or any other business to be properly brought before an annual meeting by a shareholder pursuant to Section 7(a) of Article I of these Bylaws, the shareholder must have given timely notice thereof in proper form (including, in the case of nominations, the completed and signed questionnaire, representation and agreement required by Section 9 of Article I of these Bylaws) and timely updates and supplements thereof in writing to the secretary and such other business must otherwise be a proper matter for shareholder action. To be timely, a shareholder's notice shall be delivered to the secretary at the principal executive offices of the Corporation not earlier than the close of business on the 120th day and not later than the close of business on the 90th day prior to the first anniversary of the preceding year's annual meeting; *provided, however*, that in the event that the date of the annual meeting is more than 30 days before or more than 60 days after such anniversary date, notice by the shareholder must be so delivered not earlier than the close of business on the 120th day prior to the date of such annual meeting and not later than the close of business on the later of the 90th day prior to the date of such annual meeting or, if the first public announcement of the date of such annual meeting is less than 100 days prior to the date of such annual meeting, the tenth day following the day on which public announcement of the date of such meeting is first made by the Corporation. In no event shall any adjournment or postponement of an annual meeting, or the public announcement thereof, commence a new time period for the giving of a shareholder's notice as described above. Notwithstanding anything in the preceding two sentences to the contrary, in the event that the number of directors to be elected to the Board of Directors is increased by the Board of Directors, and there is no public announcement by the Corporation naming all of the nominees for director or specifying the size of the increased Board of Directors at least 100 days prior to the first anniversary of the preceding year's annual meeting, a shareholder's notice required by this Section 8(a) of Article I shall also be considered timely, but only with respect to nominees for any new positions created by such increase, if it shall be delivered to the secretary at the principal executive offices of the Corporation not later than the close of business on the 10th day following the day on which such public announcement is first made by the Corporation. In addition, to be timely, a shareholder's notice shall further be updated and supplemented, if necessary, so that the information provided or required to be provided in such notice shall be true and correct as of the record date for the meeting and as of the date that is ten business days prior to the meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to the secretary at the principal executive offices of the Corporation not later than five business days after the record date for the meeting in the case of the update and supplement required to be made as of the record date, and not later than eight business days prior to the date for the meeting, any adjournment or postponement thereof in the case of the update and supplement required to be made as of ten business days prior to the meeting or any adjournment or postponement thereof. If a shareholder who has given timely notice as required herein to make a nomination or bring other business before any such meeting and intends to authorize another person to act for such shareholder as a proxy to present the proposal at such meeting, the shareholder shall give notice of such authorization in writing to the secretary not less than three business days before the date of the meeting, including the name and contact information for such person.

(b) Special Meeting of Shareholders. Subject to Section 8(c)(iv) of Article I of these Bylaws, in the event the Corporation calls a special meeting of shareholders for the purpose of electing one or more directors to the Board of Directors, any shareholder may nominate a person or persons (as the case may be) for election to such position(s) to be elected as specified in the Corporation's notice calling the meeting, provided that the shareholder gives timely notice thereof in proper form (including the completed and signed questionnaire, representation and agreement required by Section 9 of Article I of these Bylaws) and timely updates and supplements thereof in writing to the secretary. In order to be timely, a shareholder's notice shall be delivered to the secretary at the principal executive offices of the Corporation not earlier than the close of business on the 120th day prior to the date of such special meeting and not later than the close of business on the later of the 90th day prior to the date of such special meeting or, if the first public announcement of the date of such special meeting is less than 100 days prior to the date of such special meeting, the 10th day following the day on which public announcement is first made of the date of the special meeting and of the nominees proposed by the Board of Directors to be elected at such meeting. In no event shall any adjournment or postponement of a special meeting, or the public announcement thereof, commence a new time period for the giving of a shareholder's notice as described above. In addition, to be timely, a shareholder's notice shall further be updated and supplemented, if necessary, so that the information provided or required to be provided in such notice shall be

true and correct as of the record date for the meeting and as of the date that is ten business days prior to the meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to the secretary at the principal executive offices of the Corporation not later than five business days after the record date for the meeting in the case of the update and supplement required to be made as of the record date, and not later than eight business days prior to the date for the meeting, any adjournment or postponement thereof in the case of the update and supplement required to be made as of ten business days prior to the meeting or any adjournment or postponement thereof. If a shareholder who has given timely notice as required herein to bring any business before any such meeting and intends to authorize another person to act for such shareholder as a proxy to present the proposal at such meeting, the shareholder shall give notice of such authorization in writing to the secretary not less than three business days before the date of the meeting, including the name and contact information for such person.

(c) Other Provisions.

(i) To be in proper form, a shareholder's notice (whether given pursuant to Section 8(a) of Article I or Section 8(b) of Article I of these Bylaws) to the secretary must include the following, as applicable:

(A) as to the shareholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made, a shareholder's notice must set forth: (1) the name and address of such shareholder, as they appear on the Corporation's books, of such beneficial owner, if any, and of their respective affiliates or associates or others acting in concert therewith, (2) (a) the class or series and number of shares of the Corporation and any other equity or debt securities of the Corporation which are, directly or indirectly, owned beneficially and of record by such shareholder, such beneficial owner or their respective affiliates or associates or others acting in concert therewith and the date(s) on which such securities were acquired, and the names and number of shares of the Corporation held by any

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nominees on behalf of any such persons (and the date(s) such shares were acquired), (b) any option, warrant, convertible security, stock appreciation right or similar right with an exercise or conversion privilege or a settlement payment or mechanism at a price related to any class or series of shares of the Corporation or with a value derived in whole or in part from the value of any class or series of shares of the Corporation, or any derivative or synthetic arrangement having the characteristics of a long position in any class or series of shares of the Corporation, or any contract, derivative, swap or other transaction or series of transactions designed to produce economic benefits and risks that correspond substantially to the ownership of any class or series of shares of the Corporation, including due to the fact that the value of such contract, derivative, swap or other transaction or series of transactions is determined by reference to the price, value or volatility of any class or series of shares of the Corporation, whether or not such instrument, contract or right shall be subject to settlement in the underlying class or series of shares of the Corporation, through the delivery of cash or other property, or otherwise, and without regard to whether the shareholder of record, the beneficial owner, if any, or any affiliates or associates or others acting in concert therewith, may have entered into transactions that hedge or mitigate the economic effect of such instrument, contract or right or any other direct or indirect opportunity to profit or share in any profit derived from any increase or decrease in the value of shares of the Corporation (any of the foregoing, a "Derivative Instrument") directly or indirectly owned beneficially by such shareholder, the beneficial owner, if any, or any affiliates or associates or others acting in concert therewith (and the date(s) such securities were acquired), (c) any proxy (other than a revocable proxy given in response to a solicitation made pursuant to, and in accordance with, Section 14(a) of the Exchange Act by way of a solicitation statement filed on Schedule 14A), contract, arrangement or understanding pursuant to which such shareholder, beneficial owner, if any, or affiliates or associates or others acting in concert therewith has a right to vote any class or series of shares or other securities of the Corporation, (d) any contract, agreement, arrangement or understanding, including any repurchase or similar so-called "stock borrowing" agreement or arrangement, engaged in, directly or indirectly, by such shareholder, beneficial owner, if any, or affiliates or associates or others acting in concert therewith, the purpose or effect of which is to mitigate loss to, reduce the economic risk (of ownership or otherwise) of any class or series of the shares of the Corporation by, manage the risk of share price changes for, or increase or decrease the voting power of, such shareholder, beneficial owner, if any, or affiliates or associates or others acting in concert therewith with respect to any class or series of the shares or other securities of the Corporation, or which provides, directly or indirectly, the opportunity to profit or share in any profit derived from any decrease in the price or value of any class or series of the shares or other securities of the Corporation (any of the foregoing, "Short Interests"), (e) any rights to dividends or other distributions on the shares of the Corporation owned beneficially by such shareholder, beneficial owner, if any, or affiliates or associates or others acting in concert therewith that are separated or separable from the underlying shares of the Corporation, (f) any proportionate interest in shares of the Corporation or Derivative Instruments held, directly or indirectly, by a general or limited partnership in which such shareholder, beneficial owner, if any, or affiliates or associates or others acting in concert therewith is a general partner or, directly or indirectly, beneficially owns an interest in a general partner of such general or limited partnership, (g) any performance-related fees (other than an asset-based fee) to which such shareholder, beneficial owner, if any, or affiliates or associates or others acting in concert therewith is entitled based on any increase or decrease in the value of any class or series of the shares or other securities of the Corporation or Derivative Instruments,

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if any, (h) any significant equity interests or any Derivative Instruments or Short Interests in any principal competitor of the Corporation held by such shareholder, beneficial owner, if any, or affiliates or associates or others acting in concert therewith and (i) any direct or indirect interest of such shareholder, beneficial owner, if any, or affiliates or associates or others acting in concert therewith in any contract with the Corporation, any affiliate of the Corporation or any principal competitor of the Corporation (including, in any such case, any employment agreement, collective bargaining agreement or consulting agreement), and (3) any other information relating to such shareholder and beneficial owner, if any, that would be required to be disclosed in a proxy statement and form of proxy or other filings required to be made in connection with solicitations of proxies for, as applicable, the proposal and/or for the election of directors in a contested election pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder;

(B) if the notice relates to any business other than a nomination of a director or directors that the shareholder proposes to bring before the meeting, a shareholder's notice must, in addition to the matters set forth in paragraph (A) above, also set forth: (1) a brief description of the business desired to be brought before the meeting, the reasons for conducting such business at the meeting and any material interest of such shareholder and beneficial owner, if any, and their respective affiliates and associates or others acting in concert therewith in such business, (2) the text of the proposal or business (including the text of any resolutions proposed for consideration) and (3) a description of all agreements, arrangements and understandings between such shareholder and beneficial owner, if any, and any other person or persons (including their names) in connection with the proposal of such business by such shareholder;

(C) as to each person, if any, whom the shareholder proposes to nominate for election or reelection to the Board of Directors, a shareholder's notice must, in addition to the matters set forth in paragraph (A) above, also set forth: (1) all information relating to such person that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for election of directors in a contested election pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder (including such person's written consent to

being named in the proxy statement as a nominee and to serving as a director if elected) and (2) a description of all direct and indirect compensation and other material monetary agreements, arrangements and understandings during the past three years, and any other material relationships, between or among such shareholder and beneficial owner, if any, and their respective affiliates and associates, or others acting in concert therewith, on the one hand, and each proposed nominee, and his or her respective affiliates and associates, or others acting in concert therewith, on the other hand, including all information that would be required to be disclosed pursuant to Rule 404 promulgated under Regulation S-K if the shareholder making the nomination and any beneficial owner on whose behalf the nomination is made, if any, or any affiliate or associate thereof or person acting in concert therewith, were the "registrant" for purposes of such rule and the nominee were a director or executive officer of such registrant; and

(D) with respect to each person, if any, whom the shareholder proposes to nominate for election or reelection to the Board of Directors, a shareholder's notice must, in addition to the matters set forth in paragraphs (A) and (C) above, also include a

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completed and signed questionnaire, representation and agreement required by Section 9 of Article I of these Bylaws. The Corporation may require any proposed nominee to furnish such other information as may reasonably be required by the Corporation to determine the eligibility of such proposed nominee to serve as an independent director of the Corporation or that could be material to a reasonable shareholder's understanding of the independence, or lack thereof, of such nominee.

(ii) For purposes of these Bylaws, "public announcement" shall mean disclosure in a press release reported by a national news service, including the Dow Jones News Service or the Associated Press, or in a document publicly filed by the Corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Exchange Act and the rules and regulations promulgated thereunder.

(iii) Notwithstanding the provisions of these Bylaws, a shareholder shall also comply with all applicable requirements of the Exchange Act and the rules and regulations thereunder with respect to the matters set forth in these Bylaws; *provided, however*, that any references in these Bylaws to the Exchange Act or the rules promulgated thereunder are not intended to and shall not limit the requirements applicable to nominations or proposals as to any other business to be considered pursuant to these Bylaws.

(iv) Nothing in these Bylaws shall be deemed to affect any rights (1) of shareholders to request inclusion of proposals in the Corporation's proxy statement pursuant to Rule 14a-8 under the Exchange Act, (2) of the holders of any series of preferred stock of the Corporation if and to the extent provided for under law, the Articles of Incorporation or these Bylaws or (3) of shareholders to act by unanimous written consent in accordance with the Articles of Incorporation and applicable law.

Subject to Rule 14a-8 under the Exchange Act, nothing in these Bylaws shall be construed to permit any shareholder, or give any shareholder the right, to include or have disseminated or described in the Corporation's proxy statement any nomination of director or directors or any other business proposal.

(v) The disclosures required by Section 8(a) of Article I or Section 8(b) of Article I of these Bylaws shall not include any disclosures with respect to ordinary course business activities of any broker, dealer, commercial bank, trust company or other nominee who is a shareholder solely as a result of being the shareholder of record or nominee directed to prepare and submit the notice required by Section 8(a) of Article I or Section 8(b) of Article I, as the case may be, on behalf of a beneficial owner other than the name of any such entity and the number of shares held on behalf of such beneficial owner.

**Section 9. Submission of Questionnaire, Representation and Agreement.** - To be eligible to be a nominee for election or reelection as a director of the Corporation, a person must deliver (in accordance with the time periods prescribed for delivery of notice under Section 8 of Article I of these Bylaws) to the secretary at the principal executive offices of the Corporation a written questionnaire with respect to the background and qualification of such person and the background of any other person or entity on whose behalf the nomination is being made (which questionnaire shall be provided by the secretary upon written request), and a written

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representation and agreement (in the form provided by the secretary upon written request) that such person (a) is not and will not become a party to (i) any agreement, arrangement or understanding with, and has not given any commitment or assurance to, any person or entity as to how such person, if elected as a director of the Corporation, will act or vote on any issue or question (a "Voting Commitment") that has not been disclosed to the Corporation or (ii) any Voting Commitment that could limit or interfere with such person's ability to comply, if elected as a director of the Corporation, with such person's fiduciary duties under applicable law, (b) is not and will not become a party to any agreement, arrangement or understanding with any person or entity other than the Corporation with respect to any direct or indirect compensation, reimbursement or indemnification in connection with service or action as a director that has not been disclosed therein and (c) in such person's individual capacity and on behalf of any person or entity on whose behalf the nomination is being made, would be in compliance, if elected as a director of the Corporation, and will comply with all applicable corporate governance, conflict of interest, resignation, confidentiality and stock ownership and trading policies and guidelines of the Corporation publicly disclosed from time to time.

**Section 10. Voting.** - A shareholder may vote his or her shares in person or by proxy. Any proxy shall be delivered to the secretary of the meeting or to the inspectors of election appointed in accordance with Section 12 of Article I of these Bylaws at or prior to the time designated by the chairman of the meeting or in the order of business for so delivering such proxies. No proxy shall be valid after 11 months from its date, unless otherwise provided in the proxy. Each holder of record of stock of any class shall, as to all matters in respect of which stock of such class has voting power, be entitled to such vote as is provided in the Articles of Incorporation for each share of stock of such class standing in the holder's name on the books of the Corporation as of the voting record date for the meeting of shareholders. Unless required by statute or determined by the chairman of the meeting to be advisable, the vote on any question need not be by ballot. On a vote by ballot, each ballot shall be signed by the shareholder voting or by such shareholder's proxy, if there be such proxy; *provided, however*, that if authorized by the Board of Directors, any shareholder vote to be taken by written ballot may be satisfied by a ballot submitted by electronic transmission by the shareholder or the shareholder's proxy, provided that any such electronic transmission shall either set forth or be submitted with information from which it can be determined that the electronic transmission was authorized by the shareholder or the shareholder's proxy.

**Section 11. Proxies.** - A shareholder or a shareholder's duly authorized agent or attorney-in-fact may appoint a proxy to vote or otherwise act for the shareholder by signing an appointment form or by an electronic transmission. An electronic transmission shall contain or be accompanied by information from which one can determine that the shareholder, the shareholder's duly authorized agent or the shareholder's duly authorized attorney-in-fact authorized the transmission. Any copy, facsimile telecommunication or other reliable reproduction of the writing or transmission created pursuant to this Section 11 of Article I

**Section 12. Inspectors.** - At all meetings of the shareholders, the Corporation shall appoint one or more inspectors. Each inspector, before entering upon the discharge of his or her duties, shall certify in writing that the inspector will faithfully execute the duties of inspector with strict impartiality and according to the best of his or her ability. The inspectors shall (a) ascertain the number of shares outstanding and the voting power of each, (b) determine the shares represented at a meeting and the validity of proxies, proxy appointments and ballots, (c) count all votes, (d) determine and retain for a reasonable period a record of the disposition of any challenges made to any determination by the inspectors, (e) certify in a written report their determination of the number of shares represented at the meeting and their count of all the votes and (f) perform such other duties as required by law or requested by the Corporation or the chairman of the meeting in connection with such meeting. The inspectors may appoint or retain other persons or entities to assist the inspectors in the performance of the duties of the inspectors.

**Section 13. Record Dates.** - The Board of Directors shall fix, in advance, a record date or dates to make a determination of shareholders entitled to notice of or to vote at any meeting of shareholders or to receive any dividend or distribution or for any other purpose, such date or dates to be not more than 70 days before the meeting or action requiring a determination of shareholders. When a determination of shareholders entitled to notice of or to vote at any meeting of shareholders has been made, such determination shall be effective for any adjournment of the meeting unless the Board of Directors fixes a new record date or dates, which it shall do if the meeting is adjourned to a date more than 120 days after the date fixed for the original meeting.

## ARTICLE II

### Board of Directors

**Section 1. General Powers.** — All corporate powers shall be exercised by or under the direction of the Board of Directors.

**Section 2. Number.** - The number of directors shall be determined from time to time by resolution of the Board of Directors.

**Section 3. Term of Office.** - Each director shall hold office for his or her applicable term in accordance with the Articles of Incorporation and until his or her successor shall have been duly elected and qualified.

**Section 4. Organization.** - At all meetings of the Board of Directors, the chairman of the Board of Directors or, in the chairman's absence, the lead independent director (if any) shall act as chairman of the meeting. In the absence of the foregoing persons, the majority of the directors present at a meeting may appoint any director who is present at such meeting to act as chairman. The secretary of the Corporation or, in the secretary's absence, an assistant secretary, shall act as secretary of meetings of the Board of Directors. In the event that neither the secretary nor any assistant secretary is present at such meeting, the chairman of the meeting shall appoint any person to act as secretary of the meeting.

**Section 5. Vacancies.** - Any vacancy occurring in the Board of Directors, including a vacancy resulting from an increase in the number of directors, shall be filled in accordance with the Articles of Incorporation.

**Section 6. Place of Meeting.** - Meetings of the Board of Directors, regular or special, may be held either within or outside the Commonwealth of Virginia.

**Section 7. Organizational Meeting.** — Unless otherwise determined by the chairman or the Board of Directors, the annual organizational meeting of the Board of Directors shall be held immediately following adjournment of the annual meeting of shareholders and at the same place, without the requirement of any notice other than this provision of the Bylaws.

**Section 8. Regular Meetings; Notice.** - Regular meetings of the Board of Directors shall be held at such times and places as it may from time to time determine. Notice of such meetings need not be given if the time and place have been fixed at a previous meeting.

**Section 9. Special Meetings; Notice.** - Special meetings of the Board of Directors shall be held whenever called by order of the chairman of the Board of Directors, the lead independent director, or any two of the directors. Notice of each such meeting, which need not specify the business to be transacted thereat, shall be (a) mailed to each director, addressed to his or her residence or usual place of business, at least two days before the day on which the meeting is to be held, (b) given at least 24 hours before the time of the meeting by electronic transmission as previously consented to by the director to whom notice is given or (c) given personally or by telephone at least 24 hours before the time of the meeting.

**Section 10. Waiver of Notice.** - Whenever any notice is required to be given to a director of any meeting for any purpose under the provisions of law, the Articles of Incorporation or these Bylaws, a waiver thereof in writing signed by the person or persons entitled to such notice, either before or after the time stated therein, shall be equivalent to the giving of such notice. A director's attendance at or participation in a meeting waives any required notice to him or her of the meeting unless at the beginning of the meeting or promptly upon the director's arrival, he or she objects to holding the meeting or transacting business at the meeting and does not thereafter vote for or assent to action taken at the meeting.

**Section 11. Quorum and Manner of Acting.** - Except as otherwise required by law, the Articles of Incorporation or these Bylaws, a majority of the directors fixed by these Bylaws at the time of any regular or special meeting of the Board of Directors shall constitute a quorum for the transaction of business at such meeting, and the act of a majority of the directors present at any such meeting at which a quorum is present shall be the act of the Board of Directors. In the absence of a quorum, a majority of those present may adjourn the meeting from time to time until a quorum be had. Notice of any such adjourned meeting need not be given.

**Section 12. Telephonic Meetings.** - Any or all directors may participate in any regular or special meeting of the Board of Directors or any committee thereof, or conduct such meeting, through the use of any means of communication by which all directors participating may

simultaneously hear each other during the meeting. A director participating in a meeting by this means is deemed to be present in person at the meeting.

**Section 13. Action Without Meeting.** - Action required or permitted to be taken by the Board of Directors may be taken without a meeting if each director signs a consent describing the action to be taken and delivers it to the Corporation.

**Section 14. Order of Business.** - At all meetings of the Board of Directors, business may be transacted in such order as from time to time the Board of Directors may determine.

**Section 15. Resignation of Director.** - Any director may resign at any time by giving written notice to the Board of Directors, the chairman of the Board of Directors or the secretary of the Corporation. Unless the resignation is contingent on acceptance by the Board of Directors, or as otherwise stated in the notice of resignation, it shall take effect when delivered.

**Section 16. Chairman.** - The Board of Directors may elect a chairman from among the directors. The chairman of the Board of Directors shall preside at meetings of the Board of Directors and perform such other duties as may be set forth in these Bylaws or requested by the Board of Directors or otherwise incident to such office.

**Section 17. Committees.** - The Board of Directors may create one or more committees and appoint directors to serve on them. Each committee shall have at least two members. The creation of a committee shall be approved by the greater number of (a) a majority of all directors in office at the time the action is being taken or (b) the number of directors required to take action under Section 11 of Article II hereof. Any such committee, to the extent provided in the resolution of the Board of Directors designating the committee, shall have and may exercise the powers and authority of the Board of Directors in the management of the business and affairs of the Corporation, except as limited by law.

### ARTICLE III

#### Officers

**Section 1. Officers.** - The officers of the Corporation may include a chief executive officer, a president, a chief operating officer, one or more vice presidents (one or more of whom may be designated executive, senior, assistant or associate vice presidents or given similar designations), a treasurer, a secretary, an assistant treasurer and an assistant secretary. Any two or more offices may be held by the same person.

**Section 2. Election and Term of Office.** - All officers of the Corporation shall be elected annually by the Board of Directors, and each officer shall hold office until a successor shall have been duly elected or until such officer's resignation, death or removal in the manner hereinafter provided. The Board of Directors may delegate to an officer the authority to elect subordinate officers.

**Section 3. Duties.** - The officers of the Corporation shall have such duties as generally pertain to their offices, respectively, as well as such powers and duties as are prescribed by law or are hereinafter provided or as from time to time shall be conferred by the Board of Directors or, in the case of inferior officers, the chief executive officer. The chief executive officer, the president, the chief operating officer, any vice president, the treasurer, the secretary and such other persons as the Board of Directors or the chief executive officer may authorize may sign and execute in the name of the Corporation representations, securities, deeds, mortgages, leases, licenses, releases, bonds, powers of attorney, contracts or other instruments, and any officer may sign and execute in the name of the Corporation such instruments as are incidental to such officer's duties in the ordinary course of business, except in either case where the signing and the execution thereof shall be expressly delegated by the Board of Directors or by these Bylaws to some other officer or agent of the Corporation or shall be required by law otherwise to be signed or executed. The Board of Directors may require any officer to give such bond for the faithful performance of his or her duties as the Board may see fit.

**Section 4. Vacancies.** - If any vacancy shall occur among the officers of the Corporation, such vacancy shall be filled by the Board of Directors.

**Section 5. Removal.** - Any officer of the Corporation may be removed at any time, with or without cause, by the Board of Directors.

**Section 6. Resignation.** - Any officer may resign at any time by delivering a notice of his or her resignation to the Board of Directors or the chairman of the Board. Any such resignation shall be effective when the notice is delivered unless the notice specifies a later effective date.

**Section 7. Chief Executive Officer.** - The chief executive officer shall be responsible for the general management and control of the business and affairs of the Corporation and shall see to it that all orders and resolutions of the Board of Directors are implemented. The chief executive officer shall, from time to time, report to the Board of Directors on matters within his or her knowledge which the interests of the Corporation may require be brought to its attention. The chief executive officer shall do and perform such other duties as from time to time the Board of Directors may prescribe.

**Section 8. President.** - The president shall have such authority and perform such duties as are commonly incident to his or her office and all such other duties as are properly required of him or her by the Board of Directors or the chief executive officer or as are provided elsewhere in these Bylaws, and shall assist the chief executive officer in the administration and operation of the Corporation's business and general supervision of its policies and affairs.

**Section 9. Chief Operating Officer.** - The chief operating officer (if any) shall be responsible to the chief executive officer for the principal operating businesses of the Corporation and shall have such powers and shall perform such duties as shall be assigned to him or her by the chief executive officer or the Board of Directors.

**Section 10. Vice Presidents.** - The vice presidents of the Corporation shall have such powers and shall perform such duties as shall be assigned to them by the chief executive officer or the Board of Directors.

**Section 11. Treasurer.** - The treasurer shall exercise general supervision over the receipt, custody and disbursement of corporate funds. The treasurer shall be responsible for the performance of all duties incident to the office of treasurer. The treasurer shall have such further powers and duties and shall be subject to such directions as may be granted or imposed upon him or her from time to time by the chief executive officer or the Board of Directors.

**Section 12. Secretary.** - The secretary shall be the ex-officio clerk of the Board of Directors and shall give, or cause to be given, notices of all meetings of shareholders and directors, and all other notices required by law or by these Bylaws. The secretary shall record the proceedings of the meetings of the shareholders, Board of Directors and committees of the Board of Directors in books kept for that purpose and shall keep the seal of the Corporation and attach it to all documents requiring such impression unless some other officer is designated to do so by the Board of Directors. The secretary shall be responsible for the performance of all duties incident to the office of secretary. The secretary shall have such further powers and duties and shall be subject to such directions as may be granted or imposed upon him or her from time to time by the chief executive officer or the Board of Directors.

**Section 13. Voting Securities of Other Corporations.** - Unless otherwise provided by the Board of Directors, each of the chief executive officer, the president (if any), and any vice-president in the name and on behalf of the Corporation, may appoint from time to time himself or herself or any other person proxy, attorney or agent for the Corporation to cast the votes which the Corporation may be entitled to cast as a shareholder, member or otherwise in any other corporation, partnership or other legal entity, domestic or foreign, whose stock, interests or other securities are held by the Corporation, or to consent in writing to any action by such other entity, or to exercise any or all other powers of this Corporation as the holder of the stock, interests or other securities of such other entity. Each of the chief executive officer, the president (if any), or any vice-president may instruct the person so appointed as to the manner of casting such votes or giving such consent and may execute or cause to be executed on behalf of the Corporation and under its corporate seal such written proxies, consents, ballots, waivers or other instruments as may be deemed necessary or proper. Each of the chief executive officer, the president (if any), or any vice-president may attend any meeting of the holders of stock, interests or other securities of any such other entity and vote or exercise any and all other powers of this Corporation as the holder of the stock, interest or other securities of such other entity.

## ARTICLE IV

### Depositaries; Loans

**Section 1. Depositaries.** - The money and negotiable instruments of the Corporation shall be kept in such bank or banks as the treasurer shall from time to time direct or approve. All checks and other instruments for the disbursement of funds shall be executed manually or by

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facsimile by such officers or agents of the Corporation as may be authorized by the Board of Directors.

**Section 2. Loans.** - The chief executive officer, the president (if any), any vice president, the treasurer and such other persons as the Board of Directors may authorize shall have the power to effect loans and advances at any time for the Corporation from any bank, trust company or other institution, or from any corporation, firm or individual, and for such loans and advances may make, execute and deliver promissory notes or other evidences of indebtedness of the Corporation, and, as security for the payment of any and all loans, advances, indebtedness and liability of the Corporation, may pledge, hypothecate or transfer any and all stocks, securities and other personal or real property at any time held by the Corporation, and to that end endorse, assign and deliver the same.

## ARTICLE V

### Certificates Representing Shares

Certificates representing shares of the Corporation shall be signed by the chairman of the Board of Directors or the president of the Corporation (if any) and the secretary or an assistant secretary. Any and all signatures on such certificates, including signatures of officers, transfer agents and registrars, may be by facsimile. Notwithstanding the provisions of this Article V, the Corporation may issue shares without certificates and adopt a system of issuance, recordation and transfer of its shares by electronic or other means not involving any issuance of certificates, provided that, the use of such system by the Corporation is permitted by law.

## ARTICLE VI

### Dividends

The Board of Directors may from time to time declare dividends and other distributions from funds of the Corporation legally available therefor.

## ARTICLE VII

### Seal

The Board of Directors shall provide a suitable seal or seals, which shall be in the form of a circle, and shall bear around the circumference the words "Collegium Pharmaceutical, Inc."

## ARTICLE VIII

### Fiscal Year

The fiscal year of the Corporation shall be the calendar year unless otherwise determined by the Board of Directors.

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## ARTICLE IX

### Emergency Bylaws

If a quorum of the Board of Directors cannot be readily assembled because of some catastrophic event, and only in such event, these Bylaws shall, without further action by the Board of Directors, be deemed to have been amended for the duration of such emergency, as follows:

**Section 2. The first sentence of Section 10 of Article II shall read as follows:**

Special meetings of the Board of Directors shall be held whenever called by order of the chairman of the Board of Directors, or of the president (if any) or of the lead independent director (if any) or of any director or of any person having the powers and duties of the chairman of the Board of Directors, the president (if any) or the lead independent director (if any).

**Section 3. Section 12 of Article II shall read as follows:**

The directors present at any regular or special meeting called in accordance with these Bylaws shall constitute a quorum for the transaction of business at such meeting, and the action of a majority of such directors shall be the act of the Board of Directors; *provided, however*, that in the event that only one director is present at any such meeting no action except the election of directors shall be taken until at least two additional directors have been elected and are in attendance.



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April 27, 2015

Collegium Pharmaceutical, Inc.  
 780 Dedham Street, Suite 800  
 Canton, MA 02021

Re: Underwritten Public Offering

Ladies and Gentlemen:

We have acted as counsel to Collegium Pharmaceutical, Inc., a Virginia corporation (the "**Company**"), in connection with the Registration Statement on Form S-1, as amended (Registration No. 333-203208) (the "**Registration Statement**"), initially filed by the Company with the Securities and Exchange Commission (the "**Commission**") on April 2, 2015 under the Securities Act of 1933, as amended (the "**Act**"). The Registration Statement relates to the public offering (the "**Offering**") of 6,670,000 shares of the common stock, par value \$0.001 per share, of the Company (the "**Shares**"), all of which will be sold by the Company, and which includes 870,000 shares if the underwriters exercise in full their option to purchase additional shares.

We understand that the Shares are to be sold by the Company pursuant to the terms of an Underwriting Agreement (the "**Underwriting Agreement**") in substantially the form filed as Exhibit 1.1 to the Registration Statement.

This opinion is being furnished in accordance with the requirements of Item 601(b)(5) of Regulation S-K under the Act, and no opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement or the prospectus that is a part of the Registration Statement, other than as expressly stated herein with respect to the Shares.

In connection herewith, we have examined originals or copies, certified or otherwise identified to our satisfaction, of (i) the Registration Statement as filed with the Commission, (ii) the form of Underwriting Agreement filed as Exhibit 1.1 to the Registration Statement, (iii) the Company's Amended and Restated Articles of Incorporation, as amended, filed as Exhibits 3.1 and 3.2 to the Registration Statement, as to be amended in the Form of Second Amended and Restated Articles of Incorporation, filed as Exhibit 3.3 to the Registration Statement (the "**Amended Charter**"), (iv) the Company's Bylaws, filed as Exhibit 3.4 to the Registration Statement, as to be amended in the Form of Amended and Restated Bylaws, filed as Exhibit 3.5 to the Registration Statement, (v) resolutions of the Board of Directors and shareholders of the Company relating to the Offering and the issuance of the Shares as provided to us

Boston	Washington, D.C.	Detroit	New Pittsburgh York
Berwyn	Harrisburg	Orange County	Princeton Wilmington

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by the Company, (vi) the stock record books of the Company as provided to us by the Company, and (vii) such other documents as we have deemed necessary or appropriate for purposes of rendering the opinion set forth herein.

In rendering this opinion, we have assumed the legal capacity of all natural persons, the genuineness and authenticity of all signatures on original documents, the authenticity of all documents submitted to us as originals, the conformity to originals of all documents submitted to us as certified or photostatic copies, the accuracy and completeness of all documents and records reviewed by us, the accuracy, completeness and authenticity of certificates issued by any government official, office or agency and the absence of change in the information contained therein from the effective date of any such certificate, the due authorization, execution and delivery of all documents other than by the Company or its officers, where authorization, execution and delivery are prerequisites to the effectiveness of such documents and that the Shares will be issued against payment of valid consideration under applicable law.

We express no opinion herein as to the law of any state or jurisdiction other than the Virginia Stock Corporation Act of the Commonwealth of Virginia, including statutory provisions and all applicable provisions of the Constitution of the Commonwealth of Virginia and reported judicial decisions interpreting such laws of the Commonwealth of Virginia and the federal laws of the United States of America.

Based upon and subject to the foregoing, we are of the opinion that when (i) the Company duly files the Amended Charter with the Virginia Stock Corporation Commission, (ii) the price at which the Shares are to be sold has been approved by the Board of Directors of the Company or the Pricing Committee duly appointed by the Board of Directors of the Company, (iii) the Registration Statement has been declared effective by the Commission, (iv) the duly appointed officers of the Company and the Underwriters execute and deliver the Underwriting Agreement and (v) the Shares are duly issued and delivered against payment therefor in accordance with the terms of the Underwriting Agreement, the Shares will be validly issued, fully paid and nonassessable.

We assume no obligation to supplement this opinion if any applicable law changes after the date hereof or if we become aware of any fact that might change the opinion expressed herein after the date hereof.

We hereby consent to the filing of this opinion as a part of the Registration Statement and to the reference of our firm under the caption "Legal Matters." In giving such consent, we do not hereby admit that we are in the category of persons whose consent is required under Section 7 of the Act or the rules and regulations of the Commission.



Very truly yours,

/s/ Pepper Hamilton LLP  
Pepper Hamilton LLP

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## COLLEGIUM PHARMACEUTICAL, INC.

## 2015 EMPLOYEE STOCK PURCHASE PLAN

**1. Purpose.**

The Collegium Pharmaceutical, Inc. 2015 Employee Stock Purchase Plan (the “Plan”) is intended to encourage and facilitate the purchase of Shares of the common stock of Collegium Pharmaceutical, Inc. (the “Company”) by employees of the Company, thereby providing employees with a personal stake in the Company and a long range inducement to remain in the employ of the Company. It is the intention of the Company that the Plan qualify as an “employee stock purchase plan” within the meaning of Section 423 of the Code.

**2. Definitions.**

- (a) “Account” means a bookkeeping account established by the Committee on behalf of a Participant to hold Payroll Deductions.
- (b) “Board” means the Board of Directors of the Company.
- (c) “Business Day” means a day on which national stock exchanges are open for trading.
- (d) “Code” means the Internal Revenue Code of 1986, as amended.
- (e) “Committee” means the Committee appointed pursuant to Section 14 of the Plan.
- (f) “Company” means Collegium Pharmaceutical, Inc.

(g) “Compensation” means the regular base salary paid to a Participant by the Company during such individual’s period of participation in the Plan, plus any pre-tax contributions made by the Participant to any cash-or-deferred arrangement that meets the requirements of section 401(k) of the Code or any cafeteria benefit program that meets the requirements of section 125 of the Code, now or hereafter established by the Company. The following items of compensation shall not be included in Compensation: (i) all overtime payments, bonuses, commissions (other than those functioning as base salary equivalents), profit-sharing distributions and other incentive-type payments and (ii) any and all contributions (other than contributions subject to sections 401(k) and 125 of the Code) made on the Participant’s behalf by the Company under any employee benefit or welfare plan now or hereafter established.

(h) “Election Form” means the form acceptable to the Committee which an Employee shall use to make an election to purchase Shares through Payroll Deductions pursuant to the Plan or to decrease or discontinue Payroll Deductions during an Offering pursuant to Section 5(b) below.

(i) “Eligible Employee” means an Employee who meets the requirements for eligibility under Section 3 of the Plan.

(j) “Employee” means any person, including an officer, whose wages and other salary is required to be reported by the Company on Internal Revenue Service Form W-2 for federal income tax purposes.

(k) “Enrollment Date” means, with respect to a given Offering Period, a date established from time to time by the Committee or the Board, which shall not be later than the first day of such Offering Period.

(l) “Fair Market Value” means the closing price per Share on the principal national securities exchange on which the Shares are listed or admitted to trading or, if not listed or traded on any such exchange, on the National Market System of the National Association of Securities Dealers Automated Quotation System (“NASDAQ”), or if not listed or traded on any such exchange or system, the fair market value as reasonably determined by the Board, which determination shall be in accordance with the standards set forth in Treasury Regulation §1.421-1(e)(2) and shall be conclusive.

(m) “Five Percent Owner” means an Employee who, with respect to the Company, is described in Section 423(b) of the Code.

(n) “Offering” means an offering of Shares to Eligible Employees pursuant to the Plan.

(o) “Offering Commencement Date” means the first Business Day in an Offering Period as designated by the Board.

(p) “Offering Period” means the period extending from an Offering Commencement Date through the immediately following Offering Termination Date. Each Offering Period will be a six month period during which Payroll Deductions will be made and held for the purchase of Shares at the end of the Offering Period. The Board or the Committee may, at its discretion, choose a different Offering Period of not more than twelve (12) months for Offerings.

(q) “Offering Termination Date” means the last Business Day in an Offering Period as designated by the Board, or the date of a Change in Control (as defined in the Company’s Amended and Restated 2014 Stock Incentive Plan), which occurs in an Offering Period.

(r) “Participant” means an Employee who meets the requirements for eligibility under Section 3 of the Plan and who has timely delivered an Election Form to the Committee.

(s) “Payroll Deductions” means amounts withheld from a Participant’s Compensation pursuant to the Plan, as described in Section 5 of the Plan.

(t) “Plan” means the Collegium Pharmaceutical, Inc. 2015 Employee Stock Purchase Plan, as set forth in this document, and as may be amended from time to time.

(u) “Plan Termination Date” means the earlier of: (1) the Offering Termination Date for the Offering in which the maximum number of Shares specified in Section 4 of the Plan have been issued pursuant to the Plan; (2) the date as of which the Board chooses to terminate the Plan as provided in Section 15 of the Plan; or (3) the date of a Change in Control.

(v) “Shares” means shares of common stock of the Company, \$0.001 par value per share.

(w) “Successor-in-Interest” means the Participant’s executor or administrator, or such other person or entity to whom the Participant’s rights under the Plan shall have passed by will or the laws of descent and distribution.

(x) “Termination Form” means the form acceptable to the Committee which an Employee shall use to withdraw from an Offering pursuant to Section 8 of the Plan.

### 3. Eligibility and Participation.

(a) Initial Eligibility. Except as provided in Section 3(b) of the Plan, each individual who is an Employee on an Offering Commencement Date shall be eligible to participate in the Plan with respect to the Offering that commences on that date.

(b) Ineligibility. An Employee shall not be eligible to participate in the Plan if such Employee:

- (1) is a Five Percent Owner;
- (2) has not customarily worked more than 20 hours per week;
- (3) has not customarily worked more than 5 months in any calendar year;
- (4) has been employed with the Company for less than 21 days; or
- (5) is restricted from participating under Section 3(d) of the Plan.

(c) Restrictions on Participation. Notwithstanding any provisions of the Plan to the contrary, no Employee shall be granted an option to participate in the Plan if:

- (1) immediately after the grant, such Employee would be a Five Percent Owner; or
- (2) such option would permit such Employee’s rights to purchase stock under all employee stock purchase plans of the

Company which meet the

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requirements of Section 423(b) of the Code to accrue at a rate which exceeds \$25,000 in fair market value (as determined pursuant to Section 423(b)(8) of the Code) for each calendar year in which such option is outstanding.

(d) Commencement of Participation. An Employee who meets the eligibility requirements of Sections 3(a) and 3(b) of the Plan as of an applicable Enrollment Date and whose participation is not restricted under Section 3(d) of the Plan shall become a Participant by completing an Election Form and filing it with the Committee on or before each applicable Enrollment Date. Payroll Deductions for a Participant shall commence on the applicable Offering Commencement Date when his or her authorization for Payroll Deductions becomes effective, and shall end on the immediately following Offering Termination Date, unless sooner terminated by the Participant pursuant to Section 8 of the Plan. Notwithstanding the foregoing sentence, to the extent necessary to comply with Section 423(b)(8) of the Code and Section 3(d) of the Plan, a Participant’s payroll deductions may be decreased to zero percent (0%) at any time during an Offering Period.

### 4. Shares Per Offering.

The Plan shall be implemented by a series of Offerings that shall terminate on the Plan Termination Date. Offerings shall be made with respect to Compensation payable for each Offering Period occurring on or after adoption of the Plan by the Board and ending with the Plan Termination Date. Shares available for any Offering shall be the difference between the maximum number of Shares that may be issued under the Plan, as determined pursuant to Section 10(a) of the Plan, for all of the Offerings, less the actual number of Shares purchased by Participants pursuant to prior Offerings. If the total number of Shares for which options are exercised on any Offering Termination Date exceeds the maximum number of Shares available, the Committee shall make a pro rata allocation of Shares available for delivery and distribution in as nearly a uniform manner as practicable, and as it shall determine to be fair and equitable, and the unapplied Account balances shall be returned to Participants as soon as practicable following the Offering Termination Date.

### 5. Payroll Deductions.

(a) Amount of Payroll Deductions. An Eligible Employee who wishes to participate in the Plan shall file an Election Form (authorizing payroll deductions) with the Committee prior to the applicable Enrollment Date. With respect to any Offering made under this Plan, a Participant may authorize a Payroll Deduction in any percentage amount (in whole percentages) up to a maximum of 15% of the Compensation he or she receives during the Offering Period or such shorter period during which deductions from payroll are made. The Board or the Committee may, at its discretion, designate a lower maximum contribution rate. The minimum payroll deduction is such percentage of Compensation as may be established from time to time by the Board or the Committee.

(b) Participants’ Accounts. All Payroll Deductions with respect to a Participant pursuant to Section 5(a) of the Plan shall commence on the first payroll following the Enrollment Date and shall end of the last payroll in the Offering Period to which such authorization is applicable, unless sooner terminated by the Participant as provided in Section 8.

All Payroll Deductions will be credited to the Participant's Account under the Plan. The amounts collected from the Participant shall not be held in any segregated account or trust fund and may be commingled with the general assets of the Company and used for general corporate purposes.

(c) Changes in Payroll Deductions During Offering Period. A Participant may decrease (prospectively) or discontinue his or her Payroll Deduction once during any Offering Period, by filing either a written or electronic new Election Form. However, a Participant may not increase his or her payroll deduction during an Offering Period. If a Participant elects to discontinue his or her Payroll Deductions during an Offering Period, but does not elect to withdraw his or her funds pursuant to Section 8 hereof, funds deducted prior to his or her election to discontinue will be applied to the purchase of Shares on the applicable exercise date.

## 6. Granting of Options.

(a) Number of Shares. On each Offering Commencement Date and subject to Section 3(d) above, the Company will grant to each Participant an option to purchase on the Offering Termination Date at the applicable purchase price (the "Option Price") up to that number of Shares determined by multiplying \$2,083 by the number of full months in the Offering Period and dividing the result by the Fair Market Value on the Offering Commencement Date; *provided, however*, that the Committee may, in its discretion, set a fixed maximum number of Shares that each Participant may purchase per Offering Period which number may not be greater than the number of Shares determined by using the formula in this Section 6(a) and which number shall be subject to Section 3(d) above.

(b) Option Price. The Board or the Committee shall determine the Option Price for each Offering Period, including whether such Option Price shall be determined based on the lesser of the Fair Market Value on (i) the Offering Commencement Date or (ii) the Offering Termination Date, or shall be based solely on the Fair Market Value on the Offering Termination Date; *provided, however*, that such Option Price shall be at least 85% of the applicable Fair Market Value. In the absence of a determination by the Board or the Committee, the Option Price will be 85% of the lesser of the Fair Market Value on (i) the Offering Commencement Date or (ii) the Offering Termination Date.

## 7. Exercise of Options.

(a) Automatic Exercise. With respect to each Offering, a Participant's option for the purchase of Shares granted pursuant to Section 6 of the Plan shall be deemed to have been exercised automatically on the Offering Termination Date applicable to such Offering. Notwithstanding the foregoing, upon the occurrence of a Plan Termination Date as described in Section 2(u)(3), all Shares or Payroll Deductions (to the extent not yet applied to the purchase of Shares) under the Plan shall be distributed to the Participants as soon as administratively practicable following such Plan Termination Date.

(b) Fractional Shares and Minimum Number of Shares. Fractional Shares shall not be issued under the Plan. Amounts credited to an Account remaining after the

application of such Account to the exercise of options for a minimum of one (1) full Share will be automatically refunded to the employee, without interest.

(c) Transferability of Option. No option granted to a Participant pursuant to the Plan shall be transferable other than by will or by the laws of descent and distribution, and no such option shall be exercisable during the Participant's lifetime other than by the Participant.

(d) Delivery of Certificates for Shares. The Company shall deliver certificates for Shares acquired on the exercise of options during an Offering Period as soon as practicable following the Offering Termination Date.

## 8. Withdrawals.

(a) Withdrawal of Account. A Participant may elect to withdraw the balance credited to the Participant's Account by providing a Termination Form to the Committee at any time prior to the close of business on the twenty-first (21<sup>st</sup>) business day prior to the Offering Termination Date applicable to any Offering. The Participant may not begin participation again during the remainder of the Offering Period during which the Participant withdrew his or her balance. The Participant may participate in any subsequent Offering in accordance with terms and conditions established by the Board or the Committee.

(b) Amount of Withdrawal. A Participant may withdraw all, but not less than all, of the amounts credited to the Participant's Account by giving a Termination Form to the Committee. All amounts credited to such Participant's Account shall be paid as soon as practicable following the Committee's receipt of the Participant's Termination Form, and no further Payroll Deductions will be made with respect to the Participant for such Offering Period.

(c) Termination of Employment. Upon termination of a Participant's employment for any reason other than death, including termination due to disability, all amounts credited to such Participant's Account shall be returned to the Participant. In the event of a Participant's (1) termination of employment due to death or (2) death after termination of employment but before the Participant's Account has been returned, all amounts credited to such Participant's Account shall be returned to the Participant's Successor-in-Interest.

## 9. Interest.

No interest shall be paid or allowed with respect to amounts paid into the Plan or credited to any Participant's Account.

## 10. Shares.

(a) Maximum Number of Shares. No more than (i) 200,000 Shares; *plus* (ii) an annual increase to be added on the first day of each fiscal year, commencing on January 1, 2016 and ending on December 31, 2025, equal to the least of (x) 400,000 Shares, (y) 1% of the outstanding Shares on such date or (z) an amount determined by the Board, may be issued under the Plan. Such Shares shall be authorized but unissued or reacquired Shares of the Company, including Shares purchased on the open market. The number of Shares available for

any Offering and all Offerings shall be adjusted if the number of outstanding Shares of the Company is increased or reduced by split-up, reclassification, stock dividend or the like. All Shares issued pursuant to the Plan shall be validly issued, fully paid and nonassessable.

- (b) Participant's Interest in Shares. A Participant shall have no interest in Shares subject to an option until such option has been exercised.
- (c) Registration of Shares. Shares to be delivered to a Participant under the Plan shall be registered in the name of the Participant.
- (d) Restrictions on Exercise. The Board may, in its discretion, require as conditions to the exercise of any option such conditions as it may deem necessary to assure that the exercise of options is in compliance with applicable securities laws.

#### 11. Expenses.

The Company shall pay all fees and expenses incurred (excluding individual Federal, state, local or other taxes) in connection with the Plan, provided that the Company shall not be responsible for payment of any brokerage fees. No charge or deduction for any such expenses will be made to a Participant upon the termination of his or her participation under the Plan or upon the distribution of certificates representing Shares purchased with his or her contributions.

#### 12. Taxes.

The Company shall have the right to withhold from each Participant's Compensation an amount equal to all Federal, state, city or other taxes as the Company shall determine are required to be withheld by them in connection with the grant, exercise of the option or disposition of Shares. In connection with such withholding, the Company may make any such arrangements as are consistent with the Plan as it may deem appropriate, including the right to withhold from Compensation paid to a Participant other than in connection with the Plan and the right to withdraw such amount from the amount standing to the credit of the Participant's Account.

#### 13. Plan and Contributions Not to Affect Employment.

The Plan shall not confer upon any Eligible Employee any right to continue in the employ of the Company.

#### 14. Administration.

The Plan shall be administered by the Board, which may delegate responsibility for such administration to a committee of the Board (the "Committee"). If the Board fails to appoint the Committee, any references in the Plan to the Committee shall be treated as references to the Board. The Board, or the Committee, shall have authority to interpret the Plan, to prescribe, amend and rescind rules and regulations relating to it, and to make all other determinations deemed necessary or advisable in administering the Plan, with or without the

advice of counsel. The determinations of the Board or the Committee on the matters referred to in this paragraph shall be conclusive and binding upon all persons in interest.

#### 15. Amendment and Termination.

The Board may terminate the Plan at any time and may amend the Plan from time to time in any respect; *provided, however*, that upon any termination of the Plan, all Shares or Payroll Deductions (to the extent not yet applied to the purchase of Shares) under the Plan shall be distributed to the Participants, *provided further*, that no amendment to the Plan shall affect the right of a Participant to receive his or her proportionate interest in the Shares or his or her Payroll Deductions (to the extent not yet applied to the purchase of Shares) under the Plan, and *provided further*, that the Company may seek shareholder approval of an amendment to the Plan if such approval is determined to be required by or advisable under the regulations of the Securities or Exchange Commission or the Internal Revenue Service, the rules of any stock exchange or system on which the Shares are listed or other applicable law or regulation.

#### 16. Effective Date.

Subject to approval by the shareholders of the Company as required by Section 423 of the Code, the Plan shall take effect immediately prior to the closing of the Company's initial public offering. The initial Offering Period under the Plan shall commence on a date determined by the Board or the Committee

#### 17. Government and Other Regulations.

- (a) In General. The purchase of Shares under the Plan shall be subject to all applicable laws, rules and regulations, and to such approvals by any governmental agencies as may be required.
- (b) Securities Law. The Committee shall have the power to make each grant under the Plan subject to such conditions as it deems necessary or appropriate to comply with the then-existing requirements of the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended, including Rule 16b-3 (or any similar rule) of the Securities and Exchange Commission.

#### 18. Non-Alienation.

No Participant shall be permitted to assign, alienate, sell, transfer, pledge or otherwise encumber his interest under the Plan prior to the distribution to him of Share certificates. Any attempt at assignment, alienation, sale, transfer, pledge or other encumbrance shall be void and of no effect.

**19. Notices.**

Any notice required or permitted hereunder shall be sufficiently given only if delivered personally, telecopied, or sent by first class mail, postage prepaid, and addressed:

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If to the Company:

Collegium Pharmaceutical, Inc.  
780 Dedham Street, Suite 800  
Canton, MA 02021  
Attention: Employee Stock Purchase Plan Committee  
or any other address provided pursuant to written notice.

If to the Participant: At the address on file with the Company from time to time, or to such other address as either party may hereafter designate in writing by notice similarly given by one party to the other.

**20. Successors.**

The Plan shall be binding upon and inure to the benefit of any successor, successors or assigns of the Company.

**21. Severability.**

If any part of this Plan shall be determined to be invalid or void in any respect, such determination shall not affect, impair, invalidate or nullify the remaining provisions of this Plan which shall continue in full force and effect.

**22. Acceptance.**

The election by any Eligible Employee to participate in this Plan constitutes his or her acceptance of the terms of the Plan and his or her agreement to be bound hereby.

**23. Applicable Law.**

This Plan shall be construed in accordance with the law of the Commonwealth of Virginia, to the extent not preempted by applicable Federal law.

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## COLLEGIUM PHARMACEUTICAL, INC.

## PERFORMANCE BONUS PLAN

Section 1. Purpose. The purpose of the Collegium Pharmaceutical, Inc. Performance Bonus Plan (the “**Plan**”) is to benefit and advance the interests of Collegium Pharmaceutical, Inc., a Virginia corporation (the “**Company**”), by rewarding selected employees of the Company and its subsidiaries and divisions (each such subsidiary or division is referred to herein as a “**Business Unit**”) for their contributions to the Company’s success and thereby motivate them to continue to make such contributions in the future by granting performance-based awards (“**Awards**”).

Section 2. Certain Definitions. For the purposes of the Plan the following terms shall be defined as set forth below:

- (a) “**Applicable Employee Remuneration**” has the meaning given to such term in Section 162(m)(4) of the Code.
- (b) “**Base Salary Percentage**” means a percentage of the Participant’s annual base salary in effect as of the later of (i) the first day of the Performance Period or (ii) the common salary adjustment date within the Performance Period.
- (c) “**Board**” means the Board of Directors of the Company.
- (d) “**Code**” means the Internal Revenue Code of 1986, as amended.
- (e) “**Committee**” means the Compensation Committee of the Board.
- (f) “**Covered Employee**” has the same meaning given to such term in Section 162(m)(3) of the Code; provided, however, that a person will be considered a Covered Employee for purposes of this Plan only if such employee’s Applicable Employee Remuneration for the relevant Fiscal Year is expected to exceed \$1,000,000. No person shall be considered a Covered Employee during the applicable reliance period under Treasury Regulation 1.162-27(f).
- (g) “**Eligible Persons**” has the meaning given to that term in Section 4(a) hereof.
- (h) “**Financial Criteria**” has the meaning given to that term in Section 6(a) hereof.
- (i) “**Fiscal Year**” means the calendar year or such other period that the Company may hereafter adopt as its fiscal year.
- (j) “**Participant**” has the meaning given to that term in Section 5 hereof.
- (k) “**Performance Period**” means the period of time over which the Performance Threshold must be satisfied, which period may be of such length as the Committee,

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in its discretion, shall select. The Performance Period need not be identical for all Awards. Within one Fiscal Year, the Committee may establish multiple Performance Periods.

(l) “**Performance Threshold**” has the meaning given to such term in Section 6(b) hereof (in the case of a Covered Employee), or Section 7(b) hereof (in the case of a Participant who is not a Covered Employee).

(m) “**Target**” has the meaning given to such term in Section 6(a) hereof (in the case of a Covered Employee), or Section 7(a) hereof (in the case of a Participant who is not a Covered Employee).

Section 3. Administration of the Plan.

(a) Generally. The Plan shall be administered by the Committee. The Committee is authorized to administer, interpret and apply the Plan and from time to time may adopt such rules, regulations and guidelines consistent with the provisions of the Plan as it may deem advisable to carry out the Plan, except that the Committee may authorize any one or more of its members, or any officer of the Company, to execute and deliver documents on behalf of the Committee. The Committee’s interpretations of the Plan, and all actions taken and determinations made by the Committee pursuant to the powers vested in it hereunder, shall be conclusive and binding on all parties concerned, including the Company, its stockholders and Participants (as defined below). The Committee shall have authority to determine the terms and conditions of the Awards granted to Participants.

(b) Delegation. The Committee may delegate its responsibilities for administering the Plan to any executive officer of the Company, as the Committee deems necessary; provided however, that the Committee shall not delegate its responsibilities under the Plan relating to Covered Employees.

(c) Reliance and Indemnification. The Committee may employ attorneys, consultants, accountants or other persons, and the Committee, the Company and its officers and directors shall be entitled to rely upon the advice, opinions or valuations of any such persons. No member of the Committee nor any executive officer of the Company shall be personally liable for any action, determination or interpretation taken or made in good faith by the Committee or such executive officer of the Company with respect to the Plan or Awards granted hereunder, and all members of the Committee and each executive officer of the Company shall be fully indemnified and protected by the Company in respect of any such action, determination or interpretation.

Section 4. Eligible Persons. All employees of the Company shall be eligible to participate in the Plan (“**Eligible Persons**”). An individual shall be deemed an employee for purposes of the Plan only if such individual receives compensation from either the Company or one of its Business Units for services performed as an employee of the Company or any one of its Business Units for any period during a Performance Period. An Eligible Person who is a Covered Employee shall be entitled to participate in the Plan with respect to a Performance Period which has commenced only if he or she commenced employment on or before the

beginning of each Performance Period or any later date described in Treasury Regulation 1.162-27(e)(2) (or any successor thereto).

Section 5. Awards; Participants. Awards may be granted only to Eligible Persons with respect to each Performance Period, subject to the terms and conditions set forth in the Plan. An Eligible Person who has been chosen to receive an Award under the Plan shall be referred to as a “**Participant**.”

Section 6. Determination of Targets, Performance Thresholds and Base Salary Percentage for Covered Employees. Prior to the beginning of each Performance Period or any later date described in Treasury Regulation 1.162-27(e)(2) (or any successor thereto), the Committee shall adopt each of the following with respect to each Participant who is a Covered Employee:

(a) one or more Targets, which shall be equal to a desired level or levels (as may be measured on an absolute or relative basis, where relative performance may also be measured by reference to: past performance of the Company or a Business Unit, a group of peer companies or by a financial market index) for any Performance Period of: (i) specified levels of or increases in pre-tax earnings, return on capital, equity measures/ratios (on a gross, net, pre-tax or post tax basis), including basic earnings per share, diluted earnings per share, total earnings (including total earnings as adjusted by the Committee at the time of the Award), operating earnings, earnings growth, earnings before interest and taxes, or EBIT, and earnings before interest, taxes, depreciation and amortization, or EBITDA (including EBIT or EBITDA as adjusted by the Committee at the time of the Award); (ii) total sales or sales growth; (iii) gross margin; (iv) customer service levels; (v) employee recruiting and development; (vi) advertising effectiveness; (vii) development of new markets; (viii) financial ratios; (ix) strategic initiatives; (x) improvement in or attainment of operating expense levels; (xi) improvement in or attainment of capital expense levels; (xii) the attainment of certain target levels of, or a specified increase in, operational cash flow; (xiii) the achievement of a certain level of, reduction of, or other specified objectives with regard to limiting the level of increase in, all or a portion of, the Company’s bank debt or other long-term or short-term public or private debt or other similar financial obligations of the Company, which may be calculated net of such cash balances and/or other specified offsets; (xiv) appreciation in and/or maintenance of certain target levels in the Fair Market Value; (xv) the attainment of a certain level of, reduction of, or other specified objectives with regard to limiting the level of or rate of increase in all or a portion of specified expenses (xvi) individual objectives; and (xvii) any combination of the foregoing (collectively, the “**Financial Criteria**”). With respect to any Covered Employee who is employed by a Business Unit, the Financial Criteria shall be based on the results of such Business Unit, results of the Company, or any combination of the two;

(b) a Performance Threshold with respect to each Target, applicable to one or more Financial Criteria, which represents a minimum amount that must be attained for a Participant to receive an Award;

(c) either (i) a Base Salary Percentage, or (ii) fixed monetary amounts, which, in each case, shall be payable as an Award in the event that 100% of such Participant’s Targets are achieved.

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(d) a mathematical formula or matrix that shall contain weighting for each Target and indicate the extent to which Awards will be paid if such Participant’s Performance Thresholds with respect to his or her Targets are achieved or exceeded.

The Committee may provide, at the time of the Award, that adjustments will be made to Targets and Performance Thresholds to take into account, in any objective manner specified by that Committee, the impact of one or more of the following: (A) gain or loss from all or certain claims and/or litigation and insurance recoveries, (B) the impairment of tangible or intangible assets, (C) stock-based compensation expense, (D) restructuring activities reported in the Company’s public filings, (E) investments, dispositions or acquisitions, (F) loss from the disposal of certain assets, (G) gain or loss from the early extinguishment, redemption, or repurchase of debt, (H) changes in accounting principles, or (I) any other item, event or circumstance that would not cause an Award to fail to constitute “qualified performance-based compensation” under Section 162(m) of the Code (to the extent such Award is intended to be “qualified performance-based compensation”) (each an “**Extraordinary Event**”). An adjustment described herein may relate to the Company or any Business Unit, as determined by the Committee at the time the Award is granted. Any adjustment shall be determined in accordance with generally accepted accounting principles and standards, unless such other objective method of measurement is designated by the committee at the time of the Award.

Section 7. Determination of Targets, Performance Thresholds and Base Salary Percentage For Participants Who Are Not Covered Employees. Prior to the end of the Performance Period, the Committee shall adopt each of the following with respect to each Participant who is not a Covered Employee:

(a) one or more Targets, which shall be equal to a desired level or levels for any Performance Period of any, or a combination of any, quantitative criteria (the “**Quantitative Criteria**,” which Quantitative Criteria may include, without limitation, any Financial Criteria) or qualitative criteria (the “**Individual Criteria**”). With respect to such Participants who are employed by a Business Unit, the Quantitative Criteria may be based on the results of such Business Unit, consolidated results of the Company, or any combination of the two;

(b) a Performance Threshold with respect to each Target, applicable to one or more Quantitative Criteria or Individual Criteria, which represents a minimum that must be attained for a Participant to receive an Award;

(c) either (i) a Base Salary Percentage, or (ii) fixed monetary amounts, which, in each case, shall be payable as an Award in the event that 100% of such Participant’s Targets are achieved.

(d) a mathematical formula or matrix that shall contain weighting for each Target and indicate the extent to which Awards will be paid if such Participant’s Performance Thresholds with respect to his or her Targets are achieved or exceeded.

The Committee may make such adjustments, to the extent it deems appropriate, to the Targets and Performance Thresholds to compensate for, or to reflect, any material changes which may have occurred due to an Extraordinary Event.

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Section 8. Calculation of Awards; Certification; Payment; Deferral. As soon as practicable after the end of the Performance Period, and subject to any necessary verification, the Committee shall determine with respect to each Participant whether and the extent to which the Performance Thresholds applicable to such Participant’s Targets were achieved or exceeded. Such Participant’s Award, if any, shall be calculated in accordance with the mathematical formula or matrix determined pursuant to Section 6 or 7, as applicable, and subject to the limitations set forth in Section 9 hereof. The Committee shall certify in writing the amount



of such Award and whether each material term of the Plan relating to such Award has been satisfied. Subject to Section 9 hereof, such Award shall become payable in cash as promptly as practicable thereafter, provided, however, that any Award shall be paid within 2 ½ months of the end of the Fiscal Year in which the Award is no longer subject to a risk of forfeiture.

Section 9. Limitations; Modifications to Awards. Each Award determined pursuant to Section 6 or 7 hereof shall be subject to modification or forfeiture in accordance with the following provisions:

(a) Limitations. The aggregate amount of any Award to any Participant for any Performance Period as finally determined by the Committee, shall constitute the Participant's Award for the Fiscal Year; provided, however that no Award for any Participant for any Fiscal Year shall exceed \$5,000,000.

(b) Modifications. At any time prior to the payment of an Award, the Committee may, in its sole discretion, (i) increase, decrease or eliminate the Award payable to any Participant who is not a Covered Employee and who would not become a Covered Employee as a result of any such increase and/or (ii) decrease or eliminate the Award payable to any Covered Employee, in each case to reflect the individual performance and contribution of, and other factors relating to, such Covered Employee. The Committee may make such adjustments, to the extent it deems appropriate to any Award to compensate for, or to reflect, any Extraordinary Event. The determination of the Committee as to matters set forth in this Section 9(b) shall be final and conclusive.

Section 10. Employment Requirement. No Participant shall have any right to receive payment of any Award unless such Participant remains in the employ of the Company or a Business Unit through the date of payment of such Award; provided, however, that the Committee may, in its sole discretion, pay all or any part of an Award to any Participant who, prior to such date of payment, terminates employment, so long as the Performance Thresholds applicable to the Participant's Targets were achieved or exceeded, the Committee may, in its sole discretion, provide for payment of all or part of an award upon any event, to the extent that such provision does not violate Code Section 162(m) with respect to a Covered Employee. The maximum amount of such payment, if any, will be calculated, and to the extent determined by the Committee, paid as provided in Section 6 or 7. The determination of the Committee shall be final and conclusive.

Section 11. Miscellaneous.

(a) No Contract; No Rights to Awards or Continued Employment. The Plan is not a contract between the Company and any Participant or other employee. No Participant or

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other employee shall have any claim or right to receive Awards under the Plan. Neither the Plan nor any action taken hereunder shall be construed as giving any employee any right to be retained by the Company or any of its Business Units.

(b) No Right to Future Participation. Participation in the Plan during one Performance Period shall not guarantee participation during any other Performance Period.

(c) Restriction on Transfer. The rights of a Participant with respect to Awards under the Plan shall not be transferable by the Participant to whom such Award is granted (other than by will or the laws of descent and distribution), and any attempted assignment or transfer shall be null and void and shall permit the Committee, in its sole discretion, to extinguish the Company's obligation under the Plan to pay any Award with respect to such Participant.

(d) Tax Withholding. The Company or a subsidiary thereof, as appropriate, shall have the right to deduct from all payments made under the Plan to a Participant or to a Participant's beneficiary or beneficiaries any Federal, foreign, state or local taxes required by law to be withheld with respect to such payments.

(e) No Restriction on Right of Company to Effect Changes. The Plan shall not affect in any way the right or power of the Company or its stockholders to make or authorize any recapitalization, reorganization, merger, acquisition, divestiture, consolidation, spin off, combination, liquidation, dissolution, sale of assets, or other similar corporate transaction or event involving the Company or a subsidiary thereof or any other event or series of events, whether of a similar character or otherwise.

(f) Source of Payments. The Plan shall be unfunded. The Plan shall not create or be construed to create a trust or separate fund or segregation of assets of any kind or a fiduciary relationship between the Company and a Participant or any other individual, corporation, partnership, association, joint-stock company, trust, unincorporated organization, or government or political subdivision thereof. To the extent that any Participant is granted an Award hereunder, such Participant's right to receive payment of such Award shall be no greater than the right of any unsecured general creditor of the Company.

(g) No Interest. If the Company for any reason fails to make payment of an Award at the time such Award becomes payable, the Company shall not be liable for any interest or other charges thereon.

(h) Amendment and Termination. The Committee may at any time and from time to time alter, amend, suspend or terminate the Plan in whole or in part. No such amendment shall be effective which alters the Award, Target or other criteria relating to an Award applicable to a Covered Employee for the Performance Period in which such amendment is made or any prior Performance Period, except any such amendment that may be made without causing such Award to cease to qualify as performance-based compensation under Section 162(m)(4)(C) of the Code.

(i) Headings. The headings of sections and subsections herein are included solely for convenience of reference and shall not affect the meaning of any of the provisions of the Plan.

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(j) Governing Law. The validity, construction, interpretation, administration and effect of the Plan and of its rules and regulations, and rights relating to the Plan, shall be determined solely in accordance with the laws of the Commonwealth of Virginia, without regard to the choice-of-law principles thereof, and applicable federal law.

(k) Severability. If any term or provision ("Provision") of the Plan or the application thereof (i) as to any Participant or circumstance (other than as described in clause (ii)) is, to any extent, found to be illegal or invalid, or (ii) would cause any Award to any Covered Employee not to constitute

performance-based compensation under Section 162(m)(4)(C) of the Code, then the Committee shall sever such Provision from the Plan and, thereupon, such Provision shall not be a part of the Plan.

(l) Effective Date. The Plan will become effective immediately prior to the closing of the Company's initial public offering.

(m) Approval and Reapproval by Stockholders. To the extent required under Section 162(m) of the Code and the regulations thereunder,

(i) any change to the material terms of the Financial Criteria shall be disclosed to and approved by the Stockholders at the next annual meeting of Stockholders to be held following such change, and (ii) the material terms of the Financial Criteria shall be disclosed to and reapproved by the Stockholders no later than the annual meeting of Stockholders that occurs in the fifth year following the year in which Stockholders approve the Financial Criteria (provided, however, that with respect to the first year in which the Company becomes publicly traded, such disclosure will be made and approval will be sought no later than first Annual Meeting of Stockholders that occurs after the third year following the calendar year in which the Company became publicly traded).

## COLLEGIUM PHARMACEUTICAL, INC.

## AMENDED AND RESTATED 2014 STOCK INCENTIVE PLAN

**SECTION 1. Purpose; Definitions.** The purposes of the Collegium Pharmaceutical, Inc. Amended and Restated 2014 Stock Incentive Plan (the “Plan”) are to: (a) enable Collegium Pharmaceutical, Inc. (the “Company”) and its affiliated companies to recruit and retain highly qualified employees, directors and consultants; (b) provide those employees, directors and consultants with an incentive for productivity; and (c) provide those employees, directors and consultants with an opportunity to share in the growth and value of the Company.

For purposes of the Plan, the following terms will have the meanings defined below, unless the context clearly requires a different meaning:

- (a) “Affiliate” means, with respect to a Person, a Person that directly or indirectly controls, is controlled by, or is under common control with such Person.
- (b) “Applicable Law” means the legal requirements relating to the administration of and issuance of securities under stock incentive plans, including, without limitation, the requirements of state corporations law, federal, state and foreign securities law, federal, state and foreign tax law, and the requirements of any stock exchange or quotation system upon which the Shares may then be listed or quoted.
- (c) “Award” means an award of Options, Restricted Stock, Restricted Stock Units or Performance Awards made under this Plan.
- (d) “Award Agreement” means, with respect to any particular Award, the written document that sets forth the terms of that particular Award.
- (e) “Board” means the Board of Directors of the Company, as constituted from time to time.
- (f) “Cause” means (i) Participant’s refusal to comply with any lawful directive or policy of the Board which refusal is not cured by the Participant within ten (10) days of such written notice from the Company; (ii) the Company’s determination that, in the reasonable judgment of the Board, Participant has committed any act of dishonesty, embezzlement, unauthorized use or disclosure of confidential information or other intellectual property or trade secrets, common law fraud or other fraud against the Company or any Subsidiary or Affiliate; (iii) a material breach by the Participant of any written agreement with or any fiduciary duty owed to any Company or any Subsidiary of Affiliate; (iv) Participant’s conviction (or the entry of a plea of a nolo contendere or equivalent plea) in a court of competent jurisdiction of a felony or any misdemeanor involving material dishonesty or moral turpitude; or (v) Participant’s habitual or repeated misuse of, or habitual or repeated performance of Participant’s duties under the influence of, alcohol, illegally obtained prescription controlled substances or non-prescription controlled substances. Notwithstanding the foregoing, if a Participant and the Company (or any of its Affiliates) have entered into an employment agreement, consulting agreement or other similar agreement that specifically defines “cause,”

then with respect to such Participant, “Cause” shall have the meaning defined in such other agreement.

- (g) “Change in Control” shall mean the occurrence of any of the following events: (i) any “person” (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) is or becomes a “beneficial owner” (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing 50% or more of the total power to vote for the election of directors of the Company; (ii) during any twelve month period, individuals who at the beginning of such period constitute the Board and any new director (other than a director designated by a person who has entered into an agreement with the Company to effect a transaction described in Section 1(g)(i), Section 1(g)(iii), Section 1(g)(iv) or Section 1(g)(v) hereof) whose election by the Board or nomination for election by the Company’s stockholders was approved by a vote of at least a majority of the directors then still in office who either were directors at the beginning of the period of whose election or nomination for election was previously approved, cease for any reason to constitute a majority thereof; (iii) the merger or consolidation of the Company with another corporation where the stockholders of the Company, immediately prior to the merger or consolidation, will not beneficially own, immediately after the merger or consolidation, shares entitling such stockholders to 50% or more of all votes to which all stockholders of the surviving corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote); (iv) the sale or other disposition of all or substantially all of the assets of the Company; (v) a liquidation or dissolution of the Company or (vi) acceptance by shareholders of the Company of shares in a share exchange if the shareholders of the Company immediately before such share exchange do not or will not own directly or indirectly immediately following such share exchange more than fifty percent (50%) of the combined voting power of the outstanding voting securities of the entity resulting from or surviving such share exchange in substantially the same proportion as their ownership of the voting securities outstanding immediately before such share exchange.

Notwithstanding anything in the Plan or an Award Agreement to the contrary, if an Award is subject to Section 409A of the Code, no event that, but for the application of this paragraph, would be a Change in Control as defined in the Plan or the Award Agreement, as applicable, shall be a Change in Control unless such event is also a “change in control event” as defined in Section 409A of the Code.

- (h) “Code” means the Internal Revenue Code of 1986, as amended from time to time, and any successor thereto.
- (i) “Committee” means the committee designated by the Board to administer the Plan under Section 2. To the extent required under Applicable Law, the Committee shall have at least two members and each member of the Committee shall be a Non-Employee Director and an Outside Director.
- (j) “Director” means a member of the Board.
- (k) “Disability” means a condition rendering a Participant Disabled.

- (l) “Disabled” will have the same meaning as set forth in Section 22(e)(3) of the Code.

(m) “Exchange Act” means the Securities Exchange Act of 1934, as amended.

(n) “Fair Market Value” means, as of any date, the value of a Share determined as follows: (i) if the Shares are listed on any established stock exchange or a national market system, including, without limitation, the Nasdaq Global Select Market, the Fair Market Value of a Share will be the closing sales price for such stock as quoted on that system or exchange (or the system or exchange with the greatest volume of trading in Shares) at the close of regular hours trading on the day of determination; (ii) if the Shares are regularly quoted by recognized securities dealers but selling prices are not reported, the Fair Market Value of a Share will be the mean between the high bid and low asked prices for Shares at the close of regular hours trading on the day of determination; or (iii) if Shares are not traded as set forth above, the Fair Market Value will be determined in good faith by the Committee taking into consideration such factors as the Committee considers appropriate, such determination by the Committee to be final, conclusive and binding. Notwithstanding the foregoing, in connection with a Change in Control, Fair Market Value shall be determined in good faith by the Committee, such determination by the Committee to be final conclusive and binding.

(o) “Incentive Stock Option” means any Option intended to be an “Incentive Stock Option” within the meaning of Section 422 of the Code.

(p) “Non-Employee Director” will have the meaning set forth in Rule 16b-3(b)(3)(i) promulgated by the Securities and Exchange Commission under the Exchange Act, or any successor definition adopted by the Securities and Exchange Commission.

(q) “Non-Qualified Stock Option” means any Option that is not an Incentive Stock Option.

(r) “Outside Director” means a member of the Board who meets the definition of an “outside director” under Section 162(m) of the Code.

(s) “Option” means any option to purchase Shares (including an option to purchase Restricted Stock, if the Committee so determines) granted pursuant to Section 5 hereof.

(t) “Parent” means, in respect of the Company, a “parent corporation” as defined in Sections 424(e) of the Code.

(u) “Participant” means an employee, consultant, Director, or other service provider of or to the Company or any of its respective Affiliates to whom an Award is granted.

(v) “Performance Award” means any Award that, pursuant to Section 9, is granted, vested and/or settled upon the achievement of specified performance conditions.

(w) “Performance Goals” means a goal that must be met by the end of a period specified by the Committee (but that is substantially uncertain of being met before the grant of the Award) based upon one or more of the following business criteria: (i) specified levels of or

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increases in pre-tax earnings, return on capital, equity measures/ratios (on a gross, net, pre-tax or post tax basis), including basic earnings per share, diluted earnings per share, total earnings (including total earnings as adjusted by the Committee at the time of the Award), operating earnings, earnings growth, earnings before interest and taxes, or EBIT, and earnings before interest, taxes, depreciation and amortization, or EBITDA (including EBIT or EBITDA as adjusted by the Committee at the time of the Award); (ii) total sales or sales growth; (iii) gross margin; (iv) customer service levels; (v) employee recruiting and development; (vi) advertising effectiveness; (vii) development of new markets; (viii) financial ratios; (ix) strategic initiatives; (x) improvement in or attainment of operating expense levels; (xi) improvement in or attainment of capital expense levels; (xii) the attainment of certain target levels of, or a specified increase in, operational cash flow; (xiii) the achievement of a certain level of, reduction of, or other specified objectives with regard to limiting the level of increase in, all or a portion of, the Company’s bank debt or other long-term or short-term public or private debt or other similar financial obligations of the Company, which may be calculated net of such cash balances and/or other specified offsets; (xiv) appreciation in and/or maintenance of certain target levels in the Fair Market Value; (xv) the attainment of a certain level of, reduction of, or other specified objectives with regard to limiting the level of or rate of increase in all or a portion of specified expenses (xvi) individual objectives; and (xvii) any combination of the foregoing. The Committee shall have discretion to determine the specific targets with respect to each of these categories of Performance Goals and may apply to the Company as a whole or to any Subsidiary, division or other unit of the Company.

(x) “Person” means an individual, partnership, corporation, limited liability company, trust, joint venture, unincorporated association, or other entity or association.

(y) “Plan” means the Collegium Pharmaceutical, Inc. Amended and Restated 2014 Stock Incentive Plan herein set forth, as amended from time to time.

(z) “Restricted Stock” means Shares that are subject to restrictions pursuant to Section 7 hereof.

(aa) “Restricted Stock Unit” means a right granted under and subject to restrictions pursuant to Section 8 hereof.

(bb) “Shares” means shares of the Company’s common stock, par value \$0.001, subject to substitution or adjustment as provided in Section 3(c) hereof.

(cc) “Subsidiary” means, in respect of the Company, a subsidiary company as defined in Sections 424(f) and (g) of the Code.

**SECTION 2. Administration.** The Plan shall be administered by the Committee. Any action of the Committee in administering the Plan shall be final, conclusive and binding on all persons, including the Company, its Subsidiaries, Affiliates, their respective employees, the Participants, persons claiming rights from or through Participants and stockholders of the Company.

The Committee will have full authority to grant Awards under this Plan and determine the terms of such Awards. Such authority will include the right to:

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- (a) select the individuals to whom Awards are granted (consistent with the eligibility conditions set forth in Section 4);
- (b) determine the type of Award to be granted;
- (c) determine the number of Shares, if any, to be covered by each Award;
- (d) establish the terms and conditions of each Award;
- (e) subject to Section 9, establish the performance conditions relevant to any Award and certify whether such performance conditions have been satisfied;
- (f) approving forms of agreements (including Award Agreements) for use under the Plan;
- (g) determine whether and under what circumstances an Award may be settled in cash;
- (h) determine whether and under what circumstances an Option may be exercised without a payment of cash under Section 5(d);
- (i) accelerate the vesting or exercisability of an Award and to modify or amend each Award, subject to Section 10; and
- (j) extend the period of time for which an Option is to remain exercisable following a Participant's termination of service to the Company from the limited period otherwise in effect for that Option to such greater period of time as the Committee deems appropriate, but in no event beyond the expiration of the term of the Option.

The Committee will have the authority to adopt, alter and repeal such administrative rules, guidelines and practices governing the Plan as it, from time to time, deems advisable; to establish the terms and form of each Award Agreement; to interpret the terms and provisions of the Plan and any Award issued under the Plan (and any Award Agreement); and to otherwise supervise the administration of the Plan. The Committee may correct any defect, supply any omission or reconcile any inconsistency in the Plan or in any Award Agreement in the manner and to the extent it deems necessary to carry out the intent of the Plan.

The Committee may delegate to one or more officers of the Company the authority to grant Awards to Participants who are not subject to the requirements of Section 16 of the Exchange Act or Section 162(m) of the Code and the rules and regulations thereunder, provided that the Committee shall have fixed the total number of Shares subject to such delegation. Any such delegation shall be subject to the applicable corporate laws of the Commonwealth of Virginia. The Committee may revoke any such allocation or delegation at any time for any reason with or without prior notice.

No Director will be liable for any good faith determination, act or omission in connection with the Plan or any Award.

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### **SECTION 3. Shares Subject to the Plan.**

(a) Shares Subject to the Plan. Subject to adjustment as provided in Section 3(c) of the Plan, the maximum number of Shares that may be issued in respect of Awards under the Plan is:

- (i) 2,700,000 Shares (inclusive of Shares subject to Awards issued under any prior version of the Plan that remain outstanding as of the effective date of the Plan ); *plus*
- (ii) an annual increase to be added on the first day of each fiscal year beginning with the fiscal year ending December 31, 2016, and on each anniversary thereof until the expiration of the Plan equal to 4% of the total number of outstanding Shares on December 31st of the immediately preceding calendar year. Notwithstanding the foregoing, the Board may act prior to January 1st of a given year to provide that there will be no January 1st increase in the maximum number of Shares that may be issued in respect of Awards under the Plan or that the increase in the maximum number of Shares that may be issued in respect of Awards for such year will be a lesser number of shares of Common Stock than would otherwise occur pursuant to the preceding sentence.

Subject to the provisions of Section 3(c), the aggregate maximum number of Shares that may be issued pursuant to the exercise of Incentive Stock Options will be 8,100,000 Shares. Any Shares issued hereunder may consist, in whole or in part, of authorized and unissued Shares or treasury Shares. Any Shares issued by the Company through the assumption or substitution of outstanding grants in connection with the acquisition of another entity shall not reduce the maximum number of Shares available for delivery under the Plan. In accordance with the requirements under Section 162(m) of the Code, the maximum number of Shares underlying Awards (including Options, Restricted Stock, Restricted Stock Units and Performance Awards) that may be granted during a calendar year to any individual Participant shall be 1,250,000 Shares per calendar year.

(b) Effect of the Expiration or Termination of Awards. If and to the extent that an Option expires, terminates or is canceled or forfeited for any reason without having been exercised in full, the Shares associated with that Option will again become available for grant under the Plan. Similarly, if and to the extent an Award of Restricted Stock or Restricted Stock Units is canceled or forfeited for any reason, the Shares subject to that Award will again become available for grant under the Plan. Shares withheld in settlement of a tax withholding obligation associated with an Award, or in satisfaction of the exercise price payable upon exercise of an Option, will not become available for grant under the Plan.

(c) Other Adjustment. In the event of any corporate event or transaction such as a merger, consolidation, reorganization, recapitalization, stock split, reverse stock split, split up, spin-off, combination of shares, exchange of shares, stock dividend, dividend in kind, or other like change in capital structure (other than ordinary cash dividends) to shareholders of the Company, or other similar corporate event or transaction affecting the Shares, the Committee, to prevent dilution or enlargement of Participants' rights under the Plan, shall, in such manner as it may deem equitable, substitute or adjust, in its sole discretion, the number and kind of shares that

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may be issued under the Plan or under any outstanding Awards, the number and kind of shares subject to outstanding Awards, the exercise price, grant price or purchase price applicable to outstanding Awards, and/or any other affected terms and conditions of this Plan or outstanding Awards. The Committee shall not make any adjustment that would adversely affect the status of any Award that is “performance-based compensation” under Section 162(m) of the Code.

(d) **Change in Control.** Notwithstanding anything to the contrary set forth in the Plan, upon any Change in Control, the Committee may, in its sole and absolute discretion and without the need for the consent of any Participant, take one or more of the following actions contingent upon the occurrence of that Change in Control:

- (i) cause any or all outstanding Awards to become vested and immediately exercisable (as applicable), in whole or in part;
- (ii) cause any outstanding Option to become fully vested and immediately exercisable for a reasonable period in advance of the Change in Control and, to the extent not exercised prior to that Change in Control, cancel that Option upon closing of the Change in Control;
- (iii) cancel any unvested Award or unvested portion thereof, with or without consideration;
- (iv) cancel any Award in exchange for a substitute award;
- (v) redeem any Restricted Stock or Restricted Stock Unit for cash and/or other substitute consideration with value equal to Fair Market Value of an unrestricted Share on the date of the Change in Control;
- (vi) cancel any Option in exchange for cash and/or other substitute consideration with a value equal to: (A) the number of Shares subject to that Option, multiplied by (B) the difference, if any, between the Fair Market Value per Share on the date of the Change in Control and the exercise price of that Option; *provided*, that if the Fair Market Value per Share on the date of the Change in Control does not exceed the exercise price of any such Option, the Committee may cancel that Option without any payment of consideration therefor;
- (vii) take such other action as the Committee shall determine to be reasonable under the circumstances; and/or
- (viii) notwithstanding any provision of this Section 3(d), in the case of any Award subject to Section 409A of the Code, such Award shall vest and be distributed only in accordance with the terms of the applicable Award Agreement and the Committee shall only be permitted to use discretion to the extent that such discretion would be permitted under Section 409A of the Code.

In the discretion of the Committee, any cash or substitute consideration payable upon cancellation of an Award may be subjected to (i) vesting terms substantially identical to those that applied to the cancelled Award immediately prior to the Change in Control, or

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(ii) earn-out, escrow, holdback or similar arrangements, to the extent such arrangements are applicable to any consideration paid to stockholders in connection with the Change in Control.

**SECTION 4. Eligibility.** Employees, Directors, consultants, and other individuals who provide services to the Company or its Affiliates are eligible to be granted Awards under the Plan; *provided, however*, that only employees of the Company, any Parent or a Subsidiary are eligible to be granted Incentive Stock Options.

**SECTION 5. Options.** Options granted under the Plan may be of two types: (i) Incentive Stock Options or (ii) Non-Qualified Stock Options. The Award Agreement shall state whether such grant is an Incentive Stock Option or a Non-Qualified Stock Option. Any Option granted under the Plan will be in such form as the Committee may at the time of such grant approve.

The Award Agreement evidencing any Option will incorporate the following terms and conditions and will contain such additional terms and conditions, not inconsistent with the terms of the Plan, as the Committee deems appropriate in its sole and absolute discretion:

(a) **Option Price.** The exercise price per Share under an Option will be determined by the Committee and will not be less than 100% of the Fair Market Value of a Share on the date of the grant. However, any Incentive Stock Option granted to any Participant who, at the time the Option is granted, owns, either directly and/or within the meaning of the attribution rules contained in Section 424(d) of the Code, stock possessing more than 10% of the total combined voting power of all classes of stock of the Company, will have an exercise price per Share of not less than 110% of Fair Market Value per Share on the date of the grant.

(b) **Option Term.** The term of each Option will be fixed by the Committee, but no Option will be exercisable more than 10 years after the date the Option is granted. However, any Incentive Stock Option granted to any Participant who, at the time such Option is granted, owns, either directly and/or within the meaning of the attribution rules contained in Section 424(d) of the Code, stock possessing more than 10% of the total combined voting power of all classes of stock of the Company, may not have a term of more than 5 years. No Option may be exercised by any Person after expiration of the term of the Option.

(c) **Exercisability.** Options will vest and be exercisable at such time or times and subject to such terms and conditions as determined by the Committee.

(d) **Method of Exercise.** Subject to the terms of the applicable Award Agreement, the exercisability provisions of Section 5(c) and the termination provisions of Section 6, Options may be exercised in whole or in part from time to time during their term by the delivery of written notice to the Company specifying the number of Shares to be purchased. Such notice will be accompanied by payment in full of the purchase price, either by certified or bank check, or such other means as the Committee may accept. The Committee may, in its sole discretion, permit payment of the exercise price of an Option in the form of previously acquired Shares based on the Fair Market Value of the Shares on the date the Option is exercised or through means of a “net settlement,” whereby the Option exercise price will not be due in cash and where the number of Shares issued upon such exercise will be equal to: (A) the product of

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(i) the number of Shares as to which the Option is then being exercised, and (ii) the excess, if any, of (a) the then current Fair Market Value per Share over (b) the Option exercise price, divided by (B) the then current Fair Market Value per Share.

No Shares will be issued upon exercise of an Option until full payment therefor has been made. A Participant will not have the right to distributions or dividends or any other rights of a stockholder with respect to Shares subject to the Option until the Participant has given written notice of exercise, has paid in full for such Shares, if requested, has given the representation described in Section 15(a) hereof and fulfills such other conditions as may be set forth in the applicable Award Agreement.

(e) Incentive Stock Option Limitations. In the case of an Incentive Stock Option, the aggregate Fair Market Value (determined as of the time of grant) of the Shares with respect to which Incentive Stock Options are exercisable for the first time by the Participant during any calendar year under the Plan and/or any other plan of the Company, its Parent or any Subsidiary will not exceed \$100,000. For purposes of applying the foregoing limitation, Incentive Stock Options will be taken into account in the order granted. To the extent any Option does not meet such limitation, that Option will be treated for all purposes as a Non-Qualified Stock Option.

**SECTION 6. Termination of Service.** Unless otherwise specified with respect to a particular Option in the applicable Award Agreement or otherwise determined by the Committee, any portion of an Option that is not exercisable upon termination of service will expire immediately and automatically upon such termination and any portion of an Option that is exercisable upon termination of service will expire on the date it ceases to be exercisable in accordance with this Section 6.

(a) Termination by Reason of Death. If a Participant's service with the Company or any Affiliate terminates by reason of death, any Option held by such Participant may thereafter be exercised, to the extent it was exercisable at the time of his or her death or on such accelerated basis as the Committee may determine at or after grant, by the legal representative of the estate or by the legatee of the Participant, for a period expiring (i) at such time as may be specified by the Committee at or after grant, or (ii) if not specified by the Committee, then 12 months from the date of death, or (iii) if sooner than the applicable period specified under (i) or (ii) above, upon the expiration of the stated term of such Option.

(b) Termination by Reason of Disability. If a Participant's service with the Company or any Affiliate terminates by reason of Disability, any Option held by such Participant may thereafter be exercised by the Participant or his personal representative, to the extent it was exercisable at the time of termination, or on such accelerated basis as the Committee may determine at or after grant, for a period expiring (i) at such time as may be specified by the Committee at or after grant, or (ii) if not specified by the Committee, then 12 months from the date of termination of service, or (iii) if sooner than the applicable period specified under (i) or (ii) above, upon the expiration of the stated term of such Option.

(c) Cause. If a Participant's service with the Company or any Affiliate is terminated for Cause: (i) any Option, or portion thereof, not already exercised will be

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immediately and automatically forfeited as of the date of such termination, and (ii) any Shares for which the Company has not yet delivered share certificates will be immediately and automatically forfeited and the Company will refund to the Participant the Option exercise price paid for such Shares, if any.

(d) Other Termination. If a Participant's service with the Company or any Affiliate terminates for any reason other than death, Disability or Cause, any Option held by such Participant may thereafter be exercised by the Participant, to the extent it was exercisable at the time of such termination, or on such accelerated basis as the Committee may determine at or after grant, for a period expiring (i) at such time as may be specified by the Committee at or after grant, or (ii) if not specified by the Committee, then 90 days from the date of termination of service, or (iii) if sooner than the applicable period specified under (i) or (ii) above, upon the expiration of the stated term of such Option.

## **SECTION 7. Restricted Stock**

(a) Issuance. Restricted Stock may be issued either alone or in conjunction with other Awards. The Committee will determine the time or times within which Restricted Stock may be subject to forfeiture, and all other conditions of such Awards. The purchase price for Restricted Stock may, but need not, be zero. The prospective recipient of an Award of Restricted Stock will not have any rights with respect to such Award, unless and until such recipient has delivered to the Company an executed Award Agreement and has otherwise complied with the applicable terms and conditions of such Award.

(b) Certificates. Upon the Award of Restricted Stock, the Committee may direct that a certificate or certificates representing the number of shares of Common Stock subject to such Award be issued to the Participant or placed in a restricted stock account (including an electronic account) with the transfer agent and in either case designating the Participant as the registered owner. The certificate(s) representing such shares shall be physically or electronically legended, as applicable, as to sale, transfer, assignment, pledge or other encumbrances during the Restriction Period and if issued to the Participant, returned to the Company, to be held in escrow during the Restriction Period. As a condition to any Award of Restricted Stock, the Participant may be required to deliver to the Company a share power, endorsed in blank, relating to the Shares covered by such Award.

(c) Restrictions and Conditions. The Award Agreement evidencing the grant of any Restricted Stock will incorporate the following terms and conditions and such additional terms and conditions, not inconsistent with the terms of the Plan, as the Committee deems appropriate in its sole and absolute discretion:

(i) During a period commencing with the date of an Award of Restricted Stock and ending at such time or times as specified by the Committee (the "Restriction Period"), the Participant will not be permitted to sell, transfer, pledge, assign or otherwise encumber Restricted Stock awarded under the Plan. The Committee may condition the lapse of restrictions on Restricted Stock upon the continued employment or service of the recipient, the attainment of specified individual or corporate performance

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goals, or such other factors as the Committee may determine, in its sole and absolute discretion.

(ii) While any Share of Restricted Stock remain subject to restriction, the Participant will have, with respect to the Restricted Stock, the right to vote the Shares, but will not have the right to receive any cash distributions or dividends prior to the lapse of the Restriction Period underlying such Shares unless otherwise provided under the applicable Award Agreement or as determined by the Committee. If any cash distributions

or dividends are payable with respect to the Restricted Stock, the Committee, in its sole discretion, may require the cash distributions or dividends to be subjected to the same Restriction Period as is applicable to the Restricted Stock with respect to which such amounts are paid, or, if the Committee so determines, reinvested in additional Restricted Stock to the extent Shares are available under Section 3(a) of the Plan. A Participant shall not be entitled to interest with respect to any dividends or distributions subjected to the Restriction Period. Any distributions or dividends paid in the form of securities with respect to Restricted Stock will be subject to the same terms and conditions as the Restricted Stock with respect to which they were paid, including, without limitation, the same Restriction Period.

(iii) Subject to the provisions of the applicable Award Agreement or as otherwise determined by the Committee, if a Participant's service with the Company and its Affiliates terminates prior to the expiration of the applicable Restriction Period, the Participant's Restricted Stock that then remains subject to forfeiture will then be forfeited automatically.

**SECTION 8. Restricted Stock Units.** Subject to the other terms of the Plan, the Committee may grant Restricted Stock Units to eligible individuals and may, in its sole and absolute discretion, impose conditions on such units as it may deem appropriate, including, without limitation, continued employment or service of the recipient or the attainment of specified individual or corporate performance goals. Each Restricted Stock Unit shall be evidenced by an Award Agreement in the form that is approved by the Committee and that is not inconsistent with the terms and conditions of the Plan. Each Restricted Stock Unit will represent a right to receive from the Company, upon fulfillment of any applicable conditions, an amount equal to the Fair Market Value (at the time of the distribution) of one Share. Distributions may be made in Shares. All other terms governing Restricted Stock Units, such as vesting, time and form of payment and termination of units shall be set forth in the applicable Award Agreement. The Participant shall not have any shareholder rights with respect to the Shares subject to a Restricted Stock Unit Award until that Award vests and the Shares are actually issued thereunder. Subject to the provisions of the applicable Award Agreement or as otherwise determined by the Committee, if a Participant's service with the Company terminates prior to the Restricted Stock Unit Award vesting, the Participant's Restricted Stock Units that then remain subject to forfeiture will then be forfeited automatically.

**SECTION 9. Performance Based Awards.**

(a) Performance Awards Generally. The Committee may grant Performance Awards in accordance with this Section 9. Performance Awards may be denominated as a

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number of Shares, or a specified number of other Awards, which may be earned upon achievement or satisfaction of such Performance Goals as may be specified by the Committee. In addition, the Committee may specify that any other Award shall constitute a Performance Award by conditioning the vesting or settlement of the Award upon the achievement or satisfaction of such Performance Goals as may be specified by the Committee.

(b) Adjustments to Performance Goals. The Committee may provide, at the time Performance Goals are established, that adjustments will be made to those performance goals to take into account, in any objective manner specified by that committee, the impact of one or more of the following: (A) gain or loss from all or certain claims and/or litigation and insurance recoveries, (B) the impairment of tangible or intangible assets, (C) stock-based compensation expense, (D) restructuring activities reported in the Company's public filings, (E) investments, dispositions or acquisitions, (F) loss from the disposal of certain assets, (G) gain or loss from the early extinguishment, redemption, or repurchase of debt, (H) changes in accounting principles, or (I) any other item, event or circumstance that would not cause an Award to fail to constitute "qualified performance-based compensation" under Section 162(m) of the Code (to the extent such Award is intended to be "qualified performance-based compensation"). An adjustment described in this Section may relate to the Company or to any subsidiary, division or other operational unit of the Company or its Affiliates, as determined by the Committee at the time the performance goals are established. Any adjustment shall be determined in accordance with generally accepted accounting principles and standards, unless such other objective method of measurement is designated by the committee at the time performance objectives are established. In addition, adjustments will be made as necessary to any performance criteria related to the Company's stock to reflect changes in corporate capitalization, including a recapitalization, stock split or combination, stock dividend, spin-off, merger, reorganization or other similar event or transaction affecting the Company's equity.

(c) Other Terms of Performance Awards. The Committee may specify other terms pertinent to a Performance Award in the applicable Award Agreement, including terms relating to the treatment of that Award in the event of a Change in Control prior to the end of the applicable performance period. The Participant shall not have any shareholder rights with respect to the Shares subject to a Performance Award until the Shares are actually issued thereunder. Subject to the provisions of the applicable Award Agreement or as otherwise determined by the Committee, if a Participant's service with the Company terminates prior to the Performance Award vesting, the Participant's Performance Award or portion thereof that then remains subject to forfeiture will then be forfeited automatically.

**SECTION 10. Amendments and Termination.** The Board may amend, alter or discontinue the Plan at any time. However, except as otherwise provided in Section 3, no amendment, alteration or discontinuation will be made which would impair the rights of a Participant with respect to an Award without that Participant's consent or which, without the approval of such amendment within 365 days of its adoption by the Board by the Company's stockholders in a manner consistent with Treas. Reg. § 1.422-3 (or any successor provision), would: (i) increase the total number of Shares reserved for issuance hereunder, or (ii) change the persons or class of persons eligible to receive Awards.

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**SECTION 11. Prohibition on Repricing Programs.** Neither the Committee nor the Board shall (i) implement any cancellation/re-grant program pursuant to which outstanding Options under the Plan are cancelled and new Options are granted in replacement with a lower exercise or base price per share, (ii) cancel outstanding Options under the Plan with exercise prices or base prices per share in excess of the then current Fair Market Value per Share for consideration payable in equity securities of the Company or (iii) otherwise directly reduce the exercise price or base price in effect for outstanding Options under the Plan, without in each such instance obtaining shareholder approval.

**SECTION 12. Conditions Upon Grant of Awards and Issuance of Shares.**

(a) The implementation of the Plan, the grant of any Award and the issuance of Shares in connection with the issuance, exercise or vesting of any Award made under the Plan shall be subject to the Company's procurement of all approvals and permits required by regulatory authorities having jurisdiction over the Plan, the Awards made under the Plan and the Shares issuable pursuant to those Awards.



(b) No Shares or other assets shall be issued or delivered under the Plan unless and until there shall have been compliance with all applicable requirements of Applicable Law, including the filing and effectiveness of the Form S-8 registration statement for the Shares issuable under the Plan, and all applicable listing requirements of any stock exchange on which Shares are then listed for trading.

**SECTION 13. Limits on Transferability; Beneficiaries.** No Award or other right or interest of a Participant under the Plan shall be pledged, encumbered, or hypothecated to, or in favor of, or subject to any lien, obligation, or liability of such Participant to, any party, other than the Company, any Subsidiary or Affiliate, or assigned or transferred by such Participant otherwise than by will or the laws of descent and distribution, and such Awards and rights shall be exercisable during the lifetime of the Participant only by the Participant or his or her guardian or legal representative. Notwithstanding the foregoing, the Committee may, in its discretion, provide that Awards or other rights or interests of a Participant granted pursuant to the Plan (other than an Incentive Stock Option) be transferable, without consideration, to immediate family members (i.e., children, grandchildren or spouse), to trusts for the benefit of such immediate family members and to partnerships in which such family members are the only partners. The Committee may attach to such transferability feature such terms and conditions as it deems advisable. In addition, a Participant may, in the manner established by the Committee, designate a beneficiary (which may be a person or a trust) to exercise the rights of the Participant, and to receive any distribution, with respect to any Award upon the death of the Participant. A beneficiary, guardian, legal representative or other person claiming any rights under the Plan from or through any Participant shall be subject to all terms and conditions of the Plan and any Award Agreement applicable to such Participant, except as otherwise determined by the Committee, and to any additional restrictions deemed necessary or appropriate by the Committee.

**SECTION 14. Withholding.** No later than the date as of which an amount first becomes includible in the gross income of the Participant for federal income tax purposes with respect to any Award under the Plan, the Participant will pay to the Company, or make

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arrangements satisfactory to the Company regarding the payment of, any federal, state or local taxes of any kind required by law to be withheld with respect to such amount. The minimum required withholding obligations may be settled with Shares, including Shares that are part of the Award that gives rise to the withholding requirement. The obligations of the Company under the Plan will be conditioned on such payment or arrangements and the Company will have the right to deduct any such taxes from any payment of any kind otherwise due to the Participant.

**SECTION 15. Liability of Company.**

(a) **Inability to Obtain Authority.** If the Company cannot, by the exercise of commercially reasonable efforts, obtain authority from any regulatory body having jurisdiction for the sale of any Shares under this Plan, and such authority is deemed by the Company's counsel to be necessary to the lawful issuance of those Shares, the Company will be relieved of any liability for failing to issue or sell those Shares.

(b) **Grants Exceeding Allotted Shares.** If Shares subject to an Award exceed, as of the date of grant, the number of Shares which may be issued under the Plan without additional shareholder approval, that Award will be contingent with respect to such excess Shares, on the effectiveness under Applicable Law of a sufficient increase in the number of Shares subject to this Plan.

(c) **Rights of Participants and Beneficiaries.** The Company will pay all amounts payable under this Plan only to the applicable Participant, or beneficiaries entitled thereto pursuant to this Plan. The Company will not be liable for the debts, contracts, or engagements of any Participant or his or her beneficiaries, and rights to cash payments under this Plan may not be taken in execution by attachment or garnishment, or by any other legal or equitable proceeding while in the hands of the Company.

**SECTION 16. General Provisions.**

(a) The Board may require each Participant to represent to and agree with the Company in writing that the Participant is acquiring securities of the Company for investment purposes and without a view to distribution thereof and as to such other matters as the Board believes are appropriate.

(b) All certificates for Shares or other securities delivered under the Plan will be subject to such share-transfer orders and other restrictions as the Board may deem advisable under the rules, regulations and other requirements of the Securities Act of 1933, as amended, the Exchange Act, any stock exchange upon which the Shares are then listed, and any other Applicable Law, and the Board may cause a legend or legends to be put on any such certificates to make appropriate reference to such restrictions.

(c) Nothing contained in the Plan will prevent the Board from adopting other or additional compensation arrangements, subject to stockholder approval if such approval is required.

(d) Neither the adoption of the Plan nor the execution of any document in connection with the Plan will: (i) confer upon any employee or other service provider of the

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Company or an Affiliate any right to continued employment or engagement with the Company or such Affiliate, or (ii) interfere in any way with the right of the Company or such Affiliate to terminate the employment or engagement of any of its employees or other service providers at any time.

(e) Notwithstanding any other provisions in this Plan, any Award which is subject to recovery under any law, government regulation or stock exchange listing requirement, will be subject to such deductions and clawback as may be required to be made pursuant to such law, government regulation or stock exchange listing requirement (or any policy adopted by the Company pursuant to any such law, government regulation or stock exchange listing requirement).

**SECTION 17. Effective Date of Plan.** The Plan will become effective immediately prior to the closing of the Company's initial public offering.

**SECTION 18. Term of Plan.** Unless the Plan shall theretofore have been terminated in accordance with Section 10, the Plan shall terminate on May [ ], 2025, and no Awards under the Plan shall thereafter be granted.

**SECTION 19. Invalid Provisions.** In the event that any provision of this Plan is found to be invalid or otherwise unenforceable under any Applicable Law, such invalidity or unenforceability will not be construed as rendering any other provisions contained herein as invalid or unenforceable, and all such other provisions will be given full force and effect to the same extent as though the invalid or unenforceable provision was not contained herein.

**SECTION 20. Governing Law.** The Plan and all Awards granted hereunder will be governed by and construed in accordance with the laws and judicial decisions of the Commonwealth of Virginia, without regard to the application of the principles of conflicts of laws.

**SECTION 21. Notices.** Any notice to be given to the Company pursuant to the provisions of this Plan must be given in writing and addressed, if to the Company, to its principal executive office to the attention of its Chief Financial Officer (or such other Person as the Company may designate in writing from time to time), and, if to a Participant, to the address contained in the Company's personnel files, or at such other address as that Participant may hereafter designate in writing to the Company. Any such notice will be deemed duly given: if delivered personally or via recognized overnight delivery service, on the date and at the time so delivered; if sent via telecopier or email, on the date and at the time telecopied or emailed with confirmation of delivery; or, if mailed, five (5) days after the date of mailing by registered or certified mail.

## COLLEGIUM PHARMACEUTICAL, INC.

## Restricted Stock Award Agreement

THIS RESTRICTED STOCK AWARD AGREEMENT (this "Agreement") is made as of April 2, 2015 (the "Grant Date") by and between Collegium Pharmaceutical, Inc., a Virginia corporation (the "Company"), and Michael Heffernan (the "Participant").

WHEREAS, in consideration for the Participant's continued and future services to the Company and to further align the Participant's financial interests with those of the Company's stockholders, the Company's Board of Directors (the "Board") has approved this award of restricted Common Stock to Participant subject to the restrictions and on the terms and conditions contained in this Agreement.

NOW, THEREFORE, in consideration of these premises and the agreements set forth herein, the parties, intending to be legally bound hereby, agree as follows:

1. **Award of Restricted Shares; Termination of Transaction Bonus Plan and Any Rights Thereunder.**

(a) The Company hereby awards the Participant One Million Three Hundred Forty-Three Thousand Three Hundred Ninety One (1,343,391) shares of restricted Common Stock, subject to the restrictions and on the terms and conditions set forth in this Agreement (the "Restricted Shares"). The terms of the Plan are hereby incorporated into this Agreement by this reference, as though fully set forth herein. Except as otherwise provided herein, capitalized terms used herein will have the same meaning as defined in the Plan.

(b) Participant acknowledges and agrees that any and all rights and claims of the Participant with respect to that certain Transaction Bonus Plan adopted by the Company on July 23, 2014 ("Transaction Bonus Plan") (including, without limitation, any rights created by the amendment dated September 10, 2013 to Participant's employment agreement concerning the Transaction Bonus Plan) are hereby terminated, cancelled and of no further force or effect effective as of the date hereof and that the foregoing termination of the Transaction Bonus Plan and Participant's rights thereunder is partial consideration for, and is a condition of, the Company's award of the Restricted Shares to Participant hereunder.

2. **Forfeiture; Vesting of Restricted Shares.**

(a) **No Transfer of Unvested Restricted Shares.** Six Hundred Seventy-One Thousand Six Hundred Ninety Six (671,696) of the Restricted Shares shall be vested on the date hereof and shall not be subject to risk of forfeiture pursuant to the provisions of this Section 2. Six Hundred Seventy-One Thousand Six Hundred Ninety Five (671,695) of the Restricted Shares (the "Vesting Shares") shall be subject to forfeiture to the Company until they become vested in accordance with this Section 2. While subject to forfeiture, the Vesting Shares may not be sold, pledged, assigned, otherwise encumbered or transferred in any manner, whether voluntarily or involuntarily by the operation of law.

(b) **Unvested Vesting Shares Subject to Forfeiture.** Subject to the other sections of this Agreement, including, without limitation, the acceleration of vesting referenced in Section 2(d), upon any cessation of the Participant's service with the Company (whether initiated by the Company, Participant or otherwise): (i) any Vesting Shares which have not vested pursuant to this Section 2 will immediately and automatically, without any action on the part of the Company or payment of any consideration to Participant, be forfeited, and (ii) the Participant will have no further rights with respect to such forfeited Vesting Shares.

(c) **Vesting of Restricted Shares.** Subject to Participant's continuous service with the Company through such date and the acceleration of vesting referenced in Section 2(d), the Vesting Shares will become vested (free from forfeiture pursuant to Section 2(b)) as to one thirty sixth (1/36<sup>th</sup>) of the Vesting Shares shall vest at the end of each monthly period after April 2, 2015, with all of the Vesting Shares becoming vested on April 2, 2018. For purposes of this Agreement, service with an Affiliate of the Company will be deemed to constitute service with the Company, for so long as such entity remains an Affiliate of the Company.

(d) **Acceleration of Vesting.** The vesting of the Vesting Shares is subject to the vesting acceleration provisions contained in the employment agreement dated June 13, 2012, as amended, between the Company and Participant, or as set forth in any successor employment agreement entered into between the Company and Participant.

3. **Issuance of Shares.**

(a) The Company will cause the Restricted Shares to be issued in the Participant's name either by book-entry registration or issuance of a stock certificate or certificates. While the Vesting Shares remain forfeitable, the Company will cause an appropriate stop-transfer order to be issued and to remain in effect with respect to the Vesting Shares. As soon as practicable following the time that any Vesting Share becomes vested (and provided that appropriate arrangements have been made with the Company for the withholding or payment of any taxes that may be due with respect to such share), the Company will cause that stop-transfer order to be removed. The Company may also condition delivery of certificates for Restricted Shares upon receipt from the Participant of any undertakings that it may determine are appropriate to facilitate compliance with federal and state securities laws.

(b) If any certificate is issued in respect of Vesting Shares, that certificate will include appropriate legends and will held in escrow by the Company's secretary or his or her designee. In addition, the Participant shall be required to execute and deliver to the Company a stock power with respect to those Vesting Shares in substantially the form attached hereto as Exhibit A. At such time as those Vesting Shares become vested, the Company will cause a new certificate to be issued without that portion of the legend referencing the previously applicable forfeiture conditions and will cause that new certificate to be delivered to the Participant (again, provided that appropriate arrangements have been made with the Company for the withholding or payment of any taxes that may be due with respect to such Shares).

4. **Substitute Property.** If, while any of the Vesting Shares remain subject to forfeiture, there occurs a merger, reclassification, recapitalization, stock split, stock dividend or other similar event or transaction resulting in new, substituted or additional securities being

issued or delivered to the Participant by reason of the Participant's ownership of the Vesting Shares, such securities will constitute "Vesting Shares" for all purposes of this Agreement and any certificate issued to evidence such securities will immediately be deposited with the secretary of the Company (or his or her designee) and subject to the escrow described in Section 3, above.

5. **Rights of Participant During Restricted Period.** The Participant will have the right to vote the Restricted Shares (including any Vesting Shares) and to receive dividends and distributions with respect to the Restricted Shares (including any Vesting Shares); *provided, however*, that any cash dividends or distributions paid in respect of the Restricted Shares that are Vesting Shares while those shares remain subject to forfeiture will be placed in escrow with the secretary of the Company (or his or her designee) and will be delivered to the Participant (without interest) only if and when such Vesting Shares giving rise to such dividends or distributions become vested.

6. **Right of First Refusal.** Participant acknowledges the vested Restricted Shares are subject to, among other things, the restrictions on transfer, rights of first refusal and co-sale rights set forth in that certain Seventh Amended and Restated Stockholders' Agreement dated as of March 6, 2015, as may be amended and/or restated from time to time (the "Stockholders Agreement") by and among the Company, Participant and the other stockholders of the Company party thereto.

7. **Market Standoff Agreement.** The Participant agrees, in connection with the initial underwritten public offering of the Company's securities pursuant to a registration statement under the Securities Act, (i) not to sell, make short sale of, loan, grant any options for the purchase of, or otherwise dispose of any shares of Common Stock held by the Participant (other than those shares included in the offering) without the prior written consent of the Company or the underwriters managing such initial underwritten public offering of the Company's securities for a period of 180 days from the effective date of such registration statement (plus up to an additional 34 days to the extent requested by the managing underwriters for such offering in order to address Rule 2711(f) of the Financial Industry Regulatory Authority, Inc. or any similar successor provision), and (ii) to execute any agreement reflecting clause (i) above as may be requested by the Company or the managing underwriters at the time of such offering

8. **Securities Laws.** The Board may from time to time impose any conditions on the Restricted Shares as it deems necessary or advisable to ensure that the Restricted Shares are issued and sold in compliance with the requirements of any stock exchange or quotation system upon which the shares are then listed or quoted, the Securities Act of 1933 and all other applicable laws.

9. **Tax Consequences.**

(a) The Participant acknowledges that the Company has not advised the Participant regarding the Participant's income tax liability in connection with the grant or vesting of the Restricted Shares. The Participant has had the opportunity to review with his or her own tax advisors the federal, state and local tax consequences of the transactions contemplated by this

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Agreement. The Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents. The Participant understands that the Participant (and not the Company) shall be responsible for the Participant's own tax liability that may arise as a result of the transactions contemplated by this Agreement.

(b) The Participant acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Participant any federal, state or local taxes of any kind required by law to be withheld with respect to the award of the Shares.

(c) The Participant acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Participant any federal, state or local taxes of any kind required by law to be withheld with respect to the purchase of the Shares by the Participant or the lapse of the Purchase Option. The Participant has reviewed with the Participant's own tax advisors the federal, state, local and foreign tax consequences of this investment and the transactions contemplated by this Agreement.

(d) Participant shall make an election under Section 83(b) of the Code with respect to the grant of the Vesting Shares, the Participant agrees to notify the Company in writing on the day of such election. The amount includible in the Participant's income as a result of that election will be subject to tax withholding. The Participant will be required to remit to the Company in cash, or make other arrangements reasonably satisfactory to the Company for the satisfaction of, such tax withholding amount; failure to do so within three business days of making the Section 83(b) election will result in forfeiture of all the Restricted Shares. PARTICIPANT ACKNOWLEDGES THAT IT IS SOLELY THE PARTICIPANT'S RESPONSIBILITY AND NOT THE COMPANY'S TO FILE TIMELY THE ELECTION UNDER SECTION 83(b), EVEN IF THE PARTICIPANT REQUESTS THE COMPANY OR ITS REPRESENTATIVES TO MAKE THIS FILING ON THE PARTICIPANT'S BEHALF.

10. **Consent to Electronic Delivery.** The Participant hereby authorizes the Company to deliver electronically any prospectuses or other documentation related to this Agreement and any other compensation or benefit plan or arrangement in effect from time to time (including, without limitation, reports, proxy statements or other documents that are required to be delivered to participants in such plans or arrangements pursuant to federal or state laws, rules or regulations). For this purpose, electronic delivery will include, without limitation, delivery by means of e-mail or e-mail notification that such documentation is available on the Company's intranet site. Upon written request, the Company will provide to the Participant a paper copy of any document also delivered to the Participant electronically. The authorization described in this paragraph may be revoked by the Participant at any time by written notice to the Company.

11. **Entire Agreement.** This Agreement represents the entire agreement between the parties hereto relating to the subject matter hereof, and merges and supersedes all prior and contemporaneous discussions, agreements and understandings of every nature.

12. **Severability.** The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement and each other provision of this Agreement shall be severable and enforceable to the extent permitted by law.

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13. **Governing Law.** This Agreement will be construed in accordance with the laws of the Commonwealth of Virginia, without regard to the application of the principles of conflicts of laws.

14. **Amendment.** This Agreement may only be amended by a writing signed by each of the parties hereto.

15. **Changes in Capitalization.** In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, the number of shares subject to forfeiture and other rights of the Company hereunder and such other relevant terms this Agreement that are affected by such stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event shall be equitably adjusted by the Company (in the manner determined by the Board).

16. **Execution.** This Agreement may be executed, including execution by facsimile signature, in one or more counterparts, each of which will be deemed an original, and all of which together shall be deemed to be one and the same instrument.

[Signature Page Follows]

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IN WITNESS WHEREOF, the Company's duly authorized representative and the Participant have each executed this Restricted Stock Award Agreement as of the date first set forth above.

**COLLEGIUM PHARMACEUTICAL, INC.**

**By:** /s/ Paul Brannelly  
**Name:** Paul Brannelly  
**Title:** Chief Financial Officer

**PARTICIPANT:** Michael Heffernan

**Signature:** /s/ Michael Heffernan

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Exhibit A

**STOCK ASSIGNMENT SEPARATE FROM CERTIFICATE**

FOR VALUE RECEIVED, I hereby sell, assign and transfer unto ( ) shares of Common Stock, \$.001 par value per share, of Collegium Pharmaceutical, Inc. (the "Corporation") standing in my name on the books of the Corporation represented by Certificate(s) Number herewith, and do hereby irrevocably constitute and appoint attorney to transfer the said stock on the books of the Corporation with full power of substitution in the premises.

By: \_\_\_\_\_  
Michael Heffernan

Dated: \_\_\_\_\_

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**INDEMNITY AGREEMENT**

This Indemnification Agreement (“Agreement”) is made as of April , 2015, by and between Collegium Pharmaceutical, Inc., a Virginia corporation (the “Company”), and (“Indemnitee”).

RECITALS

WHEREAS, highly competent persons have become more reluctant to serve publicly held corporations as a director and/or officer unless they are provided with adequate indemnification against risks of claims and actions against them arising out of their service to and activities on behalf of the corporation;

WHEREAS, the Articles of Incorporation of the Company and the Virginia Stock Corporation Act (the “Virginia Act”) expressly provide that the indemnification provisions set forth therein are not exclusive, and thereby contemplate that contracts may be entered into between the Company and members of the board of directors, officers and other persons with respect to indemnification and advancement of expenses;

WHEREAS, the Company and Indemnitee recognize the substantial increase in corporate litigation in general, subjecting directors and officers to expensive litigation risks that may not be fully covered by liability insurance;

WHEREAS, the Company and Indemnitee further recognize the difficulty in obtaining and accessing directors and officers liability insurance that fully and adequately covers directors and officers for their acts and omissions on behalf of the Company and its subsidiaries; and

WHEREAS, it is reasonable and prudent for the Company contractually to obligate itself to indemnify, and to advance expenses to, its directors and officers to the fullest extent permitted by applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be protected.

NOW, THEREFORE, in consideration of the premises and the covenants contained herein, the Company and Indemnitee do hereby covenant and agree as follows:

Section 1. Services to the Company. Indemnitee agrees to serve or continue to serve as a director and/or officer of the Company. Indemnitee may at any time and for any reason resign from the board of directors or as an officer of the Company, as the case may be (subject to any other contractual obligation or any obligation imposed by operation of law). This Agreement shall not be deemed an employment contract between the Company and Indemnitee. The foregoing notwithstanding, this Agreement shall continue in force after Indemnitee has ceased to serve as a director and/or officer of the Company.

Section 2. Definitions. As used in this Agreement:

(a) A “Change in Control” shall be deemed to occur upon the earliest to occur after the date of this Agreement of any of the following events:

(i) Acquisition of Stock by Third Party. Any Person (as defined below) is or becomes the Beneficial Owner (as defined below), directly or indirectly, of securities of the Company representing fifty percent (50%) or more of the combined voting power of the Company’s then outstanding securities;

(ii) Change in Board of Directors. During any period of two (2) consecutive years (not including any period prior to the execution of this Agreement), individuals who at the beginning of such period constitute the Board, and any new director (other than a director designated by a person who has effected, or entered into an agreement with the Company to effect, a transaction described in Sections 2(a)(i), 2(a)(iii) or 2(a)(iv)) whose election by the Board or nomination for election by the Company’s shareholders was approved by a vote of at least a majority of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute a least a majority of the members of the Board;

(iii) Corporate Transactions. The effective date of a merger or consolidation of the Company with any other entity, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than 50% of the combined voting power of the voting securities of the surviving entity outstanding immediately after such merger or consolidation and with the power to elect at least a majority of the board of directors or other governing body of such surviving entity;

(iv) Dissolution or Disposition of Assets. The approval by the shareholders of the Company of the dissolution of the Company or of an agreement for the sale or disposition by the Company of all or substantially all of the Company’s assets; and

(v) Other Events. There occurs any other event of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A (or a response to any similar item on any similar schedule or form) promulgated under the Exchange Act (as defined below), whether or not the Company is then subject to such reporting requirement.

For purposes of this Section 2(a), the following terms shall have the following meanings:

(A) “Exchange Act” shall mean the Securities Exchange Act of 1934, as amended.

(B) “Person” or “person” shall have the meaning as set forth in Sections 13(d) and 14(d) of the Exchange Act; provided, however, that Person shall exclude (i) the Company, (ii) any trustee or other fiduciary holding securities under an

employee benefit plan of the Company, and (iii) any corporation owned, directly or indirectly, by the shareholders of the Company in substantially the same proportions as their ownership of stock of the Company.

(C) "Beneficial Owner" shall have the meaning given to such term in Rule 13d-3 under the Exchange Act; provided, however, that Beneficial Owner shall exclude any Person otherwise becoming a Beneficial Owner by reason of the shareholders of the Company approving a merger of the Company with another entity, and further provided, that any calculation of securities beneficially owned by a Beneficial Owner shall include securities that are the subject of a derivative that creates for the Beneficial Owner the economic equivalent of ownership in such securities for the Beneficial Owner by tying the value of the derivative to the price or value of such securities.

(b) "Corporate Status" describes the status of a person who is or was a director, officer, employee or agent of the Company or of any other corporation, limited liability company, partnership, joint venture, trust, employee benefit plan or other enterprise which such person is or was serving at the request of the Company.

(c) "Enterprise" shall mean the Company and any other corporation, limited liability company, partnership, joint venture, trust, employee benefit plan or other enterprise of which Indemnitee is or was serving at the request of the Company as a director, officer, employee, agent or fiduciary.

(d) "Expenses" shall include all reasonable attorneys' fees, retainers, court costs, transcript costs, fees of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to be a witness in, or otherwise participating in, a Proceeding. Expenses also shall include Expenses incurred in connection with any appeal resulting from any Proceeding, including without limitation the premium, security for and other costs relating to any cost bond, supersedeas bond or other appeal bond or its equivalent. Expenses, however, shall not include amounts paid in settlement by Indemnitee or the amount of judgments or fines against Indemnitee.

(e) "Independent Counsel" means a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past three years has been, retained to represent: (i) the Company or Indemnitee in any matter material to either such party (other than with respect to matters concerning the Indemnitee under this Agreement, or other indemnitees under similar indemnification agreements), or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either

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the Company or Indemnitee in an action to determine Indemnitee's rights under this Agreement. The Company agrees to pay the reasonable fees and expenses of the Independent Counsel referred to above and to indemnify such counsel fully against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

(f) The term "Proceeding" shall include any threatened, pending or completed action, suit, arbitration, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or other actual, threatened or completed proceeding, whether brought in the right of the Company or otherwise (including a derivative lawsuit) and whether of a civil, criminal, administrative or investigative nature, in which Indemnitee was, is or will be involved as a party or otherwise by reason of the fact that Indemnitee is or was a director or officer of the Company, by reason of any action taken by Indemnitee or of any action on Indemnitee's part while acting as director or officer of the Company, or by reason of the fact that Indemnitee is or was serving at the request of the Company as a director, officer, employee or agent of another corporation, limited liability company, partnership, joint venture, trust or other enterprise, in each case whether or not serving in such capacity at the time any liability or expense is incurred for which indemnification, reimbursement or advancement of expenses can be provided under this Agreement; except one initiated by Indemnitee to enforce Indemnitee's rights under this Agreement.

(g) Reference to "other enterprise" shall include employee benefit plans; references to "fines" shall include any excise tax assessed with respect to any employee benefit plan; references to "serving at the request of the Company" shall include any service as a director or officer of the Company which imposes duties on, or involves services by, such director or officer with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner he reasonably believed to be in the best interests of the participants and beneficiaries of an employee benefit plan shall be deemed not to have engaged in willful misconduct or a knowing violation of criminal law.

Section 3. (a) Indemnity in Proceedings. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 3 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding, including a Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 3, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses, liabilities, judgments, fines and amounts paid in settlement actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with such Proceeding or any claim, issue or matter therein, except for indemnification of the Indemnitee for Indemnitee's willful misconduct or Indemnitee's knowing violation of the criminal law.

(b) Settlement.

(i) The Company shall have no obligation to indemnify Indemnitee under this Agreement for any amounts paid in settlement of any Proceeding Indemnitee effected without the Company's prior written consent, which consent shall not be unreasonably withheld.

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(ii) The Company shall not, without the prior written consent of Indemnitee (which consent shall not be unreasonably withheld), consent to the entry of any judgment against Indemnitee or enter into any settlement or compromise which (A) includes an admission of fault of Indemnitee, any non-monetary remedy affecting Indemnitee or any monetary obligation for which Indemnitee is not indemnified hereunder or (B) with respect to any Proceeding with respect to which Indemnitee is likely to be or is made a party, witness or participant or is otherwise entitled to seek indemnification hereunder, does not include, as an unconditional term thereof, the full release of Indemnitee from all liability in respect of such Proceeding, which release shall be in form and substance reasonably satisfactory to Indemnitee.

Section 4. Indemnification for Expenses of a Party Who is Wholly or Partly Successful. Notwithstanding any other provisions of this Agreement (other than Section 6(a) or (c) of this Agreement), to the fullest extent permitted by applicable law and to the extent that Indemnitee is a party to (or a participant in) and is successful, on the merits or otherwise, in any Proceeding or in defense of any claim, issue or matter therein, in whole or in part, the Company shall

indemnify Indemnitee against all Expenses actually and reasonably incurred by Indemnitee in connection therewith. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company shall, subject to Section 6(a) and (c) of this Agreement, indemnify Indemnitee against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with each successfully resolved claim, issue or matter. If Indemnitee is not wholly successful in such Proceeding, the Company also shall, subject to Section 6(a) and (c) of this Agreement, indemnify Indemnitee against all Expenses reasonably incurred in connection with a claim, issue or matter related to any claim, issue, or matter on which the Indemnitee was successful. For purposes of this Section 4 and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

Section 5. Indemnification For Expenses of a Witness. Notwithstanding any other provision of this Agreement (other than Section 6(a) and (c) of this Agreement), to the fullest extent permitted by applicable law and to the extent that Indemnitee is, by reason of Indemnitee's Corporate Status, a witness in any Proceeding to which Indemnitee is not a party, Indemnitee shall be indemnified against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection therewith.

Section 6. Exclusions. Notwithstanding any provision in this Agreement, the Company shall not be obligated under this Agreement to make any indemnity in connection with any claim made against Indemnitee:

(a) for which payment has actually been made to or on behalf of Indemnitee under any insurance policy or other indemnity provision, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision[, provided, that the foregoing shall not affect the rights of Indemnitee or the Fund Indemnitors set forth in Section 12(f) below];

(b) (i) for an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Company within the meaning of Section 16(b)

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of the Securities Exchange Act of 1934, as amended, or similar provisions of state statutory law or common law, or (ii) for any reimbursement of the Company by Indemnitee of any bonus or other incentive-based or equity-based compensation or of any profits realized by Indemnitee from the sale of securities of the Company, as required in each case under the Securities Exchange Act of 1934, as amended (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 or Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the payment to the Company of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act of 2002); or

(c) in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee prior to a Change of Control against the Company or its directors, officers, employees or other indemnitees, unless (i) the Board of Directors of the Company authorized the Proceeding (or any part of any Proceeding) prior to its initiation or (ii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law.

Section 7. Advances of Expenses.

(a) Notwithstanding any provision of this Agreement to the contrary but subject to Section 7(c) of this Agreement, the Company shall advance, to the fullest extent permitted by applicable law, the Expenses reasonably incurred by Indemnitee in connection with any Proceeding, and such advancement shall be made within 30 days after the receipt by the Company of a statement or statements requesting such advances (supported by statements in reasonable detail of Expenses incurred or to be incurred within the next 30 days) from time to time, whether prior to or after final disposition of any Proceeding. Advances shall be unsecured and interest free. Advances shall be made without regard to Indemnitee's ability to repay the Expenses and without regard to Indemnitee's ultimate entitlement to indemnification under the other provisions of this Agreement. Advances shall include any and all reasonable Expenses incurred pursuing an action to enforce this right of advancement, including Expenses incurred preparing and forwarding statements to the Company to support the advances claimed. The Indemnitee shall qualify for advances upon the execution and delivery to the Company of this Agreement which shall constitute an undertaking that the Indemnitee will repay the advance to the extent that it is ultimately determined that Indemnitee is not entitled to be indemnified by the Company.

(b) In the event the Company is obligated under this Section 7 hereof to pay, and pays the Expenses of any Proceeding against Indemnitee, the Company, if appropriate, shall be entitled to assume the defense of such Proceeding, with counsel approved by Indemnitee, which approval shall not be unreasonably withheld, upon the delivery to Indemnitee of written notice of the Company's election so to do. After delivery of such notice, approval of such counsel by Indemnitee and the retention of such counsel by the Company, the Company will not be liable to Indemnitee under this Agreement for any fees of counsel subsequently incurred by Indemnitee with respect to the same Proceeding, provided that (i) Indemnitee shall have the right to employ Indemnitee's counsel in any such Proceeding at Indemnitee's expense; and (ii) if (A) the employment of counsel by Indemnitee has been previously authorized by the Company, (B)

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Indemnitee shall have reasonably concluded that there may be a conflict of interest between the Company and Indemnitee in the conduct of any such defense or (C) the Company shall not, in fact, have employed counsel approved by Indemnitee to assume the defense of such Proceeding, then the fees and expenses of Indemnitee's counsel shall be at the expense of the Company.

(c) This Section 7 shall not apply to any claim made by Indemnitee for which indemnity is excluded pursuant to Section 6(a) or (c) of this Agreement.

Section 8. Procedure for Notification and Defense of Claim. To obtain indemnification under this Agreement, Indemnitee shall submit to the Company a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification following the final disposition of such action, suit or proceeding. The omission to notify the Company will not relieve the Company from any liability which it may have to Indemnitee otherwise than under this Agreement. The Secretary of the Company shall, promptly upon receipt of such a request for indemnification, advise the Board in writing that Indemnitee has requested indemnification.



Section 9. Procedure Upon Application for Indemnification.

(a) Upon written request by Indemnitee for indemnification pursuant to the first sentence of Section 8, a determination, if required by applicable law, with respect to Indemnitee's entitlement thereto shall be made in the specific case in accordance with the determination process set forth in Section 13.1-701B of the Virginia Act. Indemnitee shall cooperate with the person, persons or entity making such determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to such determination. Any costs or expenses (including reasonable attorneys' fees and disbursements) incurred by Indemnitee in so cooperating with the person, persons or entity making such determination shall be borne by the Company (irrespective of the determination as to Indemnitee's entitlement to indemnification) and the Company hereby indemnifies and agrees to hold Indemnitee harmless therefrom.

(b) In the event the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 9(a) hereof, the Independent Counsel shall be selected as provided in this Section 9(b). If a Change in Control shall not have occurred, the Independent Counsel shall be selected by the Board of Directors, and the Company shall give written notice to Indemnitee advising Indemnitee of the identity of the Independent Counsel so selected. If a Change in Control shall have occurred, the Independent Counsel shall be selected by Indemnitee (unless Indemnitee shall request that such selection be made by the Board of Directors, in which event the preceding sentence shall apply), and Indemnitee shall give written notice to the Company advising it of the identity of the Independent Counsel so selected. In either event, Indemnitee or the Company, as the case may be, may, within 10 days after such written notice of selection shall have been given, deliver to the Company or to Indemnitee, as the case may be, a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the

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requirements of "Independent Counsel" as defined in Section 2 of this Agreement, and the objection shall set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If such written objection is so made and substantiated, the Independent Counsel so selected may not serve as Independent Counsel unless and until such objection is withdrawn or a court has determined that such objection is without merit. If, within twenty (20) days after the later of submission by Indemnitee of a written request for indemnification pursuant to Section 8 hereof and the final disposition of the Proceeding, no Independent Counsel shall have been selected and not objected to, either the Company or Indemnitee may petition the Virginia Court (as defined in Section 20 of this Agreement) for resolution of any objection which shall have been made by the Company or Indemnitee to the other's selection of Independent Counsel and/or for the appointment as Independent Counsel of a person selected by the Court or by such other person as the Court shall designate, and the person with respect to whom all objections are so resolved or the person so appointed shall act as Independent Counsel under Section 9(a) hereof. Upon the due commencement of any judicial proceeding or arbitration pursuant to Section 11(a) of this Agreement, Independent Counsel shall be discharged and relieved of any further responsibility in such capacity (subject to the applicable standards of professional conduct then prevailing).

Section 10. Presumptions and Effect of Certain Proceedings.

(a) In making a determination with respect to entitlement to indemnification hereunder, the person or persons or entity making such determination shall presume that Indemnitee is entitled to indemnification under this Agreement if Indemnitee has submitted a request for indemnification in accordance with Section 8 of this Agreement, and the Company shall have the burden of proof to overcome that presumption in connection with the making by any person, persons or entity of any determination contrary to that presumption. Neither the failure of the Company (including by its directors or Independent Counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company (including by its directors or Independent Counsel) that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(b) Subject to Section 11(e), if the person, persons or entity empowered or selected under Section 9 of this Agreement to determine whether Indemnitee is entitled to indemnification shall not have made a determination within sixty (60) days after receipt by the Company of the request therefor, the requisite determination of entitlement to indemnification shall be deemed to have been made and Indemnitee shall be entitled to such indemnification, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law; provided, however, that such 60-day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if the person, persons or entity making the determination with respect to entitlement to indemnification in good faith requires such additional time for the obtaining or evaluating of documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this Section 10(b) shall not apply if the determination of

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entitlement to indemnification is to be made by Independent Counsel pursuant to Section 9(a) of this Agreement.

(c) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of nolo contendere or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee was guilty of willful misconduct or a knowing violation of criminal law unless a court in such Proceeding made a specific determination that Indemnitee engaged in willful misconduct or a knowing violation of criminal law.

(d) Actions of Others. The knowledge and/or actions, or failure to act, of any director, officer, agent or employee of the Enterprise shall not be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement.

Section 11. Remedies of Indemnitee.

(a) Subject to Section 11(e), in the event that (i) a determination is made pursuant to Section 9 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 7 of this Agreement, (iii) no determination of entitlement to indemnification shall have been made pursuant to Section 9(a) of this Agreement within 90 days after receipt by the Company of the request for indemnification, (iv) payment of indemnification is not made pursuant to Section 4 or 5 or the last sentence of Section 9(a) of this Agreement within ten (10) days after receipt by the Company of a written request therefor, or (v) payment of indemnification pursuant to Section 3 of this Agreement is not made within ten (10) days after a determination has been made that Indemnitee is entitled to indemnification, Indemnitee shall be entitled to an adjudication by a court of Indemnitee's entitlement to such indemnification or advancement of Expenses. Alternatively, Indemnitee, at Indemnitee's option, may seek an award in arbitration

to be conducted by a single arbitrator pursuant to the Commercial Arbitration Rules of the American Arbitration Association. Indemnitee shall commence such proceeding seeking an adjudication or an award in arbitration within one hundred eighty (180) days following the date on which Indemnitee first has the right to commence such proceeding pursuant to this Section 11(a); provided, however, that the foregoing clause shall not apply in respect of a proceeding brought by Indemnitee to enforce Indemnitee's rights under Section 4 of this Agreement. The Company shall not oppose Indemnitee's right to seek any such adjudication or award in arbitration.

(b) In the event that a determination shall have been made pursuant to Section 9(a) of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding or arbitration commenced pursuant to this Section 11 shall be conducted in all respects as a de novo trial, or arbitration, on the merits and Indemnitee shall not be prejudiced by reason of that adverse determination. In any judicial proceeding or arbitration commenced pursuant to this Section 11 the Company shall have the burden of proving Indemnitee is not entitled to indemnification or advancement of Expenses, as the case may be.

(c) If a determination shall have been made pursuant to Section 9(a) of this Agreement that Indemnitee is entitled to indemnification, the Company shall be bound by such

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determination in any judicial proceeding or arbitration commenced pursuant to this Section 11, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law.

(d) The Company shall be precluded from asserting in any judicial proceeding or arbitration commenced pursuant to this Section 11 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court or before any such arbitrator that the Company is bound by all the provisions of this Agreement. The Company shall indemnify Indemnitee against any and all Expenses and, if requested by Indemnitee, shall (within ten (10) days after receipt by the Company of a written request therefor) advance, to the extent not prohibited by law, such expenses to Indemnitee, which are incurred by Indemnitee in connection with any action brought by Indemnitee for indemnification or advance of Expenses from the Company under this Agreement or under any directors' and officers' liability insurance policies maintained by the Company, regardless of whether Indemnitee ultimately is determined to be entitled to such indemnification, advancement of Expenses or insurance recovery, as the case may be.

(e) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement to indemnification under this Agreement shall be required to be made prior to the final disposition of the Proceeding.

Section 12. Non-exclusivity; Survival of Rights; Insurance; Subrogation.

(a) The rights of indemnification and to receive advancement of Expenses as provided by this Agreement shall not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Company's Articles of Incorporation, the Company's Bylaws, any agreement, a vote of shareholders, a resolution of directors, any liability policy or otherwise. No amendment, alteration or repeal of this Agreement or of any provision hereof shall limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by such Indemnitee in Indemnitee's Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in Virginia law, whether by statute or judicial decision, permits greater indemnification or advancement of Expenses than would be afforded currently under the Company's Articles of Incorporation and this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, employees or agents of the Company or of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise which such person serves at the request of the Company, Indemnitee shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage

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available for any such director, officer, employee or agent under such policy or policies. If, at the time of the receipt of a notice of a claim eligible for indemnification pursuant to the terms hereof, the Company has director and officer liability insurance in effect, the Company shall give prompt notice of the commencement of such proceeding to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such proceeding in accordance with the terms of such policies.

(c) In the event of any payment under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee, who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights.

(d) The Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable hereunder (or for which advancement is provided hereunder) if and to the extent that Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement or otherwise.

(e) The Company's obligation to indemnify or advance Expenses hereunder to Indemnitee with respect to service at the request of the Company as a director, officer, employee or agent of any other corporation, limited liability company, partnership, joint venture, trust, employee benefit plan or other enterprise shall be reduced by any amount Indemnitee has actually received as indemnification or advancement of expenses from such other corporation, limited liability company, partnership, joint venture, trust, employee benefit plan or other enterprise with respect to such service.

(f) [The Company hereby acknowledges that Indemnitee has certain rights to indemnification, advancement of expenses and/or insurance provided by [ ] and certain of its affiliates (collectively, the "Fund Indemnitors"). The Company hereby agrees (i) that it is the indemnitor of first resort (i.e., its obligations to Indemnitee are primary and any obligation of the Fund Indemnitors to advance expenses or to provide indemnification for the same expenses or liabilities incurred by Indemnitee are secondary), (ii) that it shall be required to advance the full amount of expenses incurred by Indemnitee and shall be liable for the full amount of all Expenses, judgments, penalties, fines and amounts paid in settlement to the extent legally permitted and as required by the terms of this Agreement and the Articles of Incorporation or Bylaws of the Company (or any other agreement between the Company and Indemnitee), without

regard to any rights Indemnitee may have against the Fund Indemnitors, and (iii) that it irrevocably waives, relinquishes and releases the Fund Indemnitors from any and all claims against the Fund Indemnitors for contribution, subrogation or any other recovery of any kind in respect thereof. The Company further agrees that no advancement or payment by the Fund Indemnitors on behalf of Indemnitee with respect to any claim for which Indemnitee has sought indemnification from the Company shall affect the foregoing and the Fund Indemnitors shall have a right of contribution and/or be subrogated to the extent of such advancement or payment to all of the rights of recovery of Indemnitee against the Company. The Company and Indemnitee agree that the Fund Indemnitors are express third party beneficiaries of the terms of this Section 12(f).]

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Section 13. Duration of Agreement. This Agreement shall continue until and terminate upon the date that is ten (10) years after the later of the date that Indemnitee shall have ceased to serve as a director of the Company and, if applicable, the date that Indemnitee shall have ceased to serve as an officer of the Company. This Agreement shall be binding upon the Company and its successors and assigns and shall inure to the benefit of Indemnitee and Indemnitee's heirs, estate, personal representatives, executors and administrators.

Section 14. Severability. If any provision or provisions of this Agreement shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (a) the validity, legality and enforceability of the remaining provisions of this Agreement (including, without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and shall remain enforceable to the fullest extent permitted by law; (b) such provision or provisions shall be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (c) to the fullest extent possible, the provisions of this Agreement (including, without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested thereby.

Section 15. Enforcement.

(a) The Company expressly confirms and agrees that it has entered into this Agreement and assumed the obligations imposed on it hereby in order to induce Indemnitee to continue to serve as a director and/or officer of the Company and/or to confirm to Indemnitee that after Indemnitee ceases to be a director and/or officer Indemnitee will continue to be entitled to indemnification and advancement of expenses by the Company, and the Company acknowledges that Indemnitee is relying upon this Agreement in continuing to serve as a director and/or officer of the Company and has provided other good and valuable consideration in connection with this Agreement, the sufficiency and receipt of which are hereby acknowledged.

(b) This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof; provided, however, that this Agreement is a supplement to and in furtherance of, the Articles of Incorporation of the Company, the Bylaws of the Company and applicable law, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder.

Section 16. Modification and Waiver. No supplement, modification or amendment of this Agreement shall be binding unless executed in writing by the parties thereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions of this Agreement nor shall any waiver constitute a continuing waiver.

Section 17. Notice by Indemnitee. Indemnitee agrees promptly to notify the Company in writing upon being served with any summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding or matter that may be subject to

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indemnification or advancement of Expenses covered hereunder. The failure of Indemnitee to so notify the Company shall not relieve the Company of any obligation that it may have to the Indemnitee under this Agreement or otherwise; provided, however, that a delay in giving such notice shall not deprive Indemnitee of any right to be indemnified under this Agreement unless, and then only to the extent that, such delay is materially prejudicial to the defense of such claim.

Section 18. Notices. All notices, requests, demands and other communications under this Agreement shall be in writing and shall be deemed to have been duly given if (a) delivered by hand and receipted for by the party to whom said notice or other communication shall have been directed, (b) mailed by certified or registered mail with postage prepaid, on the third business day after the date on which it is so mailed, (c) mailed by reputable overnight courier and receipted for by the party to whom said notice or other communication shall have been directed or (d) sent by facsimile transmission, with receipt of oral confirmation that such transmission has been received:

(i) if to Indemnitee, at the address indicated on the signature page of this Agreement, or such other address as Indemnitee shall provide to the Company; and

(ii) if to the Company to the Secretary, at 780 Dedham Street, Suite 800, Canton, MA 02021.

or to any other address as may have been furnished to Indemnitee by the Company or vice versa.

Section 19. Contribution. To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amount incurred by Indemnitee, whether for judgments, fines, penalties, excise taxes, amounts paid or to be paid in settlement and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by the Company and Indemnitee as a result of the event(s) and/or transaction(s) giving cause to such Proceeding; and/or (ii) the relative fault of the Company (and its directors, officers, employees and agents) and Indemnitee in connection with such event(s) and/or transaction(s).

Section 20. Applicable Law and Consent to Jurisdiction. This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the Commonwealth of Virginia, without regard to its conflict of laws rules. Except with respect to any arbitration commenced by Indemnitee pursuant to Section 11(a) of this Agreement, the Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Circuit Court for Henrico County, Commonwealth of Virginia (the "Virginia Court"), and not in any other state or federal court in the United States of America or any court in any other country, (ii) consent to submit

to the exclusive jurisdiction of the Virginia Court for purposes of any action or proceeding arising out of or in connection with this Agreement, (iii) waive any objection to the laying of venue of any such action or proceeding in the Virginia Court, and (iv) waive, and agree not to plead or to make, any claim that any such action or

proceeding brought in the Virginia Court has been brought in an improper or inconvenient forum.

Section 21. Identical Counterparts. This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. Only one such counterpart signed by the party against whom enforceability is sought needs to be produced to evidence the existence of this Agreement.

Section 22. Miscellaneous. The headings of the paragraphs of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have caused this Agreement to be signed as of the day and year first above written.

COLLEGIUM PHARMACEUTICAL, INC.

INDEMNITEE

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

Name: \_\_\_\_\_  
Address: \_\_\_\_\_

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**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We have issued our report dated April 27, 2015, with respect to the financial statements of Collegium Pharmaceutical, Inc. contained in the Registration Statement and Prospectus. We consent to the use of the aforementioned report in the Registration Statement and Prospectus, and to the use of our name as it appears under the caption "Experts."

/s/ GRANT THORNTON LLP

Boston, Massachusetts  
April 27, 2015

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