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As filed with the Securities and Exchange Commission on January 4, 2016.

Registration No. 333-208641

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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

Title of Securities Being Registered	Proposed Maximum Aggregate Offering Price <sup>(1)</sup>	Amount of Registration Fee <sup>(2)</sup>
Common Stock, \$0.001 par value per share	\$86,250,000	\$8,686

(1) Estimated solely for purposes of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes shares subject to the underwriters' option to purchase additional shares.

(2) This fee 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 JANUARY 4, 2016

PRELIMINARY PROSPECTUS

Shares



Collegium Pharmaceutical, Inc.

Common Stock

We are offering \_\_\_\_\_ shares of our common stock. The offering price is \$ \_\_\_\_\_ per share of common stock. Our common stock is listed on The NASDAQ Global Select Market ("NASDAQ") under the symbol "COLL." The last reported sales price of our common stock on December 31, 2015 was \$27.50 per share.

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 are 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>
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 173 of this prospectus for additional information regarding total underwriter compensation.

Delivery of the shares of common stock is expected to be made on or about \_\_\_\_\_, 2016. We have granted the underwriters an option for a period of 30 days to purchase an additional \_\_\_\_\_ 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**

**William Blair**

**Piper Jaffray**

**Needham & Company**

**Janney Montgomery Scott**

Prospectus dated \_\_\_\_\_, 2016

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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.

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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. On November 6, 2015, the U.S. Food and Drug Administration, or FDA, granted tentative approval to the new drug application, or NDA, for Xtampza for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The FDA granted tentative approval because Xtampza met the required quality, safety and efficacy standards for approval but remains subject to an automatic stay of up to 30 months as a result of patent litigation filed by Purdue Pharma, L.P., or Purdue, in March 2015. The FDA may grant final regulatory approval upon the earliest to occur of expiration of the automatic stay, the court invalidating Purdue's patents or issuing an opinion of non-infringement, and expiration of Purdue's listed patents.

In connection with the FDA's tentative approval of our NDA for Xtampza, the FDA tentatively approved a product label, product packaging, post-marketing commitments and a Risk Evaluation and Mitigation Strategy, or REMS, program, subject to change should new information become available prior to the time that the FDA considers the Xtampza NDA for final regulatory approval. The tentatively approved Xtampza label, in contrast to the product labels for all currently approved extended-release opioids, does not include a black box warning and related precautions stating that crushing, chewing or dissolving can cause rapid release and absorption of a potentially fatal dose of the active ingredient. The absence of these warnings is supported by data that is described in the tentatively approved product label to support the claim that when Xtampza is crushed or chewed, the drug release profile is bioequivalent to taking Xtampza intact, as directed. Furthermore, the tentatively approved product label contains differentiated abuse-deterrent claims for Xtampza and also states that Xtampza can be taken by sprinkling the capsule contents on soft foods or into a cup, and then directly into the mouth, or through a gastrostomy or nasogastric feeding tube.

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 product 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 it ultimately receives final regulatory approval, 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 2013.

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, and our tentatively approved product label states, that the contents of the Xtampza capsules can be taken by sprinkling the capsule contents on soft foods or into a cup, and then directly into the mouth, or through a gastrostomy or nasogastric feeding tube, without compromising their extended-release properties. By contrast, all other FDA-approved, orally administered, extended-release opioids have a black box warning product label stating that "crushing, dissolving or chewing can cause rapid release and absorption of a potentially fatal dose of the active drug", making them unsuitable or unattractive for patients who suffer from chronic pain with dysphagia, or CPD. If Xtampza ultimately receives final regulatory approval, Xtampza could be the only abuse-deterrent extended-release opioid product with product labeling without such a black box warning. An external marketing study performed for us in 2013 estimated that Xtampza, if it receives final regulatory approval, has a peak revenue potential for U.S. patients with CPD in excess of \$700 million annually.

**Xtampza**

Our lead product candidate, Xtampza, is an abuse-deterrent, extended-release, oral formulation of oxycodone tentatively approved by the FDA 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 regulatory approval process for abuse-deterrent 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 inform the development of improved abuse-deterrent products. We believe that all of our studies and clinical trials are consistent with the final FDA guidance. The Xtampza product label, if finally approved, could be the first abuse-deterrent opioid to include all three pre-marketing product label claim categories based upon in vitro, pharmacokinetic, or PK, and human abuse potential studies.



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 PK of Xtampza. Our tentatively approved product label includes the PK data from this human abuse potential clinical trial and also includes data showing that chewed and intact Xtampza was associated with lower drug liking than crushed immediate-release oxycodone.
- § *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. Our tentatively approved product label includes the PK data from this human abuse potential clinical trial and also includes data showing that crushed and snorted Xtampza was associated with lower drug liking than both intact Xtampza administered orally and snorted immediate-release oxycodone.
- § *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. Our tentatively approved product label states that Xtampza can be taken by sprinkling the capsule contents on soft foods or into a cup, and then directly into the mouth, or through a gastrostomy or nasogastric feeding tube.

## 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 seven issued patents in the United States, two pending applications in the European Union and one issued patent in each of Canada, Japan and Australia. We also have a Notice of Allowance for a patent in the United States and Canada. In addition, we have six patent applications pending in the United States, and one pending patent application in Japan. Our issued U.S. patents are projected to expire in 2023 and 2025, and our pending patent applications in the United States, if issued, would be projected to expire in 2023, 2025 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 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 regulatory 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 regulatory 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 July 23, 2015, Purdue voluntarily dismissed the Massachusetts case and on August 6, 2015, Purdue filed another case in Massachusetts asserting the same four patents as in the Delaware case and the original Massachusetts case. On October 7, 2015, the Delaware case was transferred to Massachusetts and on November 4, 2015, the two cases pending in Massachusetts were consolidated. On November 9, 2015, we filed a motion for partial judgment on the pleadings in relation to three of the four patents asserted against us, which had been previously invalidated by the court in the Southern District of New York in Purdue's suit against Teva Pharmaceuticals USA, Inc., or Teva. On the same date, we moved for entry of final judgment and to expedite hearing on our motions. On November 23, 2015, Purdue filed a motion to stay proceedings until resolution of its appeal against Teva. The hearing regarding our motion for partial judgment and entry of judgment and Purdue's motion to stay was held on December 22, 2015. On December 23, 2015, the District Court of Massachusetts issued an order staying proceedings in relation to the three Orange Book-listed patents asserted against us until February 25, 2016, which is the date scheduled by the Court for a status conference. The Court reserved the decision to grant our motion for judgment on the three Orange Book-listed patents to be taken up again at the February 25th status conference, at which time the Court indicated it may grant our motion for judgment or may consider extending the stay. The Court further indicated that it will consider an earlier hearing if the Court of Appeals for the Federal Circuit issues a decision on the appeal of the New York judgment of invalidity prior to the February 25th status conference.

On November 6, 2015, Purdue filed another patent infringement suit against us in Massachusetts asserting infringement of another patent that is a continuation of the three patents previously asserted by Purdue against us that were invalidated by the court in the Southern District of New York. On December 1, 2015, we filed a motion to dismiss for failure to state a claim, arguing that the patent asserted by Purdue is invalid based on collateral estoppel. Purdue filed its opposition response on December 15, 2015. That action has been consolidated into the other Massachusetts actions, and our motion remains pending.

The FDA's tentative approval of Xtampza means that the product, with its product labeling, is tentatively approved based upon the information available to the FDA at the time of tentative approval. The FDA can grant final approval following the expiration of the 30-month stay 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 stay period expires, the FDA could then provide final regulatory 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 recently completed formulation development work for our extended-release, abuse-deterrent hydrocodone program. Based upon an assessment of the market opportunity and the potential to differentiate from currently marketed hydrocodone products as well as programs in development, we are prioritizing our abuse-deterrent hydrocodone program as our second product in development. We filed an IND with the FDA in December 2015 and target initiating a clinical trial in the first quarter of 2016. We also have an extended-release, abuse-deterrent oxymorphone program for the treatment of chronic pain for

which we have filed an investigational new drug application, or IND. This program has been granted Fast Track status by the FDA. In addition, we have other extended-release, abuse-deterrent product candidates that have completed preliminary preclinical studies, including morphine for pain and methylphenidate for the treatment of attention deficit hyperactivity disorder, or ADHD. All of these product candidates share similar abuse-deterrent qualities as Xtampza and are designed to be suitable for patients with difficulty swallowing. We own all of the rights to our product candidates.

Product	Active	Preclinical	IND	Clinical Development	NDA
Xtampza ER	Oxycodone				
COL-195	Hydrocodone				Initiate clinical trial Q1 2016
COL-172	Oxymorphone				
COL-196	Morphine				
COL-171	Methylphenidate				

### 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 final regulatory approval to market Xtampza with a best-in-class abuse-deterrent product label.* Our tentatively approved product label contains differentiated abuse-deterrent claims for Xtampza. If Xtampza receives final regulatory approval, this product label may allow us to detail Xtampza to physicians and highlight its unique abuse-deterrent characteristics.
- § *Commercialize Xtampza in the United States ourselves.* We are currently building our commercial organization, including our sales force and commercial manufacturing capacity, in preparation for a potential U.S. commercial launch of Xtampza in the second quarter of 2016, although the timing of a potential commercial launch is subject to whether and when we receive final regulatory approval for Xtampza. Our management team has extensive experience commercializing pharmaceutical products, and we are in the process of establishing sales, marketing and reimbursement functions to commercialize Xtampza in the United States. Initially, we plan to detail Xtampza to approximately 11,000 physicians who write approximately 55% of the branded extended-release oral opioid prescriptions in the United States with a sales team of approximately 120 sales representatives. In addition, we plan to deploy a separate, focused sales team of approximately 25 specialty sales representatives to detail Xtampza to nursing homes, hospices, and other institutions treating large populations of the elderly and other patients who need chronic pain relief and have difficulty swallowing.
- § *Establish Xtampza as the treatment of choice for patients with CPD.* Xtampza has been tentatively approved with product labeling for sprinkling Xtampza microspheres on soft foods or into a cup, and then directly into the mouth, or through a gastrostomy or nasogastric feeding tube. If Xtampza receives final regulatory approval, Xtampza could be the only extended-release oxycodone product designed to be suitable for this approximately 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 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. We also have an IND application on file for COL-172, an abuse-deterrent, extended-release oxymorphone for the treatment of chronic pain, which has been granted Fast Track status by the FDA. In addition, we have COL-171, a proprietary preclinical DETERx extended-release, abuse-deterrent methylphenidate formulation for the treatment of ADHD.
- § *Acquire additional products and product candidates.* We may identify and license, co-promote or acquire products or product candidates being developed for pain indications and other complementary products.

### **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 final regulatory approval for Xtampza or any of our other product candidates from the FDA or foreign regulatory authorities. Despite receiving tentative approval by the FDA, additional data may emerge that could change the FDA's position on the product labeling or final regulatory approval of Xtampza;
- § 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 final regulatory approval for, and potentially begin to commercialize, Xtampza;
- § we currently do not employ sales representatives and, if we are unable to hire employees to provide the appropriate level of sales support, we may not be successful in commercializing Xtampza if we receive final regulatory approval; 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, or 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) December 31, 2020.

## THE OFFERING

Common stock offered by us	shares ( shares if the underwriters' option to purchase additional shares is exercised in full).
Common stock to be outstanding after this offering	shares ( 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 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 \$ million, based on \$ per share, the last reported sales price of our common stock on , 2016. We intend to use the net proceeds from this offering as follows:</p> <ul style="list-style-type: none"><li>§ approximately \$45.7 million for the continued development of our commercial infrastructure, including building our sales, manufacturing, marketing and reimbursement functions and funding the commercial launch of Xtampza, subject to final regulatory approval;</li><li>§ approximately \$4.6 million to fund research and development efforts of our other product candidates, including clinical development for our hydrocodone program (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>
Market for the common stock	Our common stock is listed 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 20,687,829 shares of common stock outstanding as of September 30, 2015, assumes the issuance by us of \_\_\_\_\_ shares of our common stock in this offering and excludes:

- § 1,356,246 shares of common stock issuable upon the exercise of outstanding stock options as September 30, 2015, at a weighted-average exercise price of \$9.04 per share;
- § 2,445 shares of common stock issuable upon the exercise of warrants to purchase common stock as of September 30, 2015, at a weighted-average exercise price of \$12.27 per share;
- § 1,337,584 shares of common stock reserved for future issuance under our Amended and Restated 2014 Stock Incentive Plan as of September 30, 2015; and
- § 200,000 shares reserved for future issuance under our 2015 Employee Stock Purchase Plan as of September 30, 2015.

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

- § no exercise by the underwriters of the option to purchase up to an additional \_\_\_\_\_ shares of our common stock; and
- § our existing shareholders will not purchase any shares of our common stock in this offering.



## SUMMARY FINANCIAL DATA

The following table presents our summary financial data. The following summary of our statement of operations data for the years ended December 31, 2013 and 2014 are derived from our audited financial statements appearing elsewhere in this prospectus. We have derived the summary of our statement of operations data for the nine months ended September 30, 2014 and 2015 and the balance sheet data as of September 30, 2015 from our unaudited 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,		Nine Months Ended September 30,	
	2013	2014	2014	2015
	(in thousands, except share and per share amounts)			
<b>Statement of Operations Data:</b>				
Operating expenses:				
Research and development	\$ 14,157	\$ 14,959	\$ 12,652	\$ 6,444
General and administrative	1,885	2,706	1,686	11,027
Total operating expense	16,042	17,665	14,338	17,471
Loss from operations	(16,042)	(17,665)	(14,338)	(17,471)
Interest expense, net	76	252	110	350
Other expense, net	79	—	—	(91)
Net loss	\$ (16,197)	\$ (17,917)	\$ (14,448)	\$ (17,730)
Basic and diluted net loss per common share <sup>(1)</sup> :	\$ (4.06)	\$ (22.72)	\$ (18.26)	\$ (0.94)
Weighted-average shares used to compute earnings (loss) per common share <sup>(1)</sup> :	1,697,044	933,997	926,597	11,179,756

- (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.

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	As of September 30, 2015	
	Actual	As Adjusted <sup>(2)</sup>
	(in thousands)	
<b>Balance Sheet Data:</b>		
Cash and cash equivalents	\$	105,460
Working capital <sup>(1)</sup>		97,726
Total assets		107,050
Other long-term liabilities		4,889
Total shareholders' equity (deficit)		93,561

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

(2) The as adjusted balance sheet data give effect to our issuance and the sale of \_\_\_\_\_ shares of our common stock in this offering at an assumed offering price of \$ \_\_\_\_\_ per share, which is the last reported sale price of our common stock on NASDAQ on \_\_\_\_\_, 2016, after deducting the estimated underwriting discounts and commissions 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. You should understand that it is not possible to predict or identify all such risks. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties.*

### **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 the FDA has not granted final regulatory approval to any of our product candidates, including our tentatively approved product, Xtampza, 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 and for the nine months ended September 30, 2015, we reported a net loss of \$17.9 million and \$17.7 million, respectively, and we had an accumulated deficit of \$119.5 million at September 30, 2015.

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 we receive final regulatory approval for Xtampza. 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 final regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses and expected future losses have had and will continue to have an adverse effect on our shareholders' equity and working capital.

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

As we currently have no products approved for marketing, 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 our tentatively approved product, 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 final regulatory approval for, and successfully commercialize, Xtampza;

- § successfully satisfy post-marketing requirements that the FDA will impose if Xtampza receives final regulatory approval, including studies and clinical trials that have been required for other extended-release/long acting opioid analgesics and individual studies and clinical trials of Xtampza;
- § successfully complete development activities, including the necessary clinical trials, with respect to 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 building our own commercial organization. We believe that our existing cash and cash equivalents, including the net proceeds from this offering, will be sufficient to fund our operations into 2018, including the commercialization of Xtampza, if Xtampza receives final regulatory approval, and the continuation of our development of our other product candidates. However, we may require additional capital for the further development and commercialization of our product candidates and may also need to raise additional funds sooner in order to 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 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 product labels for our product candidates;
- § our ability to successfully satisfy post-marketing requirements that the FDA will impose if Xtampza receives final regulatory approval, including studies and clinical trials that have been required for other extended-release/long-acting opioid analgesics and individual studies and clinical trials of Xtampza;
- § clinical development plans for our product candidates;
- § the FDA's final regulatory approval of inclusion of claims in the product label for Xtampza that will permit the sprinkling of 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 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 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 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. Although the FDA has given Xtampza a tentative approval, we have not yet obtained final 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 experience ownership changes in the future as a result of shifts in our stock ownership some of which are outside our control. We have not performed any current analyses under Section 382 and cannot forecast or otherwise rely on deriving benefit from our various federal or state tax attribute carryforwards. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

**Risks Related to 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 final 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, which has been tentatively approved by the FDA. Our business and future success are substantially dependent on our ability to successfully and timely obtain final 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.

On November 6, 2015, the FDA granted tentative approval to the NDA for Xtampza for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The FDA granted tentative approval because Xtampza met the required quality, safety and efficacy standards for approval as of the date that the tentative approval was granted. Because of the ongoing patent litigation brought against us by Purdue in March 2015, final regulatory approval cannot be granted until after an automatic stay of up to 30 months expires, the court invalidates

Purdue's patents or issues an opinion of non-infringement, or Purdue's listed patents expire. In addition, the FDA must also be assured that there is no new information that would affect whether final regulatory approval should be granted.

Any delay or impediment in our ability to obtain final regulatory 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 receive final regulatory approval from the FDA, our ability to successfully commercialize Xtampza will depend on many factors, including but not limited to:

- § our ability to successfully satisfy post-marketing requirements that the FDA will impose, including studies and clinical trials that have been required for other extended-release/long-acting opioid analgesics and individual studies and clinical trials of Xtampza;
- § the ability to manufacture commercial quantities of Xtampza at reasonable cost and with sufficient speed to meet commercial demand;
- § our ability to build a sales and marketing organization to market Xtampza;
- § our success in educating physicians, patients and caregivers about the benefits, administration 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 commercialize or generate revenue from Xtampza, even if we receive final regulatory approval. If we cannot do so, or are significantly delayed in doing so, our business will be materially harmed.

**Despite receiving tentative approval by the FDA, additional data may emerge that could change the FDA's position on the product labeling or prevent final regulatory approval of Xtampza. If we fail to obtain final 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 or into a cup, and then directly into the mouth, or administered through feeding tubes, without compromising their extended-release properties. On November 6, 2015, the FDA granted tentative approval for the Xtampza NDA and provided us with a tentative product label. However, we have not yet received final regulatory approval to market Xtampza and the FDA could change its position on the product labeling or not issue final regulatory approval. If we receive final regulatory approval, but such approval does not permit us to include a claim in the product label for Xtampza regarding the ability to sprinkle the Xtampza microspheres directly in the mouth, on food or in feeding tubes, or the FDA requires us to have a black box warning product label stating that "crushing, dissolving or chewing can cause rapid release and absorption of a potentially fatal dose of the active drug," 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 our product candidates in development are sufficiently bioequivalent, or demonstrate comparable bioavailability to their respective listed drugs, or if the FDA otherwise does not conclude that our product candidates satisfy the requirements for the Section 505(b)(2) approval pathway, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and the FDA may not approve those product candidates.**

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

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

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

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

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

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

Purdue, as the sponsor for OxyContin OP, the listed drug for Xtampza, has filed two lawsuits in the District of Massachusetts. In the first case, Purdue has alleged infringement of U.S. Patent Nos. 7,674,799,



7,674,800, 7,683,072 and 8,652,497. In the second case, Purdue has alleged infringement of U.S. Patent No. 9,073,933, which is a continuation patent of three of the patents asserted in the first suit. On November 9, 2015, we filed a motion requesting partial judgment and a motion requesting expedited hearing of our motion for partial judgment and for final judgment in the Massachusetts court. Purdue filed its opposition response and a cross-motion for a partial stay on November 23, 2015 in the first case. Those motions are fully briefed and the hearing on those motions was held on December 22, 2015. On December 23, 2015, the District Court of Massachusetts issued an order staying proceedings in relation to the three Orange Book-listed patents asserted against us until February 25, 2016, which is the date scheduled by the Court for a status conference. The Court reserved the decision to grant our motion for judgment on the three Orange Book-listed patents to be taken up again at the February 25th status conference, at which time the Court indicated it may grant our motion for judgment or may consider extending the stay. The Court further indicated that it will consider an earlier hearing if the Court of Appeals for the Federal Circuit issues a decision on the appeal of the New York judgment of invalidity prior to the February 25th status conference. On December 1, 2015, we filed a motion to dismiss the second case for failure to state a claim and Purdue filed its opposition on December 15, 2015. That action has been consolidated into the other Massachusetts actions, and our motion remains pending. 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, final FDA approval of Xtampza, which has been tentatively approved by the FDA, 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 we receive final regulatory approval 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 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. Although the FDA has tentatively approved Xtampza, we have not obtained final regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any future product candidates that we may in-license, acquire or develop will ever obtain final regulatory approval from the FDA or any foreign regulatory authority. Moreover, even after any product candidate receives final regulatory approval, the FDA may require, as it will for Xtampza, costly post-marketing requirements. Successful and

timely satisfaction of these post-marketing requirements will be necessary for us to maintain any final regulatory approval that we may receive.

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

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

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

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

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

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

States, the commercial prospects of that product candidate may be significantly diminished and our business prospects could decline.

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

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

- § selecting and developing a drug delivery 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 that the drug is safe and effective in patients for the intended indication; and
- § completing the manufacturing development and scale-up to permit manufacture of our product candidates in commercial quantities and at acceptable prices.

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

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

**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 candidates.**

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 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 applies to more than 20 companies that manufacture opioid analgesics. Under the ER/LA opioid REMS, companies are required to make education programs available to prescribers based on the FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics. It is expected that companies will meet this obligation by providing educational grants to continuing education providers, who will develop and deliver the training. The ER/LA opioid REMS also requires companies to distribute FDA-approved educational materials to prescribers and patients on the safe use of these drugs.

The companies must perform periodic assessments of the implementation of the ER/LA opioid REMS and the success of the program in meeting its goals. The FDA will review these assessments and may require additional elements to achieve the goals of the program.

If the FDA determines that a REMS is necessary during review of an application, the drug sponsor must agree to the REMS plan at the time of approval. As part of its tentative approval of the Xtampza NDA, the FDA has indicated that, if Xtampza receives final regulatory approval, the REMS requirement for ER/LA opioids will apply to Xtampza. The REMS includes a Medication Guide that would be dispensed with each prescription, physician training based on FDA-identified learning objectives, audits to ensure that the FDA's learning objectives are addressed in the physician trainings, letters to prescribing physicians, professional organizations and state licensing entities alerting each to the REMS, and the establishment of a call center to provide more information about the REMS. We anticipate that our future product candidates will also be subject to these REMS requirements. There may be increased cost, administrative burden and potential liability associated with the marketing and sale of these types of product candidates subject to the ER/LA opioid REMS requirements, which could reduce the commercial benefits to us from the sale of these product candidates.

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

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

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

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

We 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 FDA has tentatively approved a product label for Xtampza with the following features:

- § no black box warning or other precautions stating that crushing, chewing or dissolving can cause rapid release and absorption of a potentially fatal dose of the active ingredient;
- § dosage instruction supporting administration of the product as a sprinkle or administration through gastric or nasogastric feeding tubes;
- § inclusion of oral and nasal PK data from clinical trials; and
- § inclusion of oral and nasal human abuse potential clinical trials.

However, we have not yet received final regulatory approval to market Xtampza and additional data may emerge that could change the FDA's position on the tentatively approved product label. 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.

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 in our tentatively approved product label, there can be no assurance that Xtampza, or any of our other product candidates, will receive final FDA-approved product labeling that describes the abuse-deterrent features of such products. Furthermore, the FDA's April 2015 final guidance on abuse deterrent opioids makes clear that the FDA expects sponsors to compare their formulations against approved abuse-deterrent versions of the same opioid based on the relevant categories of testing. If a proposed product is less resistant to manipulation than an approved product, the FDA has stated that the proposed product may not be eligible for product labeling regarding abuse-deterrent properties. If the FDA does not approve product labeling containing abuse-deterrence claims, we will not be able to promote such products based on their abuse-deterrent features, may not be able to differentiate such products from other opioid products containing the same active ingredients, and may need to lower the price of our products to the extent that there are competing products with abuse-deterrent claims on their product labels.

Because the FDA closely regulates promotional materials and other promotional activities, even if the FDA initially approves product labeling that includes a description of the abuse-deterrent characteristics of our product, the FDA may object to our marketing claims and product advertising campaigns. This could lead to the issuance of warning letters or untitled letters, suspension or withdrawal of our products from the market, recalls, fines, disgorgement of money, operating restrictions, injunctions, and civil or criminal prosecution. Any of these consequences would harm the commercial success of our products.

Even if 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 product labeling revisions are needed, and potentially require the removal of our abuse-deterrence claims.

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

Even after a product is approved, we will remain subject to ongoing FDA and other regulatory requirements governing the product labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, import, export, record-keeping and reporting of safety and other post-market information. 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 we receive final regulatory approval, 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 product labeling with abuse-deterrent claims; or
- § FDA required product withdrawals or warnings arising from identification of serious and unanticipated adverse side effects in our product candidates.

**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 product labeling claims or removal of certain warnings that we believe are necessary or desirable for the successful commercialization of our product candidates.

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

Any of these delays or additional requirements could cause our product candidates to not be approved, or if approved, significantly impact the timing 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 oxymorphone for pain, and methylphenidate for the treatment of ADHD, we do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety or otherwise provide adequate information to result in regulatory approval to market any of our product candidates in any particular jurisdiction. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates, 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 product label, or result in significant negative consequences following any marketing approval.**

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

If Xtampza or any of our other product candidates receives final regulatory 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 product label that could diminish the usage or otherwise limit the commercial success of the product;
- § we may be required to conduct additional post-marketing studies;
- § we could be sued and held liable for harm caused to patients; and
- § our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of Xtampza or any of our 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, 2015, Purdue, as the sponsor for OxyContin OP, the listed drug for Xtampza, brought infringement claims against us alleging infringement of U.S. Patent Nos. 7,674,799, 7,674,800, 7,683,072 and 8,652,497. That case is venued in the District of Massachusetts. On November 6, 2015, Purdue filed another suit in the District of Massachusetts alleging infringement of U.S. Patent No. 9,073,933, which is a continuation patent of three of the patents asserted in the first case.

On November 9, 2015, we filed a motion requesting partial judgment and a motion requesting expedited hearing of our motion for partial judgment and for final judgment in the Massachusetts court. Purdue filed its opposition response and a cross-motion for a partial stay on November 23, 2015 in the first case. Those motions are fully briefed and the hearing on those motions was held on December 22, 2015. On December 23, 2015, the District Court of Massachusetts issued an order staying proceedings in relation to the three Orange Book-listed patents asserted against us until February 25, 2016, which is the date scheduled by the Court for a status conference. The Court reserved the decision to grant our motion for judgment on the three Orange Book-listed patents to be taken up again at the February 25th status conference, at which time the Court indicated it may grant our motion for judgment or may consider extending the stay. The Court further indicated that it will consider an earlier hearing if the Court of Appeals for the Federal Circuit issues a decision on the appeal of the New York judgment of invalidity prior to the

February 25th status conference. On December 1, 2015, we filed a motion to dismiss the second case for failure to state a claim and Purdue filed its opposition on December 15, 2015. That action has been consolidated into the other Massachusetts actions, and our motion remains pending. 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 license from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents, or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our patented technology, trademarks and other intellectual property rights is expensive, difficult and, may in some cases not be possible. In some cases, it may be difficult or impossible to detect third party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

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

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

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

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

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

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

Although our executive officers have experience marketing pharmaceutical products, we currently have limited sales, marketing or distribution capabilities. We do not intend to begin to hire field sales representatives until several months prior to receiving final FDA approval of one of our product candidates. Therefore, at the time of our anticipated commercial launch of Xtampza, assuming resolution of the Purdue litigation and final 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 product 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 our tentatively approved product, Xtampza, are approved for marketing 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.

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 up to 2% per fiscal year, starting in 2013 and, due to the Bipartisan Budget Act of 2015, will remain in effect through 2025 unless additional action is taken by Congress. In addition, 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. In addition, drug pricing by pharmaceutical companies has recently come under close scrutiny. For example, the U.S. House of Representatives recently formed an Affordable Drug Pricing Task Force to advance legislation intended to control pharmaceutical drug costs and investigate pharmaceutical drug pricing, and the U.S. Senate has requested information from certain pharmaceutical companies in connection with an investigation into pharmaceutical drug pricing practices. If healthcare policies or reforms intended to curb healthcare costs are adopted, or if we experience negative publicity with respect to pricing of our products or the pricing of pharmaceutical drugs generally, the prices that we charge for any approved products may be limited, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted.

We expect that the Affordable Care Act, as well as other healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may compromise our ability to generate revenue, attain profitability or commercialize our products.

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 product 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 product 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 product 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 our product candidates for our clinical trials and FDA registration, and we control only certain aspects of their activities. We are currently negotiating a product agreement with Patheon and we may not be able to obtain terms that are favorable to us or enter into a product 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 our tentatively approved product, 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, Pernix, 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 the FDA grants final regulatory approval to Xtampza, 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 for marketing 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 Chief Commercial Officer, Barry Duke. Each employee is employed by us at will and is permitted to terminate his employment with us at any time pursuant to the terms of his employment agreement. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of Mr. Heffernan or Mr. Duke could impede the achievement of our development and commercialization objectives.

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

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

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

As of December 31, 2015, we had 46 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 financial 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 or preferred stock as consideration. Any such issuance of shares would dilute the ownership of our shareholders. If the price of our common stock is low or volatile, we may not be able to acquire other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

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

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

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

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Ethics, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and

we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business and results of operations, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could have a material adverse effect on our ability to operate our business and our results of operations.

**Our relationships with customers and payors 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 annually information related to certain payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership or investment interests held by physicians and their immediate family members, including under the federal Open Payments program, commonly known as the Sunshine Act, as well as other state and foreign laws regulating

marketing activities and requiring manufacturers to report marketing expenditures, payments and other transfers of value to physicians and other healthcare providers;

- § federal government price reporting laws, which require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed drugs. Participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, potential liability for the failure to report such prices in an accurate and timely manner, and potentially limit our ability to offer certain marketplace discounts; and
- § state and foreign equivalents of each of the above laws, including state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers; state laws which require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restricting payments that may be made to healthcare providers; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

In connection with our research and development activities and our manufacture of materials and 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 Our Common Stock**

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

The market price of our common stock is highly volatile and may be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in 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 \_\_\_\_\_ shares of common stock based on 20,687,823 shares outstanding as of September 30, 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. Of the remaining shares, approximately \_\_\_\_\_ million shares are currently restricted as a result of securities laws or lock-up agreements entered into in connection with this offering but will be able to be sold as described in the "Shares Eligible for Future Sale" and "Underwriting" sections of this prospectus. The lock-up agreements pertaining to this offering will expire 90 days from the date of this prospectus, following which approximately \_\_\_\_\_ shares of common stock will be eligible for sale in the public market, all of which

shares are held by current directors, executive officers, shareholders and other affiliates and may be subject to Rule 144 under the Securities Act.

Moreover, holders of an aggregate of approximately 12.8 million shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders. Once we register these shares, they can be freely sold in the public market, subject to volume limitations applicable to affiliates and the lock-up arrangements.

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

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

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

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

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

As of September 30, 2015, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned a majority of our voting stock, including shares subject to outstanding options and warrants, and, upon the closing of this offering, we expect the same group will continue to hold approximately % of our outstanding voting stock. As a result, if these shareholders were to choose to act together, they would be able to significantly influence the outcome of all matters requiring shareholder approval, including the election of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest. The interests of this group of shareholders may not always coincide with your interests or the interests of other shareholders and they may act in a manner that advances their best interests and not necessarily those of other shareholders, including seeking a premium value for their common stock, and



might affect the prevailing market price for our common stock. Such concentration of ownership control may:

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

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

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

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

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

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

Our common stock is listed on NASDAQ. As a NASDAQ listed company, we are required to satisfy the continued listing requirements of NASDAQ for inclusion in the Global Select Market to maintain such listing, including, among other things, the maintenance of a minimum closing bid price of \$1.00 per share and shareholders' equity of at least \$10.0 million. There can be no assurance that we will be able to maintain compliance with the continued listing requirements or that our common stock will not be delisted from NASDAQ in the future. If our common stock is delisted by NASDAQ, we could face significant material adverse consequences, including:

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

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

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

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

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

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

required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

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

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

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

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting. Commencing with our annual report on Form 10-K for the year 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.**

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

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

**Risks Related to this Offering**

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

Sales of our common stock in the public market, either by us or by our current shareholders, or the perception that these sales could occur, could cause a decline in the market price of our securities. All of the shares of our common stock held by those of our current shareholders who have not entered into lock-up agreements with the underwriters may be immediately eligible for resale in the open market either in compliance with an exemption under Rule 144 promulgated under the Securities Act, or pursuant to an effective resale registration statement that we have previously filed with the SEC. Such sales, along with any other market transactions, could adversely affect the market price of our common stock.

In addition, as of September 30, 2015, there were (a) outstanding options to purchase an aggregate of 1,356,246 shares of our common stock at a weighted average exercise price of \$9.04 per share, of which options to purchase 208,438 shares of our common stock were then exercisable, and (b) 2,445 shares of common stock issuable upon the exercise of warrants to purchase common stock at a weighted-average exercise price of \$12.27 per share. The exercise of options and warrants at prices below the market price of our common stock could adversely affect the price of shares of our common stock. Additional dilution may result from the issuance of shares of our common stock in connection with collaborations or manufacturing arrangements or in connection with other financing efforts.

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

**You will suffer immediate and substantial dilution in the securities you purchase.**

The public offering price of \$ \_\_\_\_\_ per share of our common stock is substantially higher than the as adjusted net tangible book value per share of our outstanding shares immediately after this offering. As a

result, investors purchasing securities in this offering will incur immediate and substantial dilution of approximately \$ \_\_\_\_\_ per share of common stock, or approximately \_\_\_\_\_ % of the public offering price, based on an assumed public offering price of \$ \_\_\_\_\_ per share, which is the last reported sale price of our common stock on NASDAQ on \_\_\_\_\_, 2016. Accordingly, existing shareholders will benefit disproportionately from this offering. If we raise additional capital through the sale of equity, including convertible securities, your percentage of ownership will be diluted. You may also experience additional dilution if stock options or warrants to purchase our shares are exercised at less than the offering price. As of September 30, 2015, we had reserved 1,337,584 shares of our common stock for issuance under our Amended and Restated 2014 Stock Incentive Plan and 200,000 shares of our common stock for issuance under our 2015 Employee Stock Purchase Plan.

**We have broad discretion in the use of our cash and cash equivalents, including the net proceeds of this offering and, despite our efforts, we may use them in a manner that does not increase the value of your investment.**

We currently anticipate that the net proceeds from the sale of our common stock will be used for the continued development of our commercial infrastructure, including building our sales, manufacturing, marketing and reimbursement functions, funding the commercial launch of Xtampza, subject to final regulatory approval, funding research and development efforts of our other product candidates, and funding 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. However, we have not determined the specific allocation of the net proceeds among these potential uses. We have broad discretion in the use of our cash and cash equivalents, including the net proceeds of this offering, and investors must rely on the judgment of our management regarding the use of our cash and cash equivalents. Our management may not use cash and cash equivalents in ways that ultimately increase the value of your investment. Our failure to use our cash and cash equivalents effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest our cash and cash equivalents in short-term or long-term, investment-grade, interest-bearing securities. These investments may not yield favorable returns. If we do not invest or apply our cash and cash equivalents in ways that enhance shareholder value, we may fail to achieve expected financial results, which could cause the price of our common stock to decline. Please see the section entitled "Use of Proceeds" on page 60 of this prospectus for further information.

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

## 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 product 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 expectations regarding our ability to obtain and adequately maintain sufficient intellectual property protection for our product candidates;
- § our ability to operate our business without infringing the intellectual property rights of others;
- § the performance of our third-party suppliers and manufacturers;
- § 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; and
- § the accuracy of our estimates regarding expenses, future revenue, capital requirements and need for additional financing.

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 \$        million (or \$        million if the underwriters exercise their option to purchase additional shares from us in full), based on an assumed offering price of \$        , which is the last reported sale price of our common stock on        , 2016, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each \$1.00 increase (decrease) in the assumed offering price 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 \$        million.

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

- §        approximately \$45.7 million for the continued development of our commercial infrastructure, including building our sales, manufacturing, marketing and reimbursement functions and funding the commercial launch of Xtampza, subject to final regulatory approval. If Xtampza ultimately receives final regulatory approval in the United States, we plan to hire a team of approximately 120 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 \$4.6 million to fund research and development efforts of our other product candidates, including clinical development for our hydrocodone program (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 final 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 2018, including the commercialization of Xtampza, if it receives final regulatory approval, 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.

**PRICE RANGE OF COMMON STOCK**

Our common stock began trading on NASDAQ under the symbol "COLL" on May 7, 2015. Prior to that time, there was no public market for our common stock. The following table sets forth the high and low sale prices per share of our common stock, as reported on NASDAQ, for the periods indicated.

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	<u>High</u>	<u>Low</u>
<b>Year Ending December 31, 2015</b>		
Second Quarter (from May 7, 2015)	\$ 20.62	\$ 11.92
Third Quarter	\$ 24.88	\$ 12.58
Fourth Quarter	\$ 30.58	\$ 15.51

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On December 31, 2015, the last reported sale price of our common stock on NASDAQ was \$27.50 per share. As of December 31, 2015, we had approximately 60 holders of record of our common stock. The actual number of shareholders is greater than this number of record holders, and includes shareholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

## 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 September 30, 2015 on:

- § an actual basis; and
- § an as adjusted basis, giving effect to the sale by us of \_\_\_\_\_ shares of our common stock in this offering at an assumed public offering price of \$ \_\_\_\_\_ per share, which was the last reported sale price of our common stock on NASDAQ on \_\_\_\_\_, 2016, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

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 September 30, 2015</u>	
	<u>Actual</u>	<u>As Adjusted</u>
	<u>(in thousands, except share and per share data)</u>	
Cash and cash equivalents	\$ 105,460	\$ _____
Undesignated preferred stock, \$0.001 par value: 5,000,000 shares authorized and no shares issued or outstanding	—	—
Common stock, par value \$0.001 per share; 100,000,000 shares authorized, 20,687,829 shares issued and outstanding, actual; and _____ shares issued and outstanding, as adjusted	20	_____
Additional paid-in capital	213,027	_____
Accumulated deficit	(119,483)	(119,483)
Treasury stock	(3)	(3)
<b>Total shareholders' equity</b>	<u>93,561</u>	<u>_____</u>
<b>Total capitalization</b>	<u>\$ 93,561</u>	<u>\$ _____</u>

The number of shares of our common stock to be outstanding after this offering is based on 20,687,829 shares of common stock outstanding as of September 30, 2015, assumes the issuance by us of \_\_\_\_\_ shares of our common stock in this offering and excludes:

- § 1,356,246 shares of common stock issuable upon the exercise of outstanding stock options as September 30, 2015, at a weighted-average exercise price of \$9.04 per share;
- § 2,445 shares of common stock issuable upon the exercise of warrants to purchase common stock as of September 30, 2015, at a weighted-average exercise price of \$12.27 per share;
- § 1,337,584 shares of common stock reserved for future issuance under our Amended and Restated 2014 Stock Incentive Plan as of September 30, 2015; and
- § 200,000 shares reserved for future issuance under our 2015 Employee Stock Purchase Plan as of September 30, 2015.

## 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. The statements of operations data for the nine months ended September 30, 2014 and 2015 and the balance sheet data as of September 30, 2015 are derived from our unaudited financial statements included in this prospectus. The unaudited financial statements include, in the opinion of management, all adjustments that management considers necessary for the fair presentation of the financial information set forth in those statements. 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.

	<u>Years Ended December 31,</u>		<u>Nine Months Ended</u>	
	<u>2013</u>	<u>2014</u>	<u>September 30,</u>	<u>2014</u>
			<u>2015</u>	
(in thousands, except share and per share amounts)				
<b>Statement of Operations Data:</b>				
Operating expenses:				
Research and development	\$ 14,157	\$ 14,959	\$ 12,652	\$ 6,444
General and administrative	1,885	2,706	1,686	11,027
<b>Total operating expense</b>	<b>16,042</b>	<b>17,665</b>	<b>14,338</b>	<b>17,471</b>
Loss from operations	(16,042)	(17,665)	(14,338)	(17,471)
Interest expense, net	76	252	110	350
Other expense, net	79	—	—	(91)
<b>Net loss</b>	<b>\$ (16,197)</b>	<b>\$ (17,917)</b>	<b>\$ (14,448)</b>	<b>\$ (17,730)</b>
Basic and diluted net loss per common share <sup>(1)</sup> :	<u>\$ (4.06)</u>	<u>\$ (22.72)</u>	<u>\$ (18.26)</u>	<u>\$ (0.94)</u>
Weighted-average shares used to compute earnings (loss) per common share <sup>(1)</sup> :	<u>1,697,044</u>	<u>933,997</u>	<u>926,597</u>	<u>11,179,756</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.

	<u>As of</u>		
	<u>December 31,</u>	<u>December 31,</u>	<u>September 30,</u>
	<u>2013</u>	<u>2014</u>	<u>2015</u>
<b>Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 7,551	\$ 1,634	\$ 105,460
Working capital <sup>(1)</sup>	5,643	(5,921)	97,726
Total assets	9,034	5,090	107,050
Other long-term liabilities	834	6,914	4,889
Total shareholders' equity (deficit)	(68,225)	(89,348)	93,561

- (1) 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. On November 6, 2015, the FDA granted tentative approval to the NDA for Xtampza for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The FDA granted tentative approval because Xtampza met the required quality, safety and efficacy standards for approval but remains subject to an automatic stay of up to 30 months as a result of patent litigation filed by Purdue in March 2015. The FDA may grant final regulatory approval upon the earliest to occur of expiration of the automatic stay, the court invalidating Purdue's patents or issuing an opinion of non-infringement, and expiration of Purdue's listed patents.

In connection with the FDA's tentative approval of our NDA for Xtampza, the FDA tentatively approved a product label, product packaging, post-marketing commitments and a REMS program, subject to change should new information become available prior to the time that the FDA considers the Xtampza NDA for final regulatory approval. The tentatively approved Xtampza label, in contrast to the product labels for all currently approved extended-release opioids, does not include a black box warning and related precautions stating that crushing, chewing or dissolving can cause rapid release and absorption of a potentially fatal dose of the active ingredient. The absence of these warnings is supported by data that is described in the tentatively approved product label to support the claim that when Xtampza is crushed or chewed, the drug release profile is bioequivalent to taking Xtampza intact, as directed. Furthermore, the tentatively approved product label contains differentiated abuse-deterrent claims for Xtampza and also states that Xtampza can be taken by sprinkling the capsule contents on soft foods or into a cup, and then directly into the mouth, or through a gastrostomy or nasogastric feeding tube.

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 product 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 it ultimately receives final regulatory approval, 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. Prior to our initial public offering of common stock, or IPO, in May 2015, we funded our operations primarily through the private placement of preferred stock, convertible notes and commercial bank debt.

### **Outlook**

We have never been profitable and have incurred net losses in each year since inception. We incurred net losses of \$17.7 million and \$14.4 million for the nine months ended September 30, 2015 and 2014, respectively. As of September 30, 2015, we had an accumulated deficit of \$119.5 million. 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 final 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 final regulatory approval for Xtampza, we expect to incur significant commercialization expenses related to marketing, manufacturing, distribution, product sales and reimbursement functions. Initially we plan to detail Xtampza to approximately 11,000 physicians who write approximately 55% of the branded extended-release oral opioid prescriptions in the United States with a sales team of approximately 120 sales representatives. In addition, we plan to deploy a separate, focused sales team of approximately 25 specialty sales representatives to detail Xtampza to nursing homes, hospices and other institutions treating large populations of the elderly and other patients who need chronic pain relief and have difficulty swallowing. 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, which 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 nine months ended September 30, 2015 and years ended December 31, 2013 and December 31, 2014.

### ***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. Prior to our IPO, there was no public market for the trading of our common stock. Due to the lack of a public market for the trading of our common stock and a lack of Company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. For these analyses, we have selected companies with comparable characteristics to ours, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. We compute the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of our stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. The expected term represents the period of time that options are expected to be outstanding. Because there was not enough historical exercise behavior through September 30, 2015, 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 years ended December 31, 2013 and 2014 and the nine months ended September 30, 2015, the weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of those grants were as follows:

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	Years Ended December 31,		Nine Months Ended September 30, 2015
	2013	2014	
Risk-free interest rate	1.09% – 1.22%	1.80%	1.70%
Expected volatility	87.8%	77.1%	77.0%
Expected term (in years)	6.25	6.25	6.21
Expected dividend yield	0%	0%	0%

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

- § *Fair Value of Common Stock.* After our stock began trading on NASDAQ on May 7, 2015, the fair value of common stock underlying our options was determined by the closing price of our common stock on the date of the grant. Prior to the IPO, the fair value of the shares of our common stock underlying our stock options was determined by our board of directors. Because there was no public market for our common stock, our board of directors determined the fair value of our common stock at the time of grant of the option by considering a number of objective and subjective factors, including valuations of comparable companies, sales of our convertible preferred stock to unrelated third parties, our operating and financial performance and general and industry specific economic outlook.
- § *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 was limited historical price data for our common stock prior to the IPO and a lack of company-specific historical volatility, we 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.

#### 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 and September 30, 2015, we have provided a full valuation allowance for deferred tax assets.

### **Income Taxes**

We record uncertain tax positions on the basis of a two-step process whereby (i) we determine whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the positions and (ii) for those tax positions that meet the more-likely-than-not recognition threshold, we recognize the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. We recognize interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability. There were no uncertain tax positions as of December 31, 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) December 31, 2020.

### **Recently Issued Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-09, which amends the guidance for accounting for revenue from contracts with customers. This ASU supersedes the revenue recognition requirements in Accounting Standards Codification, or ASC, Topic 605, Revenue Recognition, and creates a new Topic 606, Revenue from Contracts with Customers. Two adoption methods are permitted: retrospectively to all prior reporting periods presented, with certain practical expedients permitted; or retrospectively with the cumulative effect of initially adopting the ASU recognized at the date of initial application. On August 12, 2015, the FASB issued ASU No. 2015-14, which defers the effective date of ASU No. 2014-09 by one year to December 15, 2017 for annual reporting periods beginning after that date, including interim periods within those periods. The FASB also approved permitting early adoption of the standard, but not before the original effective date of December 15, 2016. We have not yet determined which adoption method it will utilize or the effect that the adoption of this guidance will have on its financial statements.

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 July 2015, the FASB issued ASU No. 2015-11, which amends existing guidance for measurement of inventory. Current inventory guidance requires an entity to measure inventory at the lower of cost or market. Market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. The amendments do not apply to inventory that is measured using last-in, first-out (LIFO) or the retail inventory method. The amendments apply to all other inventory, which includes inventory that is measured using first-in, first-out or average cost. An entity should measure all inventory to which the amendments apply at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. The amendments in the ASU No. 2015-11 more closely align the measurement of inventory pursuant to GAAP with the measurement of inventory pursuant to International Financial Reporting Standards. The amendments are effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017. The amendments should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. We do not expect the adoption of this guidance to have a material impact on our financial statements.

## Results of Operations

### *Comparison of the Nine Months ended September 30, 2015 and September 30, 2014*

The following table summarizes the results of our operations for the nine months ended September 30, 2014 and 2015:

	Nine Months Ended September 30,		Change
	2014	2015 (in thousands)	
Research and development expenses	\$ 12,652	\$ 6,444	\$ (6,208)
General and administrative expenses	1,686	11,027	9,341
Other expense, net	110	259	149
Net loss	<u>\$ (14,448)</u>	<u>\$ (17,730)</u>	<u>\$ 3,282</u>

Research and development expenses were \$12.7 million for the nine months ended September 30, 2014, or the 2014 Period, compared to \$6.4 million for the nine months ended September 30, 2015, or the 2015 Period. The \$6.2 million decrease was primarily related to:

- § a decrease in clinical trial costs of \$8.1 million due to the completion of clinical trials for Xtampza during 2014;
- § an increase in consulting costs of \$1.2 million mainly due to costs associated with the FDA Advisory Committee meeting held in September 2015; and
- § an increase in manufacturing costs of \$1.0 million related to Xtampza.

General and administrative expenses were \$1.7 million for the 2014 Period compared to \$11.0 million for the 2015 Period. The \$9.3 million increase was primarily related to:

- § an increase in commercial costs of \$3.4 million primarily due to consultant costs related to analytics and strategies for commercialization of Xtampza;
- § an increase in salaries, wages and benefits of \$3.4 million primarily due to headcount, bonuses and stock compensation expense;
- § an increase in legal and consulting fees of \$760,000 primarily due to costs related to litigation;
- § an increase in insurance costs of \$491,000 due to directors' and officers' insurance; and
- § an increase in professional fees of \$401,000 primarily due to audit, accounting and recruitment fees.

#### **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 related primarily 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, due mainly to costs incurred for pre-validation batches; and
- § an increase of \$240,000 in personnel costs, due primarily 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 related primarily to:

- § An increase in professional fees including legal and audit fees of \$832,000, due mainly 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

### Sources of liquidity

We have incurred net losses and negative cash flows from operations since inception. Since inception, we have funded our operations primarily through the private placements of our preferred stock, our IPO, convertible notes and commercial bank debt. As of September 30, 2015, we had \$105.5 million in cash and cash equivalents.

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.

In May 2015, we closed our IPO, which resulted in the sale of 6,670,000 shares of our common stock at a public offering price of \$12.00 per share, including 870,000 shares of common stock upon the exercise by the underwriters of their option to purchase additional shares at the public offering price. We received net proceeds from the IPO of approximately \$72.0 million, after deducting underwriting discounts, commission and expenses payable by us.

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 2018, including the commercialization of Xtampza, if it receives final regulatory approval, 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. We may never become profitable, or if we do, we may not be able to sustain profitability on a recurring basis.

### Cash flows

*Operating activities.* Cash used was \$12.6 million in the 2015 Period and \$10.4 million in the 2014 Period. The increase in cash used in operating activities was due primarily to the change in net loss partially offset by changes in the working capital accounts. We expect cash used in operating activities to increase for the foreseeable future as we seek final regulatory approval for, and, prepare to commercialize Xtampza by establishing sales, marketing, manufacturing and distribution capabilities and fund research, development and clinical activities for additional product candidates.

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.* The cash used in the 2015 Period was related to the purchase of property and equipment. There was no cash used for investing activities in the 2014 Period.

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.* The cash provided by financing activities for the 2015 Period primarily represent net proceeds from the IPO and from the sale of Series D convertible preferred stock of \$72.0 million and \$44.8 million, respectively. The cash provided by financing activities for the 2014 Period primarily reflects the \$7.0 million drawdown of a term note payable.



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.

### Funding 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 final regulatory approval for, and potentially begin 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 final regulatory approval 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. We will also 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 our litigation with Purdue 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:

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

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<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 under SEC rules.

### Quantitative and Qualitative Disclosures about Market Risks

We are exposed to market risk related to changes in interest rates. As of September 30, 2015, we had cash and cash equivalents consisting of cash and money market funds of \$105.5 million. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our money market funds are short-term highly liquid investments. Due to the short-term duration and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio.

## 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. On November 6, 2015, the U.S. Food and Drug Administration, or FDA, granted tentative approval to the new drug application, or NDA, for Xtampza for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The FDA granted tentative approval because Xtampza met the required quality, safety and efficacy standards for approval but remains subject to an automatic stay of up to 30 months as a result of patent litigation filed by Purdue Pharma, L.P., or Purdue, in March 2015. The FDA may grant final regulatory approval upon the earliest to occur of expiration of the automatic stay, the court invalidating Purdue's patents or issuing an opinion of non-infringement, and expiration of Purdue's listed patents.

In connection with the FDA's tentative approval of our NDA for Xtampza, the FDA tentatively approved a product label, product packaging, post-marketing commitments and a Risk Evaluation and Mitigation Strategy, or REMS, program, subject to change should new information become available prior to the time that the FDA considers the Xtampza NDA for final regulatory approval. The tentatively approved Xtampza label, in contrast to the product labels for all currently approved extended-release opioids, does not include a black box warning and related precautions stating that crushing, chewing or dissolving can cause rapid release and absorption of a potentially fatal dose of the active ingredient. The absence of these warnings is supported by data that is described in the tentatively approved product label to support the claim that when Xtampza is crushed or chewed, the drug release profile is bioequivalent to taking Xtampza intact, as directed. Furthermore, the tentatively approved product label contains differentiated abuse-deterrent claims for Xtampza and also states that Xtampza can be taken by sprinkling the capsule contents on soft foods or into a cup, and then directly into the mouth, or through a gastrostomy or nasogastric feeding tube.

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 product 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 it ultimately receives final regulatory approval, 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 2013.

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

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

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

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

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



***Legislative and Regulatory Actions***

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

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

Recent actions to address the opioid abuse epidemic include:

- § ***STOPP Act:*** In July 2012, a bipartisan group of Congressional leaders introduced the STOPP (Stop the Tampering of Prescription Pills) Act. Reintroduced in February 2013, this bill, if approved, would require that non-abuse-deterrent opioids be removed from the market if an abuse-deterrent formulation of that opioid has already been approved for marketing by the FDA. Since being reintroduced in 2013, this bill was referred to the U.S. House of Representatives' Subcommittee on Health and there has been no further action taken.
- § ***FDA guidance:*** In January 2013, the FDA introduced draft guidance regarding studies and clinical trials that should be conducted to demonstrate that a given formulation has abuse-deterrent properties, how those studies and clinical trials will be evaluated, and what product labeling claims may be approved based on the results of those studies and clinical trials. The draft guidance described four categories of abuse-deterrence studies and clinical trials: Categories 1, 2 and 3 consist of pre-marketing studies and clinical trials designed to evaluate a product candidate's potentially abuse-deterrent properties under controlled conditions, while Category 4 post-marketing

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

- § *48 state and territorial attorneys general support development of abuse-deterrent opioids:* In March 2013, the National Association of Attorneys General urged the FDA to adopt standards requiring manufacturers and marketers of prescription opioids to develop abuse-deterrent versions of those products. Their letter, signed by 48 state and territorial attorneys general, commended the FDA for expeditiously proposing guidance that establishes clear standards for manufacturers who develop and market abuse-resistant opioid products, while considering incentives for undertaking the research and development necessary to bring such products to market. It also encouraged the FDA to ensure that generic versions of such products are designed with similar abuse-resistant features.
- § *FDA mandated product label changes:* On September 10, 2013, the FDA announced its intention to require product label changes to all approved extended-release and long-acting opioids. In particular, the FDA announced its intention to update the indications for these opioids so that they will be indicated only for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. On April 16, 2014, the FDA updated these indications. The FDA also requires post-marketing studies and clinical trials for any such opioids.
- § *29 state and territorial attorneys general speak out against the approval of non-abuse-deterrent narcotics:* In December 2013, the attorneys general of 29 states and territories urged the FDA to reconsider its approval of Zohydro™ ER, an extended-release hydrocodone formulation with no abuse-deterrent properties, or alternatively to set a rigorous timeline for reformulation of Zohydro ER in an abuse-deterrent form, with significant limitations on prescriptions of Zohydro ER in the interim. In early 2014, members of Congress from three states introduced a bill to revoke FDA approval of Zohydro ER and prevent the FDA from approving any new opioids that do not have abuse-deterrent features and the governor of Massachusetts signed an executive order (since overturned by a court) that attempted to ban the dispensing of Zohydro ER in Massachusetts.
- § *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 and Maine approved laws to mandate that insurers cover abuse-deterrent opioids:* In August 2014 and June 2015, the governors of Massachusetts and Maine, respectively, signed laws establishing a drug formulary commission charged with identifying drugs with a heightened public health risk due to their potential for abuse and formulations of abuse-deterrent drugs that may be substituted for these drugs that have a heightened public health risk. When a prescriber writes a prescription for an opioid identified as having a heightened public health risk, the pharmacist must dispense an interchangeable abuse-deterrent product from the formulary, if one exists, except when the prescriber indicates "no substitution." The Massachusetts and Maine laws also require insurers to cover abuse-deterrent opioid drugs on a basis not less favorable than corresponding non-abuse-deterrent drugs. Several other states have enacted or are in the process of introducing similar legislation.
- § *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 product label stating that "crushing, dissolving or chewing can cause rapid release and absorption of a potentially fatal dose of the active drug," making them unsuitable or unattractive for patients who suffer from chronic pain with dysphagia, or CPD. OxyContin OP's product label states that "there have been post-marketing reports of difficulty in swallowing OxyContin tablets. These reports included choking, gagging, regurgitation and tablets stuck in the throat... Consider use of an alternative analgesic in patients who have difficulty swallowing." An external marketing study performed for us in 2013 estimated that Xtampza, if finally approved, has a peak revenue potential for U.S. patients with CPD in excess of \$700 million annually.

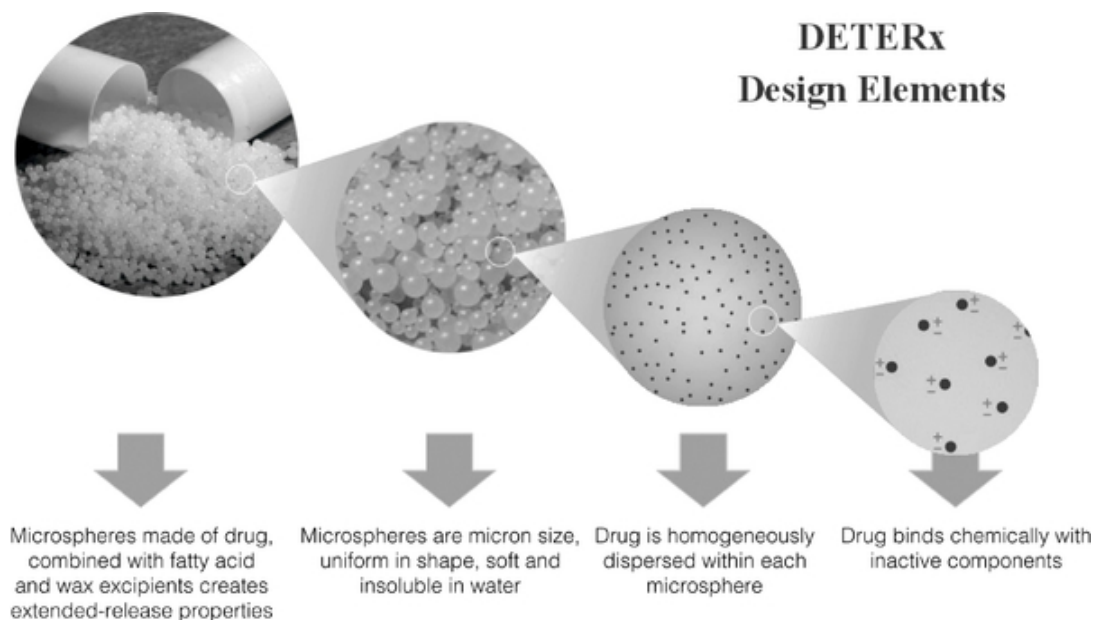
### **Our Solution: The DETERx Platform Technology**

#### **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***

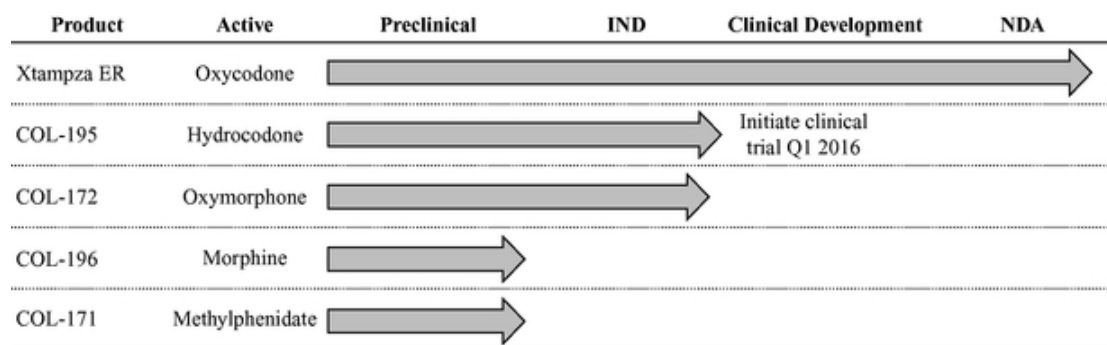
Abusers often seek to accelerate the absorption of opioids into the bloodstream by crushing them in order to swallow, snort or smoke the drug, or dissolving them in order to inject the drug. The wax-based microspheres produced using the DETERx platform technology have physical and chemical barriers that 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

<u>Method of Abuse</u>	<u>Abuse-Deterrent Feature:</u>	<u>Advantages</u>
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 recently completed formulation development work for our extended-release, abuse-deterrent hydrocodone program. Based upon an assessment of the market opportunity and the potential to differentiate from currently marketed hydrocodone products as well as programs in development, we are prioritizing our abuse deterrent hydrocodone program as our second product in development. We filed an IND with the FDA in December 2015 and target initiating a clinical trial in the first quarter of 2016. We also have an extended-release, abuse-deterrent oxymorphone program for the treatment of chronic pain for which we have filed an investigational new drug application, or IND. This program has been granted Fast Track status by the FDA. In addition, we have other extended-release, abuse-deterrent product candidates that have completed preliminary preclinical studies, including morphine for pain and methylphenidate for the treatment of attention deficit hyperactivity disorder, or ADHD. All of these product candidates share similar abuse-deterrent qualities as Xtampza and are designed to be suitable for patients with difficulty swallowing. We own all of the rights to our product candidates.



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

**Xtampza**

**Overview**

Our lead product candidate, Xtampza, is an abuse-deterrent, extended-release, oral formulation of oxycodone tentatively approved by the FDA 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. On November 6, 2015, the FDA granted tentative approval to the NDA for Xtampza for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The FDA granted tentative approval because Xtampza met the required quality, safety and efficacy standards for approval but remains subject to an automatic stay of up to 30 months as a result of patent litigation filed by Purdue in March 2015. The FDA may grant final regulatory approval upon the earliest to occur of expiration of the automatic stay, the court invalidating Purdue's patents or issuing an opinion of non-infringement, and expiration of Purdue's listed patents.

We sought 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.

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 Xtampza ultimately receives final regulatory approval, Xtampza could be the only abuse-deterrent extended-release oxycodone product with product labeling features targeting patients with

CPD. As part of the FDA's tentative approval of our NDA for Xtampza, we have a tentatively approved product label. The key product label characteristics are summarized below:

<u>Section of Tentative Product Label</u>	<u>Tentative Product Label Characteristics</u>
<b>Dosage and Administration</b>	§ Open capsule and sprinkle microspheres on soft foods or directly into a cup, and then directly into the mouth.  § Administer microspheres through nasogastric and gastrostomy feeding tubes.
<b>Pharmacology</b>	§ Pharmacokinetic data demonstrating that chewed and crushed Xtampza ER is bioequivalent to intact dosing.
<b>Black Box Warning and Precautions</b>	<b>No warnings or precautions relating to:</b>  § Crushing, chewing or dissolving the drug can cause rapid release and absorption of a potentially fatal dose.  § Difficulty swallowing, risks of IV injection, etc.
<b>Drug Abuse</b>	<b>Abuse-deterrent claims</b>  § Category 1 in vitro  § Category 2 pharmacokinetic  § Category 3 human abuse potential

### **Market Opportunity**

We believe that Xtampza, if it ultimately receives final regulatory approval, 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 approved with product 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 product label to include certain abuse-deterrent claims. Since the launch of OxyContin OP, there has been a reduction in the overall abuse of OxyContin, primarily in the snorted and injected routes of administration.

The FDA also concluded that the benefits of the previously-approved non-abuse-deterrent OxyContin no longer outweighed its risks and removed it from the list of drugs eligible to serve as a reference product for future generic or Section 505(b)(2) approvals. As a result, we 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 ultimately 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 it ultimately receives final regulatory approval, has a peak revenue potential for U.S. patients with CPD in excess of \$700 million annually.

#### **Clinical Development**

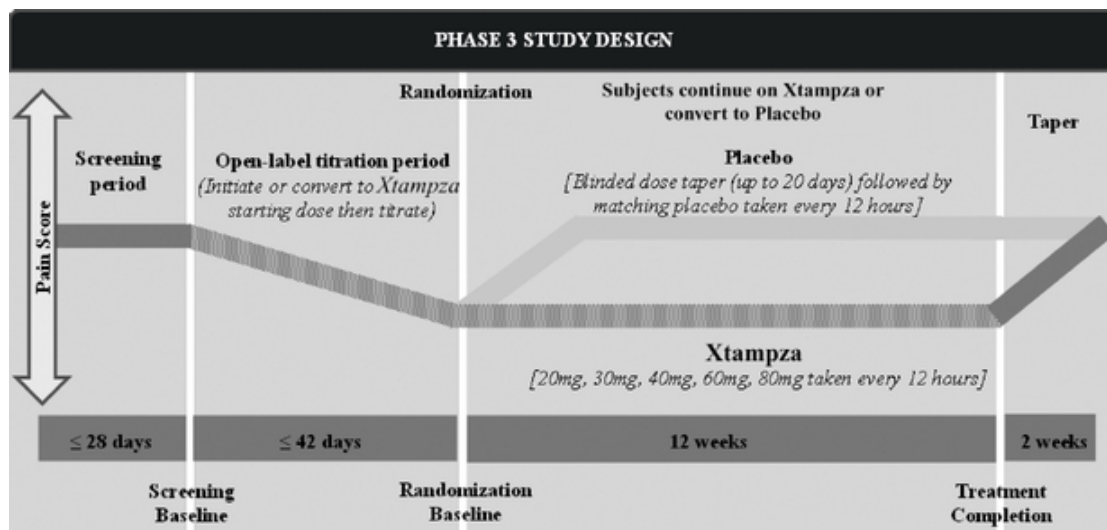
We have completed numerous studies and clinical trials on Xtampza. We submitted an NDA for Xtampza to the FDA on December 12, 2014. On September 11, 2015, the Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee of the FDA voted unanimously (23-0) to support the regulatory approval of Xtampza. Xtampza received tentative FDA approval on November 6, 2015. We sought 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.

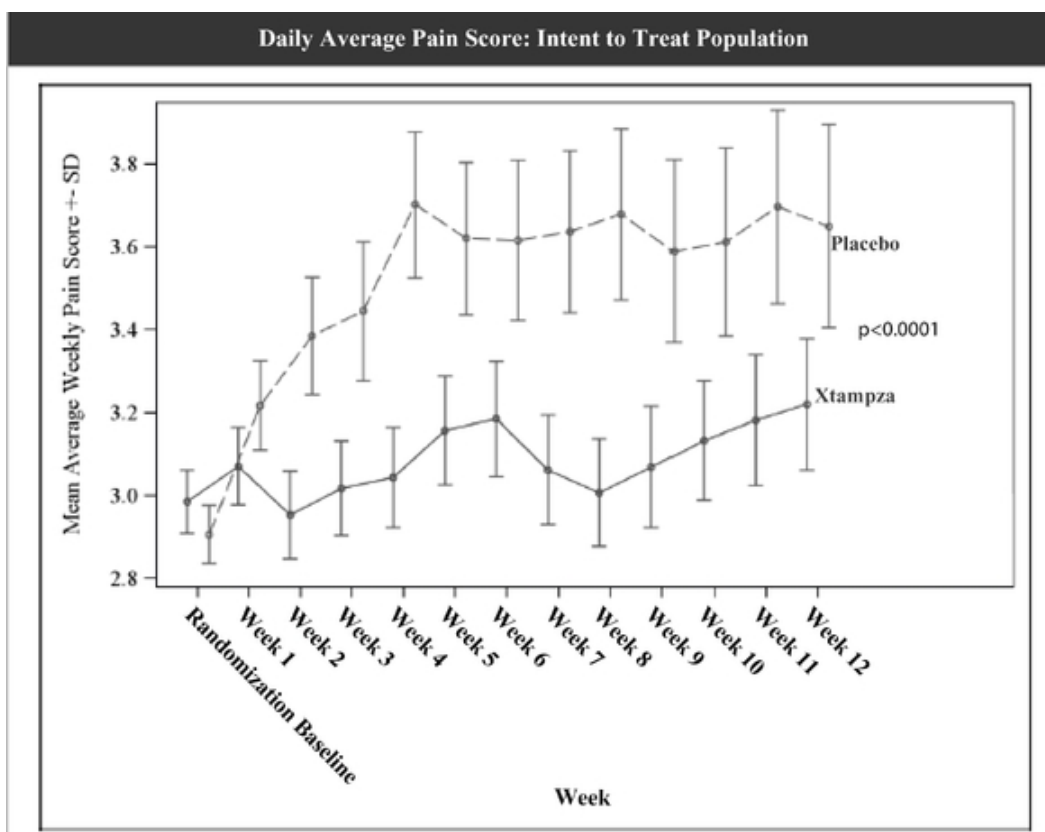
*Evaluation of Safety and Efficacy*

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.



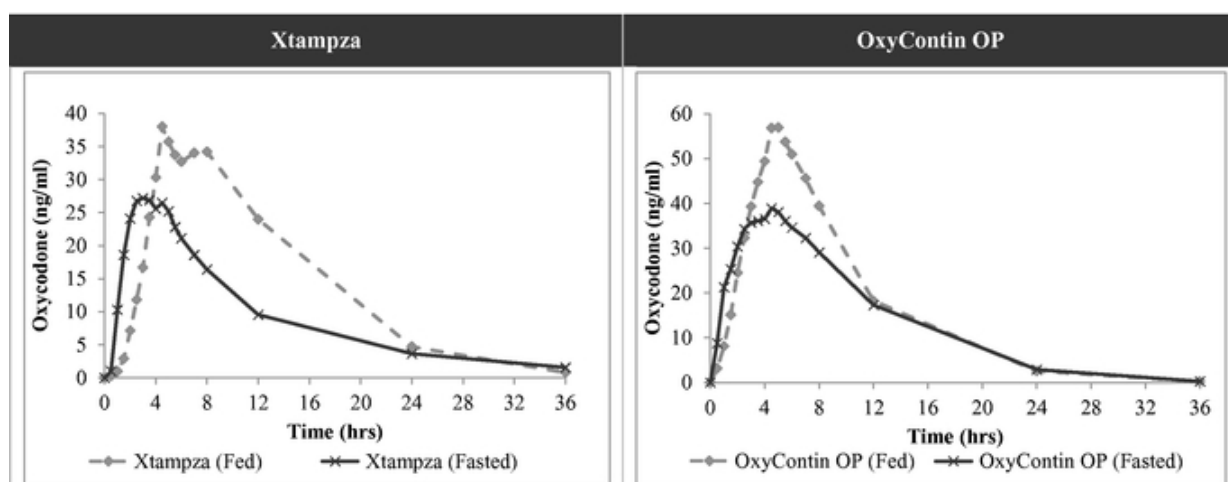
The clinical trial demonstrated that the estimated marginal mean change in average pain score from Randomization Baseline to Week 12 was greater for the placebo treatment group (1.85) than for the Xtampza treatment group (0.29). The clinical trial successfully met the primary efficacy endpoint by showing 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, our tentatively approved product label indicates that Xtampza should be taken with food and should be taken with approximately the same amount of food with every dose to ensure that consistent plasma levels are achieved.

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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	<b>C<sub>max</sub> (ng/ml)</b>	<b>AUC (hr*ng/ml)</b>
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 product 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 product 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.

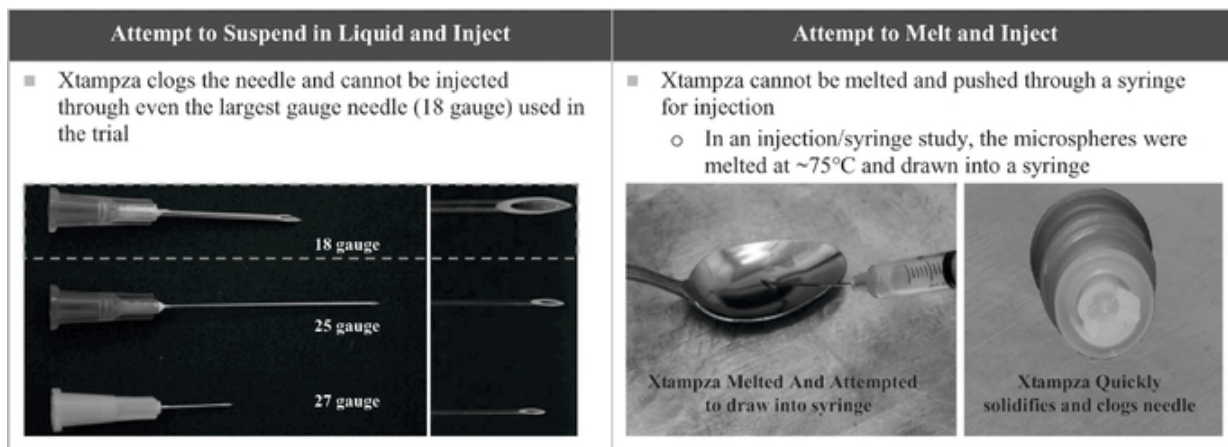
*Route Specific — Injection*

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.

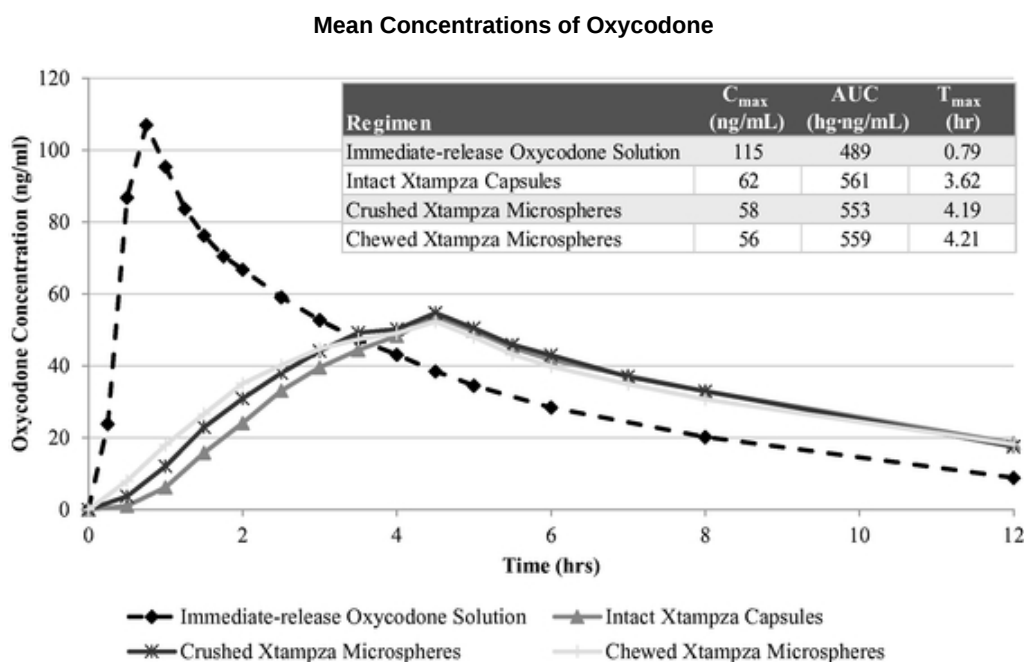
Category 2: Oral PK Clinical Trials

To support oral abuse-deterrent product 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

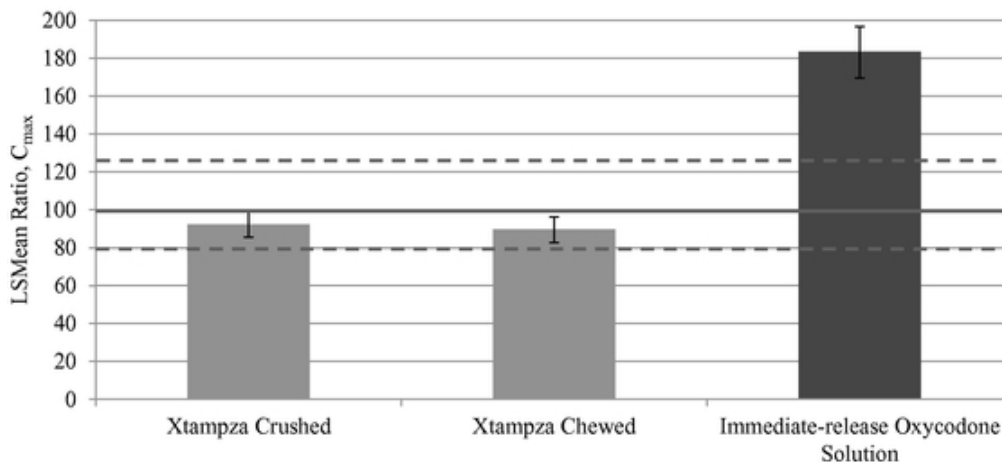
*Oral Crushed/Chewed PK Clinical Trial (CP-OXYDET-17)*

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 food effect, the tentative product label for Xtampza instructs patients to take Xtampza capsules with approximately the same amount of food for every dose in order to ensure consistent plasma levels are achieved. Accordingly, the graph below provides only the results of the clinical trial for the fed-state treatment arms.



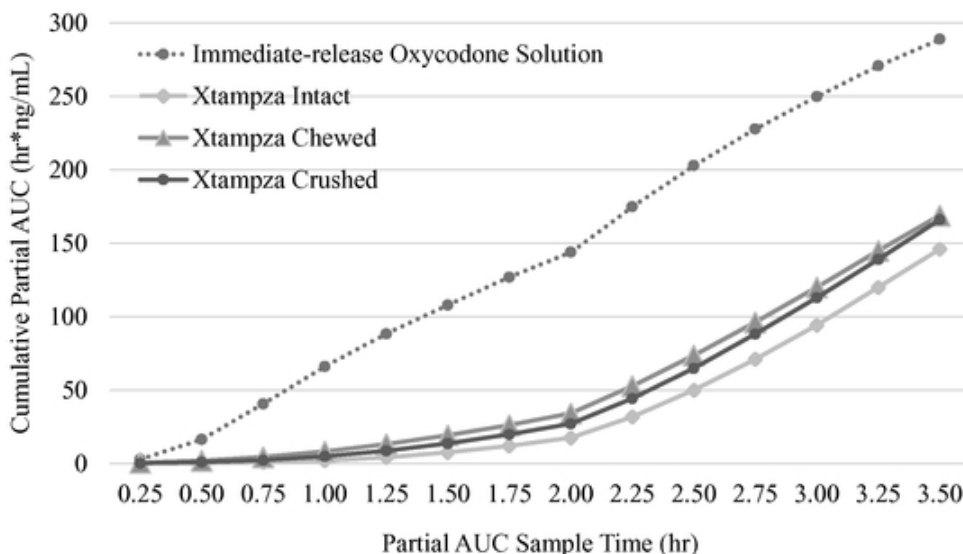
As demonstrated above, crushing or chewing Xtampza did not increase its  $C_{max}$  as compared to the intact Xtampza capsules. All treatment groups had substantially lower peak plasma levels and longer time to peak plasma level, or  $T_{max}$ , than the immediate-release oxycodone solution. The absorption 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.

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

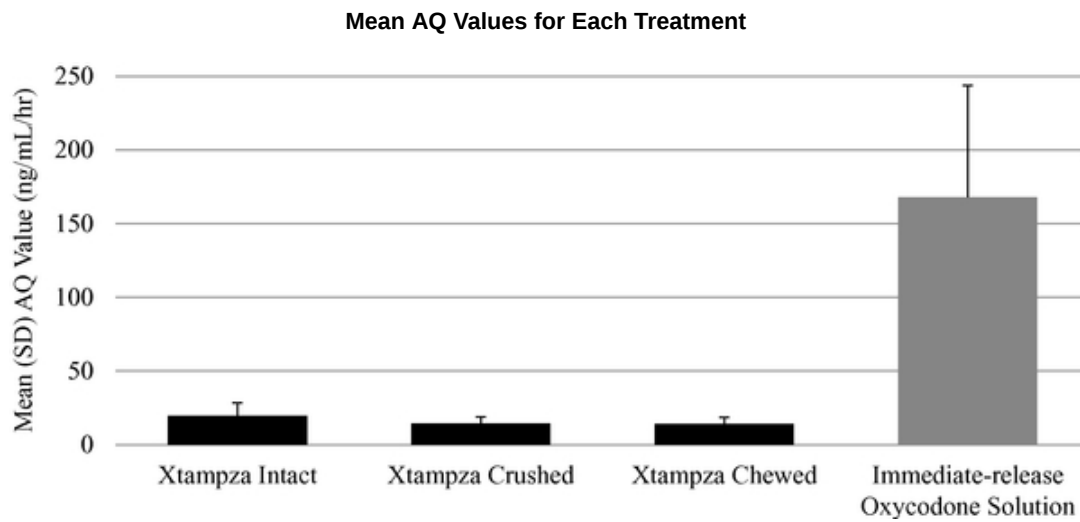


Substantial early increases in plasma concentrations after crushing or chewing, compared to intact capsules are indicative of dose dumping. As a result, the product labels for all currently available orally administered extended-release opioids include a black box warning instructing patients that "crushing, 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.



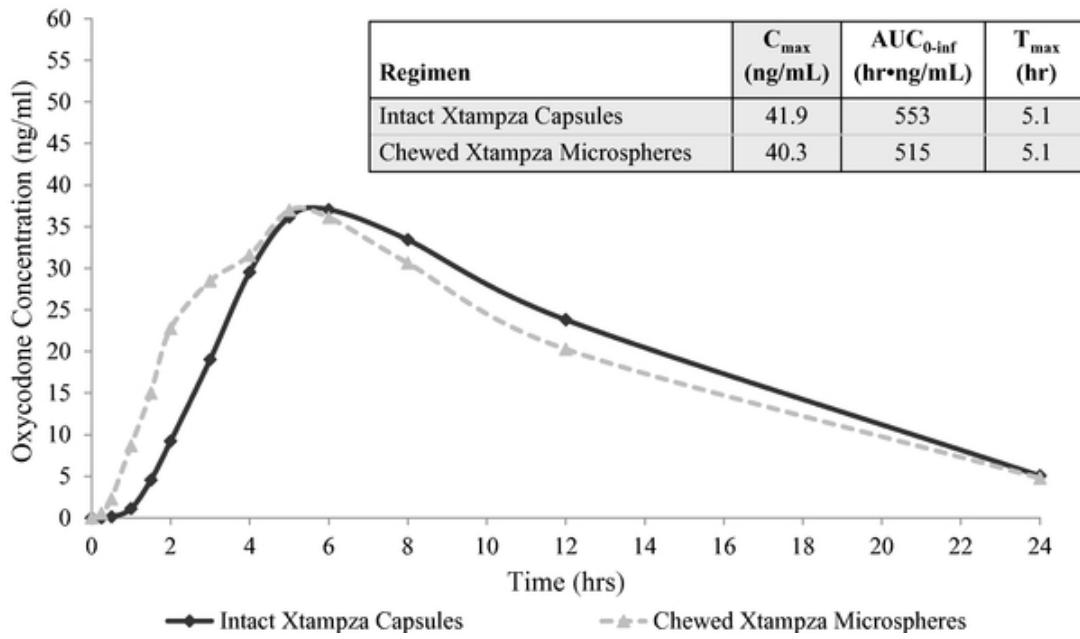
In summary, in this clinical trial, manipulation of Xtampza microspheres by crushing or chewing did not alter the extended-release properties of the Xtampza formulation in the fed-state treatment arms.

*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.

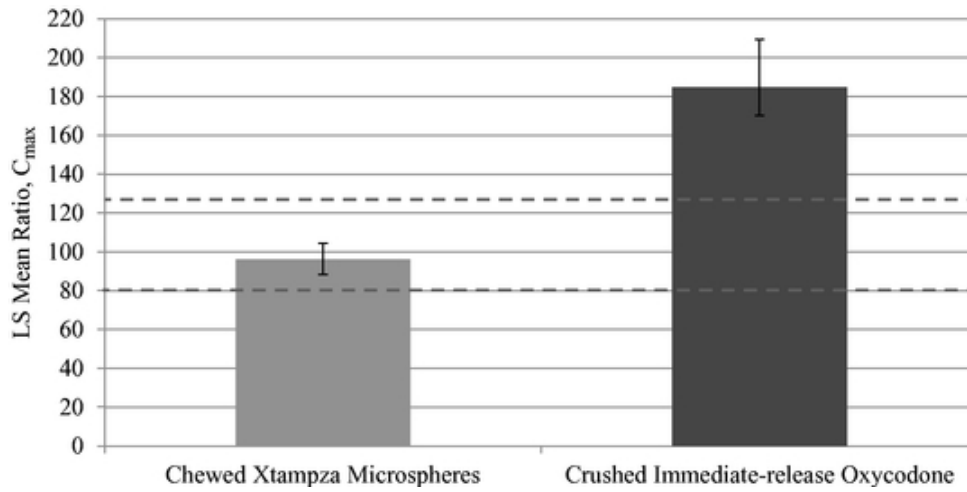
The results shown in the figure below indicate that for  $C_{max}$  and AUC, Xtampza intact and Xtampza chewed are bioequivalent with equivalent  $T_{max}$ . These results indicate that chewing Xtampza does not affect the peak and overall exposure to oxycodone.

**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**

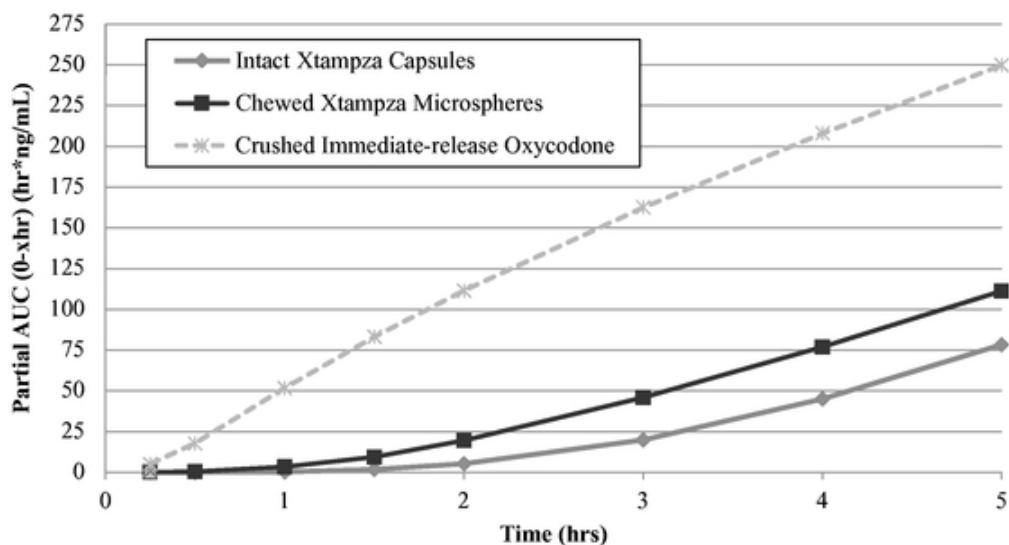


To better characterize early plasma exposure, partial area under the curve, or PAUC (which measures cumulative absorption over an initial period, in this case five hours, after dosage), and AQ values were

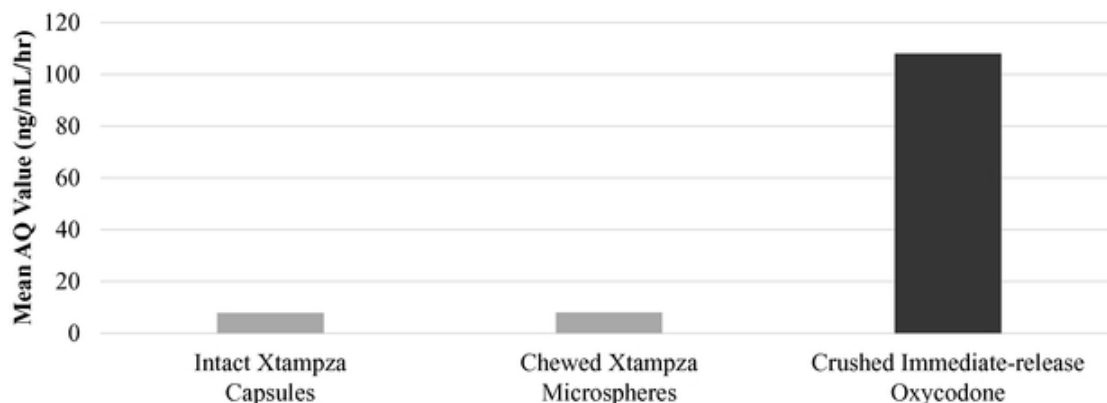


calculated for each treatment arm. Over the timeframe of the first sampling time to five hours after dosing, the PAUC values for all Xtampza treatments were substantially lower than the immediate-release oxycodone crushed solution PAUC values. The small increase in PAUC for the manipulated Xtampza capsules 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**



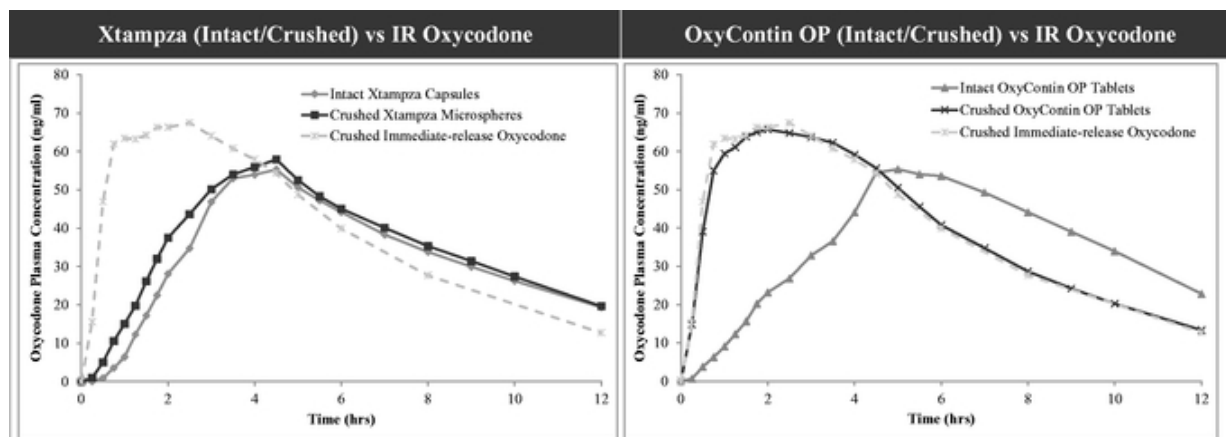
In summary, the PK data from this clinical trial indicate that there is no material increase in plasma exposure or dose dumping when Xtampza is administered after chewing, when compared to intact Xtampza. Similar to our oral crushed/chewed PK clinical trial, our oral chewed PK and HAP clinical trial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

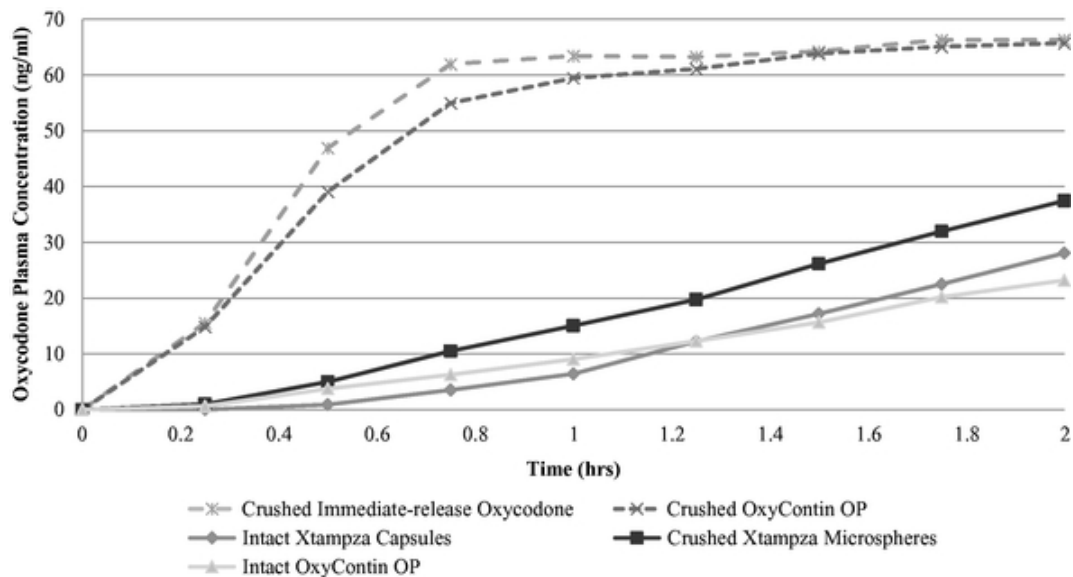
The figure on the left below indicates that crushing does not materially increase the  $C_{max}$  or materially change the AUC of Xtampza compared with the intact product, which retains its oral extended-release properties when crushed, confirming observations from our oral crushed/chewed PK clinical 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



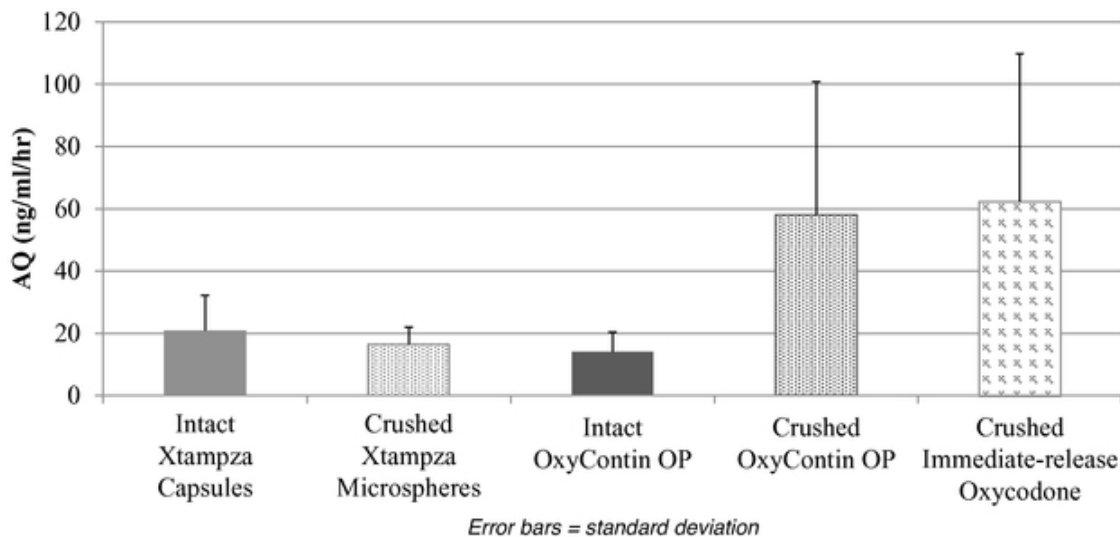
The figure below shows the mean PAUC values from the first sampling time to two hours for all treatments. Over the first two hours after dosing, the PAUC values for intact and crushed Xtampza, as well as intact OxyContin OP, treatments were substantially lower than the corresponding crushed immediate-release oxycodone values. Over this same timeframe, the PAUC values for crushed 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 product labeling for Xtampza.

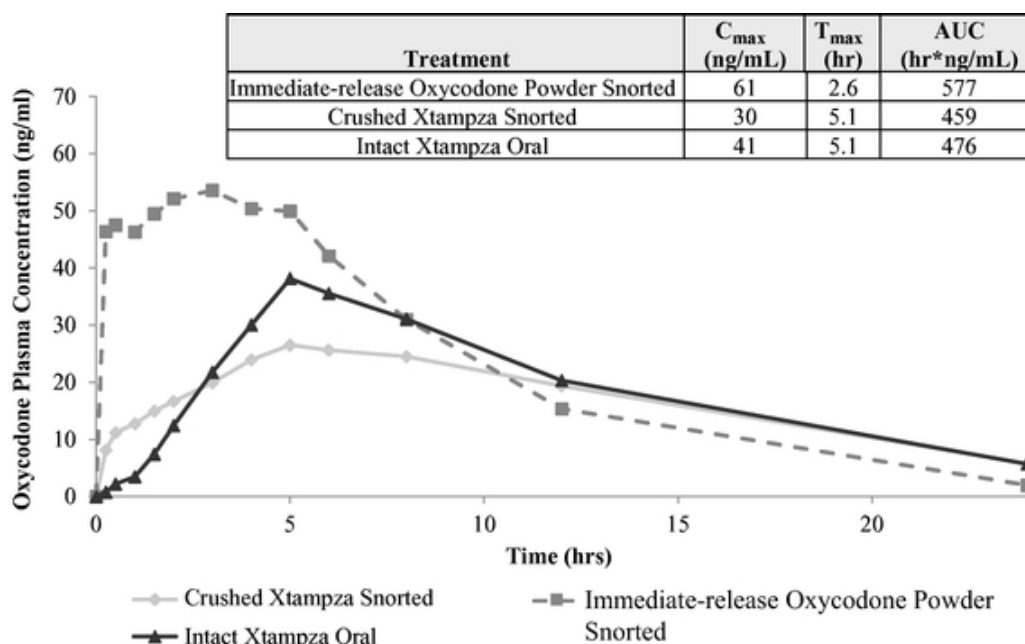
Trial & Category	Subjects	Comparator(s)	Key Objective
<b>Intranasal PK Clinical Trial (CP-OXYDET-19)</b> Category 2	n = 15	Oxycodone powder	§ Compare the safety and PK of crushed and intact Xtampza following intranasal administration.
<b>Intranasal PK and HAP Clinical Trial (CP-OXYDET-21)</b> Categories 2 & 3	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.

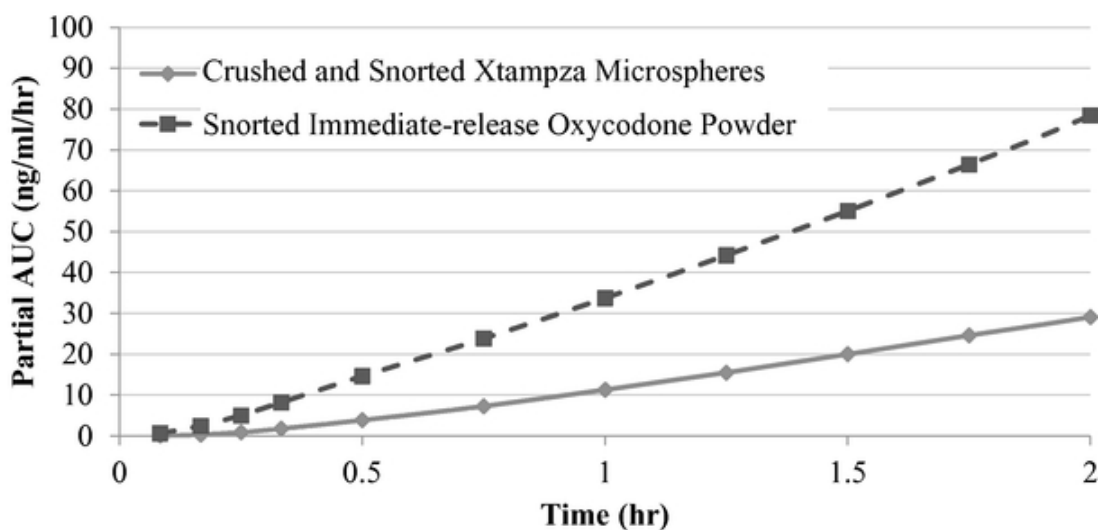
Data from this clinical trial demonstrated that administration of crushed and snorted Xtampza resulted in a lower  $C_{max}$  than both intact Xtampza taken orally and snorted immediate-release oxycodone powder; the  $C_{max}$  for crushed and snorted Xtampza was approximately 80% of intact Xtampza taken 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**



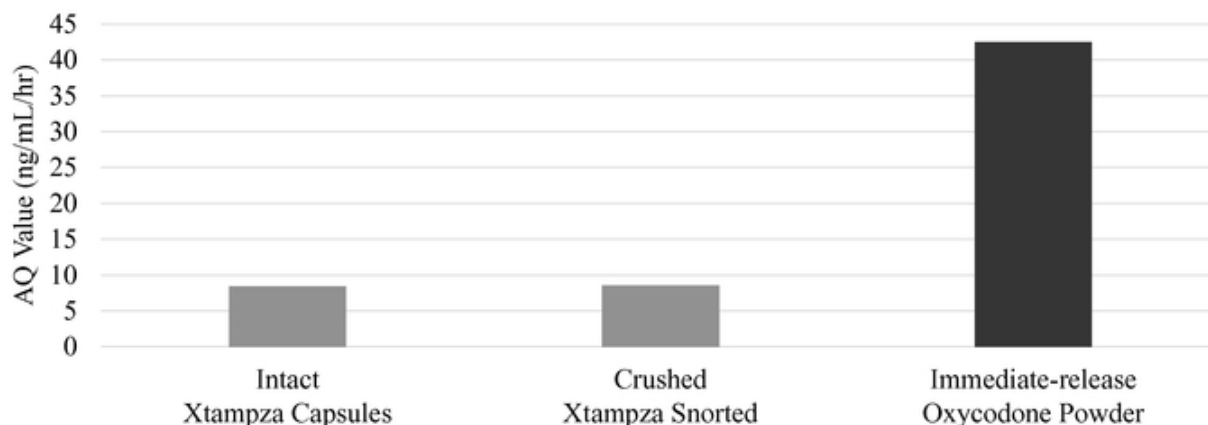
The figure below shows the mean PAUC values from the first sampling time to two hours for two treatments. Over the first two hours after dosing, the PAUC values for crushed and snorted Xtampza treatments were substantially lower than the crushed and snorted immediate-release oxycodone powder values.

**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**



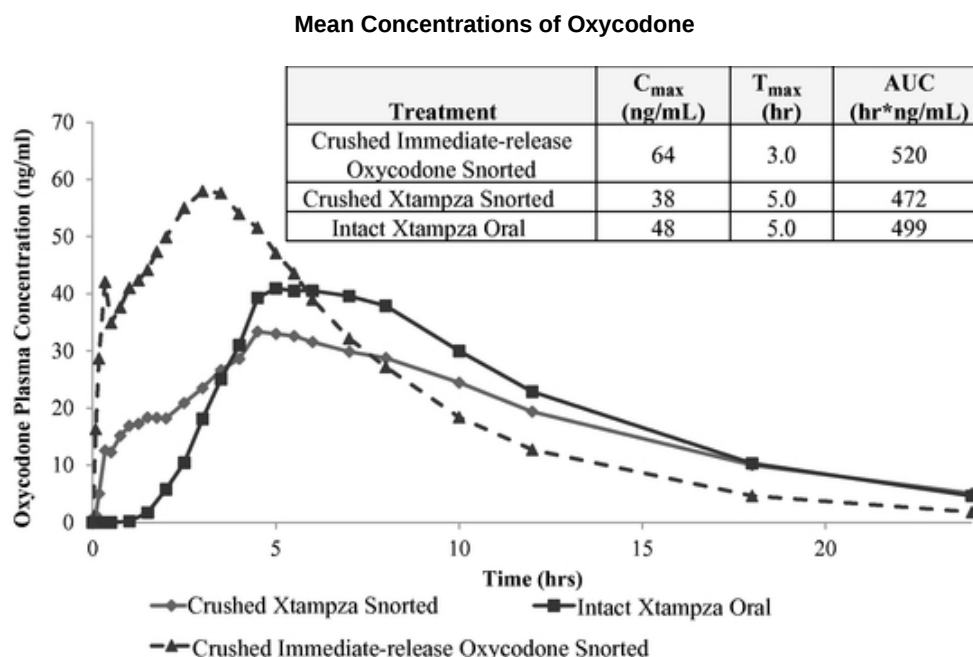
In summary, crushed and snorted Xtampza microspheres demonstrated a lower  $C_{max}$  and an equivalent  $T_{max}$  compared to taking the intact product orally as directed. The  $C_{max}$  of both crushed and snorted Xtampza and intact Xtampza taken orally are substantially lower than the  $C_{max}$  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-21)

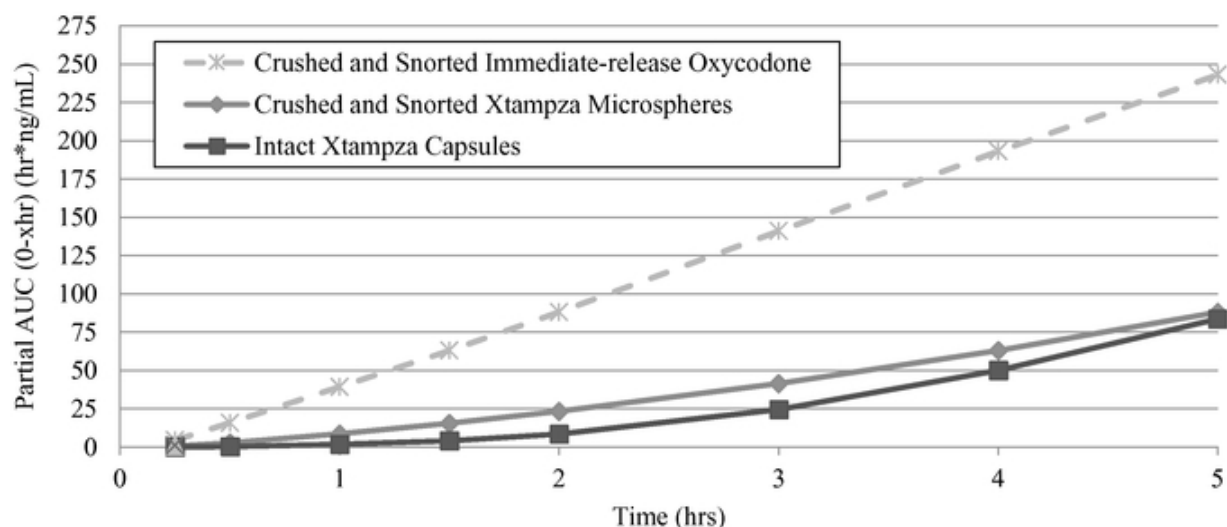
Our intranasal PK and HAP clinical trial was a randomized, open-label, active-controlled, cross-over comparison clinical trial. The primary objective was to compare the safety and PK of crushed and snorted Xtampza, intact Xtampza capsules taken orally, and snorted crushed immediate-release oxycodone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



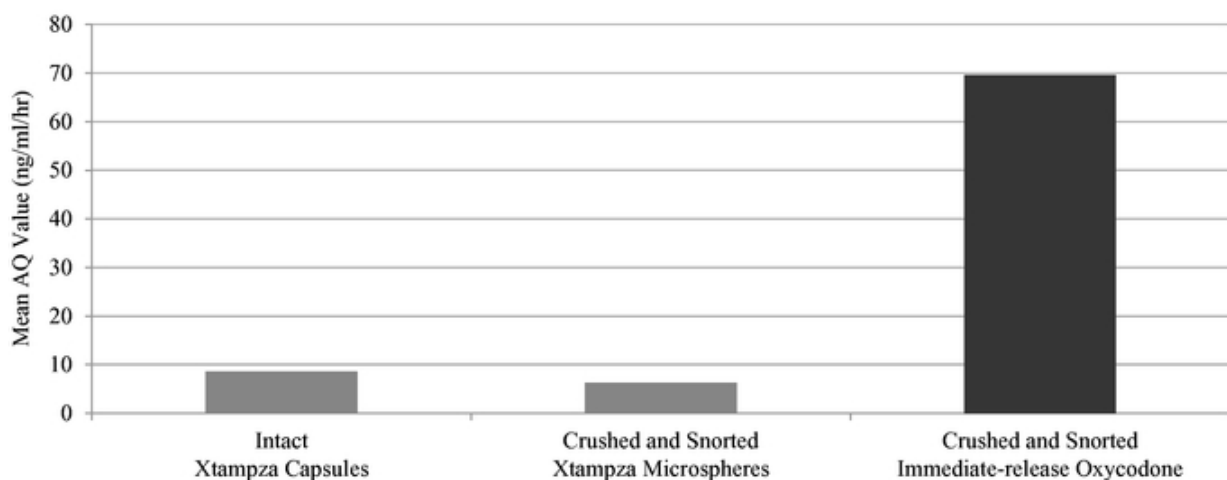
The figure below shows the mean PAUC values from the first sampling time to five hours for all three treatment arms. Over the first five hours after dosing, the PAUC values for intact Xtampza and crushed and snorted Xtampza treatments were substantially lower than those of the crushed and snorted immediate-release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

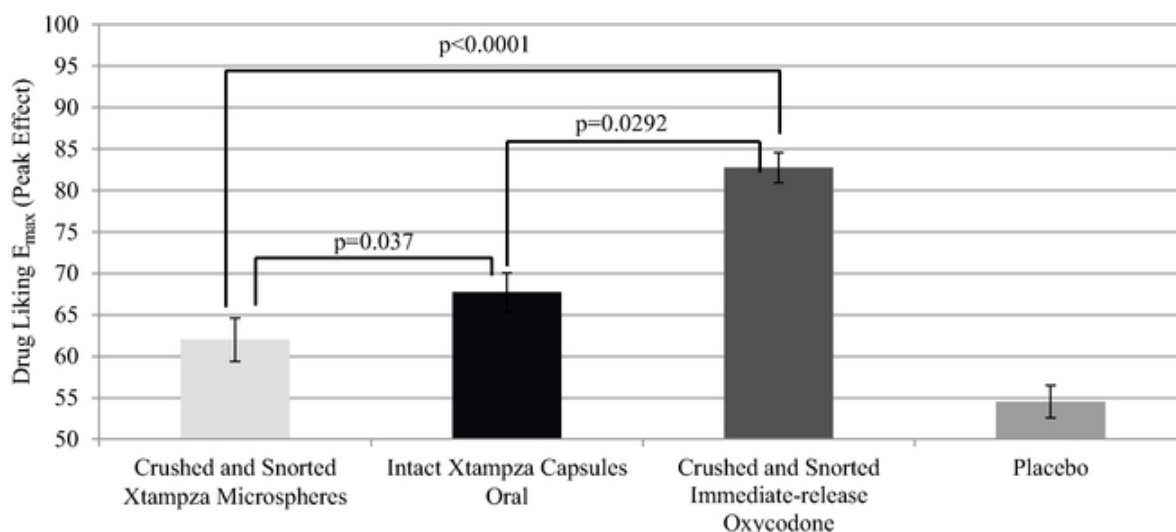
HAP trials are clinical trials that determine the intrinsic potential for abuse of a drug formulation. These clinical trials are conducted in a non-dependent, recreational drug abuser population and are designed to predict how probable it is that a particular drug formulation will be attractive to abusers (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 ( $p = 0.037$ ).

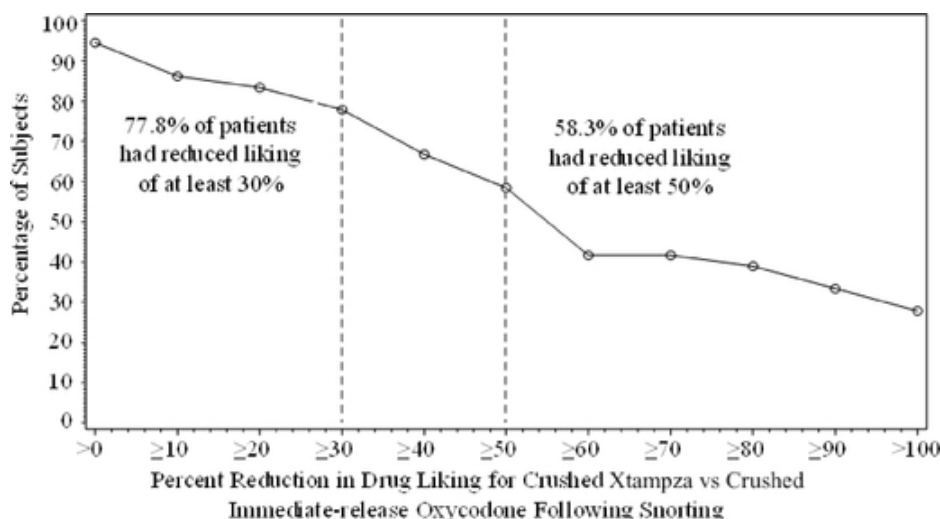


Mean Drug Liking  $E_{max}$  (Peak Effect)



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

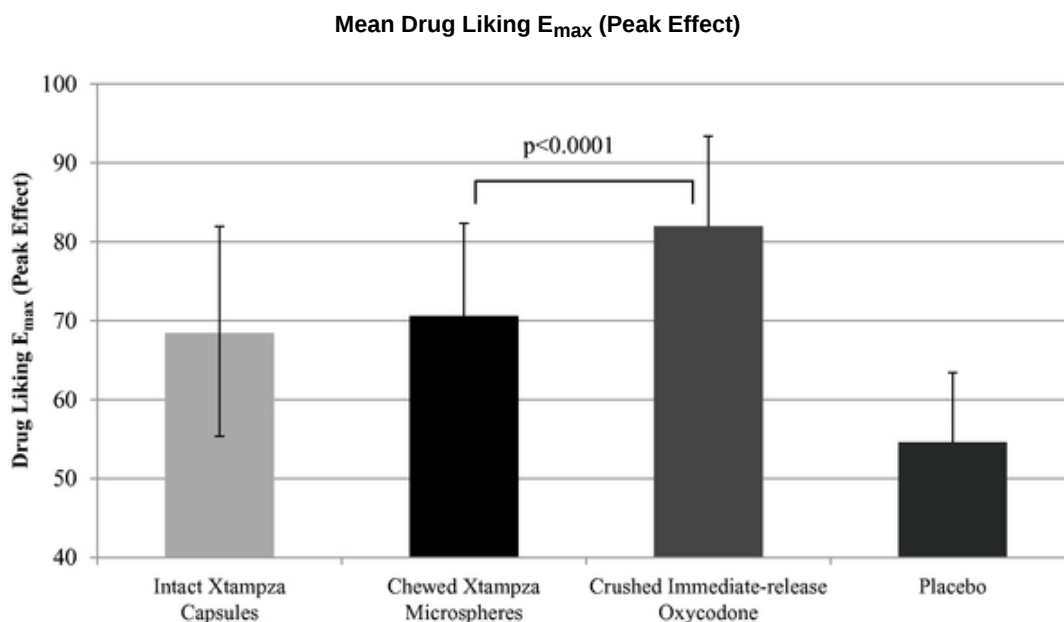


In summary, drug abusers liked crushed and snorted Xtampza microspheres significantly less than swallowing intact Xtampza capsules ( $p=0.037$ ), and they liked swallowing intact Xtampza capsules significantly less than snorting immediate-release oxycodone powder ( $p=0.0292$ ). Furthermore, crushing 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)*

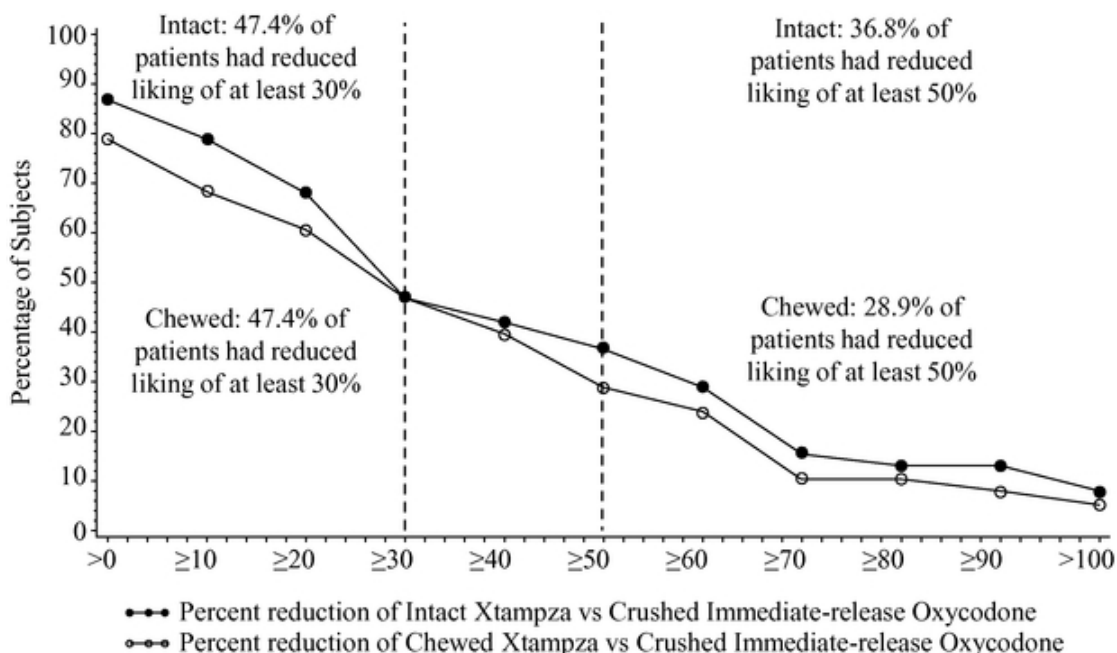
Our oral chewed PK and HAP clinical trial assessed the HAP of chewing Xtampza capsule contents compared with taking the intact Xtampza orally and with taking crushed immediate-release oxycodone tablets orally.

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**

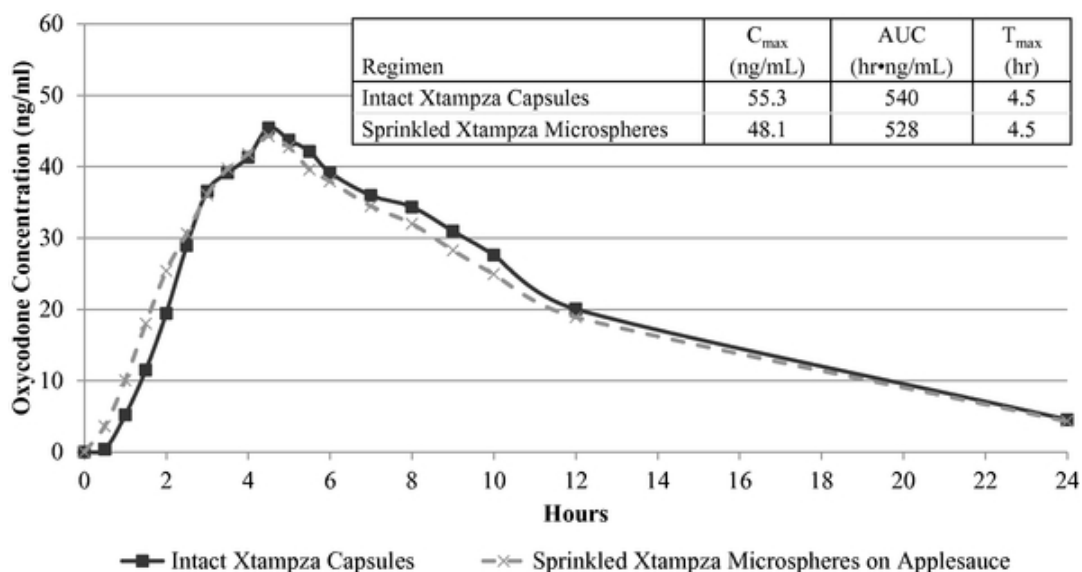


This clinical trial demonstrated that administration of chewed Xtampza resulted in lower Drug Liking  $E_{max}$  than swallowing crushed immediate-release oxycodone. Similarly, swallowing intact Xtampza resulted in lower Drug Liking  $E_{max}$  than swallowing crushed immediate-release oxycodone. This 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.

### 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 explore out-licensing partnerships for Xtampza in other international markets, such as Canada, Australia and Japan, as well as countries in Latin America and Europe.

The members of our management team, who will lead the commercialization of Xtampza, if we receive final regulatory approval, have substantial experience in pharmaceutical sales and marketing. If Xtampza receives final regulatory approval in the United States, we intend to hire a dedicated field sales force, initially consisting of approximately 120 sales professionals, to target the approximately 11,000 physicians who write approximately 55% 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 of approximately 25 specialty sales representatives to call on institutions where patients require extended-release opioids, such as skilled nursing or hospice facilities. In addition, we have employed medical sales liaisons, or MSLs, to respond to clinician inquiries about Xtampza. We have also employed 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 advanced 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 the differentiated features of Xtampza, the hazards of opioids that are not abuse-deterrent, and increasing awareness of solutions for patients with CPD who require or would benefit from extended-release opioids.

## **Intellectual Property**

We regard the protection of patents, designs, trademarks and other proprietary rights that we own or license as critical to our success and competitive position. Our patent portfolio directed toward Xtampza and our DETERx technology consists of seven issued patents in the United States (five of which claim compositions of matter, one of which claims both compositions of matter and methods of use, and 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 were granted Notice of Allowances for one patent in the United States and one patent in Canada. Finally, we have six patent applications pending in the United States, and one pending patent application in Japan. Our issued U.S. patents are projected to expire in 2023 and 2025, and our pending patent applications in the United States, if issued, would be projected to expire in 2023, 2025 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. 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 regulatory 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 regulatory 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.

On July 23, 2015, Purdue voluntarily dismissed the Massachusetts case and on August 6, 2015, Purdue filed another case in Massachusetts asserting the same four patents as in the Delaware case and the original Massachusetts case. On October 7, 2015, the Delaware case was transferred to Massachusetts and on November 4, 2015, the two cases pending in Massachusetts were consolidated. On November 9, 2015, we filed a motion for partial judgment on the pleadings in relation to three of the four patents asserted against us which, had been previously invalidated by the court in the Southern District of New York in Purdue's suit against Teva Pharmaceuticals USA, Inc., or Teva. On the same date, we moved for entry of final judgment and to expedite hearing on our motions. On November 23, 2015, Purdue filed a motion to

stay proceedings until resolution of its appeal against Teva. The hearing regarding our motion for partial judgment and entry of judgment and Purdue's motion to stay was held on December 22, 2015. On December 23, 2015, the District Court of Massachusetts issued an order staying proceedings in relation to the three Orange Book-listed patents asserted against us until February 25, 2016, which is the date scheduled by the Court for a status conference. The Court reserved the decision to grant our motion for judgment on the three Orange Book-listed patents to be taken up again at the February 25th status conference, at which time the Court indicated it may grant our motion for judgment or may consider extending the stay. The Court further indicated that it will consider an earlier hearing if the Court of Appeals for the Federal Circuit issues a decision on the appeal of the New York judgment of invalidity prior to the February 25th status conference.

On November 6, 2015, Purdue filed another patent infringement suit against us in Massachusetts asserting infringement of another patent that is a continuation of the three patents previously asserted by Purdue against us that were invalidated by the court in the Southern District of New York. On December 1, 2015, we filed a motion to dismiss for failure to state a claim, arguing that the patent asserted by Purdue is invalid based on collateral estoppel. Purdue filed its opposition response on December 15, 2015. That action has been consolidated into the other Massachusetts actions, and our motion remains pending.

The FDA's tentative approval of Xtampza means that the product, with its product labeling, is tentatively approved based upon the information available to the FDA at the time of tentative approval. The FDA can grant final approval following the expiration of the 30-month stay 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 stay period expires, the FDA could then provide final regulatory approval of Xtampza prior to the expiration of the 30-month period, at which point the product can be marketed. We do not believe we infringe Purdue's patents and intend to vigorously defend the suit. 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. The oral arguments for the pending appeal in the U.S. Court of Appeals for the Federal Circuit were held on November 3, 2015.

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 final regulatory approval to market Xtampza with a best-in-class abuse-deterrent product label.* Our tentatively approved product label contains differentiated abuse-deterrent claims for Xtampza. If Xtampza receives final regulatory approval, this product label may allow us to detail Xtampza to physicians and highlight its unique abuse-deterrent characteristics.
- § *Commercialize Xtampza in the United States ourselves.* We are currently building our commercial organization, including our sales force and commercial manufacturing capacity, in preparation for a potential U.S. commercial launch of Xtampza in the second quarter of 2016, although the timing of a potential commercial launch is subject to whether and when we receive final regulatory approval for Xtampza. Our management team has extensive experience commercializing pharmaceutical products, and we are in the process of establishing sales, marketing and reimbursement functions to commercialize Xtampza in the United States. Initially, we plan to detail Xtampza to approximately 11,000 physicians who write approximately 55% of the branded extended-release oral opioid prescriptions in the United States with a sales team of approximately 120 sales representatives. We believe that this physician group also represents a significant portion of the top prescribers of extended-release and long-acting opioids (including drugs formulated with fentanyl and methadone) currently used to treat patients with CPD. In addition, we plan to deploy a separate, focused sales team of approximately 25 specialty sales representatives to detail Xtampza to nursing homes, hospices, and other institutions treating large populations of the elderly and other patients who need chronic pain relief and have difficulty swallowing.
- § *Establish Xtampza as the treatment of choice for patients with CPD.* Xtampza has been tentatively approved with product labeling for sprinkling Xtampza microspheres on soft foods or into a cup, and then directly into the mouth, or through a gastrostomy or nasogastric feeding tube. If Xtampza receives final regulatory approval, Xtampza could be the only extended-release oxycodone product designed to be suitable for this approximately 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. 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 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. We also have an IND application on file for COL-172, an abuse-deterrent, extended-release oxymorphone for the treatment of chronic pain, which has been granted Fast Track status by the FDA. In addition, we have COL-171, a proprietary preclinical DETERx extended-release, abuse-deterrent methylphenidate formulation for the treatment of ADHD.
- § *Acquire additional products and product candidates.* We may identify and license, co-promote or acquire products or product candidates being developed for pain indications and other complementary products.

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 advanced 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 product label are OxyContin OP and Hysingla®, both of which are marketed by Purdue, and Embeda, which is marketed by Pfizer. In addition, there are two other approved extended-release opioids that have abuse-deterrent product labeling, Targiniq from Purdue and MorphaBond™ ER from Inspirion Delivery Technologies, LLC, neither of which is 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 product 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. MorphaBond ER is a twice daily morphine product formulated with a hard tablet and gelling polymers. 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, Pernix, 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, 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, oxymorphone and methadone, as well as opioids that are currently in clinical development.

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

Additionally, we are aware of companies 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 \$2,374,200, 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 \$114,450 per product and \$585,200 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. In the interim period, the FDA may grant tentative approval. Tentative approval indicates that the FDA has determined that the applicant meets the standards for approval as of the date that the tentative approval is granted. Final regulatory approval can only be granted if the FDA is assured that there is no new information that would affect final regulatory approval. As with traditional NDAs, a Section 505(b)(2) NDA may be eligible for three-year marketing exclusivity, assuming the NDA includes reports of new clinical trials (other than bioavailability clinical trials) essential to the approval of the NDA.

### **Disclosure of Clinical Trial Information**

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

### **DEA Regulation**

Our lead product candidate, Xtampza, if it ultimately receives final regulatory approval, 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 HITECH, which became effective on February 17, 2010. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," which are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

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

made to the Centers for Medicare & Medicaid Services, or CMS, by the 90th day following the end of each subsequent year and CMS subsequently is to publish the reported information on a publicly available website.

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

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

### ***Third-Party Payor Coverage and Reimbursement***

The commercial success of our product candidates, if approved, will depend, in part, upon the availability of coverage and adequate reimbursement from third-party payors at the federal, state and private levels. Third-party payors include governmental programs such as Medicare or Medicaid, private insurance plans and managed care plans. These third-party payors may deny coverage or reimbursement for a product or therapy in whole or in part if they determine that the product or therapy was not medically appropriate or necessary. Also, third-party payors have attempted to control costs by limiting coverage through the use of formularies and other cost-containment mechanisms and the amount of reimbursement for particular procedures or drug treatments.

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

Some third-party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, these requirements or any announcement or adoption of such proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and to operate profitably.

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

### **Healthcare Reform**

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

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by HHS, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness clinical trials are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

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

- § an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- § an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- § a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- § extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- § expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- § expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- § a licensure framework for follow-on biologic products;
- § a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- § a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- § creation of the Independent Payment Advisory Board, which has authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations (the IPAB has not yet been called upon to act as the annual determinations by the CMS Office of the Actuary have not identified a savings target for implementation in years 2015 or 2016); and
- § establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending that began on January 1, 2011.

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

#### ***Other Regulatory Requirements***

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

#### ***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, 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 regulatory 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 regulatory 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 July 23, 2015, Purdue voluntarily dismissed the Massachusetts case and on August 6, 2015, Purdue filed another case in Massachusetts asserting the same four patents as in the Delaware case and the original Massachusetts case. On October 7, 2015, the Delaware case was transferred to Massachusetts and on November 4, 2015, the two cases pending in Massachusetts were consolidated. On November 9, 2015, we filed a motion for partial judgment on the pleadings in relation to three of the four patents asserted against us, which had been previously invalidated by the court in the Southern District of New York in Purdue's suit against Teva. On the same date, we moved for entry of final judgment and to expedite hearing on our motions. On November 23, 2015, Purdue filed a motion to stay proceedings until resolution of its appeal against Teva. The hearing regarding our motion for partial judgment and entry of judgment and Purdue's motion to stay was held on December 22, 2015. On December 23, 2015, the District Court of Massachusetts issued an order staying proceedings in relation to the three Orange Book-listed patents asserted against us until February 25, 2016, which is the date scheduled by the Court for a status conference. The Court reserved the decision to grant our motion for judgment on the three Orange Book-listed patents to be taken up again at the February 25th status conference, at which time the Court indicated it may grant our motion for judgment or may consider extending the stay. The Court further indicated that it will consider an earlier hearing if the Court of Appeals for the Federal Circuit issues a decision on the appeal of the New York judgment of invalidity prior to the February 25th status conference.

On November 6, 2015, Purdue filed another patent infringement suit against us in Massachusetts asserting infringement of another patent that is a continuation of the three patents previously asserted by Purdue against us that were invalidated by the court in the Southern District of New York. On December 1, 2015, we filed a motion to dismiss for failure to state a claim, arguing that the patent asserted by Purdue is invalid based on collateral estoppel. Purdue filed its opposition response on December 15, 2015. That

action has been consolidated into the other Massachusetts actions, and our motion remains pending. We plan to continue to take all steps necessary 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 was extended and now terminates on the date that is five years following August 2015, which is the date that the landlord delivered the expansion space with certain improvements substantially completed. The lease term may be extended for an additional five-year term at our election.

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

## **Employees**

As of December 31, 2015, we had a total of 46 full-time employees. Of these, 11 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.	51	Chairman, President and Chief Executive Officer
Paul Brannelly	43	Executive Vice President and Chief Financial Officer
Barry S. Duke	56	Executive Vice President and Chief Commercial Officer
<i>Non-Employee Directors:</i>		
Garen G. Bohlin	68	Director
John G. Freund, M.D.	62	Director
Patrick Heron	45	Director
David Hirsch, M.D., Ph.D.	45	Director
Eran Nadav, Ph.D.	46	Director
Gino Santini	59	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 Zalicus 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.

#### 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. Prior to Syntonix, 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 Ventures, 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 worked 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: XNPT) (1999 to Present), Tetrphase Pharmaceuticals, Inc. (NASDAQ: TTPH) (2012 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: Concert Pharmaceuticals, Inc. (NASDAQ: CNCE) (2014 to 2015), 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. 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. Dr. Nadav has leadership experience in private and public companies in the healthcare sector. Dr. Nadav is currently serving as Chairman of the Board of Trevi Therapeutics, Inc. and as a board member of ShangPharma Corporation (a China-based CRO) and NovaSom, Inc. Dr. Nadav served as the lead investor and Chairman of the Board of Ultragenyx Pharmaceutical, Inc. (NASDAQ: RARE) from January 2012 to June 2015. He served on the board of directors of MacroGenics, Inc. (NASDAQ: MGNX) from June 2013 to June 2014, and the board of directors of Eden Springs Ltd., a European provider of drinking water solutions for the workplace, from July 2010 until August 2011.

Prior to TPG, Dr. Nadav served as Business Development Director at Eisai, a pharmaceutical company, from September 2003 to August 2007. He previously worked at Johnson & Johnson Development Corporation, the venture capital arm of Johnson & Johnson, from November 1999 until July 2002.

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 experience in the biopharma business.

**Gino Santini, Director.** Mr. Santini has served as a member of our board of directors since July 2012 and has served as our lead independent director since May 2015. 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 as chairman of the board of directors of AMAG Pharmaceuticals Inc. (NASDAQ: AMAG) (2012 to Present), and as a member of the board of directors of Intercept Pharmaceuticals, Inc. (NASDAQ: ICPT) (November 2015 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. Previously, Mr. Santini served on the board of directors of Sorin S.p.A., a company traded on the Italian Stock Exchange (2012 to 2015). 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.

Our amended and restated articles of incorporation and amended bylaws provide that our board of directors 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 is 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 is staggered, such that only approximately one third of our board of directors is up for election in any given year.

Our directors are divided among the three classes as follows:

- § The Class I directors are Messrs. Freund, Heron and Hirsch, and their terms will expire at the annual meeting of shareholders to be held in 2016;
- § The Class II directors are Messrs. Nadav and Santini, and their terms will expire at the annual meeting of shareholders to be held in 2017; and
- § The Class III directors are Messrs. Heffernan and Bohlin, and their terms will expire at the annual meeting of shareholders to be held in 2018.

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 operates under a charter that has been approved by our board of directors and is available on our website, [www.collegiumpharma.com](http://www.collegiumpharma.com), under the "Investor Relations" section. 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:

- § 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 reviews 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 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. Bohlin, 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 applicable to all of our employees, executive officers and directors. The Code of Ethics is available on our website at [www.collegiumpharma.com](http://www.collegiumpharma.com). Our board of directors is 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 satisfies

these independence requirements in accordance with the phase-in schedule allowed by the NASDAQ Stock Market Rules.

Our board of directors will continue to 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.

### **Board Leadership Structure**

Mr. Heffernan serves as Chairman of our board of directors in addition to his role as Chief Executive Officer. In May 2015, our board of directors appointed Mr. Santini as lead independent director. As lead independent director, Mr. Santini is responsible for, among other things:

- § advising the Chairman of the board of directors and of the committees of the board of directors as to the information needs, agenda, schedule and budgeting of time for meetings,
- § collaborating with the Chairman of the board of directors on evaluating and improving the effectiveness of the board of directors,
- § offering counsel to individual directors on the performance of their duties,
- § leading executive sessions of the board of directors' independent directors, and
- § serving as principal liaison between the non-employee directors and the Chairman of the board of directors on significant or sensitive issues.

We combine the Chairman and Chief Executive Officer positions because we believe that, at this critical juncture in our development, Mr. Heffernan is best suited to oversee the development and implementation of our strategic vision, including our planned transition from a development stage entity into a commercial pharmaceutical company. Mr. Heffernan's tenure as Chairman also reflects our board of directors' confidence in his leadership and vision for us and recognizes his accomplishments since joining us. We believe that by creating a lead independent director position held by Mr. Santini, we have designed a governance structure that best advances our objectives while maintaining proper checks and balances on senior management, and providing the independent members of the board of directors with open and transparent communication regarding our strategic planning activities.



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

The following table shows the annual compensation paid to or earned by (i) Michael T. Heffernan, our President and Chief Executive Officer, for the fiscal years ended December 31, 2015 and 2014, and (ii) Paul Brannelly, our Executive Vice President and Chief Financial Officer, and Barry S. Duke, our Executive Vice President and Chief Commercial Officer (together, our "named executive officers"), for the fiscal year ended December 31, 2015:

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$) <sup>(1)</sup>	Option Awards (\$) <sup>(2)</sup>	Non-Equity Incentive Plan Compensation (\$) <sup>(3)</sup>	All Other Compensation (\$) <sup>(4)</sup>	Total (\$)
Michael T. Heffernan, R.Ph. President and Chief Executive Officer	2015	426,242	375,000 <sup>(5)</sup>	633,984	1,776,999	—	14,168	3,262,393
	2014	380,380	—	—	—	130,851 <sup>(6)</sup>	7,570	518,801
Paul Brannelly Executive Vice President and Chief Financial Officer <sup>(7)</sup>	2015	289,038	—	—	624,009	—	4,161	922,208
Barry S. Duke Executive Vice President and Chief Commercial Officer <sup>(8)</sup>	2015	250,000	—	—	557,928	—	76,427	884,175

<sup>(1)</sup> The amounts reflect the aggregate grant date fair value of stock 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> 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>(3)</sup> Bonuses for fiscal year 2015 performance of our executive officers have not yet been determined, although information for such bonuses is described in the section below titled "— Non-Equity Incentive Plan Compensation." We anticipate that bonuses earned for fiscal year 2015 may be determined by the end of January 2016.

<sup>(4)</sup> This amount reflects our contributions to our 401(k) Plan and the amount of life and disability insurance premiums paid by us on behalf of each named executive officer. Mr. Duke's amount also includes a relocation bonus of \$75,000.

<sup>(5)</sup> Mr. Heffernan received this bonus in connection with the closing of our Series D Convertible Preferred Stock financing in March 2015.

<sup>(6)</sup> Represents annual bonus amount calculated and paid pursuant to Mr. Heffernan's employment agreement. For more information, see "— Non-Equity Incentive Plan Compensation."

<sup>(7)</sup> Mr. Brannelly joined our company on February 4, 2015.

<sup>(8)</sup> Mr. Duke joined our company on March 30, 2015.

**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.*

The 2014 data in the table above reflects compensation payable to Michael T. Heffernan, our President and Chief Executive Officer, pursuant to an amended and restated employment agreement dated June 13, 2012 (the "Prior Heffernan Agreement"). The principal compensation terms of the Prior Heffernan Agreement are as follows:

- § base salary of \$350,000 per year, subject to annual adjustments;
- § 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.

On August 4, 2015, we entered in a new employment agreement with Mr. Heffernan (the "Heffernan Agreement"), which replaced and superseded the Prior Heffernan Agreement. Pursuant to the Heffernan Agreement, Mr. Heffernan's base salary was increased to \$488,800 per year and his annual incentive bonus opportunity was increased to a target amount of 50% of his base salary.

Upon a termination of Mr. Heffernan's employment by us without cause or by Mr. Heffernan for good reason (each as defined in the Heffernan Agreement) prior to a change in control of our company, Mr. Heffernan is eligible to receive (i) continuation of his base salary for twelve months (the "Heffernan Severance Period"), (ii) a lump sum payment equal to Mr. Heffernan's then current target annual bonus, (iii) continuation of his health insurance benefits at our expense for the duration of the Heffernan Severance Period, and (iv) full vesting with respect to all unvested restricted stock, stock options and other equity incentives awarded to Mr. Heffernan, 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 twelve months following a change in control of our company, Mr. Heffernan is eligible to receive the benefits described in the preceding sentence, except that the Heffernan Severance Period will be "eighteen months" instead of "twelve months." Upon a termination of Mr. Heffernan's employment with us due to his death or disability, all unvested restricted stock, stock options and other equity incentives awarded to him by us shall become fully vested.

Mr. Heffernan is entitled to participate in all of our employee benefit plans, subject to the terms and conditions applicable to such plans. Further, the Heffernan Agreement 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.

*Paul Brannelly*

On August 4, 2015, we entered into an employment agreement with Paul Brannelly, our Executive Vice President and Chief Financial Officer (the "Brannelly Agreement"). The principal compensation terms of the Brannelly Agreement are as follows:

- § base salary of \$325,000 per year, subject to annual adjustments; and
- § annual incentive bonus opportunity in an amount up to 35% of base salary based upon the achievement of certain bonus eligibility criteria.

Additionally, Mr. Brannelly has been granted stock option awards as described below under the heading "— Outstanding Equity Awards at Fiscal Year-End."

Upon a termination of Mr. Brannelly's employment by us without cause or by Mr. Brannelly for good reason (each as defined in the Brannelly Agreement) prior to a change in control of the Company, Mr. Brannelly is eligible to receive continuation of his base salary and continuation of his health insurance benefits at our expense for nine months, subject to his execution of and non-revocation of a general release of claims. Upon a termination of Mr. Brannelly's employment by us without cause or by Mr. Brannelly for good reason

within twelve months following a change in control of our company, Mr. Brannelly is eligible to receive full vesting with respect to all unvested restricted stock, stock options and other equity incentives awarded to Mr. Brannelly and continuation of his base salary and health insurance benefits at our expense for twelve months, subject to his execution of and non-revocation of a general release of claims.

Mr. Brannelly is entitled to participate in all of our employee benefit plans, subject to the terms and conditions applicable to such plans. Further, the Brannelly Agreement contains customary non-solicitation covenants, which covenants remain in effect for nine months following any cessation of employment with respect to Mr. Brannelly.

#### *Barry S. Duke*

On August 4, 2015, we entered into an employment agreement with Barry S. Duke, our Executive Vice President and Chief Commercial Officer (the "Duke Agreement"). The principal compensation terms of the Duke Agreement are as follows:

- § base salary of \$325,000 per year, subject to annual adjustments; and
- § annual incentive bonus opportunity in an amount up to 40% of base salary based upon the achievement of certain bonus eligibility criteria.

Additionally, Mr. Duke has been granted stock option awards as described below under the heading "— Outstanding Equity Awards at Fiscal Year-End."

Upon a termination of Mr. Duke's employment by us without cause or by Mr. Duke for good reason (each as defined in the Duke Agreement) prior to a change in control of the Company, Mr. Duke is eligible to receive continuation of his base salary and continuation of his health insurance benefits at our expense for nine months, subject to his execution of and non-revocation of a general release of claims. Upon a termination of Mr. Duke's employment by us without cause or by Mr. Duke for good reason within twelve months following a change in control of our company, Mr. Duke is eligible to receive full vesting with respect to all unvested restricted stock, stock options and other equity incentives awarded to Mr. Duke and continuation of his base salary and health insurance benefits at our expense for twelve months, subject to his execution of and non-revocation of a general release of claims.

Mr. Duke is entitled to participate in all of our employee benefit plans, subject to the terms and conditions applicable to such plans. Further, the Duke Agreement contains customary non-solicitation covenants, which covenants remain in effect for nine months following any cessation of employment with respect to Mr. Duke.

#### *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 our company without cause or a resignation by such named executive officer 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 our named executive officers 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*

Each named executive officer's target bonus opportunity is expressed as a percentage of base salary, as described above. For the fiscal year ended December 31, 2015, Mr. Heffernan's target bonus opportunity was 50% of base salary and the target bonus opportunities for Messrs. Brannelly and Duke were 35% and 40%, respectively. Bonuses for fiscal 2015 performance of our executive officers have not been determined. We anticipate that bonuses earned for fiscal year 2015 may be determined by the end of January 2016. For the fiscal year ended December 31, 2014, Mr. Heffernan was eligible to earn a cash bonus, of which 70% of such bonus was determined based on achievement of corporate performance goals and 30% of such bonus was determined based on achievement of certain individual performance goals. The target amount of

the annual bonus for Mr. Heffernan was 40% of base salary. The applicable corporate performance goals were achieved at 86% of target with the applicable individual performance goals for Mr. Heffernan achieved at 86% of target. Thus, Mr. Heffernan earned an annual bonus at 86% of target. The amount shown above for Mr. Heffernan in the column titled "— Non-Equity Incentive Plan Compensation" represents the actual annual performance bonuses payable for the fiscal year ended December 31, 2014 to Mr. Heffernan.

*Equity Awards During Fiscal Years Ended December 31, 2015 and 2014*

On March 19, 2015, we awarded Mr. Brannelly stock options to purchase 102,070 shares of our common stock, with an aggregate grant date fair value computed in accordance with FASB ASC Topic 718 equal to \$400,347. The options have an exercise price of \$5.73. On March 19, 2015, Mr. Brannelly exercised options to purchase 72,463 shares of common stock in exchange for \$415,212.99. The remaining options are subject to time-based vesting conditions as described below in the section titled "— Outstanding Equity Awards at Fiscal Year-End."

On March 30, 2015, we awarded Messrs. Heffernan and Duke stock options to purchase 275,463 and 72,463 shares of our common stock, respectively, with an aggregate grant date fair value computed in accordance with FASB ASC Topic 718 equal to \$1,076,993 and \$283,313, respectively. The options have an exercise price of \$5.73 and are subject to time-based vesting conditions as described below in the section titled "— Outstanding Equity Awards at Fiscal Year-End."

On April 2, 2015, we granted Mr. Heffernan restricted stock awards equal to 194,694 shares of our common stock, with an aggregate grant date fair value computed in accordance with FASB ASC Topic 718 equal to \$633,984. The restricted stock is subject to time-based vesting conditions as described below in the section titled "— Outstanding Equity Awards at Fiscal Year-End."

On May 14, 2015, we awarded Messrs. Heffernan, Brannelly and Duke stock options to purchase 70,193, 22,929 and 27,537 shares of our common stock, respectively, with an aggregate grant date fair value computed in accordance with FASB ASC Topic 718 equal to \$700,005, \$228,661 and \$274,615, respectively. The options have an exercise price of \$14.90 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, 2015. The market value of stock awards is based on the closing market price of our common stock of \$27.50 per share on December 31, 2015.

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. President and Chief Executive Officer	9,673	—	—	\$ 3.31	11/11/2020	—	—
	3,027 <sup>(1)</sup>	3,917 <sup>(1)</sup>	—	\$ 0.48	01/30/2023	—	—
	21,578 <sup>(2)</sup>	14,755 <sup>(2)</sup>	—	\$ 5.73	03/30/2025	—	—
	44,839 <sup>(3)</sup>	194,291 <sup>(3)</sup>	—	\$ 5.73	03/30/2025	—	—
	— <sup>(4)</sup>	70,193 <sup>(4)</sup>	—	\$ 14.90	05/14/2025	—	—
	—	—	—	—	—	113,571 <sup>(5)</sup>	3,123,203
Paul Brannelly Executive Vice President and Chief Financial Officer	5,553 <sup>(6)</sup>	24,054 <sup>(6)</sup>	—	\$ 5.73	03/19/2025	—	—
	— <sup>(7)</sup>	22,929 <sup>(7)</sup>	—	\$ 14.90	05/14/2025	—	—
Barry S. Duke Executive Vice President and Chief Commercial Officer	— <sup>(8)</sup>	72,463 <sup>(8)</sup>	—	\$ 5.73	03/30/2025	—	—
	— <sup>(9)</sup>	27,537 <sup>(9)</sup>	—	\$ 14.90	05/14/2025	—	—

<sup>(1)</sup> 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. The option was initially for 14,492 shares and the option was exercised as to 7,458 shares. As of December 31, 2015, 3,917 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.

<sup>(2)</sup> A stock option to purchase 36,333 shares of our common stock was granted to Mr. Heffernan on March 30, 2015. As of December 31, 2015, 14,755 option shares were not exercisable. On March 30, 2015, 50% of the option vested and became exercisable, and the remaining 50% of the option vests and becomes exercisable monthly over the four-year period commencing on March 30, 2015. 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.

<sup>(3)</sup> A stock option to purchase 239,130 shares of our common stock was granted to Mr. Heffernan on March 30, 2015. As of December 31, 2015, 194,291 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.

<sup>(4)</sup> A stock option to purchase 70,193 shares of our common stock was granted to Mr. Heffernan on May 14, 2015. As of December 31, 2015, 70,193 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 becoming vested and exercisable on May 14, 2016 and the remaining shares underlying the option vesting in monthly installments over the remaining three years of the four-year period. 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.

<sup>(5)</sup> Mr. Heffernan was awarded 194,694 shares of restricted common stock in April 2015. 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. 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 change of control.

<sup>(6)</sup> A stock option to purchase 29,607 shares of our common stock was granted to Mr. Brannelly on March 19, 2015. As of December 31, 2015, 24,054 option shares were not exercisable. The option vests and becomes exercisable monthly over the four-year period following the grant date. Pursuant to Mr. Brannelly's employment agreement, the option will immediately become fully vested and exercisable upon a termination of Mr. Brannelly's employment without cause or upon a resignation by Mr. Brannelly for good reason within twelve months of the occurrence of a change of control.

- (7) A stock option to purchase 22,929 shares of our common stock was granted to Mr. Brannelly on May 14, 2015. As of December 31, 2015, 22,929 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 becoming vested and exercisable on May 14, 2016 and the remaining shares underlying the option vesting in monthly installments over the remaining three years of the four-year period. Pursuant to Mr. Brannelly's employment agreement, the option will immediately become fully vested and exercisable upon a termination of Mr. Brannelly's employment without cause or upon a resignation by Mr. Brannelly for good reason within twelve months of the occurrence of a change of control.
- (8) A stock option to purchase 72,463 shares of our common stock was granted to Mr. Duke on March 30, 2015. As of December 31, 2015, 72,463 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 becoming vested and exercisable on March 30, 2016 and the remaining shares underlying the option vesting in monthly installments over the remaining three years of the four-year period. Pursuant to Mr. Duke's employment agreement, the option will immediately become fully vested and exercisable upon a termination of Mr. Duke's employment without cause or upon a resignation by Mr. Duke for good reason within twelve months of the occurrence of a change of control.
- (9) A stock option to purchase 27,537 shares of our common stock was granted to Mr. Duke on May 14, 2015. As of December 31, 2015, 27,537 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 becoming vested and exercisable on May 14, 2016 and the remaining shares underlying the option vesting in monthly installments over the remaining three years of the four-year period. Pursuant to Mr. Duke's employment agreement, the option will immediately become fully vested and exercisable upon a termination of Mr. Duke's employment without cause or upon a resignation by Mr. Duke for good reason within twelve months of the occurrence of a change of control.

## 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 became effective immediately prior to the closing of the IPO. 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 the IPO, 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 administers 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, 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.

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 became effective immediately prior to the closing of the IPO. The 2015 ESPP is administered by our board of directors or by a committee appointed by our board of directors. The 2015 ESPP initially provides 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 became effective immediately prior to the closing of the IPO. The Performance Bonus Plan is 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 and 2015 was \$35,000 and \$44,095, respectively.

### 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, 2015 to our non-employee directors.

Name	Fees earned or paid in cash (\$)	Stock awards (\$)	Option Awards (\$) <sup>(1)</sup>	Total (\$)
Garen G. Bohlin	29,815	—	113,687	143,512
John G. Freund, M.D.	7,938	—	139,202	146,640
Patrick Heron	7,047	—	139,202	146,249
David Hirsch, M.D., Ph.D.	7,830	—	139,202	147,032
Eran Nadav, Ph.D.	7,438	—	139,202	146,640
Gino Santini	31,957	—	139,202	171,159

<sup>(1)</sup> Amounts represent the grant date fair value of stock options granted during 2015, as calculated in accordance with ASC Topic 718. See Note 11 of the financial statements included in this prospectus for assumptions used in calculating this amount. As of December 31, 2015, the aggregate number of shares underlying stock options held by each non-employee director were as follows; Mr. Bohlin: 28,985 (of which, 6,644 were exercisable as of December 31, 2015); Dr. Freund: 15,000; Mr. Heron: 15,000; Dr. Hirsch: 15,000; Dr. Nadav: 15,000; and Mr. Santini: 15,000.

The compensation earned by Mr. Heffernan, as President and Chief Executive Officer, for fiscal year 2015 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.

### **Non-Employee Director Compensation**

On August 4, 2015, our board of directors approved a non-employee director compensation policy, which established the following compensation guidelines:

- § each non-employee director will receive an annual retainer of \$40,000;
- § upon joining the board of directors, each non-employee director will receive an initial grant of options to purchase 15,000 shares of common stock, which will vest over a four-year period with 25% of the grant vesting on the one-year anniversary of the initial grant date and the remainder vesting ratably each month thereafter in equal installments over a three-year period, subject to continued service as a director;
- § each non-employee director will be granted options to purchase 8,700 shares of common stock at each annual meeting of shareholders, which will vest in full on the one-year anniversary of the initial grant date, subject to continued service as a director;
- § each non-employee director who serves as chairperson of a committee of the board will receive additional compensation as follows:
  - § the chairperson of the audit committee will receive an annual retainer of \$15,000;
  - § the chairperson of the compensation committee will receive an annual retainer of \$10,000; and
  - § the chairperson of the nominating and corporate governance committee will receive an annual retainer of \$7,500; and
- § each non-employee director who serves as a non-chair member of a committee of the board will receive additional compensation as follows:
  - § the members of the audit committee will receive annual retainers of \$7,500;
  - § the members of the compensation committee will receive annual retainers of \$5,000; and
  - § the members of the nominating and corporate governance committee will receive annual retainers of \$3,750.

**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."

**Participation in Initial Public Offering**

In our IPO, certain of our 5% shareholders and their affiliates purchased an aggregate of 1,300,000 shares of our common stock. Each of those purchases was made through the underwriters at the initial public offering price. The following table set forth the aggregate number of shares of our common stock that these 5% shareholders and their affiliates purchased in our IPO:

<b>Purchaser</b>	<b>Shares of Common Stock</b>
Frazier Healthcare VI, L.P. <sup>(1)</sup>	150,000
Entities affiliated with Longitude Capital Partners, LLC <sup>(2)</sup>	200,000
Skyline Venture Partners V, L.P. <sup>(3)</sup>	150,000
TPG Biotechnology Partners IV, L.P. <sup>(4)</sup>	100,000
RA Capital Healthcare Fund, LP <sup>(5)</sup>	700,000

<sup>(1)</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>(2)</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>(3)</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>(4)</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 the 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. Eran Nadav, Ph.D., a member of our board of directors, is a partner of TPG Global, LLC. The address for Messrs. Bonderman, Coulter, Nadav and TPG Biotechnology Partners IV, L.P. is c/o TPG Global, LLC, 301 Commerce Street, Suite 3300, Fort Worth, TX 76102.

<sup>(5)</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.

### **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.

### **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 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.

All outstanding convertible preferred stock converted into common stock upon the closing of the IPO.

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 the 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. Eran Nadav, Ph.D., a member of our board of directors, is a partner of TPG Global, LLC. The address for Messrs. Bonderman, Coulter, Nadav 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



(j) 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:

<u>Participants<sup>(1)</sup></u>	<u>Amount of Notes Purchased</u>
<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

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

(2) 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.

(3) 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.

(4) 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.

(5) 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 terminated automatically upon completion of the IPO.

#### **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 Millennium 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 Millennium 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 terminated automatically upon closing of the IPO.

#### **Management Rights Letters**

We entered into management rights letters with certain of our shareholders, including the Boston Millennium 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 terminated automatically upon completion of the IPO.

#### **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 — Equity Awards During Fiscal Years Ended December 31, 2015 and 2014" and "Executive and Director Compensation — Compensation of Non-Employee Directors."

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

We have entered 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. 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**

Our board of directors has adopted 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 is available on our website, [www.collegiumpharma.com](http://www.collegiumpharma.com), under the "Investor Relations" section. 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 December 31, 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 20,739,351 shares of common stock outstanding as of December 31, 2015. 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.

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.

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>	3,321,842	16.02%	%
Skyline Venture Partners V, L.P. <sup>(2)</sup>	2,949,916	14.22%	%
Frazier Healthcare VI, L.P. <sup>(3)</sup>	1,887,332	9.10%	%
RA Capital Healthcare Fund, L.P. <sup>(4)</sup>	1,545,410	7.45%	%
TPG Biotechnology Partners IV, L.P. <sup>(5)</sup>	1,325,263	6.39%	%
Entities affiliated with Boston Millennia Partners <sup>(6)</sup>	1,082,160	5.22%	%
<b>Directors and Named Executive Officers:</b>			
Michael T. Heffernan, R. Ph. <sup>(7)</sup>	609,174	2.92%	%
Paul Brannelly <sup>(8)</sup>	79,250	*	%
Barry S. Duke	—	—	—
Garen G. Bohlin <sup>(9)</sup>	7,852	*	%
John G. Freund, M.D. <sup>(10)</sup>	2,949,916	14.22%	%
Patrick Heron <sup>(11)</sup>	1,887,332	9.10%	%
David Hirsch, M.D., Ph.D. <sup>(12)</sup>	3,321,842	16.02%	%
Eran Nadav, Ph.D.	—	—	—
Gino Santini	23,188	*	%
<b>All current executive officers and directors as a group (9 persons)<sup>(13)</sup></b>	<b>8,878,554</b>	<b>42.59%</b>	<b>%</b>

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

- (1) Includes (a) 3,256,572 shares of common stock held by Longitude Venture Partners, L.P. and (b) 65,270 shares of common 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) 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) 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) 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

- (5) 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 the 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.
- (6) 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. A. Dana Callow Jr., Martin J. Hernon, 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.
- (7) Includes 90,822 shares of our common stock subject to options exercisable within 60 days of December 31, 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 6,787 shares of our common stock subject to options exercisable within 60 days of December 31, 2015.
- (9) Includes 7,852 shares of our common stock subject to options exercisable within 60 days of December 31, 2015.
- (10) 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.
- (11) 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.
- (12) 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.
- (13) Includes 105,461 shares of common stock which the directors and current executive officers (i.e., Messrs. Heffernan, Brannelly and Duke) have the right to acquire upon the exercise of stock options that were exercisable as of December 31, 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 December 31, 2015 our capital stock was held of record by 60 shareholders. Our authorized capital stock consists 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 our IPO, all outstanding shares of preferred stock 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 September 30, 2015, we had outstanding options to purchase 1,356,246 shares of our common stock at a weighted-average price of \$9.04 per share, pursuant to the Plan.

## **Restricted Common Stock**

As of September 30, 2015, we had 153,589 shares of restricted common stock issued and outstanding.

## **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. 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. Upon the completion of our IPO, the warrant converted into a warrant to purchase 2,445 shares of common stock at an exercise price of \$12.27.

## **Registration Rights**

Pursuant to the Investor Rights Agreement, certain holders of shares of our common stock have registration rights 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***

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. 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. All investors entitled to piggyback registration rights have waived such rights in connection with this offering.

### **Other Provisions**

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 is 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 is staggered, such that only approximately one third of our board of directors is 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 entered into indemnification agreements with our directors and executive officers. 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 is Computershare Trust Company, N.A.

***Listing***

Our common stock is listed on NASDAQ under the symbol "COLL."

## SHARES ELIGIBLE FOR FUTURE SALE

Future sales of substantial amounts of common stock in the public market could adversely affect prevailing market prices.

Based on the number of shares of common stock outstanding as of September 30, 2015, upon the closing of this offering, \_\_\_\_\_ 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 or warrants. 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 90 days after the date of this offering.

### Rule 144

In general, under Rule 144 of the Securities Act, 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. 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 \_\_\_\_\_ 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, our directors and executive officers 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

In general, under Rule 701 of the Securities Act, any of our employees, directors, officers, consultants or advisors who acquired common stock from us in connection with a written compensatory stock or option plan or other written agreement in compliance with Rule 701 before the IPO is entitled to rely on Rule 701 to resell such shares in reliance on Rule 144, but without compliance with the holding period requirements contained in Rule 144. Accordingly, subject to any applicable lock-up agreements, under Rule 701 persons who are not our "affiliates," as defined in Rule 144, may resell those shares without complying with the minimum holding period or public information requirements of Rule 144, and persons who are our "affiliates" may resell those shares without compliance with Rule 144's minimum holding period requirements.

## **Lock-Up Agreements**

We, along with our directors, executive officers and certain of our shareholders have agreed that for a period of 90 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**

The holders of 12.8 million shares of our common stock are 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 have filed 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. Accordingly, shares registered under the registration statement are available for sale in the open market, 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 will generally 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 this case, 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. If the foregoing exception does not apply, and if we are or were to become a "United States real property holding corporation", a purchaser may be required to withhold 15% of the proceeds payable to a non-U.S. holder from a sale of our common stock and such non-U.S. holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to U.S. persons (as defined in the Code).

## 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, 2018. 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.	
William Blair & Company, L.L.C.	
Needham & Company, LLC	
Janney Montgomery Scott LLC	
Total	

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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 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 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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We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$ . 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.

### Listing

Our common stock is listed 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 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.

### No Sales of Similar Securities

We, our officers, directors and certain holders of 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 90 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 90<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 90-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.

## **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 annual audited 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.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. 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.

We also maintain a website at [www.collegiumpharma.com](http://www.collegiumpharma.com), at which 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 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)

	<b>December 31,</b>	
	<b>2013</b>	<b>2014</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 7,551	\$ 1,634
Refundable PDUFA fee	—	2,335
Prepaid expenses and other current assets	710	527
Total current assets	8,261	4,496
Property and equipment, net	693	514
Restricted cash	80	80
Total assets	<u>\$ 9,034</u>	<u>\$ 5,090</u>
<b>LIABILITIES, CONVERTIBLE REDEEMABLE PREFERRED STOCK AND SHAREHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 1,217	\$ 2,208
Accrued expenses	1,013	1,956
Current portion of deferred rent and lease note payable	55	59
Current portion of term loan payable	333	1,194
Convertible bridge notes with related parties	—	5,000
Total current liabilities	2,618	10,417
Deferred rent and lease note payable, long-term	59	—
Lease incentive obligation	135	101
Term loan payable, long-term	640	6,813
Total liabilities	3,452	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 and December 31, 2014; issued and outstanding shares — 9,232,334 at December 31, 2013 and December 31, 2014; liquidation preference of \$12,277 at December 31, 2013 and \$12,781 at December 31, 2014	12,277	12,781
Series B convertible redeemable preferred stock, \$0.001 par value; authorized shares — 27,324,237 at December 31, 2013 and December 31, 2014; issued and outstanding shares — 27,324,237 at December 31, 2013 and December 31, 2014; liquidation preference of \$49,376 at December 31, 2013 and \$51,212 at December 31, 2014	49,376	51,212
Series C convertible redeemable preferred stock, \$0.001 par value; authorized shares — 8,658,344 at December 31, 2013 and December 31, 2014; issued and outstanding shares — 8,658,008 at December 31, 2013 and December 31, 2014; liquidation preference of \$12,154 at December 31, 2013 and \$13,114 at December 31, 2014	12,154	13,114
Shareholders' deficit:		
Common stock, \$0.001 par value; authorized shares — 72,000,000 at December 31, 2013 and December 31, 2014; issued and outstanding shares — 962,960 at December 31, 2013 and 1,006,219 at December 31, 2014	1	1
Additional paid-in capital	12,313	12,407
Accumulated deficit	(80,536)	(101,753)
Treasury stock	(3)	(3)
Total shareholders' deficit	(68,225)	(89,348)
Total liabilities, convertible redeemable preferred stock and shareholders' deficit	<u>\$ 9,034</u>	<u>\$ 5,090</u>

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

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

	<b>Year Ended December 31,</b>	
	<b>2013</b>	<b>2014</b>
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	<u>\$ (16,197)</u>	<u>\$ (17,917)</u>
Basic and diluted net loss per common share (See Note 3)	<u>\$ (4.06)</u>	<u>\$ (22.72)</u>
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)		<u>\$ (2.84)</u>
Weighted-average shares used to compute pro forma net loss per common share (unaudited)		<u>7,471,303</u>

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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	<u>9,232,334</u>	<u>\$ 12,781</u>	<u>27,324,237</u>	<u>\$ 51,212</u>	<u>8,658,008</u>	<u>\$ 13,114</u>	<u>1,006,219</u>	<u>\$ 1</u>	<u>12,407</u>	<u>(3)</u>	<u>(101,753)</u>	<u>(89,348)</u>

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	(206)	(8)
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	(4,385)	(5,917)
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 Net Loss per Share Information**

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.

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.

**COLLEGIUM PHARMACEUTICAL, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

(in thousands, except share and per share data)

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)****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, 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.

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(in thousands, except share and per share data)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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 other expenses including allocated expenses for rent and maintenance of facilities. Government grants are recognized as a reduction of the qualifying cost being reimbursed.

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(in thousands, except share and per share data)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

**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.

**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.

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(in thousands, except share and per share data)

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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.

**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.

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(in thousands, except share and per share data)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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 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.

## COLLEGIUM PHARMACEUTICAL, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

(in thousands, except share and per share data)

## 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 of those periods.

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

	Years Ended December 31,	
	2013	2014
Net loss	\$ (16,197)	\$ (17,917)
Performance Adjustment of Series A	12,239	—
Accruals of dividends and accretion to redemption value of preferred stock	(2,925)	(3,300)
Loss attributable to common shareholders — basic and diluted	\$ (6,883)	\$ (21,217)
Weighted-average shares used in computing basic and diluted net loss per common share	1,697,044	933,997
Basic and diluted net loss per common share	\$ (4.06)	\$ (22.72)

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

	Years Ended December 31,	
	2013	2014
Stock Options	229,791	281,029
Warrants	4,170	18,809
Redeemable convertible preferred stock	6,552,820	6,552,820
Unvested restricted stock	55,298	15,387

**COLLEGIUM PHARMACEUTICAL, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****(in thousands, except share and per share data)****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.

**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>



**COLLEGIUM PHARMACEUTICAL, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****(in thousands, except share and per share data)****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:

<u>Year Ending December 31,</u>	
2015	\$ 106
2016	111
2017	116
Total minimum lease payments	<u>\$ 333</u>

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.

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(in thousands, except share and per share data)**

**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.

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.

**COLLEGIUM PHARMACEUTICAL, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****(in thousands, except share and per share data)****8. DEBT (Continued)**

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 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,

**COLLEGIUM PHARMACEUTICAL, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

(in thousands, except share and per share data)

**10. EQUITY (Continued)**

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.

*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:

	As of <u>December 31, 2014</u>
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><u>57,893,685</u></b>

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

(in thousands, except share and per share data)

**10. EQUITY (Continued)**

**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 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%.

**COLLEGIUM PHARMACEUTICAL, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****(in thousands, except share and per share data)****10. EQUITY (Continued)**

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 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.

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(in thousands, except share and per share data)**

**10. EQUITY (Continued)**

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.

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.

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(in thousands, except share and per share data)**

**10. EQUITY (Continued)**

*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 option holder would receive one share of common stock for every two shares of common stock underlying the grant.



## COLLEGIUM PHARMACEUTICAL, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

(in thousands, except share and per share data)

## 11. STOCK-BASED COMPENSATION (Continued)

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	15,387	\$ 0.69

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	\$ 62	\$ 22

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

	Years Ended December 31,	
	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:

	<u>As of December 31,</u>	
	<u>2013</u>	<u>2014</u>
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.

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(in thousands, except share and per share data)**

**14. SUBSEQUENT EVENTS (Continued)**

- (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.

**COLLEGIUM PHARMACEUTICAL, INC.**  
**CONDENSED BALANCE SHEETS**  
**(unaudited)**  
**(in thousands, except share and per share amounts)**

	December 31, 2014	September 30, 2015
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 1,634	\$ 105,460
Refundable PDUFA fee	2,335	—
Prepaid expenses and other current assets	527	866
Total current assets	4,496	106,326
Property and equipment, net	514	627
Restricted cash	80	97
Total assets	<u>\$ 5,090</u>	<u>\$ 107,050</u>
<b>Liabilities, convertible redeemable preferred stock and shareholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 2,208	\$ 3,237
Accrued expenses	1,956	2,681
Current portion of deferred rent and lease note payable	59	15
Current portion of term loan payable	1,194	2,667
Convertible bridge notes with related parties	5,000	—
Total current liabilities	10,417	8,600
Lease incentive obligation	101	76
Term loan payable, long-term	6,813	4,813
Total liabilities	<u>17,331</u>	<u>13,489</u>
Commitments and contingencies (See Note 9)		
Series A convertible redeemable preferred stock, \$0.001 par value; authorized shares — 18,498,419 at December 31, 2014 and none at September 30, 2015; issued and outstanding shares — 9,232,334 at December 31, 2014 and none at September 30, 2015; liquidation preference of \$12,781 at December 31, 2014 and none at September 30, 2015		
	12,781	—
Series B convertible redeemable preferred stock, \$0.001 par value; authorized shares — 27,324,237 at December 31, 2014 and none at September 30, 2015; issued and outstanding shares — 27,324,237 at December 31, 2014 and none at September 30, 2015; liquidation preference of \$51,212 at December 31, 2014 and none at September 30, 2015		
	51,212	—
Series C convertible redeemable preferred stock, \$0.001 par value; authorized shares — 8,658,344 at December 31, 2014 and none at September 30, 2015; issued and outstanding shares — 8,658,008 at December 31, 2014 and none at September 30, 2015; liquidation preference of \$13,114 at December 31, 2014 and none at September 30, 2015		
	13,114	—
Series D convertible redeemable preferred stock, \$0.001 par value; authorized shares — none at December 31, 2014 and September 30, 2015; issued and outstanding shares — none at December 31, 2014, September 30, 2015; liquidation preference of none at December 31, 2014 and September 30, 2015		
	—	—
Shareholders' equity (deficit):		
Common stock, \$0.001 par value; authorized shares — 72,000,000 at December 31, 2014 and 100,000,000 at September 30, 2015; issued and outstanding shares — 1,006,219 at December 31, 2014, 20,687,829 at September 30, 2015		
	1	20
Additional paid-in capital	12,407	213,027
Accumulated deficit	(101,753)	(119,483)
Treasury stock	(3)	(3)
Total shareholders' equity (deficit)	<u>(89,348)</u>	<u>93,561</u>
Total liabilities, convertible redeemable preferred stock and shareholders' equity (deficit)	<u>\$ 5,090</u>	<u>\$ 107,050</u>

See accompanying notes to the unaudited condensed financial statements.

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**COLLEGIUM PHARMACEUTICAL, INC.**  
**CONDENSED STATEMENTS OF OPERATIONS**  
**(unaudited)**  
**(in thousands, except share and per share amounts)**

	<b>Nine months ended</b>	
	<b>September 30,</b>	
	<b>2014</b>	<b>2015</b>
Operating expenses:		
Research and development	\$ 12,652	\$ 6,444
General and administrative	1,686	11,027
Total operating expenses	<u>14,338</u>	<u>17,471</u>
Loss from operations	(14,338)	(17,471)
Other expense:		
Interest expense, net	110	350
Gain on extinguishment	—	(91)
Total other expense, net	<u>110</u>	<u>259</u>
Net loss	<u>\$ (14,448)</u>	<u>\$ (17,730)</u>
Net loss per share — basic and diluted	<u>\$ (18.26)</u>	<u>\$ (0.94)</u>
Weighted-average number of common shares used in net loss per share-basic and diluted	<u>926,597</u>	<u>11,179,756</u>

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See accompanying notes to the unaudited condensed financial statements.



**COLLEGIUM PHARMACEUTICAL, INC.**  
**CONDENSED STATEMENTS OF CASH FLOWS**  
(unaudited)  
(in thousands)

	Nine months ended September 30,	
	2014	2015
<b>Operating activities</b>		
Net loss	\$ (14,448)	\$ (17,730)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	141	130
Lease incentive	(25)	(25)
Stock-based compensation expense	16	1,217
Non cash interest expense	6	6
Accrual of back end fees related to note payable	(12)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(139)	(338)
Refundable PDUFA fee	—	2,335
Accounts payable	1,563	962
Accrued expenses	2,518	815
Net cash used in operating activities	<u>(10,380)</u>	<u>(12,628)</u>
<b>Investing activities</b>		
Purchases of property and equipment	—	(175)
Net cash used in investing activities	<u>—</u>	<u>(175)</u>
<b>Financing activities</b>		
Proceeds from issuance of common stock, net of issuance costs of \$2,408	—	72,029
Proceeds from issuance of Series D convertible redeemable preferred stock, net of issuance costs of \$193	—	44,807
(Repayment of) borrowing from term note	7,044	(619)
Repayment of lease note payable	(46)	(44)
Restricted cash	—	(16)
Proceeds from the exercise of stock options	9	472
Net cash provided by financing activities	<u>7,007</u>	<u>116,629</u>
Net increase (decrease) in cash and cash equivalents	(3,373)	103,826
Cash and cash equivalents at beginning of period	7,551	1,634
Cash and cash equivalents at end of period	<u>\$ 4,178</u>	<u>\$ 105,460</u>
<b>Supplemental disclosure of non-cash activities</b>		
Preferred stock conversion to common stock	\$ —	\$ 120,302
Accruals of dividends and accretion to redemption value	\$ 2,469	\$ 24,572
Conversion of bridge note to preferred stock	\$ —	\$ 5,000
Cash paid for interest	\$ 46	\$ 260
Cash paid for taxes	\$ —	\$ 4
Repayment of term note with proceeds of notes payable	\$ 944	\$ —

See accompanying notes to the unaudited condensed financial statements.

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

**(unaudited, in thousands, except share and per share amounts)**

**1. NATURE OF BUSINESS**

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. 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. On November 6, 2015, the FDA granted tentative approval to the Xtampza NDA 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. With a tentative approval, the FDA has determined that Xtampza meets the required quality, safety and efficacy standards for approval but that it is subject to an automatic stay of up to 30 months as a result of patent litigation filed by Purdue Pharma, L.P (Purdue) in March 2015.

The Company's operations are subject to certain risks and uncertainties. The principal 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.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Basis of presentation**

The accompanying unaudited condensed financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (including those which are normal and recurring) considered necessary for a fair presentation of the interim financial information have been included. When preparing financial statements in conformity with GAAP, the Company must make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures at the date of the financial statements. Actual results could differ from those estimates. Additionally, operating results for the interim periods ended September 30, 2015 and 2014 are not necessarily indicative of the results that may be expected for any other interim period or for the full year. The condensed interim financial statements should be read in conjunction with the audited financial statements and notes as of and for the year ended December 31, 2014.

**Initial Public Offering**

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

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)**

**(unaudited, in thousands, except share and per share amounts)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

approximately \$72,029, after deducting underwriting discounts, commissions and expenses payable by the Company.

In connection with preparing for the IPO, the Company's Board of Directors and shareholders approved a one-for-6.9 reverse stock split of the Company's common stock. The reverse stock split became effective in April 2015. All share and per share amounts in the condensed interim financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this reverse stock split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital. In connection with the closing of the IPO, all of the Company's outstanding convertible preferred stock automatically converted to common stock in May 2015, resulting in an additional 12,591,456 shares of common stock of the Company becoming outstanding. The significant increase in common stock outstanding in May 2015 is expected to impact the year-over-year comparability of the Company's net loss per share calculations in future periods.

**Subsequent Events**

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. Through November 12, 2015, the Company has concluded that no subsequent events have occurred that require disclosure, except as described in Note 9.

**Critical Accounting Policies**

*Earnings (Loss) per Common Share*

Earnings (loss) per common share is calculated using the two-class method, which is an earnings allocation formula that determines earnings (loss) per share for the holders of the Company's common shares and participating securities. All series of preferred stock contain participation rights in any dividend paid by the Company and are deemed to be participating securities. Earnings available to common shareholders and participating convertible redeemable preferred shares is allocated first to the preferred stock based upon the distribution criteria in the Company's Articles of Incorporation then the remainder to the common shareholders. The participating securities do not include a contractual obligation to share in losses of the Company and are not included in the calculation of net loss per share in the periods that have a net loss.

Diluted earnings per share is computed using the more dilutive of (a) the two-class method, or (b) 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.

**Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB"), issued Accounting Standards Update ("ASU"), No. 2014-09, which amends the guidance for accounting for revenue from contracts with

## COLLEGIUM PHARMACEUTICAL, INC.

## NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)

(unaudited, in thousands, except share and per share amounts)

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

customers. This ASU supersedes the revenue recognition requirements in Accounting Standards Codification ("ASC"), Topic 605, Revenue Recognition, and creates a new Topic 606, Revenue from Contracts with Customers. Two adoption methods are permitted: retrospectively to all prior reporting periods presented, with certain practical expedients permitted; or retrospectively with the cumulative effect of initially adopting the ASU recognized at the date of initial application. On August 12, 2015, the FASB issued ASU No. 2015-14, which defers the effective date of ASU No. 2014-09 by one year to December 15, 2017 for annual reporting periods beginning after that date, including interim periods within those periods. The FASB also approved permitting early adoption of the standard, but not before the original effective date of December 15, 2016. The Company has not yet determined which adoption method it will utilize or the effect that the adoption of this guidance will have on its financial statements.

In July 2015, the FASB issued ASU No. 2015-11, which amends existing guidance for measurement of inventory. Current inventory guidance requires an entity to measure inventory at the lower of cost or market. Market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. The amendments do not apply to inventory that is measured using last-in, first-out (LIFO) or the retail inventory method. The amendments apply to all other inventory, which includes inventory that is measured using first-in, first-out or average cost. An entity should measure all inventory to which the amendments apply at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. The amendments in the ASU No. 2015-11 more closely align the measurement of inventory pursuant to GAAP with the measurement of inventory pursuant to International Financial Reporting Standards. The amendments are effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017. The amendments should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company does not expect the adoption of this guidance to have a material impact on its condensed financial statements.

## 3. NET LOSS PER COMMON SHARE

	Nine months ended September 30,	
	2014	2015
Net loss	\$ (14,448)	\$ (17,730)
Extinguishment of preferred stock — see note 7	—	31,806
Accretion of prior preferred stock — see note 7	(2,469)	(23,327)
Accretion and dividends of Series D preferred stock	—	(1,245)
Loss attributable to common shareholders — basic and diluted	<u>\$ (16,917)</u>	<u>\$ (10,496)</u>
Weighted-average number of common shares used in net loss per share — basic and diluted	<u>926,597</u>	<u>11,179,756</u>
Net loss per share — basic and diluted	<u>\$ (18.26)</u>	<u>\$ (0.94)</u>

## COLLEGIUM PHARMACEUTICAL, INC.

## NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)

(unaudited, in thousands, except share and per share amounts)

## 3. NET LOSS PER COMMON SHARE (Continued)

The following potentially dilutive securities, which represent all outstanding potentially dilutive securities, were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect (in common stock equivalent shares):

	Nine months ended September 30,	
	2014	2015
Outstanding stock options	311,365	1,356,246
Warrants	18,810	2,445
Redeemable convertible preferred stock	6,552,820	—
Unvested restricted stock	28,536	153,589

## 4. FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. The fair value hierarchy is now established that prioritizes valuation inputs based on the observable nature of those inputs. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The hierarchy defines three levels of valuation inputs:

Level 1 inputs Quoted prices in active markets for identical assets or liabilities

Level 2 inputs Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly

Level 3 inputs Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability

The following tables present the Company's financial instruments carried at fair value using the lowest level input applicable to each financial instrument at December 31, 2014 and September 30, 2015.

Description	Total	Quoted Prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>December 31, 2014</b>				
Money market funds, included in cash equivalents	\$ 457	\$ 457	\$ —	\$ —
<b>September 30, 2015</b>				
Money market funds, included in cash equivalents	\$ 104,911	\$ 104,911	\$ —	\$ —

The Company's cash equivalents are comprised of money market funds that are measured on a recurring basis based on quoted market prices.

**COLLEGIUM PHARMACEUTICAL, INC.****NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)****(unaudited, in thousands, except share and per share amounts)****5. ACCRUED EXPENSES**

Accrued expenses consisted of the following:

	December 31, 2014	September 30, 2015
Accrued compensation	\$ 635	\$ 1,169
Accrued development costs	970	597
Accrued marketing	—	685
Accrued audit and legal	249	109
Accrued interest	71	31
Accrued other	31	90
Total accrued expenses	<u>\$ 1,956</u>	<u>\$ 2,681</u>

**6. CONVERTIBLE BRIDGE NOTE WITH RELATED PARTY**

In November and December 2014, the Company entered into a Note Purchase Agreement (the "Bridge Notes") allowing for the issuance of \$5,000 of convertible promissory notes to a group of investors (the "Holders") bearing interest at a rate per annum of 6.0%. The Holders are related parties of the Company. In connection with the Series D convertible preferred stock financing (see note 7), the Bridge Notes converted into Series D convertible preferred stock. Upon the conversion, the Company recognized a gain on extinguishment of \$91.

**7. CONVERTIBLE PREFERRED STOCK**

In March 2015, the Company issued and sold an aggregate of 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 Bridge Notes. The accrued interest on the convertible notes was waived.

Concurrently with the issuance of the Series D Preferred Stock, the Company amended and restated its Articles of Incorporation (the "Amended Articles"). The Company made certain amendments to the terms of the Series A, Series B, and Series C Preferred Stock (together, the "Prior Preferred Stock"). Prior to the adoption of the Amended Articles, the Series A, Series B, and Series C Preferred Stock accrued dividends at a rate of 4.5%, 8.0% and 8.0% per annum, respectively, per share. All accrued and unpaid dividends on the Prior Preferred Stock were automatically cancelled and forfeited and the Prior Preferred Stock no longer accrued dividends. Prior to the cancellation and forfeiture of accrued dividends, the Prior Preferred Stock had accrued dividends of \$622 during 2015. The holders of outstanding shares of Prior Preferred Stock were entitled to receive dividends, when, as and if declared by the Board of Directors. The mandatory conversion for all series of Prior Preferred Stock was modified so as to occur upon an initial public offering with gross proceeds in excess of \$50,000. The amendments to the Prior Preferred Stock were treated as an extinguishment which resulted in a gain on extinguishment of \$31,806. The gain on extinguishment was added to net loss to arrive at income available to common shareholders in the calculation of earnings per share. During the nine months ended September 30, 2015, total accrued dividends and accretion for preferred stock was \$24,572.

**COLLEGIUM PHARMACEUTICAL, INC.****NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)****(unaudited, in thousands, except share and per share amounts)****7. CONVERTIBLE PREFERRED STOCK (Continued)**

In connection with the closing of the IPO, all of the Company's outstanding convertible preferred stock automatically converted to common stock in May 2015, resulting in an additional 12,591,456 shares of common stock of the Company becoming outstanding.

**8. STOCK-BASED COMPENSATION**

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. In connection with the Company's reincorporation into Virginia in July 2014, each outstanding option to purchase shares of common stock under the Company's 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 April 2015, the Plan was amended to increase the maximum number of shares of common stock that may be issued to 2,700,000 shares. In addition, an "evergreen provision" was added to the Plan that allows for an annual increase in the number of shares of common stock available for issuance under the Plan. The annual increase will 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 31st of the immediately preceding fiscal year (or such lesser number of shares of common stock as determined by the board of directors).

**Restricted common stock**

A summary of the Company's restricted stock activity for the nine months ended September 30, 2015 and related information is as follows:

	Shares	Weighted average purchase price per share
Unvested at December 31, 2014	15,387	\$ 0.69
Granted	194,694	5.73
Vested	(128,955)	5.13
Unvested at September 30, 2015 <sup>(1)</sup>	<u>81,126</u>	<u>\$ 5.73</u>

<sup>(1)</sup> Excludes 72,463 shares of unvested restricted stock remaining from the early exercise of stock options as of September 30, 2015.

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)**

(unaudited, in thousands, except share and per share amounts)

**8. STOCK-BASED COMPENSATION (Continued)**

**Stock options**

A summary of the Company's stock option activity and related information follows:

	Shares	Weighted- average exercise price per share	Weighted- average remaining contractual term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2014	281,029	\$ 0.69		
Granted	1,197,452	10.47		
Exercised	(121,729)	3.89		
Cancelled	(506)	2.06		
Outstanding at September 30, 2015	<u>1,356,246</u>	<u>\$ 9.04</u>	<u>9.2</u>	<u>\$ 17,722</u>
Exercisable at September 30, 2015	<u>208,438</u>	<u>\$ 2.65</u>	<u>7.9</u>	<u>\$ 4,056</u>
Vested and expected to vest at September 30, 2015	<u>1,341,543</u>	<u>\$ 9.13</u>	<u>9.2</u>	<u>\$ 18,595</u>

The fair value of each stock option is estimated on the grant date using the Black-Scholes option-pricing model using the following assumptions:

	Nine months ended September 30,	
	2014	2015
Risk-free interest rate	1.8%	1.7%
Dividend yield	—	—
Volatility	77%	77%
Expected term (years)	6.25	6.21

**9. COMMITMENTS AND CONTINGENCIES**

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. 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. On July 23, 2015, Purdue voluntarily dismissed the Massachusetts suit. On August 6, 2015, the Delaware court dismissed the suit in



**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)**

**(unaudited, in thousands, except share and per share amounts)**

**9. COMMITMENTS AND CONTINGENCIES (Continued)**

Delaware and issued a memorandum opinion finding the Delaware court lacks personal jurisdiction over the Company. Following the dismissal in Delaware, on August 6, 2015, the Company filed a complaint in the Southern District of New York asserting an action to obtain patent certainty, and requesting that the New York court find that Xtampza will not infringe any valid patent claim of the patents asserted by Purdue in the Delaware action. Also on August 6, 2015, Purdue sued the Company in the District of Massachusetts asserting the same claims as the prior suit. On August 7, 2015, Purdue filed a motion in the Delaware court requesting reconsideration of the August 6, 2015 order that dismissed the case. In the motion requesting reconsideration, Purdue asked that the Delaware court find that it does have personal jurisdiction over the Company and then transfer the case to the District of Massachusetts. On October 7, 2015, the Delaware court transferred the case to the District of Massachusetts. On November 9, 2015, the Company filed a motion for summary judgment, for which it requested expedited hearing in Massachusetts. At this time the Company is unable to provide meaningful quantification of how this litigation may impact its future financial condition, results of operations, or cash flows.

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 August 2015 which is the date that the landlord delivered 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.

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Shares



**Collegium Pharmaceutical, Inc.**

**Common Stock**

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**PRELIMINARY PROSPECTUS**

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**Jefferies**

**Piper Jaffray**

**William Blair**

**Needham & Company**

**Janney Montgomery Scott**

, 2016

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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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	<b>Amount Paid or to be Paid</b>
SEC registration fee	\$ 8,686
FINRA filing fee	13,438
NASDAQ listing fee	*
Blue sky qualification fees and expenses, if any	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous expenses	*
Total	<u>\$ *</u>

\* To be completed by amendment.

**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 entered into indemnification agreements with each of our directors and executive 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**

- § From May 12, 2015 to September 30, 2015, 6,170 shares of common stock were acquired through the exercise of stock option awards granted prior to the completion of our initial public offering in May 2015 under our equity incentive plan by certain employees, prior to the effectiveness of our Registration Statement on Form S-8 filed on November 2, 2015. The exercise price for the options ranged from \$0.90 to \$3.38, and the gross proceeds from the exercises was approximately \$13,000. These transactions were exempt from the registration requirements of the Securities Act in reliance upon Rule 701 promulgated under the Securities Act.
- § 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.

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- § 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.**

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 Amendment No. 1 to 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 4<sup>th</sup> day of January, 2016.

**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 Amendment No. 1 to 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	January 4, 2016
*		
<u>                  Paul Brannelly</u>	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	January 4, 2016
*		
<u>                  Garen G. Bohlin</u>	Director	January 4, 2016
*		
<u>                  John G. Freund, M.D.</u>	Director	January 4, 2016
*		
<u>                  Patrick Heron</u>	Director	January 4, 2016
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<u>                  David Hirsch, M.D., Ph.D.</u>	Director	January 4, 2016
*		
<u>                  Eran Nadav, Ph.D.</u>	Director	January 4, 2016



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Gino Santini

Director

January 4, 2016

\* /s/ MICHAEL T. HEFFERNAN, R.PH.

Name: Michael T. Heffernan, R.Ph.

Title: *Attorney-in-Fact*

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**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†	Second Amended and Restated Articles of Incorporation of Collegium Pharmaceutical, Inc. <sup>(2)</sup>
3.2†	Amended and Restated Bylaws of Collegium Pharmaceutical, Inc. <sup>(2)</sup>
4.1†	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>
4.2†	Warrant to Purchase Stock, dated October 28, 2010, issued by Collegium Pharmaceutical, Inc. to Comerica Bank. <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>
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†	Subordination Agreement, dated November 14, 2014, by and among Collegium Pharmaceutical, Inc., Silicon Valley Bank and the creditors named therein. <sup>(1)</sup>
10.8†	Subordination Agreement, dated December 2, 2014, by and among Collegium Pharmaceutical, Inc., Silicon Valley Bank and the creditors named therein. <sup>(1)</sup>
10.9+†	Restricted Stock Award Agreement, dated June 13, 2012, by and between Collegium Pharmaceutical, Inc. and Michael T. Heffernan. <sup>(1)</sup>
10.10+†	Restricted Stock Award Agreement, dated July 18, 2012, by and between Collegium Pharmaceutical, Inc. and Gino Santini. <sup>(1)</sup>
10.11+†	Restricted Stock Award Agreement, dated March 5, 2014, by and between Collegium Pharmaceutical, Inc. and Gino Santini. <sup>(1)</sup>
10.12†	Form of Confidentiality and Inventions Agreement. <sup>(1)</sup>
10.13+†	Offer Letter, dated January 29, 2015, by and between Collegium Pharmaceutical, Inc. and Garen Bohlin. <sup>(1)</sup>
10.14†	Series D Convertible Preferred Stock Purchase Agreement, dated March 6, 2015, by and among Collegium Pharmaceutical, Inc. and the purchasers thereto. <sup>(1)</sup>

<b>Exhibit Number</b>	<b>Exhibit Description</b>
10.15†	First Amendment to Lease, dated March 24, 2015, by and between Park at 95, LLC (as successor in interest to 780 Dedham Street Holdings, LLC) and Collegium Pharmaceutical, Inc. <sup>(1)</sup>
10.16+†	2015 Employee Stock Purchase Plan. <sup>(3)</sup>
10.17+†	Performance Bonus Plan. <sup>(4)</sup>
10.18(a)+†	Amended and Restated 2014 Stock Incentive Plan. <sup>(3)</sup>
10.18(b)+†	Form of Incentive Stock Option Agreement under the Amended and Restated 2014 Stock Incentive Plan. <sup>(3)</sup>
10.18(c)+†	Form of Non-Qualified Stock Option Agreement under the Amended and Restated 2014 Stock Incentive Plan. <sup>(3)</sup>
10.18(d)+†	Form of Restricted Stock Award Agreement under the Amended and Restated 2014 Stock Incentive Plan. <sup>(3)</sup>
10.19+†	Restricted Stock Award Agreement, dated April 2, 2015, by and between Collegium Pharmaceutical, Inc. and Michael T. Heffernan. <sup>(4)</sup>
10.20†	Form of Indemnification Agreement. <sup>(4)</sup>
10.21+†	Employment Agreement, dated August 4, 2015, by and between Michael Heffernan and Collegium Pharmaceutical, Inc. <sup>(5)</sup>
10.22+†	Employment Agreement, dated August 4, 2015, by and between Paul Brannelly and Collegium Pharmaceutical, Inc. <sup>(5)</sup>
10.23+†	Employment Agreement, dated August 4, 2015, by and between Barry S. Duke and Collegium Pharmaceutical, Inc. <sup>(6)</sup>
10.24+	Employment Agreement, dated August 4, 2015, by and between Ernest A. Kopecky, Ph.D. and Collegium Pharmaceutical, Inc.
10.25+	Employment Agreement, dated August 4, 2015, by and between Douglas R. Carlson and Collegium Pharmaceutical, Inc.
21.1	Subsidiaries of Collegium Pharmaceutical, Inc.
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 signature page of the Registration Statement (File No. 333-208641) initially filed with the Commission on December 18, 2015) <sup>(7)</sup>
101.INS	Instance Document
XBRL	
101.SCH	Schema Document
XBRL	
101.CAL	Calculation Linkbase Document
XBRL	
101.LAB	Labels Linkbase Document
XBRL	
101.PRE	Presentation Linkbase Document
XBRL	
101.DEF	Definition Linkbase Document
XBRL	

† Previously filed.

+ Indicates management contract or compensatory plan.

\* To be filed by amendment.

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- (1) Previously filed as an exhibit to the registrant's Registration Statement on Form S-1 (File No. 333-203208) filed with the Commission on April 2, 2015.
- (2) Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the Commission on May 12, 2015.
- (3) Previously filed as an exhibit to the registrant's Registration Statement on Form S-8 (File No. 333-207744) filed with the Commission on November 2, 2015.
- (4) Previously filed as an exhibit to the registrant's Registration Statement on Form S-1/A (File No. 333-203208) filed with the Commission on April 27, 2015.
- (5) Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the Commission on August 10, 2015.
- (6) Previously filed as an exhibit to the registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015 filed with the Commission on August 12, 2015.
- (7) Previously filed as an exhibit to the registrant's Registration Statement on Form S-1 (File No. 333-208641) filed with the Commission on December 18, 2015.



EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the “Agreement”) is made by and between COLLEGIUM PHARMACEUTICAL, INC. (the “Company”) and Ernest Kopecky (the “Executive”).

WHEREAS, the Company desires to continue to employ Executive on at will basis, and the Executive wishes to continue to be employed by the Company on at will basis, on the terms and conditions set forth herein.

WHEREAS, the Company and the Executive are parties to an Employment Agreement dated May 30, 2012 (the “Existing Agreement”); and

WHEREAS, the parties wish to enter into this Agreement to memorialize the terms of Executive’s continued employment by the Company.

NOW, THEREFORE, in consideration of the foregoing and intending to be bound hereby, the parties agree as follows:

1. Duration of Agreement. This Agreement is effective on the date it is fully executed (the “Effective Date”) and has no specific expiration date. Unless terminated by agreement of the parties, this Agreement will govern Executive’s continued employment by the Company until that employment ceases.
2. Title; Duties. Executive will be employed as the Company’s Vice President, Clinical Development and Head, Neuroscience. Executive will devote his best efforts and substantially all of his business time and services to the Company and its affiliates to perform such duties as may be customarily incident to his position and as may reasonably be assigned to him from time to time. Executive shall report to such individual as designated by the Company. Executive will not, in any capacity, engage in other business activities or perform services for any other individual, firm or corporation without the prior written consent of the Company; *provided, however*, that without such consent, Executive may engage in charitable, non-profit and public service activities, so long as such activities do not in any respect interfere or conflict with Executive’s performance of his duties and obligations to the Company.
3. Place of Performance. Executive will perform his services hereunder at the principal executive offices of the Company in Canton, Massachusetts; *provided, however*, that Executive may be required to travel from time to time for business purposes.
4. Compensation and Indemnification.
  - 4.1. Base Salary. Executive’s annual salary will be \$299,027 (the “Base Salary”), paid in accordance with the Company’s payroll practices as in effect from time to time. The Base Salary will be reviewed annually by the Compensation Committee of the Company’s Board of Directors (the “Committee”).
  - 4.2. Annual Bonuses.
    - 4.2.1. For each fiscal year ending during his employment, Executive will be eligible to earn an annual bonus. The target amount of that bonus will be 30% percent of Executive’s Base Salary for the applicable fiscal year. The actual bonus payable with respect to a particular year will be determined by the Committee, based on the achievement of corporate and /or individual performance objectives established by the Committee. Any bonus payable under this paragraph will be paid during the calendar year immediately following the fiscal year in respect of which the bonus is payable and, except as otherwise provided in Section 5.1.1, will only be paid if Executive remains continuously employed by the Company through the actual bonus payment date.
    - 4.2.2. For purposes of determining any bonus payable to Executive, the measurement of corporate and individual performance will be performed by the Committee in good faith. From time to time, the Committee may, in its sole discretion, make adjustments to corporate or individual performance goals, so that required departures from the Company’s operating budget, changes in accounting principles, acquisitions, dispositions, mergers, consolidations and other corporate transactions, and other factors influencing the achievement or calculation of such goals do not affect the operation of this provision in a manner inconsistent with its intended purposes.
  - 4.3. Employee Benefits. During Executive’s employment, Executive will be eligible to participate in all employee benefit plans and programs made available by the Company from time to time to employees generally, subject to applicable plan terms and policies. The Company periodically reviews its benefits, policies, benefits providers and practices and may terminate, alter or change them at its discretion from time to time.
  - 4.4. Reimbursement of Expenses. The Executive will be reimbursed by the Company for all reasonable business expenses incurred by Executive in accordance with the Company’s customary expense reimbursement policies as in effect from time to time. Notwithstanding anything herein to the contrary, to the extent any expense, reimbursement or in-kind benefit provided to the Executive constitutes a “deferral of compensation” within the meaning of Section 409A of the Internal Revenue Code (the “Code”) (i) the amount of expenses eligible for reimbursement or in-kind benefits provided to the Executive must be incurred during the Executive’s term of employment; (ii) the amount of expenses eligible for reimbursement or in-kind benefits provided to the Executive during any calendar year will not affect the amount of expenses eligible for reimbursement or in-kind benefits provided to the Executive in any other calendar year, (iii) the reimbursements for expenses for which the Executive is entitled to be reimbursed shall be made on or before the last day of the calendar year following the calendar year in which the applicable expense is incurred and (iv) the right to payment or reimbursement or in-kind benefits hereunder may not be liquidated or exchanged for any other benefit.
5. Termination. Executive’s employment with the Company may be terminated by the Company or Executive at any time and for any reason. Upon any cessation of his employment with the Company, Executive will be entitled only to such compensation and benefits as described in this Section 5. Upon any cessation of his employment for any reason, unless otherwise requested by the Company, Executive agrees to resign immediately from all officer and director positions he then holds with the Company and its affiliates.

5.1. Termination without Cause or for Good Reason. If Executive's employment by the Company ceases due to a termination by the Company without Cause (as defined below) or a resignation by Executive for Good Reason (as defined below), Executive will be entitled to:

5.1.1. payment of any annual bonus otherwise payable (but for the cessation of Executive's employment) with respect to a year ended prior to the cessation of Executive's employment;

5.1.2. continuation of Executive's Base Salary for a period equal to 6 months, payable in accordance with the Company's standard payroll practices; and

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5.1.3. waiver of the applicable premium otherwise payable for COBRA continuation coverage for Executive (and, to the extent covered immediately prior to the date of such cessation, his eligible dependents) for a period equal to 6 months.

Except as otherwise provided in this Section 5.1, and except for payment of all (i) accrued and unpaid Base Salary through the date of such cessation, (ii) any expense reimbursements to be paid in accordance with Company policy and (iii) payments for any accrued but unused paid time off in accordance with the Company's policies and applicable law, all compensation and benefits will cease at the time of such cessation and the Company will have no further liability or obligation by reason of such cessation. The payments and benefits described in this Section 5.1 are in lieu of, and not in addition to, any other severance arrangement maintained by the Company. Notwithstanding any provision of this Agreement, the payments and benefits described in Section 5.1 are conditioned on: (a) the Executive's execution and delivery to the Company and the expiration of all applicable statutory revocation periods, by the 45th day following the effective date of his cessation of employment, of a general release of claims against the Company and its affiliates in a form reasonably prescribed by the Company (the "Release"); and (b) the Executive's continued compliance with the Restrictive Covenants (as defined below). Subject to Section 5.4, below, the benefits described in Section 5.1 will be paid or provided (or begin to be paid or provided) as soon as administratively practicable (or determinable in the case of the benefits described in Section 5.1.1) after the Release becomes irrevocable, provided that if the 45 day period described above begins in one taxable year and ends in a second taxable year such payments or benefits shall not commence until the second taxable year.

5.2. Termination Following a Change in Control. For cessations of employment described in Section 5.1 that occur during the twelve (12) month period immediately following the occurrence of a Change in Control (as defined below), the Executive will receive the payments and benefits described in Section 5.1 above, subject to the following modifications:

5.2.1. the references in Sections 5.1.2 and 5.1.3 to "6 months" will each be replaced with a reference to "9 months"; and

5.2.2. all unvested restricted stock, stock options and other equity incentives awarded to Executive by the Company will become immediately and automatically fully vested and exercisable (as applicable).

5.3. Other Terminations. If Executive's employment with the Company ceases for any reason other than as described in Section 5.1, above (including but not limited to termination (i) by the Company for Cause, (ii) as a result of Executive's death, (iii) as a result of Executive's Disability or (d) by Executive without Good Reason, then the Company's obligation to Executive will be limited solely to (a) accrued and unpaid Base Salary through the date of such cessation, (b) any expense reimbursements to be paid in accordance with Company policy and (c) payments for any accrued but unused paid time off in accordance with the Company's policies and applicable law. All compensation and benefits will cease at the time of such cessation and, except as otherwise provided by COBRA or this Section 5.3, the Company will have no further liability or obligation by reason of such termination. The foregoing will not be construed to limit Executive's right to payment or reimbursement for claims incurred prior to the date of such termination under any insurance contract funding an employee benefit plan, policy or arrangement of the Company in accordance with the terms of such insurance contract.

5.4. Compliance with Section 409A. If the termination giving rise to the payments described in Section 5.1 is not a "Separation from Service" within the meaning of Treas. Reg. § 1.409A-1(h)(1) (or any successor provision), then the amounts otherwise payable pursuant to that section will instead be deferred without interest and will not be paid until Executive experiences a Separation from

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Service. To the maximum extent permitted under Section 409A of the Code and its corresponding regulations, the cash severance benefits payable under this Agreement are intended to meet the requirements of the short-term deferral exemption under Section 409A of the Code and the "separation pay exception" under Treas. Reg. § 1.409A-1(b)(9)(iii). To the extent compliance with the requirements of Treas. Reg. § 1.409A-3(i)(2) (or any successor provision) is necessary to avoid the application of an additional tax under Section 409A of the Internal Revenue Code to payments due to Executive upon or following his Separation from Service, then notwithstanding any other provision of this Agreement (or any otherwise applicable plan, policy, agreement or arrangement), any such payments that are otherwise due within six months following Executive's Separation from Service (taking into account the preceding sentence of this paragraph) will be deferred without interest and paid to Executive in a lump sum immediately following that six month period. For purposes of the application of Treas. Reg. § 1.409A-1(b)(4) (or any successor provision), each payment in a series of payments will be deemed a separate payment.

5.5. PPACA. Notwithstanding anything in this Agreement to the contrary, the waiver in respect of COBRA premiums pursuant to this Sections 5.1 and 5.2 shall cease to the extent required to avoid adverse consequences to the Company under the Patient Protection and Affordable Care Act of 2010 and regulations thereunder.

5.6. Section 280G. If any payment or distribution by the Company to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise pursuant to or by reason of any other agreement, policy, plan, program or arrangement or the lapse or termination of any restriction on or the vesting or exercisability of any payment or benefit (each a "Payment"), would be subject to the excise tax imposed by Section 4999 of the Code (or any successor provision thereto) or to any similar tax imposed by state or local law (such tax or taxes are hereafter collectively referred to as the "Excise Tax"), then the aggregate amount of Payments payable to Executive shall be reduced to the aggregate amount of Payments that may be made to the Executive without incurring an excise tax (the "Safe-Harbor Amount") in accordance with the immediately following sentence; *provided that* such reduction shall only be imposed if the aggregate after-tax value of the Payments retained by Executive (after giving effect to such reduction) is equal to or greater than the aggregate after-tax value (after giving effect to the Excise Tax) of the Payments to Executive without any such reduction. Any such reduction shall be made in the following order: (i) first, any future cash payments (if any) shall be reduced

(if necessary, to zero); (ii) second, any current cash payments shall be reduced (if necessary, to zero); (iii) third, all non-cash payments (other than equity or equity derivative related payments) shall be reduced (if necessary, to zero); and (iv) fourth, all equity or equity derivative payments shall be reduced.

5.7. Definitions. For purposes of this Agreement:

5.7.1. “Cause” means (a) commission or conviction of any felony or any crime involving dishonesty; (b) commission of any fraud against the Company; (c) intentional and material damage to any material property of the Company; (d) Executive’s material breach of any agreement with or duty owed to the Company or any of its affiliates (including, without limitation, Executive’s material breach of any of the Restrictive Covenants, as defined below); or (e) refusal to perform the lawful, reasonable and material directives of the Company’s Board of Directors (the “Board”) or the Company’s Chief Executive Officer.

5.7.2. “Change in Control” means the first to occur of any of the events described in Section 1(g) of the Company’s Amended and Restated 2014 Stock Incentive Plan (or any successor provision).

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5.7.3. “Disability” means a condition entitling the Executive to benefits under the Company’s long term disability plan, policy or arrangement; *provided, however*, that if no such plan, policy or arrangement is then maintained by the Company and applicable to the Executive, “Disability” will mean the Executive’s inability to perform his duties under this Agreement due to a mental or physical condition that can be expected to result in death or that can be expected to last (or has already lasted) for a continuous period of 90 days or more, or for 120 days in any 180 consecutive day period. Termination as a result of a Disability will not be construed as a termination by the Company “without Cause.”

5.7.4. “Good Reason” means any of the following, without the Executive’s prior consent: (a) a diminution of the Executive’s title below the rank of Vice President; (b) a reduction in Base Salary; or (c) the relocation of the Executive’s primary place of employment to a location that is (i) more than 50 miles from the location of the Executive’s permanent primary place of employment prior to such relocation and (ii) more than 50 miles from the location of the Executive’s residence. However, none of the foregoing events or conditions will constitute Good Reason unless the Executive provides the Company with written objection to the event or condition within 30 days following the occurrence thereof, the Company does not reverse or otherwise cure the event or condition within 30 days of receiving that written objection, and the Executive resigns Executive’s employment within 30 days following the expiration of that cure period. Notwithstanding the foregoing and for the avoidance of doubt, a diminution of the Executive’s title as a result of Change in Control shall not constitute Good Reason.

6. Restrictive Covenants. To induce the Company to enter into this Agreement and in recognition of the compensation to be paid to the Executive pursuant to Sections 4 and 5 of this Agreement, the Executive agrees to be bound by the provisions of this Section 6 (the “Restrictive Covenants”). These Restrictive Covenants will apply without regard to whether any termination or cessation of the Executive’s employment is initiated by the Company or the Executive, and without regard to the reason for that termination or cessation.

6.1. Covenant Not To Compete. The Executive covenants that, during his employment by the Company and for a period of 6 months following immediately thereafter (the “Restricted Period”), the Executive will not (except in his capacity as an employee or director of the Company) do any of the following, directly or indirectly:

6.1.1. engage or participate in any Competing Business (as defined below) wherever the Company or its affiliates do business, do or plan to do business or sell or market their products or services;

6.1.2. become interested in (as owner, stockholder, lender, partner, co-venturer, director, officer, employee, agent or consultant) any person, firm, corporation, association or other entity engaged in a Competing Business. Notwithstanding the foregoing, the Executive may hold up to 1% of the outstanding securities of any class of any publicly-traded securities of any company;

6.1.3. influence or attempt to influence any employee, consultant, supplier, licensor, licensee, contractor, agent, strategic partner, distributor, customer or other person to terminate or modify any written or oral agreement, arrangement or course of dealing with the Company or any of its affiliates; or

6.1.4. solicit for employment or retention as an independent contractor (or arrange to have any other person or entity solicit for employment or retention) any person employed or retained by the Company or any of its affiliates.

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6.2. Confidentiality. The Executive recognizes and acknowledges that the Proprietary Information (as defined in below) is a valuable, special and unique asset of the business of the Company and its affiliates. As a result, both during the Term and thereafter, the Executive will not, without the prior written consent of the Company, for any reason divulge to any third-party or use for his own benefit, or for any purpose other than the exclusive benefit of the Company and its affiliates, any Proprietary Information. Notwithstanding the foregoing, if the Executive is compelled to disclose Proprietary Information by court order or other legal or regulatory process, to the extent permitted by applicable law, he shall promptly so notify the Company so that it may seek a protective order or other assurance that confidential treatment of such Proprietary Information shall be afforded, and the Executive shall reasonably cooperate with the Company and its affiliates in connection therewith. If the Executive is so obligated by court order or other legal process to disclose Proprietary Information it will disclose only the minimum amount of such Proprietary Information as is necessary for the Executive to comply with such court order or other legal process.

6.3. Property of the Company.

6.3.1. Proprietary Information. All right, title and interest in and to Proprietary Information will be and remain the sole and exclusive property of the Company and its affiliates. The Executive will not remove from the Company’s or its affiliates’ offices or premises any documents, records, notebooks, files, correspondence, reports, memoranda or similar materials of or containing Proprietary Information, or other materials or property of any kind belonging to the Company or its affiliates unless necessary or appropriate in the performance of his duties to the Company and its affiliates. If the



Executive removes such materials or property in the performance of his duties, he will return such materials or property promptly after the removal has served its purpose. The Executive will not make, retain, remove and/or distribute any copies of any such materials or property, or divulge to any third person the nature of and/or contents of such materials or property, except to the extent necessary to satisfy contractual obligations of the Company or its affiliates or to perform his duties on behalf of the Company and its affiliates. Upon termination of the Executive's employment with the Company, he will leave with the Company and its affiliates or promptly return to the Company and its affiliates all originals and copies of such materials or property then in his possession.

6.3.2. Intellectual Property. The Executive agrees that all the Intellectual Property (as defined below) will be considered "works made for hire" as that term is defined in Section 101 of the Copyright Act (17 U.S.C. § 101) and that all right, title and interest in such Intellectual Property will be the sole and exclusive property of the Company and its affiliates. To the extent that any of the Intellectual Property may not by law be considered a work made for hire, or to the extent that, notwithstanding the foregoing, the Executive retains any interest in the Intellectual Property, the Executive hereby irrevocably assigns and transfers to the Company and its affiliates any and all right, title, or interest that the Executive may now or in the future have in the Intellectual Property under patent, copyright, trade secret, trademark or other law, in perpetuity or for the longest period otherwise permitted by law, without the necessity of further consideration. The Company and its affiliates will be entitled to obtain and hold in its own name all copyrights, patents, trade secrets, trademarks and other similar registrations with respect to such Intellectual Property. The Executive further agrees to execute any and all documents and provide any further cooperation or assistance reasonably required by the Company, at the Company's expense, to perfect, maintain or otherwise protect its rights in the Intellectual Property. If the Company or its affiliates, as applicable, are unable after reasonable efforts to secure the Executive's signature, cooperation or assistance in accordance with the preceding sentence, whether because of the Executive's incapacity or any other reason whatsoever, the Executive hereby designates and appoints the Company, the appropriate affiliate, or their respective designee as the Executive's agent and attorney-in-fact, to act on his behalf, to execute and file documents and to do all other lawfully permitted acts necessary or desirable to perfect, maintain or otherwise protect the Company's or its affiliates' rights

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in the Intellectual Property. The Executive acknowledges and agrees that such appointment is coupled with an interest and is therefore irrevocable.

6.4. Definitions. For purposes of this Agreement:

6.4.1. "Competing Business" means any person, firm, corporation, partnership, association or other entity engaged in developing, manufacturing, marketing, distributing or selling, directly or indirectly, pharmaceutical abuse-deterrent products or any other product for pain indications that directly competes with a product developed, manufactured, marketed, distributed or sold by the Company. A division, subsidiary or similar business unit of an entity that does not engage in the business activities described in this definition will not be considered a Competing Business even if another separate division, subsidiary or similar business unit does engage in such activities.

6.4.2. "Intellectual Property" means (a) all inventions (whether patentable or unpatentable and whether or not reduced to practice), all improvements thereto, and all patents and patent applications claiming such inventions, (b) all trademarks, service marks, trade dress, logos, trade names, fictitious names, brand names, brand marks and corporate names, together with all translations, adaptations, derivations, and combinations thereof and including all goodwill associated therewith, and all applications, registrations, and renewals in connection therewith, (c) all copyrightable works, all copyrights, and all applications, registrations, and renewals in connection therewith, (d) all mask works and all applications, registrations, and renewals in connection therewith, (e) all trade secrets (including research and development, know-how, formulas, compositions, manufacturing and production processes and techniques, methodologies, technical data, designs, drawings and specifications), (f) all computer software (including data, source and object codes and related documentation), (g) all other proprietary rights, (h) all copies and tangible embodiments thereof (in whatever form or medium), or (i) similar intangible personal property which have been or are developed or created in whole or in part by the Executive (1) at any time and at any place while the Executive is employed by Company and which, in the case of any or all of the foregoing, are related to and used in connection with the business of the Company or its affiliates, or (2) as a result of tasks assigned to the Executive by the Company or its affiliates.

6.4.3. "Proprietary Information" means any and all proprietary information developed or acquired by the Company or any of its subsidiaries or affiliates that has not been specifically authorized to be disclosed. Such Proprietary Information shall include, but shall not be limited to, the following items and information relating to the following items: (a) all intellectual property and proprietary rights of the Company (including, without limitation, the Intellectual Property), (b) computer codes and instructions, processing systems and techniques, inputs and outputs (regardless of the media on which stored or located) and hardware and software configurations, designs, architecture and interfaces, (c) business research, studies, procedures and costs, (d) financial data, (e) distribution methods, (f) marketing data, methods, plans and efforts, (g) the identities of actual and prospective suppliers, (h) the terms of contracts and agreements with, the needs and requirements of, and the Company's or its affiliates' course of dealing with, actual or prospective suppliers, (i) personnel information, (j) customer and vendor credit information, and (k) information received from third parties subject to obligations of non-disclosure or non-use. Failure by the Company or its affiliates to mark any of the Proprietary Information as confidential or proprietary shall not affect its status as Proprietary Information.

6.5. Acknowledgements. The Executive acknowledges that the Restrictive Covenants are reasonable and necessary to protect the legitimate interests of the Company and its affiliates, that the duration and geographic scope of the Restrictive Covenants are reasonable given the nature of this Agreement and the position the Executive holds within the Company, and that the Company would not

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enter into this Agreement or otherwise employ or continue to employ the Executive unless the Executive agrees to be bound by the Restrictive Covenants set forth in this Section 6.

6.6. Remedies and Enforcement Upon Breach.

6.6.1. Specific Enforcement. The Executive acknowledges that any breach by him, willfully or otherwise, of the Restrictive Covenants will cause continuing and irreparable injury to the Company or its affiliates for which monetary damages would not be an adequate remedy. The Executive shall not, in any action or proceeding to enforce any of the provisions of this Agreement, assert the claim or defense that such an adequate remedy at law exists. In the event of any such breach or threatened breach by the Executive of any of the Restrictive Covenants, the Company or its affiliates, as

applicable, shall be entitled to injunctive or other similar equitable relief in any court, without any requirement that a bond or other security be posted, and this Agreement shall not in any way limit remedies of law or in equity otherwise available to the Company and its affiliates.

6.6.2. Judicial Modification. If any court determines that any of the Restrictive Covenants, or any part thereof, is unenforceable because of the duration or geographical scope of such provision, such court shall have the power to modify such provision and, in its modified form, such provision shall then be enforceable.

6.6.3. Enforceability. If any court holds the Restrictive Covenants unenforceable by reason of their breadth or scope or otherwise, it is the intention of the parties hereto that such determination not bar or in any way affect the right of the Company and its affiliates to the relief provided above in the courts of any other jurisdiction within the geographic scope of such Restrictive Covenants.

6.6.4. Disclosure of Restrictive Covenants. The Executive agrees to disclose the existence and terms of the Restrictive Covenants to any employer that the Executive may work for during the Restricted Period.

6.6.5. Extension of Restricted Period. If the Executive breaches Section 6.1 in any respect, the restrictions contained in that section will be extended for a period equal to the period that the Executive was in breach.

## 7. Miscellaneous.

7.1. Other Agreements. Executive represents and warrants to the Company that there are no restrictions, agreements or understandings whatsoever to which he is a party that would prevent or make unlawful his execution of this Agreement, that would be inconsistent or in conflict with this Agreement or Executive's obligations hereunder, or that would otherwise prevent, limit or impair the performance by Executive of his duties under this Agreement.

7.2. Successors and Assigns. The Company may assign this Agreement to any successor to its assets and business by means of liquidation, dissolution, sale of assets or otherwise. The duties of Executive hereunder are personal to Executive and may not be assigned by him.

7.3. Governing Law and Enforcement. This Agreement will be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to the principles of conflicts of laws. Any legal proceeding arising out of or relating to this Agreement will be instituted in a state or federal court in the Commonwealth of Massachusetts, and Executive and the Company hereby consent to the personal and exclusive jurisdiction of such court(s) and hereby waive any

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objection(s) that they may have to personal jurisdiction, the laying of venue of any such proceeding and any claim or defense of inconvenient forum.

7.4. Waivers. The waiver by either party of any right hereunder or of any breach by the other party will not be deemed a waiver of any other right hereunder or of any other breach by the other party. No waiver will be deemed to have occurred unless set forth in a writing. No waiver will constitute a continuing waiver unless specifically stated, and any waiver will operate only as to the specific term or condition waived.

7.5. Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law. However, if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provision, and this Agreement will be reformed, construed and enforced as though the invalid, illegal or unenforceable provision had never been herein contained.

7.6. Survival. This Agreement will survive the cessation of Executive's employment to the extent necessary to fulfill the purposes and intent the Agreement.

7.7. Notices. Any notice or communication required or permitted under this Agreement will be made in writing and (a) sent by overnight courier, (b) mailed by overnight U.S. express mail, return receipt requested or (c) sent by telecopier. Any notice or communication to Executive will be sent to the address contained in his personnel file. Any notice or communication to the Company will be sent to the Company's principal executive offices, to the attention of its Chief Executive Officer. Notwithstanding the foregoing, either party may change the address for notices or communications hereunder by providing written notice to the other in the manner specified in this paragraph.

7.8. Entire Agreement; Amendments. This Agreement contains the entire agreement and understanding of the parties hereto relating to the subject matter hereof, and merges and supersedes all prior and contemporaneous discussions, agreements and understandings of every nature relating to that subject matter (including, without limitation, the Existing Agreement). This Agreement may not be changed or modified, except by an agreement in writing signed by each of the parties hereto.

7.9. Withholding. All payments (or transfers of property) to Executive will be subject to tax withholding to the extent required by applicable law.

7.10. Section Headings. The headings of sections and paragraphs of this Agreement are inserted for convenience only and will not in any way affect the meaning or construction of any provision of this Agreement.

7.11. Counterparts; Facsimile. This Agreement may be executed in multiple counterparts (including by facsimile signature), each of which will be deemed to be an original, but all of which together will constitute but one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

*<remainder of page intentionally left blank; signature page follows>*

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IN WITNESS WHEREOF, the Company has caused this Agreement to be executed by its duly authorized officer, and Executive has executed this Agreement, on the date(s) indicated below.

**COLLEGIUM PHARMACEUTICAL, INC.**

By: /s/ Paul Brannelly

Name: Paul Brannelly

Title: Chief Financial Officer

Date: August 4, 2015

**ERNEST KOPECKY**

/s/ Ernest Kopecky

Date: August 3, 2015

*Signature Page to Employment Agreement*

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EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the “Agreement”) is made by and between COLLEGIUM PHARMACEUTICAL, INC. (the “Company”) and Douglas Carlson (the “Executive”).

WHEREAS, the Company desires to continue to employ Executive on at will basis, and the Executive wishes to continue to be employed by the Company on at will basis, on the terms and conditions set forth herein.

WHEREAS, the Company and the Executive are parties to an Employment Agreement dated March 13, 2013 (the “Existing Agreement”); and

WHEREAS, the parties wish to enter into this Agreement to memorialize the terms of Executive’s continued employment by the Company.

NOW, THEREFORE, in consideration of the foregoing and intending to be bound hereby, the parties agree as follows:

1. Duration of Agreement. This Agreement is effective on the date it is fully executed (the “Effective Date”) and has no specific expiration date. Unless terminated by agreement of the parties, this Agreement will govern Executive’s continued employment by the Company until that employment ceases.

2. Title; Duties. Executive will be employed as the Company’s Vice President, Corporate Development. Executive will devote his best efforts and substantially all of his business time and services to the Company and its affiliates to perform such duties as may be customarily incident to his position and as may reasonably be assigned to him from time to time. Executive shall report to such individual as designated by the Company. Executive will not, in any capacity, engage in other business activities or perform services for any other individual, firm or corporation without the prior written consent of the Company; *provided, however*, that without such consent, Executive may engage in charitable, non-profit and public service activities, so long as such activities do not in any respect interfere or conflict with Executive’s performance of his duties and obligations to the Company.

3. Place of Performance. Executive will perform his services hereunder at the principal executive offices of the Company in Canton, Massachusetts; *provided, however*, that Executive may be required to travel from time to time for business purposes.

4. Compensation and Indemnification.

4.1. Base Salary. Executive’s annual salary will be \$241,000 (the “Base Salary”), paid in accordance with the Company’s payroll practices as in effect from time to time. The Base Salary will be reviewed annually by the Compensation Committee of the Company’s Board of Directors (the “Committee”).

4.2. Annual Bonuses.

4.2.1. For each fiscal year ending during his employment, Executive will be eligible to earn an annual bonus. The target amount of that bonus will be 30% percent of Executive’s Base Salary for the applicable fiscal year. The actual bonus payable with respect to a particular year will be determined by the Committee, based on the achievement of corporate and /or individual performance objectives established by the Committee. Any bonus payable under this paragraph will be paid during the calendar year immediately following the fiscal year in respect of which the bonus is payable and, except

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as otherwise provided in Section 5.1.1, will only be paid if Executive remains continuously employed by the Company through the actual bonus payment date.

4.2.2. For purposes of determining any bonus payable to Executive, the measurement of corporate and individual performance will be performed by the Committee in good faith. From time to time, the Committee may, in its sole discretion, make adjustments to corporate or individual performance goals, so that required departures from the Company’s operating budget, changes in accounting principles, acquisitions, dispositions, mergers, consolidations and other corporate transactions, and other factors influencing the achievement or calculation of such goals do not affect the operation of this provision in a manner inconsistent with its intended purposes.

4.3. Employee Benefits. During Executive’s employment, Executive will be eligible to participate in all employee benefit plans and programs made available by the Company from time to time to employees generally, subject to applicable plan terms and policies. The Company periodically reviews its benefits, policies, benefits providers and practices and may terminate, alter or change them at its discretion from time to time.

4.4. Reimbursement of Expenses. The Executive will be reimbursed by the Company for all reasonable business expenses incurred by Executive in accordance with the Company’s customary expense reimbursement policies as in effect from time to time. Notwithstanding anything herein to the contrary, to the extent any expense, reimbursement or in-kind benefit provided to the Executive constitutes a “deferral of compensation” within the meaning of Section 409A of the Internal Revenue Code (the “Code”) (i) the amount of expenses eligible for reimbursement or in-kind benefits provided to the Executive must be incurred during the Executive’s term of employment; (ii) the amount of expenses eligible for reimbursement or in-kind benefits provided to the Executive during any calendar year will not affect the amount of expenses eligible for reimbursement or in-kind benefits provided to the Executive in any other calendar year, (iii) the reimbursements for expenses for which the Executive is entitled to be reimbursed shall be made on or before the last day of the calendar year following the calendar year in which the applicable expense is incurred and (iv) the right to payment or reimbursement or in-kind benefits hereunder may not be liquidated or exchanged for any other benefit.

5. Termination. Executive’s employment with the Company may be terminated by the Company or Executive at any time and for any reason. Upon any cessation of his employment with the Company, Executive will be entitled only to such compensation and benefits as described in this Section 5. Upon any cessation of his employment for any reason, unless otherwise requested by the Company, Executive agrees to resign immediately from all officer and director positions he then holds with the Company and its affiliates.

5.1. Termination without Cause or for Good Reason. If Executive's employment by the Company ceases due to a termination by the Company without Cause (as defined below) or a resignation by Executive for Good Reason (as defined below), Executive will be entitled to:

5.1.1. payment of any annual bonus otherwise payable (but for the cessation of Executive's employment) with respect to a year ended prior to the cessation of Executive's employment;

5.1.2. continuation of Executive's Base Salary for a period equal to 6 months, payable in accordance with the Company's standard payroll practices; and

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5.1.3. waiver of the applicable premium otherwise payable for COBRA continuation coverage for Executive (and, to the extent covered immediately prior to the date of such cessation, his eligible dependents) for a period equal to 6 months.

Except as otherwise provided in this Section 5.1, and except for payment of all (i) accrued and unpaid Base Salary through the date of such cessation, (ii) any expense reimbursements to be paid in accordance with Company policy and (iii) payments for any accrued but unused paid time off in accordance with the Company's policies and applicable law, all compensation and benefits will cease at the time of such cessation and the Company will have no further liability or obligation by reason of such cessation. The payments and benefits described in this Section 5.1 are in lieu of, and not in addition to, any other severance arrangement maintained by the Company. Notwithstanding any provision of this Agreement, the payments and benefits described in Section 5.1 are conditioned on: (a) the Executive's execution and delivery to the Company and the expiration of all applicable statutory revocation periods, by the 45th day following the effective date of his cessation of employment, of a general release of claims against the Company and its affiliates in a form reasonably prescribed by the Company (the "Release"); and (b) the Executive's continued compliance with the Restrictive Covenants (as defined below). Subject to Section 5.4, below, the benefits described in Section 5.1 will be paid or provided (or begin to be paid or provided) as soon as administratively practicable (or determinable in the case of the benefits described in Section 5.1.1) after the Release becomes irrevocable, provided that if the 45 day period described above begins in one taxable year and ends in a second taxable year such payments or benefits shall not commence until the second taxable year.

5.2. Termination Following a Change in Control. For cessations of employment described in Section 5.1 that occur during the twelve (12) month period immediately following the occurrence of a Change in Control (as defined below), the Executive will receive the payments and benefits described in Section 5.1 above, subject to the following modifications:

5.2.1. the references in Sections 5.1.2 and 5.1.3 to "6 months" will each be replaced with a reference to "9 months"; and

5.2.2. all unvested restricted stock, stock options and other equity incentives awarded to Executive by the Company will become immediately and automatically fully vested and exercisable (as applicable).

5.3. Other Terminations. If Executive's employment with the Company ceases for any reason other than as described in Section 5.1, above (including but not limited to termination (i) by the Company for Cause, (ii) as a result of Executive's death, (iii) as a result of Executive's Disability or (d) by Executive without Good Reason, then the Company's obligation to Executive will be limited solely to (a) accrued and unpaid Base Salary through the date of such cessation, (b) any expense reimbursements to be paid in accordance with Company policy and (c) payments for any accrued but unused paid time off in accordance with the Company's policies and applicable law. All compensation and benefits will cease at the time of such cessation and, except as otherwise provided by COBRA or this Section 5.3, the Company will have no further liability or obligation by reason of such termination. The foregoing will not be construed to limit Executive's right to payment or reimbursement for claims incurred prior to the date of such termination under any insurance contract funding an employee benefit plan, policy or arrangement of the Company in accordance with the terms of such insurance contract.

5.4. Compliance with Section 409A. If the termination giving rise to the payments described in Section 5.1 is not a "Separation from Service" within the meaning of Treas. Reg. § 1.409A-1(h)(1) (or any successor provision), then the amounts otherwise payable pursuant to that section will instead be deferred without interest and will not be paid until Executive experiences a Separation from

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Service. To the maximum extent permitted under Section 409A of the Code and its corresponding regulations, the cash severance benefits payable under this Agreement are intended to meet the requirements of the short-term deferral exemption under Section 409A of the Code and the "separation pay exception" under Treas. Reg. §1.409A-1(b)(9)(iii). To the extent compliance with the requirements of Treas. Reg. § 1.409A-3(i)(2) (or any successor provision) is necessary to avoid the application of an additional tax under Section 409A of the Internal Revenue Code to payments due to Executive upon or following his Separation from Service, then notwithstanding any other provision of this Agreement (or any otherwise applicable plan, policy, agreement or arrangement), any such payments that are otherwise due within six months following Executive's Separation from Service (taking into account the preceding sentence of this paragraph) will be deferred without interest and paid to Executive in a lump sum immediately following that six month period. For purposes of the application of Treas. Reg. § 1.409A-1(b)(4)(or any successor provision), each payment in a series of payments will be deemed a separate payment.

5.5. PPACA. Notwithstanding anything in this Agreement to the contrary, the waiver in respect of COBRA premiums pursuant to this Sections 5.1 and 5.2 shall cease to the extent required to avoid adverse consequences to the Company under the Patient Protection and Affordable Care Act of 2010 and regulations thereunder.

5.6. Section 280G. If any payment or distribution by the Company to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise pursuant to or by reason of any other agreement, policy, plan, program or arrangement or the lapse or termination of any restriction on or the vesting or exercisability of any payment or benefit (each a "Payment"), would be subject to the excise tax imposed by Section 4999 of the Code (or any successor provision thereto) or to any similar tax imposed by state or local law (such tax or taxes are hereafter collectively referred to as the "Excise Tax"), then the aggregate amount of Payments payable to Executive shall be reduced to the aggregate amount of Payments that may be made to the Executive without incurring an excise tax (the "Safe-Harbor Amount") in accordance with the immediately following sentence; *provided that* such reduction shall only be imposed if the aggregate after-tax value of the Payments retained by Executive (after giving effect to such reduction) is equal to or greater than the aggregate after-tax value (after giving effect to the Excise Tax) of the Payments to Executive without any such reduction. Any such reduction shall be made in the following order: (i) first, any future cash payments (if any) shall be reduced

(if necessary, to zero); (ii) second, any current cash payments shall be reduced (if necessary, to zero); (iii) third, all non-cash payments (other than equity or equity derivative related payments) shall be reduced (if necessary, to zero); and (iv) fourth, all equity or equity derivative payments shall be reduced.

5.7. Definitions. For purposes of this Agreement:

5.7.1. “Cause” means (a) commission or conviction of any felony or any crime involving dishonesty; (b) commission of any fraud against the Company; (c) intentional and material damage to any material property of the Company; (d) Executive’s material breach of any agreement with or duty owed to the Company or any of its affiliates (including, without limitation, Executive’s material breach of any of the Restrictive Covenants, as defined below); or (e) refusal to perform the lawful, reasonable and material directives of the Company’s Board of Directors (the “Board”) or the Company’s Chief Executive Officer.

5.7.2. “Change in Control” means the first to occur of any of the events described in Section 1(g) of the Company’s Amended and Restated 2014 Stock Incentive Plan (or any successor provision).

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5.7.3. “Disability” means a condition entitling the Executive to benefits under the Company’s long term disability plan, policy or arrangement; *provided, however*, that if no such plan, policy or arrangement is then maintained by the Company and applicable to the Executive, “Disability” will mean the Executive’s inability to perform his duties under this Agreement due to a mental or physical condition that can be expected to result in death or that can be expected to last (or has already lasted) for a continuous period of 90 days or more, or for 120 days in any 180 consecutive day period. Termination as a result of a Disability will not be construed as a termination by the Company “without Cause.”

5.7.4. “Good Reason” means any of the following, without the Executive’s prior consent: (a) a diminution of the Executive’s title below the rank of Vice President; (b) a reduction in Base Salary; or (c) the relocation of the Executive’s primary place of employment to a location that is (i) more than 50 miles from the location of the Executive’s permanent primary place of employment prior to such relocation and (ii) more than 50 miles from the location of the Executive’s residence. However, none of the foregoing events or conditions will constitute Good Reason unless the Executive provides the Company with written objection to the event or condition within 30 days following the occurrence thereof, the Company does not reverse or otherwise cure the event or condition within 30 days of receiving that written objection, and the Executive resigns Executive’s employment within 30 days following the expiration of that cure period. Notwithstanding the foregoing and for the avoidance of doubt, a diminution of the Executive’s title as a result of Change in Control shall not constitute Good Reason.

6. Restrictive Covenants. To induce the Company to enter into this Agreement and in recognition of the compensation to be paid to the Executive pursuant to Sections 4 and 5 of this Agreement, the Executive agrees to be bound by the provisions of this Section 6 (the “Restrictive Covenants”). These Restrictive Covenants will apply without regard to whether any termination or cessation of the Executive’s employment is initiated by the Company or the Executive, and without regard to the reason for that termination or cessation.

6.1. Covenant Not To Compete. The Executive covenants that, during his employment by the Company and for a period of 6 months following immediately thereafter (the “Restricted Period”), the Executive will not (except in his capacity as an employee or director of the Company) do any of the following, directly or indirectly:

6.1.1. engage or participate in any Competing Business (as defined below) wherever the Company or its affiliates do business, do or plan to do business or sell or market their products or services;

6.1.2. become interested in (as owner, stockholder, lender, partner, co-venturer, director, officer, employee, agent or consultant) any person, firm, corporation, association or other entity engaged in a Competing Business. Notwithstanding the foregoing, the Executive may hold up to 1% of the outstanding securities of any class of any publicly-traded securities of any company;

6.1.3. influence or attempt to influence any employee, consultant, supplier, licensor, licensee, contractor, agent, strategic partner, distributor, customer or other person to terminate or modify any written or oral agreement, arrangement or course of dealing with the Company or any of its affiliates; or

6.1.4. solicit for employment or retention as an independent contractor (or arrange to have any other person or entity solicit for employment or retention) any person employed or retained by the Company or any of its affiliates.

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6.2. Confidentiality. The Executive recognizes and acknowledges that the Proprietary Information (as defined in below) is a valuable, special and unique asset of the business of the Company and its affiliates. As a result, both during the Term and thereafter, the Executive will not, without the prior written consent of the Company, for any reason divulge to any third-party or use for his own benefit, or for any purpose other than the exclusive benefit of the Company and its affiliates, any Proprietary Information. Notwithstanding the foregoing, if the Executive is compelled to disclose Proprietary Information by court order or other legal or regulatory process, to the extent permitted by applicable law, he shall promptly so notify the Company so that it may seek a protective order or other assurance that confidential treatment of such Proprietary Information shall be afforded, and the Executive shall reasonably cooperate with the Company and its affiliates in connection therewith. If the Executive is so obligated by court order or other legal process to disclose Proprietary Information it will disclose only the minimum amount of such Proprietary Information as is necessary for the Executive to comply with such court order or other legal process.

6.3. Property of the Company.

6.3.1. Proprietary Information. All right, title and interest in and to Proprietary Information will be and remain the sole and exclusive property of the Company and its affiliates. The Executive will not remove from the Company’s or its affiliates’ offices or premises any documents, records, notebooks, files, correspondence, reports, memoranda or similar materials of or containing Proprietary Information, or other materials or property of any kind belonging to the Company or its affiliates unless necessary or appropriate in the performance of his duties to the Company and its affiliates. If the

Executive removes such materials or property in the performance of his duties, he will return such materials or property promptly after the removal has served its purpose. The Executive will not make, retain, remove and/or distribute any copies of any such materials or property, or divulge to any third person the nature of and/or contents of such materials or property, except to the extent necessary to satisfy contractual obligations of the Company or its affiliates or to perform his duties on behalf of the Company and its affiliates. Upon termination of the Executive's employment with the Company, he will leave with the Company and its affiliates or promptly return to the Company and its affiliates all originals and copies of such materials or property then in his possession.

6.3.2. Intellectual Property. The Executive agrees that all the Intellectual Property (as defined below) will be considered "works made for hire" as that term is defined in Section 101 of the Copyright Act (17 U.S.C. § 101) and that all right, title and interest in such Intellectual Property will be the sole and exclusive property of the Company and its affiliates. To the extent that any of the Intellectual Property may not by law be considered a work made for hire, or to the extent that, notwithstanding the foregoing, the Executive retains any interest in the Intellectual Property, the Executive hereby irrevocably assigns and transfers to the Company and its affiliates any and all right, title, or interest that the Executive may now or in the future have in the Intellectual Property under patent, copyright, trade secret, trademark or other law, in perpetuity or for the longest period otherwise permitted by law, without the necessity of further consideration. The Company and its affiliates will be entitled to obtain and hold in its own name all copyrights, patents, trade secrets, trademarks and other similar registrations with respect to such Intellectual Property. The Executive further agrees to execute any and all documents and provide any further cooperation or assistance reasonably required by the Company, at the Company's expense, to perfect, maintain or otherwise protect its rights in the Intellectual Property. If the Company or its affiliates, as applicable, are unable after reasonable efforts to secure the Executive's signature, cooperation or assistance in accordance with the preceding sentence, whether because of the Executive's incapacity or any other reason whatsoever, the Executive hereby designates and appoints the Company, the appropriate affiliate, or their respective designee as the Executive's agent and attorney-in-fact, to act on his behalf, to execute and file documents and to do all other lawfully permitted acts necessary or desirable to perfect, maintain or otherwise protect the Company's or its affiliates' rights

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in the Intellectual Property. The Executive acknowledges and agrees that such appointment is coupled with an interest and is therefore irrevocable.

6.4. Definitions. For purposes of this Agreement:

6.4.1. "Competing Business" means any person, firm, corporation, partnership, association or other entity engaged in developing, manufacturing, marketing, distributing or selling, directly or indirectly, pharmaceutical abuse-deterrent products or any other product for pain indications that directly competes with a product developed, manufactured, marketed, distributed or sold by the Company. A division, subsidiary or similar business unit of an entity that does not engage in the business activities described in this definition will not be considered a Competing Business even if another separate division, subsidiary or similar business unit does engage in such activities.

6.4.2. "Intellectual Property" means (a) all inventions (whether patentable or unpatentable and whether or not reduced to practice), all improvements thereto, and all patents and patent applications claiming such inventions, (b) all trademarks, service marks, trade dress, logos, trade names, fictitious names, brand names, brand marks and corporate names, together with all translations, adaptations, derivations, and combinations thereof and including all goodwill associated therewith, and all applications, registrations, and renewals in connection therewith, (c) all copyrightable works, all copyrights, and all applications, registrations, and renewals in connection therewith, (d) all mask works and all applications, registrations, and renewals in connection therewith, (e) all trade secrets (including research and development, know-how, formulas, compositions, manufacturing and production processes and techniques, methodologies, technical data, designs, drawings and specifications), (f) all computer software (including data, source and object codes and related documentation), (g) all other proprietary rights, (h) all copies and tangible embodiments thereof (in whatever form or medium), or (i) similar intangible personal property which have been or are developed or created in whole or in part by the Executive (1) at any time and at any place while the Executive is employed by Company and which, in the case of any or all of the foregoing, are related to and used in connection with the business of the Company or its affiliates, or (2) as a result of tasks assigned to the Executive by the Company or its affiliates.

6.4.3. "Proprietary Information" means any and all proprietary information developed or acquired by the Company or any of its subsidiaries or affiliates that has not been specifically authorized to be disclosed. Such Proprietary Information shall include, but shall not be limited to, the following items and information relating to the following items: (a) all intellectual property and proprietary rights of the Company (including, without limitation, the Intellectual Property), (b) computer codes and instructions, processing systems and techniques, inputs and outputs (regardless of the media on which stored or located) and hardware and software configurations, designs, architecture and interfaces, (c) business research, studies, procedures and costs, (d) financial data, (e) distribution methods, (f) marketing data, methods, plans and efforts, (g) the identities of actual and prospective suppliers, (h) the terms of contracts and agreements with, the needs and requirements of, and the Company's or its affiliates' course of dealing with, actual or prospective suppliers, (i) personnel information, (j) customer and vendor credit information, and (k) information received from third parties subject to obligations of non-disclosure or non-use. Failure by the Company or its affiliates to mark any of the Proprietary Information as confidential or proprietary shall not affect its status as Proprietary Information.

6.5. Acknowledgements. The Executive acknowledges that the Restrictive Covenants are reasonable and necessary to protect the legitimate interests of the Company and its affiliates, that the duration and geographic scope of the Restrictive Covenants are reasonable given the nature of this Agreement and the position the Executive holds within the Company, and that the Company would not

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enter into this Agreement or otherwise employ or continue to employ the Executive unless the Executive agrees to be bound by the Restrictive Covenants set forth in this Section 6.

6.6. Remedies and Enforcement Upon Breach.

6.6.1. Specific Enforcement. The Executive acknowledges that any breach by him, willfully or otherwise, of the Restrictive Covenants will cause continuing and irreparable injury to the Company or its affiliates for which monetary damages would not be an adequate remedy. The Executive shall not, in any action or proceeding to enforce any of the provisions of this Agreement, assert the claim or defense that such an adequate remedy at law exists. In the event of any such breach or threatened breach by the Executive of any of the Restrictive Covenants, the Company or its affiliates, as

applicable, shall be entitled to injunctive or other similar equitable relief in any court, without any requirement that a bond or other security be posted, and this Agreement shall not in any way limit remedies of law or in equity otherwise available to the Company and its affiliates.

6.6.2. Judicial Modification. If any court determines that any of the Restrictive Covenants, or any part thereof, is unenforceable because of the duration or geographical scope of such provision, such court shall have the power to modify such provision and, in its modified form, such provision shall then be enforceable.

6.6.3. Enforceability. If any court holds the Restrictive Covenants unenforceable by reason of their breadth or scope or otherwise, it is the intention of the parties hereto that such determination not bar or in any way affect the right of the Company and its affiliates to the relief provided above in the courts of any other jurisdiction within the geographic scope of such Restrictive Covenants.

6.6.4. Disclosure of Restrictive Covenants. The Executive agrees to disclose the existence and terms of the Restrictive Covenants to any employer that the Executive may work for during the Restricted Period.

6.6.5. Extension of Restricted Period. If the Executive breaches Section 6.1 in any respect, the restrictions contained in that section will be extended for a period equal to the period that the Executive was in breach.

## 7. Miscellaneous.

7.1. Other Agreements. Executive represents and warrants to the Company that there are no restrictions, agreements or understandings whatsoever to which he is a party that would prevent or make unlawful his execution of this Agreement, that would be inconsistent or in conflict with this Agreement or Executive's obligations hereunder, or that would otherwise prevent, limit or impair the performance by Executive of his duties under this Agreement.

7.2. Successors and Assigns. The Company may assign this Agreement to any successor to its assets and business by means of liquidation, dissolution, sale of assets or otherwise. The duties of Executive hereunder are personal to Executive and may not be assigned by him.

7.3. Governing Law and Enforcement. This Agreement will be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to the principles of conflicts of laws. Any legal proceeding arising out of or relating to this Agreement will be instituted in a state or federal court in the Commonwealth of Massachusetts, and Executive and the Company hereby consent to the personal and exclusive jurisdiction of such court(s) and hereby waive any

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objection(s) that they may have to personal jurisdiction, the laying of venue of any such proceeding and any claim or defense of inconvenient forum.

7.4. Waivers. The waiver by either party of any right hereunder or of any breach by the other party will not be deemed a waiver of any other right hereunder or of any other breach by the other party. No waiver will be deemed to have occurred unless set forth in a writing. No waiver will constitute a continuing waiver unless specifically stated, and any waiver will operate only as to the specific term or condition waived.

7.5. Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law. However, if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provision, and this Agreement will be reformed, construed and enforced as though the invalid, illegal or unenforceable provision had never been herein contained.

7.6. Survival. This Agreement will survive the cessation of Executive's employment to the extent necessary to fulfill the purposes and intent the Agreement.

7.7. Notices. Any notice or communication required or permitted under this Agreement will be made in writing and (a) sent by overnight courier, (b) mailed by overnight U.S. express mail, return receipt requested or (c) sent by telecopier. Any notice or communication to Executive will be sent to the address contained in his personnel file. Any notice or communication to the Company will be sent to the Company's principal executive offices, to the attention of its Chief Executive Officer. Notwithstanding the foregoing, either party may change the address for notices or communications hereunder by providing written notice to the other in the manner specified in this paragraph.

7.8. Entire Agreement; Amendments. This Agreement contains the entire agreement and understanding of the parties hereto relating to the subject matter hereof, and merges and supersedes all prior and contemporaneous discussions, agreements and understandings of every nature relating to that subject matter (including, without limitation, the Existing Agreement). This Agreement may not be changed or modified, except by an agreement in writing signed by each of the parties hereto.

7.9. Withholding. All payments (or transfers of property) to Executive will be subject to tax withholding to the extent required by applicable law.

7.10. Section Headings. The headings of sections and paragraphs of this Agreement are inserted for convenience only and will not in any way affect the meaning or construction of any provision of this Agreement.

7.11. Counterparts; Facsimile. This Agreement may be executed in multiple counterparts (including by facsimile signature), each of which will be deemed to be an original, but all of which together will constitute but one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

*<remainder of page intentionally left blank; signature page follows>*

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IN WITNESS WHEREOF, the Company has caused this Agreement to be executed by its duly authorized officer, and Executive has executed this Agreement, on the date(s) indicated below.

**COLLEGIUM PHARMACEUTICAL, INC.**

By: /s/ Paul Brannelly

Name: Paul Brannelly

Title: Chief Financial Officer

Date: August 4, 2015

**DOUGLAS CARLSON**

/s/ Douglas Carlson

Date: August 3, 2015

*Signature Page to Employment Agreement*

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## SUBSIDIARIES

	<b>Subsidiary</b>	<b>Jurisdiction of Incorporation</b>
1	Collegium Securities Corporation	Massachusetts

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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  
January 4, 2016

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QuickLinks

[Exhibit 23.1](#)

[CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM](#)