UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of the Securities and Exchange Act of 1934

Date of Report (Date of earliest reported): **June 19, 2015**

COLLEGIUM PHARMACEUTICAL, INC.
(Exact Name of Registrant as Specified in Charter)

Virginia	**001-37372**	**03-0416362**
(State or Other Jurisdiction of Incorporation or Organization)	(Commission File Number)	(IRS Employer Identification No.)

780 Dedham Street
Suite 800
Canton, MA 02021
(Address of principal executive offices) (Zip Code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events

We are filing the following information with the U.S. Securities and Exchange Commission for the purpose of updating our publicly disclosed risk factors, as set forth below.

RISK FACTORS

The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects. In that case, the trading price of our common stock could decline, and you may 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 we currently have no products approved by the U.S. Food and Drug Administration, or FDA, and we continue to incur significant research, development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since January 1, 2011. For the year ended December 31, 2014, we reported a net loss of $17.9 million, and we had an accumulated deficit of $101.8 million at December 31, 2014.

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

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

As we currently have no approved products, we are not generating any revenue from product sales. We have not generated any revenue since we divested our former subsidiary in 2010. Our

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

- obtain regulatory approval for, and successfully commercialize, Xtampza;
- successfully complete development activities, including the necessary clinical trials, with respect to our other product candidates;
- complete and submit NDAs to the FDA and obtain regulatory approval for indications for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities, if we choose to commercialize our product candidates outside the United States;
- set a commercially viable price for our products;
- manufacture commercial quantities of our products at acceptable cost levels;
- develop a commercial organization capable of sales, marketing and distribution for the products we intend to sell ourselves in the markets in which we have retained commercialization rights;
- find suitable distribution collaborators to help us market, sell and distribute our products, if approved, in markets outside the United States; and
- obtain coverage and adequate reimbursement from third-parties, including government payors.

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

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

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

Our operations have consumed substantial amounts of cash. We expect to continue to spend substantial amounts to advance the clinical development of our product candidates and launch and commercialize any product candidates for which we may receive regulatory approval, including building our own commercial organization. We believe that our existing cash and cash equivalents, including the net proceeds from our initial public offering in May 2015 will be sufficient to fund our operations into mid-2017, including the commercialization of Xtampza, if approved, and the continuation of our development of our other product candidates. 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 labels for these product candidates;
- clinical development plans we establish for Xtampza and any other future product candidates;

- the FDA's approval of inclusion of claims in the label for Xtampza that will permit the sprinkling of Xtampza microspheres on food, directly in the mouth or administered through feeding tubes;
- the outcome, timing and cost of the regulatory approval process by the FDA and foreign regulatory authorities, including the potential for the FDA or foreign regulatory authorities to require that we perform more studies than those that we currently expect;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, including defending Purdue's patent infringement claims against us;
- the cost and timing of completion of existing or expanded commercial-scale outsourced manufacturing activities;
- the cost of establishing sales, marketing and distribution capabilities for Xtampza and any other product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own; and
- the initiation, progress, timing, costs and results of clinical trials for our product candidates and any future product candidates we may in-license.

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

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

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

Our predecessor was originally incorporated in Delaware in April 2002 under the name Collegium Pharmaceuticals, Inc. In October 2003, our predecessor changed its name to Collegium Pharmaceutical, Inc. In July 2014, we reincorporated in the Commonwealth of Virginia pursuant to a merger whereby Collegium Pharmaceutical, Inc., a Delaware corporation, merged with and into Collegium Pharmaceutical, Inc., a Virginia corporation, with the Virginia corporation surviving the merger. From 2002 until 2010, our operations focused primarily on marketing innovative proprietary therapies to the wound care and dermatology industry through our former subsidiary, Onset Therapeutics, LLC, which was spun off and became a part of Precision Dermatology, Inc. in 2010. Since 2010, our operations have focused primarily on developing the DETERx platform technology and identifying and developing product candidates that utilize the DETERx technology, including our lead product candidate, Xtampza. We have not yet obtained regulatory approval for any of our product candidates or demonstrated an ability to commercialize a product candidate. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market.

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

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

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

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

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

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

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

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

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

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

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

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

It is estimated that the U.S. market includes approximately 11 million patients with chronic pain with dysphagia. Our Xtampza microspheres are designed to be removed from the capsule and sprinkled on food, directly into the mouth or administered through feeding tubes, without compromising their extended-release properties. If the FDA approves Xtampza, but does not permit us to include a claim in the label for Xtampza regarding the ability to sprinkle the Xtampza microspheres directly in the mouth, on food or in feeding tubes, or requires us to have a black box warning label stating that ''crushing, dissolving or chewing can cause rapid release and absorption of a potentially fatal dose of the active drug,'' it will limit our ability to differentiate Xtampza from other abuse-deterrent opioid formulations on the basis of alternative dosing options and we may not be able to market Xtampza to patients with chronic pain with dysphagia. As a result, this may have an adverse effect on our business and our prospects for future growth.

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

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

If the FDA does not allow us to pursue the Section 505(b)(2) approval pathway for Xtampza or any of our other product candidates, or if we cannot demonstrate bioequivalence or comparable

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

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

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

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

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

the patents asserted and the interpretation of these patents. However, we could be unsuccessful in advancing non-infringement and invalidity arguments in our defense. Purdue need only prove infringement by a preponderance of the evidence, which is a low burden of proof. If before the expiration of the 30-month period, the Court issues a final order that any of the listed patents are valid and have been infringed, FDA approval would be delayed until either a date ordered by the Court or when the Court determines that the patents will expire.

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

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

The time required to obtain approvals by the FDA and foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval varies among jurisdictions and may change during the course of a product candidate's clinical development. For example, we cannot guarantee that the FDA will not require additional or different clinical trials in support of our submission of an NDA for Xtampza. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any future product candidates we may in-license, acquire or develop will ever obtain regulatory approval from the FDA or any foreign regulatory authority.

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

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

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

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

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

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

In order to market and sell our products outside the United States, we will likely need to obtain separate marketing approvals and comply with numerous and varied regulatory requirements and regimes, which can involve additional testing, may take substantially longer than the FDA approval process, and still generally includes all of the risks associated with obtaining FDA

approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. FDA approval does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by the FDA or regulatory authorities in other countries or jurisdictions. We may not obtain any regulatory approvals on a timely basis, if at all. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our product candidates by regulatory authorities in countries outside the United States, the commercial prospects of that product candidate may be significantly diminished and our business prospects could decline.

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

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

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

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

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

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

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

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

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

Even if we comply with all FDA pre-approval regulatory requirements, the FDA may determine that Xtampza or our other product candidates are not safe or effective, and we may never obtain regulatory approval for such product candidates. If we fail to obtain regulatory approval for some or all of our product candidates, we will have fewer commercial products, if any, and correspondingly lower product revenues, if any. Even if our product candidates, including

Xtampza, receive regulatory approval, such approval may involve limitations on the indications and conditions of use or marketing claims for our products, or may not include certain of the abuse-deterrence claims that we are seeking to include in the label for Xtampza and our other DETERx-based product candidates. Further, later discovery of previously unknown problems or adverse events could result in additional regulatory restrictions, including withdrawal of products and addition of warnings or other statements on the product label. The FDA is likely to require us to perform lengthy Phase 4 post-approval clinical efficacy or safety trials. These trials could be very expensive.

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

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

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

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

Our failure to achieve FDA approval of product labeling containing such information will prevent or substantiality limit our promotion of the abuse-deterrent features of our product candidates in order to differentiate them from other opioid products containing the same active ingredients. This would make our products less competitive in the market.

The FDA has publicly stated that explicit claims that a product is expected to result in a meaningful reduction of abuse must be supported by randomized, double-blind, controlled clinical studies of the abuse potential of the drug and that explicit claims that a product has demonstrated reduced abuse in the community will be required to be supported by post-marketing data, including formal post-marketing studies evaluating the effect of abuse-deterrent formulations. Although we believe that we have conducted all of the preclinical studies and clinical trials that are required to support certain abuse-deterrent claims for Xtampza, there can be no assurance that Xtampza, or any of our other product candidates, will receive FDA-approved labeling that describes the abuse-deterrent features of such products. Furthermore, the FDA's April 2015 final guidance on abuse deterrent opioids makes clear that the FDA expects sponsors to compare their formulations against approved abuse-deterrent

versions of the same opioid based on the relevant categories of testing. If a proposed product is less resistant to manipulation than an approved product, the FDA has stated that the proposed product may not be eligible for labeling regarding abuse- deterrent properties. If the FDA does not approve labeling containing abuse-deterrence claims, we will not be able to promote such products based on their abuse-deterrent features, may not be able to differentiate such products from other opioid products containing the same active ingredients, and may need to lower the price of our products to the extent that there are competing products with abuse-deterrent claims on their labels.

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

Even if Xtampza and any of our other product candidates are approved for marketing with certain abuse- deterrence claims, the April 2015 final FDA guidance on abuse-deterrent opioids is not binding law and may be superseded or modified at any time. Also, if the FDA determines that our post-marketing data do not demonstrate that the abuse-deterrent properties result in reduction of abuse, or demonstrate a shift to routes of abuse that present a greater risk, the FDA may find that labeling revisions are needed, and potentially require the removal of our abuse-deterrence claims.

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

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

- issue warning letters or untitled letters;

- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include the imposition of various fines, reimbursements for inspection costs and penalties for noncompliance, and require due dates for specific actions;
- seek an injunction or impose civil, criminal and/or administrative penalties, damages, monetary fines, require disgorgement, consider exclusion from participation in Medicare, Medicaid and other federal healthcare programs and require curtailment or restructuring of our operations;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall; or
- refuse to allow us to enter into government contracts.

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

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

Failure to comply with ongoing governmental regulations for marketing our product candidates could delay or inhibit our ability to generate revenues from their sale and could also expose us to claims or other sanctions.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by, among others, the FDA, the Department of Justice, or the DOJ, the Office of Inspector General of the Department of Health and Human Services, or HHS, state attorneys general, members of Congress and the public. Violations, including promotion of our product candidates, if approved, for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or other government agencies. Additionally, advertising and promotion of any product candidate that obtains approval outside the United States will be heavily scrutinized by foreign regulatory authorities.

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

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

In addition, later discovery of previously unknown problems with a product, manufacturer or facility, or our failure to update regulatory files, may result in restrictions, including withdrawal of the product from the market. Any of the following or other similar events, if they were to occur, could delay or preclude us from further developing, marketing or realizing the full commercial potential of our product candidates:

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

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

Our product candidates, including Xtampza, contain, and our future product candidates will likely contain, controlled substances which are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Xtampza's active ingredient, oxycodone, is classified as a controlled substance under the Controlled Substances Act of 1970, or CSA, and regulations of the U.S. Drug Enforcement Administration, or DEA. A number of states also independently regulate these drugs, including oxycodone, as controlled substances. Controlled substances are classified by the DEA as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredient in our lead product candidate Xtampza, oxycodone, is listed by the DEA as a Schedule II controlled substance under the CSA. For our product candidates containing controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription. Furthermore, the amount of Schedule II substances that can be obtained for clinical trials and commercial distribution is limited by the CSA and DEA regulations. We may not be able to obtain sufficient quantities of these controlled substances in order to complete our clinical trials or meet commercial demand, if our product candidates are approved for marketing.

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

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

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

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

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

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

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

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

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

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

Other than Xtampza, all of our product candidates are in preclinical development. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. Many companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in clinical trials, even after reporting promising results in earlier clinical trials. Despite the results reported in preliminary preclinical studies for our other extended-release, abuse-deterrent product candidates, including hydrocodone and 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 label, or result in significant negative consequences following any marketing approval.

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

If Xtampza or any of our other product candidates receives marketing approval, and we or others later identify undesirable adverse events associated with such product, a number of potentially significant negative consequences could result, including:

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

Any of these events could prevent us from achieving or maintaining market acceptance of Xtampza or any of our other product candidates, if approved.

Risks Related to Intellectual Property

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

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

Third parties may assert infringement claims against us, or other parties we have agreed to indemnify, based on existing patents or patents that may be granted in the future. We are aware of third-party patents and patent applications related to oxycodone, oxymorphone, hydrocodone, morphine, and methylphenidate drugs and formulations, including those listed in the FDA's Orange Book for oxycodone products. Because of the delay between filing and publication of patent applications, and because applications can take several years to issue, there may be currently pending third-party patent applications that are unknown to us, which may later result in issued patents. Because of the uncertainty inherent in intellectual property litigation, we could lose, even if the case against us was weak or flawed.

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

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

patent litigation before our product candidates may be commercialized. On March 24 and March 26, 2015, Purdue, as the sponsor for OxyContin OP, the listed drug for Xtampza, brought infringement claims against us in the District of Delaware and the District of Massachusetts, respectively, alleging infringement of U.S. Patent Nos. 7,674,799, 7,674,800, 7,683,072 and 8,652,497. On April 6, 2015, in the District of Delaware case, we filed a motion to dismiss for lack of personal jurisdiction or, in the alternative, to transfer venue to the Southern District of New York where three of the patents have already been invalidated.

Purdue's opposition to our motion was filed on April 23, 2015 and our reply in support of the motion is due on May 4, 2015. The complaint in the District of Massachusetts case has not yet been served. We plan to continue to take all steps necessary to vigorously defend ourselves against these claims. The strength of our defenses will depend on the patents asserted and the interpretation of these patents. However, we could be unsuccessful in advancing non-infringement and invalidity arguments in our defense. Purdue need only prove infringement by a preponderance of the evidence, which is a low burden of proof.

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

Even if we are found not to infringe or Purdue's, or any other potential plaintiff's, patent claims are found invalid or unenforceable, defending any such infringement claim would be expensive and time-consuming, and could delay the launch of Xtampza and distract management from their normal responsibilities.

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

If we are unable to obtain or maintain intellectual property rights for our technology and product candidates, we may lose valuable assets or experience reduced market share.

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

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

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

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

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

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

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and these foreign laws may also be subject to change.

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions typically are not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot be certain that we were the first to make

the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights, both in the United States and abroad, are highly uncertain.

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

Pursuant to the Leahy-Smith Act, the United States transitioned to a ''first to file'' system in which the first inventor to file a patent application will be entitled to the patent. In addition, third parties are allowed to submit prior art before the issuance of a patent by the U.S. Patent and Trademark Office, or USPTO, and may become involved in opposition, derivation, reexamination, or inter partes review challenging our patent rights or the patent rights of others. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including novelty, nonobviousness and enablement. It is possible that prior art of which both we and the patent examiner were unaware during prosecution exists, which could render our patents invalid. Moreover, there may exist prior art of which we were or are aware, and which we did not or do not consider relevant to our patents, but which could nevertheless be determined to render our patents invalid. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could have a material adverse effect on our competitive position with respect to third parties.

Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or 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 no sales or marketing capabilities and, if we are unable to develop our own sales and marketing capabilities or enter into strategic alliances with marketing collaborators, we may not be successful in commercializing our product candidates and may be unable to generate any product revenue.

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

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our product candidates;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

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

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

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

- availability of coverage and adequate reimbursement for our product candidates from government or other third-party payors;
- any negative publicity related to our or our competitors' products that include the same active ingredient as our product candidates;
- the prevalence and severity of adverse side effects, including limitations or warnings contained in a product's FDA approved labeling;
- our ability to implement a REMS prior to the distribution of any product candidates requiring a REMS; and
- effectiveness of marketing and distribution efforts by us and other licensees and distributors.

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

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

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities or affect our ability to profitably sell any product candidates for which we obtain marketing approval.

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

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial new provisions intended to, among other things, broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, and impose additional health policy reforms, any of

which could have a material adverse effect on our business. A significant number of provisions are not yet, or have only recently become, effective, but the Affordable Care Act is likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Other legislative changes have also been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of 2% per fiscal year, starting in 2013, and the American Taxpayer Relief Act of 2012,

among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could impose additional financial pressure on our customers, which could in turn diminish demand for our products or result in pricing pressure on us.

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

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

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

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

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

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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

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

Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of oxycodone or other opioid drugs; the limitations of abuse-resistant formulations; the ability of

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

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

be indicated only for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. On April 16, 2014, the FDA updated these indications. It is possible that such changes could reduce the number of prescriptions for opioids written by physicians and negatively impact the potential market for our product candidates.

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

Once an NDA, including a Section 505(b)(2) application, is approved, the product covered thereby becomes a ‘‘listed drug’’ which can, in turn, be cited by potential competitors in support of approval of an abbreviated NDA, or ANDA. The FD&C Act, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredients, dosage form, strength, route of administration, and conditions of use, or labeling, as our product candidate and that the generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our product candidate. These generic equivalents would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product. Accordingly, competition from generic equivalents to our product candidates would substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our product candidates.

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

Government agencies promulgate regulations and guidelines directly applicable to us and to our product candidates. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time

may also publish guidelines or recommendations to the healthcare and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our products.

Risks Related to Our Dependence on Third Parties

If we encounter difficulties in negotiating a commercial manufacturing agreement with the third party manufacturer of Xtampza or the third-party manufacturer fails to devote sufficient time and resources to Xtampza, or its performance is substandard, our product launch may be delayed and our costs may be higher than expected and could have a material adverse effect on our business.

We do not own any manufacturing facilities and have limited experience in drug development and commercial manufacturing. We currently have no plans to build our own clinical or commercial scale manufacturing facility. We lack the resources and expertise to manufacture and test, on a commercial scale, the technical performance of our product candidates. We currently rely, and expect to continue to rely, on a limited number of experienced personnel and one contract manufacturer, Patheon, as well as other vendors to formulate, test, supply, store and distribute Xtampza for our clinical trials and FDA registration, and we control only certain aspects of their activities. We are currently negotiating a commercial manufacturing agreement with Patheon and we may not be able to obtain terms that are favorable to us or enter into a commercial manufacturing agreement at all. Although we have identified alternate sources for these services, it would be time-consuming, and require us to incur additional cost, to qualify these sources.

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

- our contract manufacturer, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, and may experience shortages of qualified personnel to adequately staff production operations.
- our contract manufacturer could default on its agreement with us to meet our requirements for commercialization of Xtampza.
- the use of alternate manufacturers may be difficult because the number of potential manufacturers that have the necessary governmental licenses to produce narcotic products is limited. Additionally, the FDA and the DEA

must approve any alternative manufacturer of Xtampza before we may use the alternative manufacturer to produce Xtampza.

- it may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all. Our contract manufacturer and vendors may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products.
- if our contract manufacturer were to terminate our arrangement or fail to meet our commercial manufacturing demands, we may be forced to delay our development and commercial programs.

Our reliance on third parties reduces our control over our product candidate development and commercialization activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. The FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturer to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of

product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, imposing civil penalties or pursuing criminal prosecution.

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

We presently depend upon a single source as the sole supplier of the active ingredient for Xtampza — oxycodone base — and we intend to contract with this supplier, as necessary, for commercial supply of our products. Although we have identified an alternate source for oxycodone base, it would be time-consuming and costly to qualify this source. Since we currently obtain our active ingredient from this manufacturer on a purchase-order basis, either we or our supplier may terminate our arrangement, without cause, at any time without notice. If our supplier were to terminate our arrangement or fail to meet our supply needs we might incur substantial cost and be forced to delay our development or commercialization programs. Any such delay could have a material adverse effect on our business.

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

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

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

Switching or adding additional CROs involves additional cost and requires management time and focus, and there is a limited number of CROs that are equipped and willing to manage clinical trials that involve recreational drug abusers. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the patients participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. Identifying, qualifying and managing performance of third-party service providers can be difficult, time-consuming and cause delays in our development programs. In addition,

there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. If any of our relationships with our CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines.

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

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

We may not be successful in establishing development and commercialization collaborations which could adversely affect, and potentially prohibit, our ability to develop or commercialize our product candidates. Collaborations involving our product candidates pose the following risks to us:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations.
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities.
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing.

- collaborators may conduct clinical trials inappropriately, or may obtain unfavorable results in their clinical trials, which may have an adverse effect on the development of our own programs.
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such products.
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources.
- we may lose certain valuable rights under circumstances specified in our collaborations.
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

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

We may utilize strategic collaborators or contract sales forces, where appropriate, to assist in the commercialization of our product candidates, if approved, including Xtampza. We currently possess limited resources and may not be successful in establishing collaborations or co-promotion arrangements on acceptable terms, if at all. We also face competition in our search for collaborators and co-promoters. If we enter into strategic collaborations or similar arrangements, we will rely on third parties for financial resources and for development, commercialization,

sales and marketing and regulatory expertise. Our collaborators, if any, may fail to develop or effectively commercialize our product candidates because they cannot obtain the necessary regulatory approvals, they lack adequate financial or other resources or they decide to focus on other initiatives. Any failure of our third-party collaborators to successfully market and commercialize our product candidates would diminish our revenues.

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

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

Risks Related to Our Business and Strategy

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

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

We face and will continue to face competition from other companies in the pharmaceutical and medical device industries. Our product candidates, if approved, will compete with currently marketed oral opioids, transdermal opioids, local anesthetic patches, stimulants and implantable and external infusion pumps that can be used for infusion of opioids and local anesthetics. Products of these types are marketed by Purdue, Johnson & Johnson, Pfizer, Endo, Mallinckrodt, 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 our NDA for Xtampza is filed and approved, we could be subject to a delay that would dramatically reduce the expected market penetration for Xtampza. Additionally, even if our 505(b)(2) application for Xtampza is approved first, we may still be subject to competition from other oxycodone products, including approved products or other approved 505(b)(2) NDAs for different conditions of use that would not be restricted by any grant of exclusivity to us.

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

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

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

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

- filing ''citizen petitions'' with the FDA that may delay competition by causing delays of our product approvals;
- seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate a product's bioequivalence or ''sameness'' to the related innovator product;

- filing suits for patent infringement, like the Purdue litigation, that automatically delay FDA approval of products seeking approval based on the Section 505(b)(2) pathway;
- obtaining extensions of market exclusivity by conducting clinical trials of innovator drugs in pediatric populations or by other methods;
- persuading the FDA to withdraw the approval of innovator drugs for which the patents are about to expire, thus allowing the innovator company to develop and launch new patented products serving as substitutes for the withdrawn products;
- seeking to obtain new patents on drugs for which patent protection is about to expire; and
- initiating legislative and administrative efforts in various states to limit the substitution of innovator products by pharmacies.

These strategies could delay, reduce or eliminate our entry into the market and our ability to generate revenues associated with our product candidates.

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

We are highly dependent upon the services of our key personnel, including our President and Chief Executive Officer, Michael T. Heffernan, and our 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. We anticipate entering into new employment agreements with Mr. Heffernan and Mr. Duke, but we expect that Mr. Heffernan and Mr. Duke will continue to be employed at will. We do not maintain ''key person'' insurance for any of our executives or other employees. The loss of the services of Mr. Heffernan or 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 May 31, 2015, we had 27 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 information related to payments and other transfers of value made to physicians and other healthcare providers, as well as ownership or investment interests held by physicians and their immediate family members, including under the federal Open Payments program, commonly known as the Sunshine Act, as well as other state and foreign laws regulating marketing activities; and

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

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Nonetheless, it is possible that

governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

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

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

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

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

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

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

Risks Related to 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 likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this in this filing, 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. Of the approximately 20.6 million shares of common stock outstanding as of May 31, 2015, approximately 14.0 million shares are restricted as a result of 180-day lock-up arrangements entered into in connection with our May 2015 initial public offering. The restrictions under these 180-day lock-up arrangements are due to expire on November 1, 2015, resulting in these shares becoming eligible for public sale on November 2, 2105 if they are registered under the Securities Act of 1933, as amended, or the Securities Act, or if they qualify for an exemption from registration under the Securities Act, including under Rules 144 or 701

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.

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

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

We have broad discretion in the use of our cash and cash equivalents and may not use them effectively.

We have broad discretion in the use of our cash and cash equivalents, and investors must rely on the judgment of our management regarding the use of our cash and cash equivalents. Our management may not use cash and cash equivalents in ways that ultimately increase the value of 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.

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 May 31, 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. 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 the Company, even if the acquisition would be beneficial to our shareholders.

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

- a provision allowing our board of directors to set the terms of and issue preferred stock with rights senior to those of the common stock without any vote or action by the holders of our common stock. The issuance of preferred stock could adversely affect the rights and powers, including voting rights, of the holders of common stock;
- advance written notice procedures and notice requirements with respect to shareholder proposals and shareholder nomination of candidates for election as directors;
- a provision that only the board of directors, the chairman of the board of directors or the president may call a special meeting of the shareholders;
- the application of Virginia law prohibiting us from entering into certain transactions with the beneficial owner of more than 10 percent of our outstanding voting stock for a period of three years after such person first reached that level of stock ownership, unless certain conditions are met;

- a provision dividing our board of directors into three classes, each serving three-year terms;
- the requirement that the authorized number of our directors be changed only by resolution of our board of directors;
- a provision that our board of directors shall fill any vacancies on our board of directors, including vacancies resulting from a board of directors resolution to increase the number of directors;
- limitations on the manner in which shareholders can remove directors from the board of directors;
- the lack of cumulative voting in the election of directors; and
- the prohibition on shareholders acting by less-than-unanimous written consent.

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

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 The NASDAQ Global Select Market. As a NASDAQ Global Select Market 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) the end of the fiscal year following the fifth anniversary of our initial public offering, (ii) the first fiscal year after our annual gross revenue are $1.0 billion or more, (iii) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt securities or (iv) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700 million as of the end of the second quarter of that fiscal year.

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

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

volatile.

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

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

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting. Commencing with our annual report on Form 10-K for the year ending December 31, 2016, we will be required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, in internal

control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirement.

Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion, which could potentially subject us to sanctions or investigations by the Securities and Exchange Commission, or the SEC, or other regulatory authorities. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its reviews, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

COLLEGIUM PHARMACEUTICAL, INC.

Date: June 19, 2015

By: /s/ Paul Brannelly
Name: Paul Brannelly
Title: Executive Vice President and Chief Financial Officer