

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-K**

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2015

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File No. 001-36913

**KEMPHARM, INC.**

(Exact Name of Registrant as Specified in Its Charter)

Delaware  
(State or Other Jurisdiction of Incorporation or Organization)  
2656 Crosspark Road, Suite 100, Coralville, IA 52241  
(Address of principal executive offices and zip code)

20-5894398  
(I.R.S. Employer Identification No.)  
(319) 665-2575  
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class  
Common Stock, \$0.0001 par value

Name of Each Exchange on Which Registered  
The NASDAQ Stock Market LLC  
(NASDAQ Global Market)

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. Yes  No

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2015, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$206,967,240, based upon the closing sales price for the registrant's common stock, as reported on the NASDAQ Global Market. The calculation of the aggregate market value of voting and non-voting common equity excludes 2,961,812 shares of common stock the registrant held by executive officers, directors and shareholders that the registrant concluded were affiliates of the registrant on that date. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of management or policies of the registrant or that such person is controlled by or under common control with the registrant.

As of March 11, 2016, the registrant had 14,498,474 shares of common stock outstanding.

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**Documents Incorporated by Reference**

Portions of the registrant's definitive proxy statement for its 2016 annual meeting of stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2015. Except with respect to information specifically incorporated by reference in this Annual Report on Form 10-K, the definitive proxy statement is not deemed to be filed as part of this Annual Report on Form 10-K.

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**FORM 10-K**

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” contains forward-looking statements regarding future events and our future results that are subject to the safe harbors created under the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements relate to future events or our future financial performance. We generally identify forward-looking statements by terminology such as “may,” “will,” “would,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “target,” “projects,” “contemplates,” “believes,” “estimates,” “predicts,” “assume,” “intend,” “potential,” “continue” or other similar words or the negative of these terms. These statements are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in “Risk Factors” and elsewhere in this report. Accordingly, you should not place undue reliance upon these forward-looking statements. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur, the timing of events and circumstances and actual results could differ materially from those projected in the forward looking statements. Forward-looking statements contained in this report include, but are not limited to, statements about:

- the progress of, timing of and amount of expenses associated with our research, development and commercialization activities;
- the timing, conduct and success of our clinical studies for our product candidates;
- our ability to obtain U.S. and foreign regulatory approval for our product candidates and the ability of our product candidates to meet existing or future regulatory standards;
- our expectations regarding federal, state and foreign regulatory requirements;
- the therapeutic benefits and effectiveness of our product candidates;
- the accuracy of our estimates of the size and characteristics of the markets that may be addressed by our product candidates;
- our ability to manufacture sufficient amounts of our product candidates for clinical studies and products for commercialization activities;
- our intention to seek to establish strategic collaborations or partnerships for the development or sale of our product candidates;
- our expectations as to future financial performance, expense levels and liquidity sources;
- the timing of commercializing our product candidates;
- our ability to compete with other companies that are or may be developing or selling products that are competitive with our product candidates;
- anticipated trends and challenges in our potential markets;
- our ability to attract and retain key personnel; and
- other factors discussed elsewhere in this report.

The forward-looking statements made in this report relate only to events as of the date on which the statements are made. We have included important factors in the cautionary statements included in this report, particularly in the section entitled “Risk Factors” that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. Except as required by law, we do not assume any intent to update any forward-looking statements after the date on which the statement is made, whether as a result of new information, future events or circumstances or otherwise.

## **NOTE REGARDING COMPANY REFERENCE**

*Unless the context otherwise requires, we use the terms “KemPharm,” “Company,” “we,” “us” and “our” in this Annual Report on Form 10-K to refer to KemPharm, Inc. We have proprietary rights to a number of trademarks used in this Annual Report on Form 10-K that are important to our business, including KemPharm® and the KemPharm logo. All other trademarks, trade names and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report on Form 10-K are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.*

## **NOTE REGARDING MARKET AND INDUSTRY DATA**

*This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties.*

*Any information in this Annual Report on Form 10-K provided by IMS Health Incorporated, or IMS, is an estimate derived from the use of information under license from the following IMS Health information service: IMS National Sales Perspectives and NPA Audits, in each case, for the period January 2011 to September 2014. IMS expressly reserves all rights, including rights of copying, distribution and republication.*

**ITEM 1. BUSINESS.****Overview**

We are a clinical-stage specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs that we believe will be improved versions of widely prescribed, approved drugs. We employ our Ligand Activated Therapy, or LAT, platform technology to create our prodrugs. Our most advanced product candidate, KP201/APAP, consists of KP201, our prodrug of hydrocodone, combined with acetaminophen, or APAP. We are developing KP201/APAP as an immediate release, or IR, product candidate for the short-term, or no longer than 14 days, management of acute pain. We designed KP201/APAP with abuse-deterrent properties to address the epidemic of opioid abuse in the United States. We submitted a new drug application, or NDA, under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, otherwise known as a 505(b)(2) NDA, for KP201/APAP to the U.S. Food and Drug Administration, or FDA, in December 2015. The FDA subsequently accepted this NDA for priority review in February 2016. The FDA has set a target action date for review of the NDA under the Prescription Drug User Free Act, or PDUFA, of June 9, 2016. We are also building a pipeline of additional prodrug product candidates that target large market opportunities in pain and attention deficit hyperactivity disorder, or ADHD.

Key members of our senior management, while at New River Pharmaceuticals Inc., were instrumental in the development of Vyvanse, a prodrug of amphetamine indicated for ADHD, through FDA approval. New River Pharmaceuticals was acquired by Shire plc in 2007 and Vyvanse generated over \$1.7 billion in sales in 2015.

We use our LAT platform technology to discover and develop prodrugs that improve one or more of the attributes of approved drugs, such as susceptibility to abuse, bioavailability and safety. A prodrug is a precursor chemical compound of a drug that is inactive or less than fully active, which is then converted in the body to its active form through a normal metabolic process. We primarily seek to develop prodrugs that will be eligible for approval under the 505(b)(2) NDA pathway, which allows us to rely on the FDA's previous findings of safety and effectiveness for one or more approved products, if we demonstrate such reliance is scientifically appropriate. Because our prodrugs are novel combinations of an FDA-approved drug, referred to as the parent drug, with one or more ligands, they may be new molecular entities, or NMEs, and thus may be eligible for composition-of-matter patent protection. An NME is a drug containing an active ingredient that has not been approved or marketed in the United States.

IMS, a healthcare information firm, estimates that IR hydrocodone bitartrate, or HB, formulated in combination with APAP, or hydrocodone/APAP, products accounted for 127 million prescriptions in the United States in 2013. We designed KP201/APAP to offer significant benefits over these widely prescribed hydrocodone/APAP products. We believe that KP201/APAP will provide abuse-deterrence while offering equivalent efficacy to these products.

According to the U.S. Department of Health and Human Services, or HHS, prescription drug overdose death rates in the United States have increased five-fold since 1980, and by 2009, drug overdose deaths outnumbered deaths due to motor vehicle crashes. HHS also estimates that, in 2010, opioid analgesics were involved in approximately 60% of U.S. drug overdose deaths where a drug was specified.

We designed KP201/APAP to deter tampering and abuse by selecting a molecular structure that prevents the release of the opioid upon crushing, physical manipulation and the application of other commonly employed extraction techniques. This approach to abuse-deterrence at the molecular level contrasts with other abuse-deterrent technologies, which are formulation-based, combining the opioid drug with another drug or use an abuse-deterrent capsule or physical matrix. We believe our molecular-based approach to abuse deterrence may be more effective than many formulation-based approaches. We believe the KP201 prodrug releases hydrocodone less effectively than hydrocodone bitartrate, the form of hydrocodone in Norco, upon intranasal administration. We also believe the KP201 prodrug has very poor solubility in blood, water and other solvents, thus rendering it unsuitable for intravenous, or IV, administration.

We believe the data from our clinical trials suggest comparable bioavailability between the hydrocodone released from KP201/APAP and the hydrocodone in Vicoprofen, and comparable bioavailability between the APAP in KP201/APAP and the APAP in Ultracet. In addition, the FDA has confirmed that the results of our bioavailability trial comparing KP201/APAP to Norco, an approved hydrocodone/APAP combination product, support a finding that KP201/APAP is bioequivalent to Norco for hydrocodone. Vicoprofen, Ultracet and Norco are listed drugs that we cited in our 505(b)(2) NDA. Two drugs are said to be bioequivalent if there is no clinically significant difference in their bioavailability. Based on communications with the FDA, we believe that we will not be required to conduct any additional efficacy trials for KP201/APAP. At our pre-NDA meeting with the FDA in May 2015, we received feedback on the bioequivalence findings to Norco, the potential sufficiency of our proposed preclinical and clinical data package to support our NDA and the design of our abuse liability studies.

We believe that KP201/APAP has the potential to be the first FDA-approved IR product for the short-term management of acute pain with the efficacy of hydrocodone/APAP combination products and abuse-deterrent labeling. We have conducted clinical trials designed with the goal of obtaining abuse-deterrent claims in our product label for KP201/APAP. We conducted these trials in accordance with guidance that the FDA finalized in 2015 specifying the necessary studies and data required for obtaining abuse-deterrent claims in a product label. We submitted our NDA to the FDA in December 2015. The FDA subsequently accepted this NDA for priority review in February 2016. The FDA has set a target action date for review of the NDA under PDUFA of June 9, 2016.

Additionally, we intend to advance our pipeline of other product candidates for the treatment of various pain indications and ADHD and we anticipate reporting human proof-of-concept, or POC, data for three product candidates in 2016 and 2017. We filed an IND for KP511 in March 2016, and we expect to file an Investigational New Drug application, or IND, for each of KP415 and KP201/IR (APAP-free) in 2016, followed with an NDA for KP201/IR (APAP-free) as early as 2017. We plan to employ our LAT platform technology and development expertise to develop additional product candidates that address unmet medical needs in large, established markets. We believe our product candidates will be eligible for composition-of-matter patent protection and we intend to use the 505(b)(2) NDA pathway when available, which we believe will reduce drug development time, risk and expense. We own worldwide commercial rights for all of our product candidates, including KP201/APAP, except that Shire has a right of first refusal to acquire, license or commercialize KP415.

As of December 31, 2015, our patent portfolio consisted of 47 granted patents and 77 pending patent applications worldwide, including a granted U.S. composition-of-matter patent covering KP201, a granted U.S. patent covering KP201-related compositions-of-matter, and granted U.S. composition-of-matter patents covering the prodrugs underlying two of our other product candidates.

## Our Strategy

Our goal is to be a leading specialty pharmaceutical company focused on the discovery, development and commercialization of novel and proprietary prodrugs. Key components of our strategy are:

- **Secure FDA approval for KP201/APAP as the first IR pain therapeutic product with the efficacy of hydrocodone/APAP combination products and an abuse-deterrent label.** We are developing KP201/APAP for the short-term management of acute pain. We submitted a 505(b)(2) NDA to the FDA in December 2015. The FDA subsequently accepted this NDA for priority review in February 2016. The FDA has set a target action date for review of the NDA under PDUFA of June 9, 2016. Prior to product launch, the U.S. Drug Enforcement Administration, or the DEA, would then need to determine the controlled substance schedule of KP201/APAP, taking into account the recommendation of the FDA, which we expect could occur as early as the third quarter of 2016.
- **Commercialize KP201/APAP.** We intend to evaluate U.S. commercialization options for KP201/APAP, if it is approved by the FDA, including pursuing a commercial collaboration, building a proprietary sales force, utilizing a contract sales force or pursuing a strategic transaction. We may also license the international commercial rights to KP201/APAP to one or more collaborators.
- **Advance the development of our other pipeline product candidates.** We plan to advance the development of KP201/IR (APAP-free), our APAP-free formulation of our prodrug of hydrocodone, for the short-term management of acute pain, KP415, our prodrug of methylphenidate, for the treatment of ADHD, KP511/ER, our extended release, or ER, formulation of our prodrug for hydromorphone, 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, KP606/IR, our IR formulation of our prodrug of oxycodone, for the management of moderate to severe pain where the use of an opioid analgesic is appropriate, and KP746, our prodrug of oxymorphone, for the management of moderate to severe pain where the use of an opioid analgesic is appropriate. We plan to advance three of these product candidates through human proof-of-concept trials to evaluate their bioequivalence to appropriate FDA-approved drugs, and expect to report data from these trials in 2016 and 2017. We filed an IND for KP511 in March 2016, and we expect to file INDs for KP415 and KP201/IR (APAP-free) in 2016, following with an NDA for KP201/IR (APAP-free) in 2017.
- **Leverage our LAT platform technology to develop additional product candidates.** We plan to employ our LAT platform technology to develop additional prodrugs that have improved properties over approved drugs and address unmet medical needs in large, established markets. We intend to develop prodrugs of FDA-approved drugs in multiple therapeutic areas.

- **Continue to build a global intellectual property portfolio.** We intend to vigorously pursue composition-of-matter patent protection for our prodrugs in markets covering a majority of the global commercial opportunity. As of December 31, 2015, our patent portfolio consisted of 47 granted patents and 77 pending patent applications worldwide, including a granted U.S. composition-of-matter patent covering KP201, a granted U.S. patent covering KP201-related compositions-of-matter, and granted U.S. composition-of-matter patents covering KP511, the prodrug underlying our KP511/ER product candidate, and KP415, the prodrug underlying our KP415 product candidate.

## Our LAT Prodrug Platform Technology

We use our LAT platform technology to create prodrugs by chemically attaching one or more molecules, referred to as ligands, to an FDA-approved parent drug. We typically use ligands that have been demonstrated to be safe in toxicological studies or have been granted Generally Recognized as Safe, or GRAS, status for food use by the FDA. Our prodrugs are chemical successors of the parent drugs, but may be considered to be NMEs and thus may be eligible for protection by composition-of-matter patents. When the prodrug is administered to a patient as intended, the targeted human metabolic processes, such as those in the GI tract, separate the ligand from the prodrug and release the parent drug, which can then exert its therapeutic effect. We select particular ligands that, when combined with the parent drug, create prodrugs designed to have improved drug attributes while maintaining efficacy equivalent to the parent drug.

We believe that our LAT platform technology offers the following potential benefits:

- **Improved drug properties.** We seek to develop prodrugs with improved attributes over FDA-approved drugs, such as reduced susceptibility to abuse, enhanced bioavailability and increased safety. For example, the molecular structure of KP201/APAP is designed to resist tampering and deter abuse.
- **Composition-of-matter patent protection.** Our prodrugs combine an FDA-approved parent drug with one or more ligands to create NMEs and may be eligible for patent protection as novel compositions of matter, provided that all other applicable requirements are met. We seek patent protection not only for our prodrug product candidates, but also for related compounds with the intention of creating heightened barriers to market entry.
- **Eligibility for 505(b)(2) NDA pathway.** Our LAT platform technology allows us to develop prodrugs that may be eligible to use the 505(b)(2) NDA pathway. Under that regulatory pathway, if we are able to demonstrate the bioequivalence of our product candidates to appropriate approved drugs, we will then be able to reference the FDA's previous findings of safety and effectiveness for the approved drugs in our 505(b)(2) NDA submissions. This may allow us to avoid the significant time and expense of conducting large clinical trials and eliminate the need for some preclinical activities.

## The Epidemic of Prescription Drug Abuse in the United States

The United States is facing a growing epidemic of prescription drug abuse. According to HHS, prescription drug overdose death rates in the United States have increased five-fold since 1980, and by 2009, drug overdose deaths outnumbered deaths due to motor vehicle crashes. HHS also estimates that opioid analgesics were involved in approximately 60% of U.S. drug overdose deaths where a drug was specified in 2010. The economic costs of this public health problem are significant. A study published in 2011 in a peer-reviewed medical journal estimated that the costs of the non-medical use of prescription opioids in the United States are over \$50 billion annually, including medical and substance abuse treatment costs, lost work productivity and criminal justice costs.

The increasing negative social consequences and costs of prescription drug abuse have led to a number of regulatory and legislative actions and proposals, including:

- **FDA Guidance.** In January 2013, the FDA published draft guidance with regard to the evaluation and labeling of abuse-deterrent opioids. The guidance was published in final form in April 2015. The FDA guidance provides direction as to the studies and data required for obtaining abuse-deterrent claims in a product label. The draft guidance describes four categories of label claims for abuse-deterrent products. Depending on product and study data, a combination of categories can be included in the label claims. The FDA guidance lists the following theoretical examples:
  - Category 1—in vitro data demonstrate the product has physical and chemical properties that are expected to deter intravenous abuse. However, abuse is still possible by the oral and nasal routes.
  - Category 1 and 2—in vitro data demonstrate that the product has physical and chemical properties that are expected to deter oral, nasal and intravenous abuse. However, abuse of intact product is still possible by the oral route.



- Category 2 and 3—pharmacokinetic and clinical abuse potential studies indicate that the product has properties that are expected to deter abuse via the oral, intranasal and intravenous routes. However, abuse of product by these routes is still possible.
- Category 4—data demonstrated a reduction in the abuse of the product in the community setting compared to the levels of abuse, overdose, and death that occurred when only formulations of the same opioid without abuse-deterrent properties were available. This reduction in abuse appears to be attributable to the product’s formulation, which deters abuse by injection or snorting of the manipulated product. However, such abuse of this product is still possible, and the product’s abuse deterrence properties do not deter abuse associated with swallowing the intact formulation.

If a product is approved by the FDA to include such claims in its label, the applicant may use information about the abuse-deterrent features of the product in its marketing efforts to physicians.

- **FDA Authority.** In an April 2013 letter to the U.S. House of Representatives’ Committee on Energy and Commerce, the FDA outlined its authority to address the issue of prescription opioid abuse in the United States. The FDA asserted that, if it determines that a formulation of an extended-release opioid drug product has abuse-deterrent properties, it has the authority to refrain from approving non-abuse-deterrent formulations of the drug and to initiate procedures to withdraw the non-abuse-deterrent formulations already on the market.
- **FDA Action.** The FDA has approved the inclusion of language regarding the ability to deter abuse in the product labels for five abuse-deterrent opioids, OxyContin, Targiniq ER, Embeda, Hysingla and MorphaBond. These actions reinforce the FDA’s public statement that the development of abuse-deterrent opioid analgesics is a public health priority.
- **STOPP Act.** In July 2012, a bipartisan group of Congressional leaders introduced the STOPP (Stop the Tampering of Prescription Pills) Act. Reintroduced in May 2015, the STOPP Act would require that non-abuse-deterrent opioids be removed from the market if an abuse-deterrent formulation of the same opioid is approved for marketing by the FDA. The STOPP Act is currently assigned to the House Committee on Energy and Commerce’s Subcommittee on Health.
- **FDA Public Meeting.** In October 2014, the FDA hosted a public meeting to discuss the development, assessment and regulation of abuse-deterrent formulations of opioid medications. In the announcement for the public meeting, the FDA anticipated that, after abuse-deterrent formulations become available for a number of different opioid medications and after it gains more experience with formulations with meaningful abuse-deterrent properties, the FDA may determine that the risks outweigh the benefits for all or most opioid products without abuse-deterrent properties.

## Our Prodrug Product Candidates

We have employed our LAT platform technology to create a portfolio of product candidates that we believe will offer significant improvements over FDA-approved and widely prescribed drugs. Our pipeline of product candidates is summarized in the table below:

### Selected KemPharm Prodrug Product Candidates

Indication / Parent Drug	Product Candidate	Development Status	Key Milestone
<b>Pain</b>			
Hydrocodone (IR)	KP201/APAP	NDA Accepted for Priority Review February 2016	Potential NDA Approval - As Early As June 9, 2016 (PDUFA date) DEA Scheduling - As Early As Q3 2016
Hydrocodone (IR)	KP201/IR (APAP-free)	Clinical	NDA Submission - 2017 Human POC Data - 2016
Hydrocodone (ER)	KP511/ER	IND Submitted to FDA March 2016	NDA Submission - 2018 Human POC Data - 2017
Oxycodone (IR)	KP606/IR	Preclinical	NDA Submission - 2018
Oxymorphone	KP746	Preclinical	Human POC Data - 2017
<b>ADHD</b>			
Methylphenidate (controlled release)	KP415	Preclinical	Human POC Data - 2016 NDA Submission - 2019

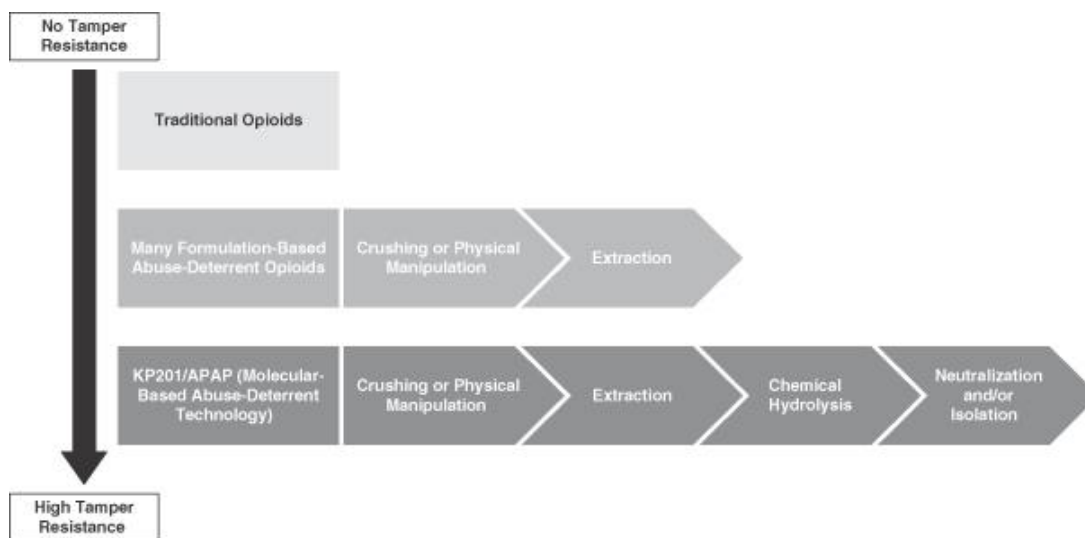
#### KP201/APAP

##### Overview

Our most advanced product candidate, KP201/APAP, is an IR combination of KP201, our prodrug of hydrocodone, and APAP. We are developing KP201/APAP for the short-term management of acute pain. KP201/APAP is designed to be an abuse-deterrent opioid product that offers equivalent efficacy to the existing standard-of-care, IR hydrocodone/APAP combination products, such as Vicodin, Norco and Lortab. KP201 combines hydrocodone with the ligand benzoic acid to form benzhydrocodone and can be formulated in both IR and ER dosage forms. KP201 is designed not to release its hydrocodone component until it is metabolized in the GI tract following oral administration. We believe KP201/APAP is highly tamper-resistant and is stable under conditions that can potentially defeat many other abuse-deterrent technologies.

The graphic below illustrates the steps required to extract abusable opioid from traditional opioid products that do not incorporate abuse-deterrent technology, from many formulation-based abuse-deterrent products and from KP201/APAP. We believe the molecular-based abuse-deterrent characteristics of KP201/APAP present a higher barrier to abuse than many formulation-based abuse-deterrent approaches.

### Number and Complexity of Steps Required to Access Abusable Opioid



We are seeking approval of KP201/APAP under the 505(b)(2) NDA pathway, which permits companies to rely upon the FDA’s previous findings of safety and effectiveness for an approved product or products and published medical and scientific literature. We submitted our 505(b)(2) NDA for KP201/APAP to the FDA in December 2015. The FDA subsequently accepted this NDA for priority review in February 2016. The FDA has set a target action date for review of the NDA under PDUFA of June 9, 2016. However, we are relying in our 505(b)(2) NDA in part on the FDA’s prior findings of safety and effectiveness of Vicoprofen, a product that has two listed patents in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book. Both listed patents expire in June 2017. As a result, FDA approval of our 505(b)(2) NDA may be delayed until June 10, 2017 or later if the patent or NDA holder files a patent infringement claim against us. In addition, and prior to product launch, the DEA would also need to determine the controlled substance schedule of KP201/APAP, taking into account the recommendation of the FDA. Subject to potential delay as a result of any delay in approval of our 505(b)(2) NDA, we expect the DEA could make a scheduling determination as early as the third quarter of 2016.

### Market Opportunity

IMS estimates that in 2013, IR hydrocodone/APAP combination products represented the most frequently prescribed opioid products in the United States, accounting for 127 million U.S. prescriptions. Typically, patients are instructed to take four pills per day and prescriptions provide approximately 14 days of therapy. Hydrocodone is associated with more drug abuse and diversion than any other opioid and IR hydrocodone abuse results in more emergency department visits than any other prescription opioid. Currently, there are no IR hydrocodone/APAP combination products approved in the United States with an abuse-deterrent label.

### Key Product Features of KP201/APAP

We believe KP201/APAP, if approved by the FDA, may have many valuable product features and may provide significant benefits to patients, physicians and society when compared to other FDA-approved and widely prescribed IR hydrocodone/APAP combination products:

- Molecular-based abuse-deterrent technology.** Unlike formulation-based opioid abuse-deterrent approaches, KP201/APAP incorporates our LAT platform technology to create its abuse-deterrent properties at the molecular level. This may provide a higher barrier against attempted abuse than many existing formulation-based approaches. Physical manipulation, common solvent extraction, smoking and other conventional extraction methods applied to KP201/APAP do not release significant amounts of hydrocodone when compared to hydrocodone/APAP. We believe the KP201 prodrug releases hydrocodone less

effectively than hydrocodone bitartrate upon intranasal administration and has very poor solubility in blood, water and other solvents, thus rendering it unsuitable for IV administration.

- **Composition-of-matter patent protection.** KP201/APAP is protected by a U.S. composition-of-matter patent on KP201 that will expire, after utilizing all appropriate patent term adjustments but excluding possible patent term extensions, in 2031. Our patent strategy is focused primarily on key geographic market opportunities, and, as of December 31, 2015, KP201 had received granted, issued or allowed patent status in 14 foreign jurisdictions and patent applications covering KP201 were pending in an additional 16 foreign jurisdictions.
- **No generic equivalent product.** KP201 is a prodrug with a new chemical name, benzhydrocodone. We expect KP201/APAP, if approved, will have a lower prescribed milligram strength of KP201 than the therapeutic equivalent amount of hydrocodone bitartrate used in existing IR hydrocodone/APAP combination products. The difference in chemical name and prescription strength will mean that there will be no generic equivalent product for KP201/APAP in most states, making substitution difficult at the pharmacy.
- **Convenient dosing.** Based on data from our food-effect clinical trial, we believe that KP201/APAP can be administered under both fed and fasting conditions and, accordingly, we believe that KP201/APAP will be as convenient as existing IR hydrocodone/APAP combination products.

#### ***KP201/APAP Clinical Development Program***

We submitted our 505(b)(2) NDA for KP201/APAP to the FDA in December 2015. The FDA subsequently accepted this NDA for priority review in February 2016. The FDA has set a target action date for review of the NDA under PDUFA of June 9, 2016. We are seeking approval of KP201/APAP under the 505(b)(2) NDA pathway, which permits companies to rely upon the FDA's previous findings of safety and effectiveness for one or more approved products and published medical and scientific literature. We completed a bioavailability trial comparing KP201/APAP to Norco, an approved hydrocodone/APAP combination product, and the FDA confirmed at our May 2015 pre-NDA meeting that the results of the trial support a finding that KP201/APAP is bioequivalent to Norco for hydrocodone. For APAP, the FDA found that KP201/APAP was close to meeting the agency's metrics for bioequivalence but that we may be able to justify the difference. In order to rely on the FDA's previous findings of safety and effectiveness for an approved product in a 505(b)(2) NDA, the approved product must be an NDA product. Because there are no approved NDAs for hydrocodone/APAP combination products, including for Norco, we are required to establish the safety and effectiveness of hydrocodone and the safety and effectiveness of APAP separately through other methods. We completed a bridging bioavailability trial of KP201/APAP and Vicoprofen, an FDA-approved hydrocodone/ibuprofen combination NDA product. The data from this trial suggests comparable bioavailability between the hydrocodone released from KP201/APAP and the hydrocodone in Vicoprofen. We also completed a bridging bioavailability trial of KP201/APAP and Ultracet, an FDA-approved tramadol/APAP combination NDA product. The data from this trial suggests comparable bioavailability between the APAP in KP201/APAP and the APAP in Ultracet. We referenced the FDA's prior findings of safety and effectiveness for the hydrocodone component of Vicoprofen and the APAP component of Ultracet in our 505(b)(2) NDA. Based on communications with the FDA, we believe that no additional efficacy trials will be required for KP201/APAP.

We also conducted two human abuse liability trials and one intranasal bioavailability study, each of which generated data that we included in our 505(b)(2) NDA submission. We designed these trials and this study with the goal of obtaining abuse-deterrent claims in our product label for KP201/APAP in accordance with FDA guidance.

#### ***Clinical Trials and Bioavailability Studies.***

**Abuse Quotient and Relative Abuse Potential.** Clinical observations suggest that euphoric effects are enhanced both by increasing the peak plasma concentration, or C<sub>max</sub>, of an active opioid and by reducing the time to peak plasma concentration, or T<sub>max</sub>. The higher the opioid concentrations are in the blood and brain, and the faster they rise, the greater the reward to the abuser. It has also become apparent, however, that neither T<sub>max</sub> nor C<sub>max</sub> considered alone are sufficient to predict euphoria. Both parameters are important and need to be evaluated together.

As a result, the abuse quotient, or AQ, calculated as C<sub>max</sub>/T<sub>max</sub>, has been introduced to allow numerical assessment of peak drug exposure relative to the rate of rise in plasma concentration. AQ increases both as C<sub>max</sub> is increased and as T<sub>max</sub> is shortened. Thus higher AQ scores suggest greater abuse potential.

The AQ values for all treatments we assessed in studies KP201.A01, KP201.A02 and KP201.A03, our abuse deterrence clinical trials and intranasal bioavailability study, have been calculated to allow comparison of their relative abuse potentials based on pharmacokinetics and hydrocodone exposure, and are shown in the table below:

**Abuse Quotient Values (Cmax/Tmax) for All Treatments Administered in Studies KP201.A01, KP201.A02, and KP201.A03**

Rank(1)	Treatment	ROA(2)	Dose Units (mg)	AQ (SD)(3) (ng/mL/ hours)
1	KP201 API	IN	2 (13.34)	17.0 (11.6)
2	KP201/APAP	IN	2 (13.34/650)	31.9 (18.4)
3	HB/APAP	PO	2 (15/650)	34.5 (23.3)
4	KP201/APAP	PO	2 (13.34/650)	38.6 (21.8)
5	HB/APAP	IN	2 (15/650)	56.5 (43.8)
6	HB API	IN	2 (15)	87.3 (69.0)
7	KP201/APAP	PO	4 (26.68/1300)	99.6 (58.9)
8	HB/APAP	PO	4 (30/1300)	99.7 (57.1)
9	KP201/APAP	PO	8 (53.36/2600)	204.8 (125.2)
10	HB/APAP	PO	8 (60/2600)	222.7 (125.1)
11	KP201/APAP	PO	12 (80.04/3900)	287.58 (189.8)
12	HB/APAP	PO	12 (90/3900)	329.7 (201.9)

- (1) All treatments from studies KP201.A01, KP201.A02 and KP201.A03 are ranked from smallest to largest AQ.
- (2) ROA = Route of Administration, IN = intranasal, PO = oral
- (3) SD = Standard Deviation

Of all the treatments we evaluated, intranasal KP201, either with or without APAP, had the lowest AQ when administered at an equimolar dose. This was the case when compared to oral KP201/APAP and when compared to all other hydrocodone treatments included in the trials, whether with or without APAP, oral or intranasal.

*KP201 Pilot Pharmacokinetics and Comparative Bioavailability Trials.* We submitted our IND application for KP201 to the FDA in January 2011, and conducted our first human clinical trial of KP201 from February through March 2011. This trial was intended to provide proof of concept of KP201's bioavailability compared to Norco. This trial assessed the pharmacokinetics of KP201, hydrocodone and hydromorphone, an opioid resulting from the metabolism of hydrocodone, over a 24-hour period after oral administration of KP201 at doses of 5 mg and 10 mg and the commercially available tablet version of Norco (10 mg of hydrocodone bitartrate / 325 mg of APAP) under fasted conditions. The 10 mg dose of KP201 and the tablet version of Norco are equimolar, meaning the number of KP201 molecules in the KP201 dose is the same as the number of molecules of hydrocodone in the Norco dose. Pharmacokinetics refers to the process by which a drug is distributed and metabolized in the body, including information on drug levels in the systemic circulation and how these levels change over time. A total of 24 healthy adult volunteers were enrolled in the trial and 21 of the subjects completed it.

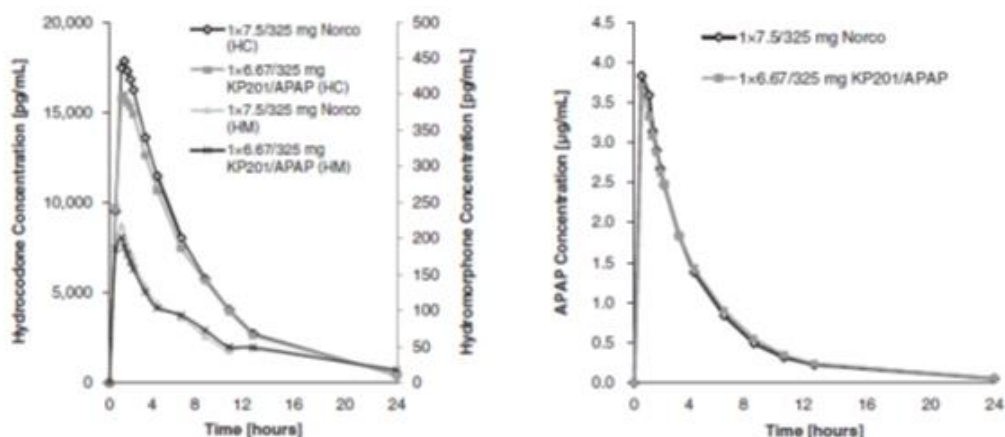
The results of the trial were that the plasma concentrations for both hydrocodone and hydromorphone after administration of 10 mg of KP201 were comparable to the levels following an equimolar dose of Norco and the results were within the statistical parameters established for bioequivalence by the FDA. In addition, we observed dose proportionality of 5 mg of KP201 as compared to 10 mg of KP201. The systemic exposure to intact KP201 was below the measurement threshold in each subject at all of the measurement points.

A total of 58 adverse events following dose administration were reported over the course of the trial. Of these, 35 were mild and 23 were moderate. We do not believe any of the adverse events were occurring in the trial unusual or unexpected following the administration of opioid medication.

*KP201/APAP Bioequivalence Trial.* In August 2013, we conducted our second human clinical trial of KP201, an open-label, bioequivalence trial comparing KP201/APAP to Norco. The primary objective of this trial was to compare the pharmacokinetic profile and exposure of hydrocodone, hydromorphone and APAP over a 24-hour period after a single dose of KP201/APAP (6.67 mg / 325 mg) relative to a single dose of Norco (7.5 mg / 325 mg) when administered orally under fasted conditions. These doses of KP201/APAP and Norco are equimolar even though the milligram dose of each drug per tablet is slightly different. Randomized subjects received two single-dose treatments, each separated by a seven-day washout period. A total of 30 healthy volunteers participated in the trial and 23 of the subjects completed it.

The following charts summarize the bioequivalence data from this trial.

### KP201/APAP Bioequivalence Trial



Note: HC refers to hydrocodone and HM refers to hydromorphone

The results of the trial were that the plasma concentration levels for hydrocodone, hydromorphone and APAP after administration of KP201/APAP were comparable to the levels following an equimolar dose of Norco, and the results for hydrocodone and hydromorphone were within the statistical parameters established for bioequivalence by the FDA. The bioavailability data for APAP was slightly outside of the statistical range for bioequivalence.

In addition, systemic exposure to intact KP201 was below the measurement threshold in each subject at all of the measurement points. We do not believe any of the adverse events occurring in the trial were unusual or unexpected following the administration of opioid medication.

**KP201/APAP Multi-Dose/Steady State Trial.** This trial, which we conducted in July and August 2013, was intended to assess the pharmacokinetics of KP201 after single and multiple doses of KP201/APAP in healthy volunteers. The primary objectives of this trial were to assess the pharmacokinetics of KP201, hydrocodone, hydromorphone and APAP following a single dose of two KP201/APAP tablets (6.67 mg / 325 mg) and to assess the steady-state pharmacokinetics of KP201, hydrocodone, hydromorphone and APAP following 13 doses of two KP201/APAP tablets administered every four hours under fasted conditions. A total of 26 healthy adult volunteers were enrolled in the trial and 24 of the subjects completed it.

The results of the trial were that all plasma concentrations of KP201 were below the measurement threshold at all time points for all subjects, indicating that there was no systemic exposure to the prodrug even after administration of two tablets every four hours for 13 doses. Naltrexone, a narcotic antagonist, was administered to minimize the occurrence of adverse effects often associated with administration of opioids. We do not believe any of the adverse events occurring in the trial were unusual or unexpected following the administration of opioid medication.

**KP201/APAP Food-Effect Trial.** This trial, which we conducted in December 2013 and January 2014, was intended to assess the effect of food on the bioavailability and pharmacokinetics of hydrocodone and APAP from KP201/APAP tablets, as well as to assess the relative bioavailability of hydrocodone and APAP from KP201/APAP tablets as compared to equimolar doses of Norco, each under fed conditions. Randomized subjects received a single dose of KP201/APAP (6.67 mg / 325 mg) administered orally under fed conditions in one period, a single dose of KP201/APAP (6.67 mg / 325 mg) under fasted conditions in one period, and a single dose of Norco (7.5 mg / 325 mg) under fed conditions in one period. Fed conditions reflected an FDA-standard high-fat, high-calorie breakfast. A total of 42 healthy adult volunteers enrolled in the trial and 38 of the subjects completed it.

The results of the trial were that there were no overall changes in exposure to hydrocodone or to APAP when KP201/APAP tablets were administered under fed conditions that would be of clinical significance compared to KP201/APAP administered under fasted conditions or compared to Norco administered under fed conditions. We believe the data from this trial suggest there is no food effect with regard to the administration of KP201/APAP and that the labeling for KP201 could indicate that it can be administered without regard to meals.

In addition, systemic exposure to intact KP201 was below the measurement threshold in each subject at all of the measurement points. We do not believe any of the adverse events occurring in the trial were unusual or unexpected following the administration of opioid medication.

*Comparative Bioavailability of KP201/APAP and Vicoprofen Trial.* This trial, which was conducted in June and July 2014, was intended to assess the relative bioavailability of KP201/APAP compared to Vicoprofen in order to allow us to reference the FDA's prior findings of safety and effectiveness of Vicoprofen in our 505(b)(2) NDA. Vicoprofen, like KP201/APAP, is a product containing hydrocodone. The primary objective of this trial was to compare the rate and extent of absorption of hydrocodone and hydromorphone from KP201/APAP relative to Vicoprofen when administered orally to healthy subjects under fasted conditions. Randomized subjects received a single dose of KP201/APAP (6.67 mg / 325 mg) and a single dose of Vicoprofen (7.5 mg of hydrocodone / 200 mg of ibuprofen) with the two administrations separated by a seven-day washout period. A total of 30 healthy adult volunteers enrolled in the trial and 28 of the 30 subjects completed it.

The results of the trial were that there were no overall differences in exposure to hydrocodone and active metabolite hydromorphone from KP201/APAP as compared to Vicoprofen. We do not believe any of the adverse events occurring in the trial were unusual or unexpected following the administration of opioid medication.

*Comparative Bioavailability of KP201/APAP and Ultracet Trial.* This trial, which was conducted in July and August 2014, was intended to assess the relative bioavailability of KP201/APAP compared to Ultracet in order to allow us to reference the FDA's prior findings of safety and effectiveness of Ultracet in our 505(b)(2) NDA. Ultracet, like KP201/APAP, is a combination product containing an opioid, in this case tramadol, and APAP. The primary objective of this trial was to compare the rate and extent of absorption of APAP from KP201/APAP relative to Ultracet when administered orally to healthy subjects under fasted conditions. Randomized subjects received a single dose of KP201/APAP (6.67 mg / 325 mg) and a single dose of Ultracet (37.5 mg of tramadol / 325 mg of APAP) with the two administrations separated by a seven-day washout period. A total of 30 healthy adult volunteers enrolled in the trial and 27 of the 30 subjects completed it.

The results of the trial were that there were no overall differences in exposure to APAP from KP201/APAP as compared to Ultracet. We do not believe any of the adverse events occurring in the trial were unusual or unexpected following the administration of opioid medication.

#### *Abuse Deterrence Clinical Trials and Intranasal Bioavailability Study*

In 2015, we completed two human abuse liability trials and one intranasal bioavailability study, each of which generated data that we included in our 505(b)(2) NDA submission. We believe the data from these trials and study, together with the data from the tamper-resistant extraction studies we have completed, may allow us to obtain the FDA's Category 1, Category 2 and potentially Category 3 abuse-deterrent language in the KP201/APAP product label, if it is approved.

*KP201.A01 Oral Human Abuse Liability Trial.* This trial, which was conducted from August 2014 through January 2015, was intended to compare the pharmacodynamic, or drug likability, effects, exposure levels and safety of KP201/APAP compared to Norco after oral administration at four, eight and twelve tablet dosages. Pharmacodynamics refers to the biochemical and physiological effects of a drug on the human body and the purpose of a drug likeability analysis is to assess how probable it is that the drug will be attractive to abusers. Randomized subjects received tablets of Norco (7.5 mg hydrocodone bitartrate/325 mg APAP), and an equivalent amount of KP201/APAP. This was a single-center, double-blind, active-and placebo-controlled, crossover trial. A total of 71 opioid-experienced nondependent volunteers enrolled in the trial and 62 of the 71 subjects completed it.

The results of the trial were that KP201/APAP released less hydrocodone as compared to Norco at the two highest doses administered (eight and twelve tablets). At the lowest doses administered, there was no statistical difference in hydrocodone exposure between KP201/APAP and Norco. In addition, there was a numerically lower incidence of adverse events related to hypoxia for KP201/APAP at both the eight and twelve tablet doses as compared to Norco. Drug liking, as measured by peak maximum effect on the Visual Analogue Scale, was similar for KP201/APAP and Norco at each equivalent dose level. The Visual Analogue Scale is a psychometric response scale used to measure the subjective effect of a dose level based on responses from the subject and is commonly used to evaluate drug likability.

*KP201.A02 Intranasal Human Abuse Liability Trial.* This trial, which was conducted from September 2014 through July 2015, was intended to assess the relative drug likability effects, exposure levels and safety of KP201/APAP compared to Norco after crushing and intranasal administration. Randomized subjects received an intranasal or oral dose of Norco (7.5 mg hydrocodone bitartrate/325 mg APAP) and an intranasal or oral dose of KP201/APAP (6.67 mg / 325 mg). This was a single-center, double-blind, double-dummy, placebo-controlled, single-dose, two-part, five-way crossover trial. A total of 46 opioid-experienced nondependent volunteers enrolled in the trial and 42 of the 46 subjects completed it.

The results of the trial were that, overall, administration of intranasal crushed or oral intact KP201/APAP resulted in statistically similar results for drug liking relative to intranasal crushed or oral intact Norco. We believe this was potentially due to the effects of APAP. An important component of the APAP mechanism involves indirect activation of cannabinoid CB1 receptors, which likely contribute to the analgesia of APAP and some of its other behavioral effects, such as euphoria. While the role of APAP associated with potential drug liking effects has not yet been determined, it appears plausible that APAP may “mask” negative drug effects or reduce differences in pharmacodynamic parameters, such as drug liking, between opioid combination products that contain large volumes of APAP. However, intranasal crushed KP201/APAP demonstrated, as compared to intranasal crushed Norco, a lower peak hydrocodone exposure and a decrease in exposure to hydrocodone in the early time points typically associated with an increased safety risk. We do not believe any of the adverse events occurring in the trial were unusual or unexpected following the administration of opioid medication.

*KP201.A03 Intranasal Bioavailability Study.* This study, which was conducted from May 2015 through July 2015, was intended to measure the amount of hydrocodone released from KP201, when insufflated without APAP, as compared directly to hydrocodone bitartrate. Randomized subjects received an intranasal dose of hydrocodone bitartrate (15 mg) and an intranasal dose of KP201 (13.34 mg). This was a single-center, cross-over pharmacokinetic study. A total of 66 opioid-experienced nondependent volunteers enrolled in the study and 51 of the 66 subjects completed it.

The results of the study were that KP201 demonstrated a statistically significant lowering in peak hydrocodone exposure, a delay in the time to achieve peak exposure and a decrease in total exposure to hydrocodone, especially in the early time points typically associated with increased drug liking and abuse. We do not believe any of the adverse events occurring in the trial were unusual or unexpected following the administration of opioid medication.

#### *Tamper-Resistant Extraction Studies*

In 2015, we completed three tamper-resistant extraction studies, each of which generated data that we included in our 505(b)(2) NDA submission. We believe the data from these three studies, together with the data from our two human abuse liability trials and one intranasal bioavailability study described above, may allow us to obtain the FDA’s Category 1, Category 2 and potentially Category 3 abuse-deterrent language in the KP201/APAP product label, if it is approved.

*KP201.T01 Study.* Our KP201.T01 study was designed to evaluate KP201/APAP for the possibility and potential for individuals to extract KP201 from its tablet formulation and convert the extracted KP201 active pharmaceutical ingredient, or API, into active hydrocodone, following a protocol that we developed with input from the FDA. The study evaluated how the abuse-deterrent properties of KP201 could be defeated or compromised, as compared to hydrocodone bitartrate/APAP tablets. The results of the study were that efforts to extract and hydrolyze KP201/APAP were less efficient compared to hydrocodone bitartrate/APAP tablets. Under the more than 1,000 conditions tested, KP201/APAP released less hydrocodone compared to the hydrocodone released from the hydrocodone bitartrate/APAP tablets in every case, and in many cases KP201/APAP released only the inactive prodrug, KP201.

*KP201.T02 Study.* Our KP201.T02 study was designed to evaluate the properties of KP201 that could reduce the likelihood of IV abuse of KP201/APAP as compared to hydrocodone bitartrate/APAP, based on a protocol developed by us with input from the FDA. The study evaluated the amount of KP201, APAP and hydrocodone detected in an extract derived from KP201/APAP tablets that would be suitable for IV abuse. The results of the study were that the traditional means used to prepare a drug for injection were likely not suitable for KP201/APAP. In each condition employed, only inactive KP201 was extracted, if anything at all, while up to 100% of the hydrocodone from hydrocodone bitartrate/APAP tablets could be extracted for injection. Cold water extraction methods typically used by abusers to “enrich” or “purify” the hydrocodone from hydrocodone bitartrate/APAP also yielded only inactive KP201 with no release of hydrocodone from the prodrug. Hydrocodone was readily extracted from hydrocodone bitartrate/APAP tablets by this method.

*KP201.T03 Study.* Our KP201.T03 study was designed to evaluate the potential to abuse KP201/APAP by smoking. The results of the study were that KP201/APAP could not be smoked in either tablet or KP201 form. The results also showed that freebasing KP201/APAP was not possible. By contrast, hydrocodone bitartrate/APAP can be prepared as a freebase and also smoked in the API form.

### ***KP201/IR (APAP-free)***

#### ***Overview***

Our second most advanced product candidate, KP201/IR (APAP-free), is an IR formulation of KP201 without any APAP. We are developing KP201/IR (APAP-free) for the short-term management of acute pain. KP201/IR (APAP-free) is designed to be an abuse-



deterrent opioid product that offers comparable efficacy to the existing standard-of-care, IR hydrocodone/APAP combination products, such as Vicodin, Norco and Lortab, but with the potential safety advantage of having no added APAP.

Based on our current development timelines, we anticipate submitting a 505(b)(2) NDA for KP201/IR (APAP-free) in 2017. We expect that KP201/IR (APAP-free), like other abuse-deterrent opioids, would receive priority review.

### **Market Opportunity**

Currently, there are no IR hydrocodone products approved in the United States that are formulated without APAP, with or without an abuse-deterrent label. We believe KP201/IR (APAP-free) will provide physicians with a highly differentiated abuse-deterrent hydrocodone product to help them with the short-term management of acute pain.

### **Key Product Features of KP201/IR (APAP-free)**

We believe KP201/IR (APAP-free), if approved by the FDA, may have many valuable product features and may provide significant benefits to patients, physicians and society:

- **Molecular-based abuse-deterrent technology.** Similar to KP201/APAP, KP201/IR (APAP-free) uses our KP201 prodrug which incorporates our LAT platform technology to create its abuse-deterrent properties at the molecular level and thus may provide a higher barrier against attempted abuse than many existing formulation-based approaches.
- **No added APAP.** KP201/IR (APAP-free) contains no acetaminophen. According to the FDA, overdoses of APAP are the most common cause of drug-related liver injury. In 2011, the FDA limited the amount of APAP in prescription combination products and required warnings be added to all APAP prescription products.
- **Composition-of-matter patent protection.** KP201/IR (APAP-free) is protected by a U.S. composition-of-matter patent on KP201 that will expire, after utilizing all appropriate patent term adjustments but excluding possible patent term extensions, in 2031.
- **No generic equivalent product.** Similar to KP201/APAP, the difference in chemical name, prescription strength and lack of APAP in the formulation will mean that there will be no generic equivalent product for KP201/IR (APAP-free) in most states.
- **Convenient dosing.** Based on data from our food-effect clinical trial of KP201/APAP, we believe that KP201/IR (APAP-free) will also be able to be administered under both fed and fasting conditions and, accordingly, we believe that KP201/IR (APAP-free) will be as convenient as existing IR hydrocodone/APAP combination products.

### **KP511/ER**

#### **Overview**

KP511/ER is our ER formulation of KP511, our prodrug of hydromorphone, which we are developing 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. KP511/ER is designed to be an abuse-deterrent opioid product that offers equivalent efficacy to approved ER hydromorphone products. KP511 combines hydromorphone with one or more ligands and can be formulated in both IR and ER dosage forms. KP511 is designed not to release its hydromorphone component until it is metabolized in the GI tract following oral administration. We believe KP511 is highly tamper-resistant and is stable under conditions that can potentially defeat many formulation-based abuse-deterrent technologies.

We plan to seek approval of KP511/ER under the 505(b)(2) NDA pathway. Based on our preclinical data, we believe that KP511 may release hydromorphone after oral administration in humans in a manner that is comparable to the appropriate approved hydromorphone drug. We filed an IND for KP511 in March 2016. We anticipate reporting human proof-of-concept data for KP511/ER in 2016 and submitting a 505(b)(2) NDA for KP511/ER in 2018.

#### **Market Opportunity**

Oral hydromorphone products are typically used 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. IMS estimates that in 2013 there were 3.5

million dispensed prescriptions of hydromorphone in the United States. Currently, there are no hydromorphone products approved in the United States with an abuse-deterrent label.

### **Key Product Features of KP511/ER**

Based on our preclinical data, we believe KP511/ER, if approved by the FDA, may have valuable product features and provide significant benefits to patients, physicians and society when compared to FDA-approved hydromorphone products:

- **Molecular-based abuse-deterrent technology.** In order to evaluate the abuse-deterrent qualities of KP511, we conducted preclinical studies in rats to compare the exposure to hydromorphone following intranasal and IV administration of KP511 as compared to intranasal and IV administration of hydromorphone hydrochloride. We observed significantly lower concentrations of hydromorphone following intranasal and IV administration of KP511 compared to intranasal and IV administered hydromorphone hydrochloride. KP511/ER incorporates our LAT platform technology to create its abuse-deterrent properties at the molecular level and, based on our preclinical studies, we believe it may have abuse-deterrent characteristics similar to KP201/APAP.
- **Oral overdose protection.** In our preclinical studies, we observed that hydromorphone blood levels in rats increased more slowly and to a lesser extent after oral administration of increasing excessively large doses of KP511, as compared to increasing equimolar oral doses of hydromorphone hydrochloride. We also observed that the study animals began dying from the increasing excessively large oral doses of hydromorphone hydrochloride, but never died from an equimolar oral dose of KP511. Based on the molecular structure of KP511, we believe it is possible that the metabolic processes of releasing hydromorphone from the prodrug become saturated at excessively large oral doses. If confirmed by further studies, this could potentially mean that KP511 and KP511/ER may reduce the risk of oral overdosing by a mechanism that is inherent in the prodrug molecule itself.
- **Composition-of-matter patent protection.** KP511/ER is protected by a U.S. composition-of-matter patent on KP511 that will expire, after utilizing all appropriate patent term adjustments but excluding possible patent term extensions, in 2032. Our patent strategy is focused primarily on key geographic market opportunities, and, as of December 31, 2015, a composition-of-matter patent on KP511 was granted in Australia, Japan, Philippines, New Zealand, South Africa, and Singapore, and applications covering KP511 were pending in the United States and an additional 20 foreign jurisdictions.
- **No generic equivalent product.** KP511 is a prodrug that we believe will be given a new chemical name, which would mean that there would be no generic equivalent product for KP511/ER in most states, making substitution difficult at the pharmacy.

### **KP415**

#### **Overview**

KP415 is our prodrug of methylphenidate, which we are developing for the treatment of ADHD. The ADHD market is largely served by the stimulant products methylphenidate and amphetamine. KP415 is designed to be a controlled release, or CR, abuse-deterrent methylphenidate product.

We plan to seek approval of KP415 under the 505(b)(2) NDA pathway. We anticipate reporting human proof-of-concept data for KP415 in 2016 and submitting a 505(b)(2) NDA for KP415 in 2019.

#### **Market Opportunity**

We believe the ADHD market would be receptive to new branded drugs that have improved properties when compared to current treatments. We believe a new product in the form of a prodrug that has abuse-deterrent features and a more consistent controlled release drug delivery mechanism may provide a preferred treatment option in this large market segment. While methylphenidate is available as a generic product, the branded formulations, Concerta, Focalin and Ritalin, accounted for sales of \$1.2 billion in 2015.

### **Key Product Features of KP415**

Based on our preclinical data, we believe KP415, if approved by the FDA, may have valuable product features and provide significant benefits to patients, physicians, and society when compared to other FDA-approved and widely prescribed methylphenidate products:

- **Molecular-based abuse-deterrent technology.** In order to evaluate the abuse-deterrent qualities of KP415, we conducted preclinical studies in rats to compare the exposure to methylphenidate following intranasal and IV administration of KP415 as compared to intranasal and IV administration of methylphenidate hydrochloride. We observed significantly lower concentrations of methylphenidate following intranasal and IV administration of KP415 compared to intranasal and IV administered methylphenidate hydrochloride. KP415 incorporates our LAT platform technology to create its abuse-deterrent properties at the molecular level and, based on our preclinical studies, we believe it will have abuse-deterrent characteristics similar to KP201/APAP.
- **Once-daily dosing.** Pharmacokinetic data from our preclinical studies suggest that the time to maximum plasma concentration of methylphenidate after oral administration of KP415 is approximately three times longer than that after oral administration of currently marketed IR methylphenidate. We believe this inherent CR attribute of KP415's molecular structure may allow for convenient, once-daily dosing.
- **Amenable to patient-friendly formulations.** Although we believe our prodrug, KP415, possesses abuse-deterrent properties at the molecular level similar to KP201, our preclinical data shows that KP415 is highly water soluble and we believe it could ultimately be used in a variety of patient-friendly dosage forms such as oral thin film, orally dissolving tablets, chewable tablets and liquids as a means of increasing patient convenience and compliance.
- **Composition-of-matter patent protection.** KP415 is protected by a U.S. composition-of-matter patent that will expire, after utilizing all appropriate patent term adjustments but excluding possible term extensions, in 2032. Our patent strategy is focused primarily on key geographic market opportunities, and, as of December 31, 2015, a composition-of-matter patent on KP415 was granted in New Zealand and South Africa, and additional KP415 patent filings were pending in the United States and an additional 23 foreign jurisdictions. In addition, subject to further discussions with the FDA, KP415 may be eligible for new chemical entity, or NCE, exclusivity status, which could allow for five years of U.S. market exclusivity following the FDA's approval of an NDA for KP415.
- **No generic equivalent product.** KP415 is a prodrug that we believe will be given a new chemical name, which would mean that there would be no generic equivalent product for KP415 in most states, making substitution difficult at the pharmacy.

#### **Other Product Candidates**

We are using our LAT platform technology to develop other product candidates in pain. One example is KP606/IR, an IR formulation of KP606, our prodrug of oxycodone, which we are developing for the management of moderate to severe pain where the use of an opioid analgesic is appropriate. KP606/IR is designed to be an IR abuse-deterrent opioid product that offers equivalent efficacy to OxyContin. KP606 combines oxycodone with one or more ligands.

We anticipate reporting human proof-of-concept data for KP606/IR in 2017 and submitting a 505(b)(2) NDA for KP606/IR in 2019.

Another example is KP746, our prodrug of oxymorphone, which is currently in preclinical development. We are developing KP746 for the management of moderate to severe pain where the use of an opioid analgesic is appropriate.

#### **Our Intellectual Property**

Our intellectual property strategy includes seeking composition-of-matter patents, among other patents, for our prodrugs and product candidates and conjugates of our prodrugs while also protecting as trade secrets our LAT platform technology, the process by which we identify, screen, evaluate and select ligands to be conjugated with parent drugs to create our prodrugs. Our current prodrugs all consist of an approved parent drug and one or more ligands that we have selected using our LAT platform technology. The parent drug and ligand or ligands together may potentially constitute an NME and thus may be eligible for composition-of-matter patent protection, among other patent protections, in the United States and abroad.

To date, we have internally developed all of our intellectual property, including our LAT platform technology, and have not in-licensed or otherwise acquired our technology, patents, show-how or know-how from an outside source. As of December 31, 2015, we owned 12 issued patents within the United States, and an additional 35 foreign patents covering our prodrugs or product candidates. The terms of the 12 issued U.S. patents extend to various dates between 2030 and 2032. The term of our overall domestic and foreign patent portfolio related to our prodrugs and product candidates, including patent term adjustments but excluding possible patent term extensions, extend to various dates between 2030 and 2032, if pending patent applications in each of our patent families issue as patents. As of December 31, 2015, we owned eight pending patent applications under active prosecution in the United States, and an additional 69 pending foreign patent applications covering our prodrugs and product candidates. Our issued and granted patents

provide protection in jurisdictions that include the United States, Australia, Canada, China, Colombia, Israel, Japan, Kazakhstan, Malaysia, Mexico, New Zealand, Philippines, Russia, Ukraine, Singapore, Indonesia and South Africa.

In 2013, the United States Patent and Trademark Office, or the USPTO, issued a composition-of-matter patent covering KP201, which will expire, after utilizing all appropriate patent term adjustments but excluding possible patent term extensions, in 2031. Further, there are granted or recently allowed compositions-of-matter patents covering KP201 in Australia, Canada, China, Colombia, Israel, Japan, Kazakhstan, Malaysia, Mexico, New Zealand, Russia, Ukraine, Indonesia and South Africa. In addition, one U.S. patent application covering KP201-related compositions-of-matter were pending as of December 31, 2015, and patent applications covering KP201 were pending as of December 31, 2015, in the United Arab Emirates, Brazil, Belarus, Chile, Costa Rica, Cuba, Egypt, Europe, Hong Kong, India, South Korea, Oman, Philippines, Singapore, Thailand and Vietnam.

In August 2014, the USPTO issued a composition-of-matter patent covering KP511, which will expire, after utilizing all appropriate patent term adjustments but excluding possible patent term extensions, in 2032. In July 2015, the USPTO issued a composition-of-matter patent covering KP415, which will expire, after utilizing all appropriate patent term adjustments but excluding patent term extensions, in 2032. We have also filed composition-of-matter patent applications for KP415 and KP511 in the United States and in Argentina, Australia, Brazil, Canada, Chile, China, Egypt, Hong Kong, Europe, India, Israel, Indonesia, Japan, South Korea, Kazakhstan, Mexico, Malaysia, New Zealand, Philippines, Russia, Singapore, Thailand, Ukraine, Vietnam and South Africa. We anticipate filing additional patent applications for our prodrug product candidates.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. To help protect our LAT platform technology as well as any proprietary know-how and show-how that is not patentable, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we generally require our employees, consultants and advisors to enter into confidentiality agreements prohibiting the disclosure of confidential information and, in some cases, requiring disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

### **Commercialization**

We have begun initial pre-approval commercialization activities for KP201/APAP although currently we do not have any internal sales or distribution infrastructure. These initial pre-approval commercialization activities include developing the marketing strategy, designing the product distribution infrastructure, coordinating managed care access and identifying the promotional sales force size and structure. These activities are aligned to support a planned promotional launch of KP201/APAP as early as the first quarter of 2017, subject to FDA approval and DEA scheduling.

Because many of our product candidates, including KP201/APAP, may have large potential market opportunities, and may require significant marketing resources, we may conclude that the most appropriate approach to their commercialization, if they receive regulatory approval, will involve forming a commercial collaboration or strategic relationship, or consummating some type of strategic transaction, with a larger pharmaceutical marketing organization. Alternatively, we may conclude that building our own focused sales and marketing organization will be most appropriate, perhaps as part of a co-promotional arrangement, or some other form of collaboration. As we get closer to potential approval of our product candidates, we will work to identify and implement the commercialization strategies that we conclude are the most desirable with regard to the specific product candidates.

### **Research and Development**

Historically, we have devoted a significant amount of resources to develop our product candidates. For the years ended December 31, 2015, 2014 and 2013, we recorded \$13.9 million, \$11.9 million and \$3.4 million, respectively, in research and development expenses. We plan to increase our research and development expense for the foreseeable future as we continue our efforts to commercialize, if approved, and further advance the development of our product candidates, subject to the availability of additional funding.

### **Competition**

Our industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We will face competition and potential competition from a number of sources, including pharmaceutical and biotechnology companies, specialty pharmaceutical companies, generic drug companies, drug delivery companies and academic and research institutions. We believe the key competitive factors that will affect the development and commercial success of our product candidates include their potential degree of abuse deterrence, onset of action, bioavailability, therapeutic efficacy, convenience of dosing, safety, tolerability and cost. Many of our potential competitors have substantially greater financial, technical and human resources than we do, as well as more experience in the development of product candidates, obtaining FDA and other regulatory approvals of products

and the commercialization of those products. Consequently, our competitors may develop abuse-deterrent or other products for the short-term management of acute pain, or for other indications we are pursuing or may pursue in the future, and such competitors' products may be more effective, better tolerated and less costly than our product candidates. Our competitors may also be more successful in manufacturing and marketing their products than we are. We will also face competition in recruiting and retaining qualified personnel and establishing clinical trial sites and patient enrollment in clinical trials.

If approved, our abuse-deterrent opioid product candidates will face competition from commercially available branded and generic opioid drugs, including hydrocodone, hydromorphone, oxycodone, fentanyl, morphine, oxymorphone and methadone, as well as other marketed non-opioid products for the treatment of pain, and potential competition from opioid and non-opioid products for the treatment of pain that are currently in clinical development. In addition, our product candidates will face competition from approved and abuse-deterrent labeled opioid drugs and potential competition from abuse-deterrent opioid drugs that are currently in clinical development. We may compete with multiple companies that have developed and are developing abuse-deterrent technologies that may be applied to a variety of drugs, including those being developed for the short-term management of acute pain as well as for other indications that we are pursuing or may pursue in the future. If approved, our abuse-deterrent opioid product candidates may face competition from opioid products or abuse-deterrent technologies from companies including Allergan plc, Acura Pharmaceuticals, Inc., Cara Therapeutics, Inc., Collegium Pharmaceutical, Inc., Depomed, Inc., DURECT Corporation, Egalet Corporation, Elite Pharmaceuticals, Inc., Endo International plc, Grünenthal Group, Inspirion Delivery Technologies, LLC, IntelliPharmaceuticals International Inc., Mallinckrodt plc, Mylan Inc., Nektar Therapeutics, Pain Therapeutics, Inc., Pfizer Inc., Purdue Pharma L.P., Signature Pharmaceuticals, Teva Pharmaceutical Industries Ltd., Trevena Inc. and UCB S.A.

If approved, KP201/APAP will compete against currently marketed, branded and generic IR hydrocodone/APAP combination products indicated for the short-term management of acute pain. Some of these currently marketed products include AbbVie's Vicodin, Allergan's Norco, Shionogi's Xodol and UCB Pharma's Lortab, in addition to multiple other branded and generic hydrocodone/APAP combination products marketed by companies including Allergan plc, Endo International plc and Mallinckrodt plc. In addition, if approved, KP201/APAP will face potential competition from any abuse-deterrent IR or other hydrocodone/APAP combination products for the short-term management of acute pain that are currently in or may enter into clinical development.

If approved, KP415 will compete against currently marketed, branded and generic methylphenidate products for the treatment of ADHD. Some of these currently marketed products include Johnson & Johnson's Concerta, Novartis AG's Ritalin, Ritalin LA, Focalin and Focalin XR, UCB S.A.'s Metadate CD, and Noven Pharmaceuticals' Daytrana, in addition to multiple other branded and generic methylphenidate products marketed by companies including Allergan plc and Mallinckrodt plc. In addition, if approved, KP415 will face potential competition from any abuse-deterrent or other methylphenidate products for the treatment of ADHD that are currently in or which may enter into clinical development.

If approved, KP511/ER will compete against currently marketed, branded and generic, IR and ER hydromorphone products approved for use in opioid-tolerant patients 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. Some of these currently marketed products include Purdue Pharma L.P.'s Dilaudid and Mallinckrodt plc's Exalgo, in addition to multiple other branded and generic IR and ER hydromorphone products marketed by companies including Allergan plc, Mallinckrodt plc, Rhodes Pharmaceuticals L.P. and Roxanne Laboratories, Inc. In addition, if approved, KP511/ER will face potential competition from any abuse-deterrent or other IR and ER hydromorphone products for the treatment of pain that are currently in or which may enter into clinical development.

If approved, KP606/IR will compete against currently marketed, branded and generic, abuse-deterrent and other IR and ER oxycodone products approved for the management of moderate to severe pain where the use of an opioid analgesic is appropriate or for use in opioid-tolerant patients for the treatment of acute pain and pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Some of these currently marketed products include Purdue Pharma L.P.'s OxyContin and Mallinckrodt plc's Roxicodone, in addition to multiple other branded and generic, abuse-deterrent and other, IR and ER oxycodone products marketed by companies including Allergan plc, Endo International plc, and Mallinckrodt plc. In addition, if approved, KP606/IR will face potential competition from any abuse-deterrent and other, IR and ER oxycodone products that are currently in or which may enter into clinical development.

If approved, KP746 will compete against currently marketed, branded and generic oxymorphone products for the management of moderate to severe pain where the use of an opioid analgesic is appropriate. Some of these currently marketed products include Endo International plc's Opana ER, in addition to other generic oxymorphone products marketed by companies including CorePharma, LLC, Impax Laboratories Inc., Mallinckrodt Inc., Roxane Laboratories, Inc. and Teva Pharmaceuticals USA, Inc. In addition, if approved, KP746 will face potential competition from any abuse-deterrent and other IR and ER oxymorphone products that are currently in or which may enter into clinical development.

## **Manufacturing**

Our manufacturing strategy is to rely on contract manufacturers to produce our prodrug product candidates for clinical trials and, if approved, drug product for commercial sale. We currently have no manufacturing facilities and limited personnel with manufacturing experience. We rely on a third-party manufacturer to produce KP201/APAP for our clinical trials and we expect to continue to rely on third-party manufacturers to manufacture commercial quantities of KP201/APAP if and when we receive approval for marketing from the FDA. We also rely on Johnson Matthey Inc., or JMI, a third-party manufacturer, to produce the bulk quantities of KP201 required for the manufacture of the KP201/APAP used in our clinical trials under a supply agreement. We plan to continue to rely on JMI to manufacture commercial quantities of KP201 used in production of KP201/APAP for sale in the United States if and when we receive approval for marketing by the FDA. We expect to contract with third-party manufacturers for the manufacture of KP201 and KP201/APAP outside the United States if and when we receive approval for marketing by regulatory authorities outside the United States.

Our current and any future third-party manufacturers, their facilities and all lots of drug substance and drug products used in our clinical trials are required to be in compliance with current good manufacturing practices, or cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities for our products must meet cGMP requirements and FDA satisfaction before any product is approved and we can manufacture commercial products. Our current and any future third-party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations.

Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, cyber letters, modification of promotional materials or labeling, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, debarment, injunctions, fines, consent decrees, corporate integrity agreements, refusals of government contracts and new orders under existing contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement or civil or criminal penalties, including fines and imprisonments.

### **Supply Agreement with Johnson Matthey**

Under our supply agreement with JMI, or the Supply Agreement, JMI has agreed to supply us with all of the KP201 necessary for clinical trials and commercial sale for a price equal to JMI's manufacturing cost and to provide process development services for KP201. In exchange, we issued shares of our common stock to JMI, provided that the commercial supply arrangement for KP201 would be exclusive to them in the United States. In addition, for further process optimization and manufacture of NDA registration batches, we agreed to pay a minimum royalty on the net sales on the commercial sale of KP201/APAP, if approved by the FDA. The percentage royalty rate ranges from the high teens at low volumes to the mid-single digits at higher volumes. Under the agreement, JMI has completed manufacture of our registration batches of KP201/APAP and stability testing for those batches is in process.

Under the Supply Agreement, we retain sole ownership of KP201 and are required to use commercially reasonable efforts to develop and to pursue FDA marketing approval of KP201/APAP. We are responsible for product development, including formulation, preclinical studies and clinical trials, and for regulatory approval, quality assurance and commercialization. If KP201 is subject to a DEA scheduling quota, then each quarter, both we and JMI are responsible for using commercially reasonable efforts to obtain a quota from the DEA for the production of the KP201 API and for KP201.

We are responsible for all costs of any KP201 manufactured during a specified validation process for KP201. After completion of the validation process, but prior to the commercial launch of KP201, JMI will manufacture batches of KP201 at a price to be negotiated. Failure to agree upon this pricing would result in JMI supplying these batches to us free of charge and we would pay JMI an additional royalty payment on such batches. The percentage royalty rate ranges from the low teens at low volumes to the low single digits at higher volumes and is additive to any minimum royalty we may owe JMI on such batch. After the commercial launch of KP201/APAP, JMI will manufacture and supply KP201 at a price equal to JMI's fully allocated manufacturing cost.

We must purchase all of our U.S. KP201 needs from JMI and JMI cannot supply KP201 to other companies. After the commercial launch of KP201, JMI is required to identify a secondary manufacturing site and qualify and validate that site for the production of KP201.

The term of the Supply Agreement extends as long as we hold a valid and enforceable patent for KP201 or until the tenth anniversary of KP201's commercial launch, whichever date is later. Upon the expiration of such term, the agreement will automatically renew for a period of two years unless either party provides 12 months' prior notice of its intent not to renew.

### **Asset Purchase Agreement with Shire LLC**

In March 2012, as a result of a litigation settlement, we and our chief executive officer, Travis C. Mickle, Ph. D., entered into an asset purchase agreement with Shire LLC, or Shire, pursuant to which we sold assets and intellectual property to Shire for proceeds of \$5.1 million. As partial consideration for this sale, we and Dr. Mickle agreed not to compete with Shire in the development, commercialization, production or distribution of amphetamine amino acid conjugate products until March 21, 2017. Pursuant to this agreement, we also granted Shire a right of first refusal to acquire, license or commercialize KP415.

### **Third-Party Reimbursement**

Sales of pharmaceutical products depend in significant part on the availability of coverage and adequate reimbursement by third-party payors, such as state and federal governmental authorities, including those that administer the Medicare and Medicaid programs, managed care organizations and private insurers. Decisions regarding the extent of coverage and amount of reimbursement to be provided for each of our product candidates will be made on a plan-by-plan basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Each third-party payor determines whether or not it will provide coverage for a drug, what amount it will pay providers for the drug, and on what tier of its formulary the drug will be placed. These decisions are influenced by the existence of multiple drug products within a therapeutic class and the net cost to the plan, including the amount of the prescription price, if any, rebated by the drug's manufacturer. Typically, generic versions of drugs are placed in a preferred tier. The position of a drug on the formulary generally determines the co-payment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Additionally, a third-party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Also, third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. As a result, coverage, reimbursement and placement determinations are complex and are often the subject of extensive negotiations between the payor and the owner of the drug.

Unless we enter into a strategic collaboration under which our collaborator assumes responsibility for seeking coverage and reimbursement for a given product, we will be responsible for negotiating coverage, reimbursement and placement decisions for our product candidates. Coverage, reimbursements and placement decisions for a new product are based on many factors including the coverage, reimbursement and placement of already marketed branded drugs for the same or similar indications, the safety and efficacy of the new product, availability of generics for similar indications, the clinical need for the new product and the cost-effectiveness of the product. Increasingly, both purchasers and payors are also conducting comparative clinical and cost effectiveness analyses involving application of metrics, including data on patient outcomes, provided by manufacturers.

Within the Medicare program, as self-administered drugs, KP201/APAP, KP201/IR (APAP-free), KP415, KP511/ER, KP606/IR and KP746 would be reimbursed under the expanded prescription drug benefit known as Medicare Part D. This program is a voluntary Medicare benefit administered by private plans that operate under contracts with the federal government. These plans develop formularies that determine which products are covered and what co-pay will apply to covered drugs. The plans have considerable discretion in establishing formularies and tiered co-pay structures, negotiating rebates with manufacturers and placing prior authorization and other restrictions on the utilization of specific products, subject to review by the Centers for Medicare and Medicaid Services, or CMS, for discriminatory practices. These Part D plans negotiate discounts with drug manufacturers, which are passed on, in whole or in part, to each of the plan's enrollees through reduced premiums. Historically, Part D beneficiaries have been exposed to significant out-of-pocket costs after they surpass an annual coverage limit and until they reach a catastrophic coverage threshold. However, changes made by the Patient Protection and Affordable Care Act as amended by the Health Care Education and Reconciliation Act, or the ACA, will reduce this patient coverage gap, known as the "donut hole", by transitioning patient responsibility in that coverage range from 100% in 2010 to only 25% in 2020. To help achieve this reduction, pharmaceutical manufacturers are required to provide quarterly discounts of 50% off the negotiated price of branded drugs dispensed to Medicare Part D patients in the donut hole.

If a drug product is available for reimbursement by Medicare or Medicaid, its manufacturer must comply with various health regulatory requirements and price reporting metrics, which may include, as applicable, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, or the OBRA, and the Veterans Health Care Act of 1992, or the VHCA, each as amended. Among other things, the OBRA requires drug manufacturers with certain drugs covered by Medicaid to pay rebates on prescription drugs to state Medicaid programs. States may

also negotiate “supplemental” Medicaid rebates on drug products dispensed under Medicaid. Manufacturers participating in Medicaid are also generally required to participate in the Public Health Service 340B Drug Discount Program, which imposes a mandatory discount on purchases by certain customers. Manufacturers of innovator drugs, including 505(b)(2) drugs, that participate in the Medicaid program are also required to offer the drugs on the Federal Supply Schedule purchasing program of the General Services Administration for purchase by the Department of Veterans Affairs, the Department of Defense and other authorized users at a mandatory discount. Additional laws and requirements apply to these contracts. Participation in such federal programs may result in prices for our future products that will likely be lower than the prices we might otherwise obtain.

Third-party payors, including the U.S. government, continue to apply downward pressure on the reimbursement of pharmaceutical products. Also, the trend towards managed health care in the United States and the concurrent growth of organizations such as health maintenance organizations may result in lower reimbursement for pharmaceutical products. We expect that these trends will continue as these payors implement various proposals or regulatory policies, including various provisions of the recent health reform legislation that affect reimbursement of these products. There are currently, and we expect that there will continue to be, a number of federal and state proposals to implement controls on reimbursement and pricing, directly and indirectly.

## **Government Regulation**

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, packaging, recordkeeping, tracking, approval, import, export, distribution, advertising and promotion of our products.

The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- nonclinical laboratory and animal tests that must be conducted in accordance with good laboratory practices, or GLPs;
- submission of an IND, which must become effective before clinical trials may begin;
- approval by an independent institutional review board, or IRB, for each clinical site or centrally before each trial may be initiated;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed product candidate for its intended use, performed in accordance with good clinical practices, or GCPs;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- pre-approval inspection of manufacturing facilities and selected clinical investigators for their compliance with cGMP and GCPs; and
- FDA approval of an NDA to permit commercial marketing for particular indications for use.

Prior to the commencement of marketing of controlled substances, the DEA must also determine the controlled substance schedule, taking into account the recommendation of the FDA.

The testing and approval process requires substantial time, effort and financial resources. Preclinical studies include laboratory evaluation of drug substance chemistry, pharmacology, toxicity and drug product formulation, as well as animal studies to assess potential safety and efficacy. Prior to commencing the first clinical trial with a product candidate, we must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical studies may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the conduct of the clinical trial by imposing a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development, as well as amendments to previously submitted clinical trials. Further, an independent IRB for each study site proposing to conduct the clinical trial must review and approve the plan for any clinical trial, its informed consent form and other communications to



study subjects before the clinical trial commences at that site. The IRB must continue to oversee the clinical trial while it is being conducted, including any changes to the study plans. Regulatory authorities, an IRB or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk, the clinical trial is not being conducted in accordance with the FDA's or the IRB's requirements, if the drug has been associated with unexpected serious harm to subjects, or based on evolving business objectives or competitive climate. Some studies also include a data safety monitoring board, which receives special access to unblinded data during the clinical trial and may advise us to halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

In general, for purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- *Phase 1*—Studies are initially conducted to test the product candidate for safety, dosage tolerance, structure-activity relationships, mechanism of action, absorption, metabolism, distribution and excretion in healthy volunteers or subjects with the target disease or condition. If possible, Phase 1 trials may also be used to gain an initial indication of product effectiveness.
- *Phase 2*—Controlled studies are conducted with groups of subjects with a specified disease or condition to provide enough data to evaluate the preliminary efficacy, optimal dosages and dosing schedule and expanded evidence of safety. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- *Phase 3*—These clinical trials are undertaken in larger subject populations to provide statistically significant evidence of clinical efficacy and to further test for safety in an expanded subject population at multiple clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. These trials may be done globally to support global registrations so long as the global sites are also representative of the U.S. population and the conduct of the study at global sites comports with FDA regulations and guidance, such as compliance with GCPs.

In the case of a 505(b)(2) NDA, which is a marketing application in which sponsors may rely on investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted, some of the above-described studies and preclinical studies may not be required or may be abbreviated. Bridging studies may be needed, however, to demonstrate the relevance of the studies that were previously conducted by other sponsors to the drug that is the subject of the NDA.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 studies may be made a condition to be satisfied after approval. The results of Phase 4 studies can confirm the effectiveness of a product candidate and can provide important safety information.

Clinical trials must be conducted under the supervision of qualified investigators in accordance with GCP requirements, which includes the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, and the review and approval of the study by an IRB. Investigators must also provide information to the clinical trial sponsors to allow the sponsors to make specified financial disclosures to the FDA. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated and a statistical analysis plan. Information about some clinical trials, including a description of the trial and trial results, must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their ClinicalTrials.gov website.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the Federal Food, Drug and Cosmetic Act, or the FDCA. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and the IRB and more frequently if serious adverse events occur.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the

identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

### **505(b)(2) Approval Process**

Section 505(b)(2) of the FDCA, or 505(b)(2), provides an alternate regulatory pathway to FDA approval for new or improved formulations or new uses of previously approved drug products. Specifically, 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The applicant may rely upon the FDA's prior findings of safety and effectiveness for an approved product that acts as the reference listed drug for purposes of a 505(b)(2) NDA. The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support any changes from the reference listed drug. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Our current and anticipated product candidates are or will be based on already approved APIs in combination with a ligand. Accordingly, we have and expect to be able to continue to rely on information from studies previously conducted by the companies that obtained approval for drugs containing such APIs.

### **Orange Book Listing**

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include preclinical and clinical data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo, or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug.

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. These products may be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug or method of use that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a Paragraph IV certification. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through a Paragraph IV certification. If the applicant does not challenge the listed patents or does not indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired, or, if permissible, are carved out.

If the competitor has provided a Paragraph IV certification to the FDA, the competitor must also send notice of the Paragraph IV certification to the holder of the NDA for the reference listed drug and the patent owner once the application has been accepted for filing by the FDA. The NDA holder or patent owner may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification prevents the FDA from approving the application until the earlier of 30 months from the date of the lawsuit, expiration of the patent, settlement of the lawsuit, a decision in the infringement case that is favorable to the applicant or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a Paragraph IV certification, the NDA holder or patent owner regularly take action to trigger the 30-month stay,

recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation. The applicant may also elect to submit a statement certifying that its proposed label does not contain, or carves out, any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

We have made a Paragraph IV certification in our 505(b)(2) NDA for KP201/APAP based on our reliance in part on the FDA's prior findings of safety and effectiveness of Vicoprofen, a product that remains under patent until June 2017. FDA approval of our 505(b)(2) NDA may be delayed until June 10, 2017 or later if the patent or application holder files a patent infringement claim against us. See "Risk Factors—Risks Related to the Development of Our Product Candidates—Our NDA for KP201/APAP includes a Paragraph IV certification and, therefore, we have provided notice of this certification to the holders of certain patents and NDAs upon the FDA's acceptance of our NDA for review. This notice may result in a delay in the approval of our NDA by the FDA and potential patent infringement lawsuit by the patent or NDA holder" for additional information regarding the risk associated with the 505(b)(2) NDA pathway and associated patent infringement lawsuits that may delay FDA approval of 505(b)(2) NDAs.

### ***Exclusivity***

The FDA provides periods of regulatory exclusivity, which provides the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug for a period of three or five years following the FDA's approval of the NDA. Five years of exclusivity are available to NCEs. An NCE is a drug that contains no active moiety that has been approved by the FDA in any other NDA. An active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt, including a salt with hydrogen or coordination bonds, or other noncovalent derivatives, such as a complex, chelate, or clathrate, of the molecule, responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review or approve an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. An ANDA or 505(b)(2) application, however, may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. Applicants may also seek to carve out certain drug labeling that is protected by exclusivity.

If a product is not eligible for the NCE exclusivity, it may be eligible for three years of exclusivity. Three-year exclusivity is available to the holder of an NDA, including a 505(b)(2) NDA, for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials, other than bioavailability or bioequivalence trials, was essential to the approval of the application and was conducted or sponsored by the applicant. This three-year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDAs for the condition of the new drug's approval. As a general matter, three-year exclusivity does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

### ***NDA Submission and Review by the FDA***

Assuming successful completion of the required clinical and preclinical testing, among other items, the results of product development, including chemistry, manufacture and controls, nonclinical studies and clinical trials are submitted to the FDA, along with proposed labeling, as part of an NDA. The submission of an NDA requires payment of a substantial user fee to the FDA. These user fees must be filed at the time of the first submission of the application, even if the application is being submitted on a rolling basis. Fee waivers or reductions are available in some circumstances. One basis for a waiver of the application user fee is if the applicant employs fewer than 500 employees, including employees of affiliates, the applicant does not have an approved marketing application for a product that has been introduced or delivered for introduction into interstate commerce, and the applicant, including its affiliates, is submitting its first marketing application.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA for a new active ingredient, indication, dosage form, dosage regimen or route of administration must contain data that are adequate to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers from the pediatric data requirements. We have agreed with the FDA on a Pediatric Study Plan which outlines the adult, pediatric and nonclinical studies, as well as formulation work, that we plan to conduct and the associated schedule, which is subject to post-approval amendment of the NDA. We have requested a deferral of these efforts.

The FDA must refer applications for drugs that contain active ingredients, including any ester or salt of the active ingredients, that have not previously been approved by the FDA to an advisory committee or provide in an action letter a summary of the reasons for not referring it to an advisory committee. The FDA may also refer drugs which present difficult questions of safety, purity or potency to an advisory committee. An advisory committee is typically a panel that includes clinicians and other experts who review, evaluate and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA has also previously indicated that our NDA for KP201/APAP raises issues that will likely require advisory committee review.

The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities, including contract manufacturers and subcontracts, are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCPs.

Once the FDA receives an application, it has 60 days to review the NDA to determine if it is substantially complete to permit a substantive review, before it accepts the application for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. The timeline for the FDA to complete its review of an NDA may differ based on whether the application is a standard review or priority review application. The FDA may give a priority review designation to drugs that are intended to treat serious conditions and provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has set the review goal of ten months from the 60-day filing date to complete its initial review of a standard NDA for an NME and make a decision on the application. For non-NME standard applications, the FDA has set the review goal of ten months from the submission date to complete its initial review and to make a decision on the application. For priority review applications, the FDA has set the review goal of reviewing NME NDAs within six months of the 60-day filing date and non-NME applications within six months of the submission date. Such deadlines are referred to as the PDUFA date. The PDUFA date is only a goal and the FDA does not always meet its PDUFA dates. The review process and the PDUFA date may also be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding the submission.

Once the FDA's review of the application is complete, the FDA will issue either a Complete Response Letter, or CRL, or approval letter. A CRL indicates that the review cycle of the application is complete and the application is not ready for approval. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing, or other information or analyses in order for the FDA to reconsider the application. The FDA has the goal of reviewing 90% of application resubmissions in either two or six months of the resubmission date, depending on the kind of resubmission. Even with the submission of additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

The FDA may delay or refuse approval of an NDA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product, or impose other conditions, including distribution restrictions or other risk management mechanisms. For example, the FDA may require a risk evaluation and mitigation strategy, or REMS, as a condition of approval or following approval to mitigate any identified or suspected serious risks and ensure safe use of the drug. The FDA may prevent or limit further marketing of a product, or impose additional post-marketing requirements, based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements, FDA notification and FDA review and approval. Further, should new safety information arise, additional testing, product labeling or FDA notification may be required.

FDA approval of any NDA submitted by us will be at a time the FDA chooses. Also, if regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed or may include contraindications, warnings or precautions in the product labeling, including a black box warning. For instance, we expect that at least some of our product candidates would likely be required to carry black box warnings, including warnings regarding tampering, lethality if our oral tablets are prepared for injection and hepatotoxicity. For example, Norco carries a black box warning related to the APAP component and the risk of liver failure or injury. If the FDA requires a black box warning, we would also be subject to specified promotional restrictions, such as the prohibition of reminder advertisements. The FDA also may not approve the inclusion of labeling claims necessary for successful marketing. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In

addition, the FDA may require Phase 4 post-marketing studies to monitor the effect of approved products, and may limit further marketing of the product based on the results of these post-marketing studies.

### ***Post-approval Requirements***

Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including manufacturing, periodic reporting, product sampling and distribution, advertising, promotion, drug shortage reporting, compliance with any post-approval requirements imposed as a condition of approval such as Phase 4 clinical trials, REMS and surveillance, recordkeeping and reporting requirements, including adverse experiences.

After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any approved products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and to list their drug products, and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with cGMPs and other requirements, which impose procedural and documentation requirements upon us and our third-party manufacturers. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP regulations and other FDA regulatory requirements.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented, or FDA notification. FDA regulations also require investigation and correction of any deviations from cGMPs and specifications, and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in withdrawal of marketing approval, mandatory revisions to the approved labeling to add new safety information or other limitations, imposition of post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS program, among other consequences.

The FDA closely regulates the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA. Physicians, in their independent professional medical judgment, may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. We, however, are prohibited from marketing or promoting drugs for uses outside of the approved labeling.

In addition, the distribution of prescription pharmaceutical products, including samples, is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. The Drug Supply Chain Security Act also imposes obligations on manufacturers of pharmaceutical products related to product tracking and tracing.

Failure to comply with any of the FDA's requirements could result in significant adverse enforcement actions. These include a variety of administrative or judicial sanctions, such as refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, cyber letters, modification of promotional materials or labeling, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, debarment, injunctions, fines, consent decrees, corporate integrity agreements, refusals of government contracts and new orders under existing contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement or civil or criminal penalties, including fines and imprisonment. Any of these sanctions could result in adverse publicity, among other adverse consequences.

### ***Risk Evaluation and Mitigation Strategy (REMS)***

The FDA has the authority to require a REMS to ensure the safe use of the drug. In determining whether a REMS is necessary, the FDA must consider the size of the population likely to use the drug, the seriousness of the disease or condition to be treated, the expected benefit of the drug, the duration of treatment, the seriousness of known or potential adverse events, and whether the drug is an NME. If the FDA determines a REMS is necessary, the drug sponsor must develop the REMS program, which the FDA reviews and approves. A REMS may be required for a single drug or an entire class of drugs.

A REMS may be required to include various elements, including, but not limited to, a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, elements to assure safe use, or ETASU, an implementation system, or other measures that the FDA deems necessary to assure the safe use of the drug. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under specified circumstances, special monitoring, and the use of patient registries. In addition, the REMS must include a timetable to periodically assess the strategy. The FDA may also impose a REMS requirement on a drug already on the market if the FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug's benefits outweigh its risks. The requirement for a REMS can materially affect the potential market and profitability of a drug.

Based upon currently approved product REMS programs and class-wide REMS programs, including the class-wide REMS programs for extended-release and long-acting opioid analgesics, we believe that most of our product candidates, if approved, may be subject to a REMS. Accordingly, we expect to have to take prescribed measures to ensure the safe use of our products, if they are approved.

### **DEA Regulation**

Most of our product candidates, if approved, will be regulated as "controlled substances" as defined in the Controlled Substances Act of 1970, or CSA, and the DEA's implementing regulations, which establish registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA. These requirements are directly applicable to us and also applicable to our contract manufacturers and to distributors, prescribers and dispensers of our product candidates. The DEA regulates the handling of controlled substances through a closed chain of distribution. This control extends to the equipment and raw materials used in their manufacture and packaging in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Schedule II drugs are those that meet the following characteristics:

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

We expect that most of our product candidates may be listed by the DEA as Schedule II controlled substances under the CSA. However, we have requested in our NDA that KP201/APAP be listed as a Schedule III controlled substance based on its differential abuse potential when compared to other Schedule II controlled substances, such as IR hydrocodone combination products. None of the previously approved abuse deterrent formulations of opioids have received Schedule III designation. In 2014, the DEA also rescheduled hydrocodone combination products into Schedule II from Schedule III. If our product candidates are ultimately listed as Schedule II controlled substances, then the importation of APIs for our product candidates, as well as the manufacture, shipping, storage, sales and use of the products, will be subject to a high degree of regulation. In addition to maintaining an importer and/or exporter registration, importers and exporters of controlled substances must obtain a permit for every import of a Schedule I or II substance and a narcotic substance in Schedule III, IV and V, as well as every export of a Schedule I or II substance and a narcotic substance in Schedule III and IV. For all other drugs in Schedule III, IV and V, importers and exporters must submit an import or export declaration. Schedule II drugs are subject to the strictest requirements for registration, security, recordkeeping and reporting. Also, distribution and dispensing of these drugs are highly regulated. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription. Electronic prescriptions may also be permissible depending on the state, so long as the prescription complies with the DEA's requirements for electronic prescriptions.

Controlled substances classified in Schedule III, IV, and V are also subject to registration, recordkeeping, reporting, and security requirements. For example, Schedule III drug prescriptions must be authorized by a physician and may not be refilled more than six months after the date of the original prescription or more than five times. A prescription for controlled substances classified in Schedules III, IV, and V issued by a physician, may be communicated either orally, in writing or by facsimile to the pharmacies. Controlled substances that are also classified as narcotics, such as hydrocodone, oxycodone and hydromorphone, are also subject to additional DEA requirements, such as manufacturer reporting of the import of narcotic raw material.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized. Similarly, separate registrations are also required for separate facilities. Acquisition and distribution transactions must also be reported for Schedule I and II controlled substances, as well as Schedule III narcotic substances.

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

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Distributions of any Schedule I or II controlled substance or Schedule III narcotic must also be accompanied by special order forms, with copies provided to the DEA. Because most of our product candidates may be regulated as Schedule II controlled substances, they may be subject to the DEA's production and procurement quota scheme. The DEA establishes annually an aggregate quota for how much of a controlled substance may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. The limited aggregate amount of opioids and stimulants that the DEA allows to be produced in the United States each year is allocated among individual companies, which must submit applications annually to the DEA for individual production and procurement quotas. We and our contract manufacturers must receive an annual quota from the DEA in order to produce or procure any Schedule I or Schedule II for use in manufacturing of our product candidates. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Our, or our contract manufacturers', quota of an active ingredient may not be sufficient to meet commercial demand or complete clinical trials. Any delay, limitation or refusal by the DEA in establishing our, or our contract manufacturers', quota for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position and results of operations. To enforce these requirements, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in administrative, civil or criminal enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate administrative proceedings to revoke those registrations. In some circumstances, violations could result in criminal proceedings.

Individual states also independently regulate controlled substances. We and our contract manufacturers will be subject to state regulation on distribution of these products, including, for example, state requirements for licensures or registration.

#### ***Other Healthcare Regulations***

Our business activities, including but not limited to, research, sales, promotion, distribution, medical education and other activities following product approval will be subject to regulation by numerous regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Department of Justice, the U.S. Department of Health and Human Services and its various divisions, including the CMS and the Health Resources and Services Administration, the Department of Veterans Affairs, the Department of Defense and state and local governments. Our business activities must comply with numerous healthcare laws, including those described below.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, the referral of an individual, or purchasing, leasing, ordering, or arranging for the purchase, lease or order of, any good, facility, item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Additionally, the ACA amended the intent requirement of the federal Anti-Kickback Statute, and some other healthcare criminal fraud statutes, so that a person or entity no longer needs to have actual knowledge of the Anti-Kickback Statute, or the specific intent to violate it, to

have violated the statute. The ACA also provided that a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the False Claims Act.

The federal civil and criminal false claims laws, including the federal False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government, including the Medicare and Medicaid programs, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government.

We, and our business activities, are subject to the civil monetary penalties statute which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

As a condition of Medicaid payment for prescription drugs, the Medicaid Drug Rebate statute requires manufacturers to calculate and report to CMS their Average Manufacturer Price, which is used to determine rebate payments shared between the states and the federal government and, for some multiple source drugs, Medicaid payment rates for the drug, and for drugs paid under Medicare Part B, to also calculate and report their average sales price, which is used to determine the Medicare Part B payment rate for the drug. Drugs that are approved under a biologics license application, or BLA, or an NDA, including a 505(b)(2) NDA, are subject to an additional requirement to calculate and report the manufacturer's best price for the drug and inflation penalties which can substantially increase rebate payments. For BLA and NDA drugs, the Veterans Health Care Act requires manufacturers to calculate and report to the Department of Veterans Affairs a different price called the Non-Federal Average Manufacturing Price, offer the drugs for sale on the Federal Supply Schedule, and charge the government no more than a statutory price referred to as the Federal Ceiling Price, which includes an inflation penalty. A separate law requires manufacturers to pay rebates on these drugs when paid by the Department of Defense under its TRICARE Retail Pharmacy Program. Knowingly submitting false pricing information to the government creates potential False Claims Act liability.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Additionally, the ACA amended the intent requirement of some of these criminal statutes under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation.

Additionally, the federal Open Payments program, created under Section 6002 of the ACA and its implementing regulations, require some manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with specified exceptions) to report information related to specified payments or other transfers of value provided to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually specified ownership and investment interests held by physicians and their immediate family members.

Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of \$150,000 per year and up to an aggregate of \$1.0 million per year for "knowing failures." Manufacturers must submit reports by the 90th day of each calendar year. CMS released the data for the first reporting period on a public website on September 30, 2014.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of



health information in some circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers.

Enforcement actions can be brought by federal or state governments or as “qui tam” actions brought by individual whistleblowers in the name of the government. Depending on the circumstances, failure to comply with these laws can result in penalties, including criminal, civil and/or administrative criminal penalties, damages, fines, disgorgement, debarment from government contracts, exclusion of products from reimbursement under government programs, refusal to allow us to enter into supply contracts, including government contracts, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our business.

### ***Healthcare Reform Measures***

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals designed to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, in March 2010, the ACA was passed. The ACA has substantially changed health care financing by both governmental and private insurers, and significantly affected the U.S. pharmaceutical industry. We expect that the ACA will continue to create significant changes in the healthcare industry. The ACA, among other things, subjected manufacturers to new annual fees and taxes for specified branded prescription drugs, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, expanded health care fraud and abuse laws, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, imposed an inflation penalty on new formulations of drugs, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, expanded the 340B program which caps the price at which manufacturers can sell covered outpatient pharmaceuticals to specified hospitals, clinics and community health centers, and provided incentives to programs that increase the federal government’s comparative effectiveness research. There have been judicial and congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. We continue to evaluate the effect that the ACA has on our business. Final regulations, guidance, amendments and judicial orders are anticipated in the future and we will continue to assess the ACA’s impact on us as final regulations, guidance, amendments and judicial orders are issued.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. In addition, in January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

### ***The Foreign Corrupt Practices Act***

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the companies to maintain books and records that accurately and fairly reflect all transactions of the companies, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

### ***Foreign Regulation***

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products to the extent we choose to develop or sell any products outside of the United States.

The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

### **Employees**

As of December 31, 2015, we employed 26 full-time employees. We have never had a work stoppage, and none of our employees is represented by a labor organization or under any collective bargaining arrangements. We consider our employee relations to be good.

### **Segments and Geographic Information**

We view our operations and manage our business as one operating segment. See our consolidated financial statements for a discussion of revenues, operating loss, net loss and total assets. All of our assets were held in the United States for the years ended December 31, 2015, 2014 and 2013.

### **Corporate Information**

We were incorporated under the laws of the State of Iowa in October 2006 and were reincorporated under the laws of the State of Delaware in May 2014. Our principal executive offices are located at 2656 Crosspark Road, Suite 100, Coralville, IA 52241 and our telephone number is (319) 665-2575. Our website address is [www.kempharm.com](http://www.kempharm.com). The information contained on our website is not incorporated by reference into this Annual Report on Form 10-K.

## **ITEM 1A. RISK FACTORS.**

You should carefully consider all of the risk factors and uncertainties described below, in addition to other information contained in this Annual Report on Form 10-K, including the section of this report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes, before investing in our common stock. If any of the following risks materialize, our business, financial condition and results of operations could be seriously harmed. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Annual Report on Form 10-K.

### **Risks Related to Our Financial Position and Capital Needs**

*We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.*

We have incurred losses since our inception and, as of December 31, 2015, had an accumulated deficit of \$104.8 million. Our net losses for the years ended December 31, 2015, 2014 and 2013, were \$54.7 million, \$24.5 million and \$5.2 million, respectively. We have financed our operations to date with \$23.1 million raised in private placements of redeemable convertible preferred stock, \$105.1 million in convertible promissory notes and term debt and \$59.9 million in aggregate net proceeds from our initial public offering.

We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials. We are still in the early stages of development of many of our product candidates, and we have not completed development of any of our product candidates. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue our ongoing preclinical studies, clinical trials and our product development activities for our pipeline of product candidates;
- seek regulatory approvals for KP201/APAP and for any other product candidates that successfully complete clinical trials;
- continue research and preclinical development and initiate clinical trials of our other product candidates;
- seek to discover and develop additional product candidates;

- potentially establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, manufacturing and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our prodrug development and planned future commercialization efforts; and
- incur additional legal, accounting and other expenses in operating as a public company.

To become and remain profitable, we must succeed in developing and eventually commercializing prodrugs that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials and obtaining regulatory approval of our product candidates, and manufacturing, marketing and selling any product candidates for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with prodrug development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress our value and could impair our ability to raise capital, expand our business, maintain our research and development efforts, obtain product approvals, diversify our product offerings or continue our operations. A decline in our value could also cause you to lose all or part of your investment.

***We will need substantial additional funding to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to delay, reduce or altogether cease our prodrug development programs or commercialization efforts.***

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next 21 months. However, we will need to obtain substantial additional funding in connection with our continuing operations. Our future capital requirements will depend on many factors, including:

- the progress and results of our preclinical studies, clinical trials and other product development and commercialization activities;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the ability to obtain abuse-deterrent claims in the labels for our product candidates, including KP201/APAP;
- the number and development requirements of other product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the efforts necessary to institute post-approval regulatory compliance requirements;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;

- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval, which may be affected by market conditions, including obtaining coverage and adequate reimbursement of our product candidates from third-party payors, including government programs and managed care organizations, and competition within the therapeutic class to which our product candidates are assigned;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the extent to which we acquire or in-license other product candidates and technologies.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval for our product candidates or claims necessary to make such candidates profitable, and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of prodrug products that we do not expect to be commercially available for at least 15 months, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, or exercise our right to borrow additional tranches under the Deerfield facility, the terms of these securities or this debt may restrict our ability to operate. The Deerfield facility includes, and any future debt financing and equity financing, if available, may involve agreements that include, covenants limiting and restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, entering into profit-sharing or other arrangements or declaring dividends. Additionally, in February 2016, we issued \$86.25 million aggregate principal amount of our 5.50% senior convertible notes due 2021, or the 2021 Notes. We are required to make periodic interest payments to the holders of the 2021 Notes and to make payments of principal upon maturity. In this regard, if holders of the 2021 Notes do not convert their 2021 Notes prior to the maturity date, we will be required to repay the principal amount of all then outstanding 2021 Notes plus any accrued and unpaid interest. We may also be required to repurchase the 2021 Notes for cash upon the occurrence of a change of control or certain other fundamental changes involving us. If our capital resources are insufficient to satisfy our debt service obligations, we will be required to seek to sell additional equity or debt securities or to obtain debt financing. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

***Our operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

We commenced active operations in 2006, and our operations to date have been largely focused on raising capital, identifying potential product candidates, broadening our expertise in the development of our prodrugs, undertaking preclinical studies and conducting clinical trials. We have not yet demonstrated an ability to obtain regulatory approvals, manufacture a prodrug on a commercial scale or arrange for a third party to do so, or conduct sales and marketing activities necessary for successful commercialization or enter into a collaboration for that purpose. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

### **Risks Related to the Development of Our Product Candidates**

***Our research and development is focused on discovering and developing proprietary prodrugs, and we are taking an innovative approach to discovering and developing prodrugs, which may never lead to marketable prodrug products.***

A key element of our strategy is to use our LAT platform technology to build a pipeline of prodrugs and progress product candidates based on these prodrugs through clinical development for the treatment of a variety of diseases and conditions. The scientific discoveries that form the basis for our efforts to discover and develop prodrugs are relatively new. The scientific evidence to

support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. Although our research and development efforts to date have resulted in a pipeline of prodrug product candidates, we may not be able to develop prodrugs that are bioequivalent, safe and effective and that have commercially significant improvements over already approved drugs. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects, a lack of efficacy, or other characteristics that indicate that they are unlikely to be prodrugs that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our LAT platform technology, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

***If we are not able to obtain required regulatory approvals for KP201/APAP or any of our other product candidates, we will not be able to commercialize them and our ability to generate revenue or profits or to raise future capital could be limited.***

In December 2015, we submitted to the FDA an NDA for KP201/APAP for an indication of the short-term management of acute pain. The FDA subsequently accepted this NDA for priority review in February 2016. The FDA has set a target action date under PDUFA of June 9, 2016. Despite this acceptance, we cannot guarantee that the FDA will ultimately approve KP201/APAP for commercial sale in the United States. For instance, the FDA has indicated that our NDA for KP201/APAP raises issues that will likely require advisory committee review. Accordingly, the FDA may not approve our NDA on a timely basis, or at all, and therefore we may never receive approval to market KP201/APAP in the United States.

The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country and change over time. We are not permitted to market KP201/APAP in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approvals in such countries. In the United States, the FDA generally requires the completion of nonclinical testing and clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality and other factors before an NDA is approved. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization.

Even if regulatory approval is obtained, subsequent safety, efficacy, quality or other issues can result in a product approval being suspended or withdrawn. Other than the submission of our NDA for KP201/APAP to the FDA, we have not yet submitted comparable applications to other regulatory authorities. If our development efforts for KP201/APAP, including regulatory approval, are not successful for its planned indications or are delayed, or if adequate demand for KP201/APAP is not generated, our business will be harmed.

The success of KP201/APAP will depend on the receipt and maintenance of regulatory approval and the issuance and maintenance of such approval is uncertain and subject to a number of risks, including the following:

- the FDA or comparable foreign regulatory authorities, institutional review boards, or IRBs, or ethics committees may disagree with the design or conduct of our clinical trials;
- the FDA may determine that our bridging analysis to Ultracet and Vicoprofen may not provide acceptable evidence of KP201/APAP's safety and efficacy;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or other regulatory agencies for marketing approval or for us to receive approval for claims that are necessary for commercialization;
- the dosing of KP201/APAP in a particular clinical trial may not be at an optimal level;
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to KP201/APAP;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies or may later suspend or withdraw such approval;

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and
- even if we obtain marketing approval in one or more countries, future safety or other issues could result in the suspension or withdrawal of regulatory approval in such countries.

In particular, we cannot guarantee that regulators will agree with our assessment of the results of the clinical trials we have conducted to date or that any future trials will be successful. For example, the FDA may not agree that the data from our completed clinical trials, our bridging analysis to Ultracet and Vicoprofen and other data and information in our NDA demonstrate sufficient efficacy or clinical benefit of KP201/APAP. We have no way of knowing whether the FDA will deem the data and literature review in our NDA sufficient to demonstrate KP201/APAP's safety and efficacy. The FDA and other regulators have substantial discretion in the approval process and may decide that our data are insufficient for approval and require additional clinical trials, or nonclinical or other studies.

We have only limited experience in filing the applications necessary to gain regulatory approvals and have relied, and expect to continue to rely, on consultants and third-party contract research organizations, or CROs, with expertise in this area to assist us in this process. Securing FDA approval requires the submission of extensive nonclinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA for each therapeutic indication to establish a product candidate's safety and efficacy for each indication and manufacturing quality. KP201/APAP or any future product candidates we may develop may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the product candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of the regulatory authorities. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application or may result in future withdrawal of approval. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction. Failure to obtain regulatory marketing approval of our product candidates in any indication will prevent us from commercializing those product candidates, and our ability to generate revenue will be impaired.

***Our NDA for KP201/APAP includes a Paragraph IV certification and, therefore, we have provided notice of this certification to the holders of certain patents and NDAs upon the FDA's acceptance of our NDA for review. This notice may result in a delay in the approval of our NDA by the FDA and potential patent infringement lawsuit by the patent or NDA holder.***

The NDA for KP201/APAP that was accepted for filing by the FDA in February 2016 included a Paragraph IV certification. A Paragraph IV certification is a certification to the FDA that any patents referenced in an NDA and that are listed for an approved drug in the Orange Book are invalid, unenforceable or will not be infringed by the manufacture, use or sale of our prodrug. This certification was required since the reference listed drug product, Vicoprofen, has two unexpired patents in the Orange Book. Because the FDA accepted our 505(b)(2) NDA for KP201/APAP for filing, we were required to notify the patent owner and NDA holder of our Paragraph IV certification and of the factual and legal bases therefore. We sent this notice on February 26, 2016. Upon receipt of such notice, the patent owner or NDA holder may file a patent infringement suit on one or both of the patents included in the Paragraph IV certification. If the patent owner or NDA holder does not bring suit within 45 days of receiving such notice, the FDA may issue final approval of our NDA once its approval requirements have been satisfied. If an infringement suit is brought by the patent owner or NDA holder within this 45-day period, the FDA may not approve our NDA until the earlier of the end of 30 months, the patents expiration or the patents involved are deemed invalid or not infringed, or such shorter or longer period as determined by a court. Approval of our 505(b)(2) NDA could therefore be delayed for a significant period of time if the owner of the Vicoprofen patent or NDA decides to initiate patent litigation. We will also be subject to a similar risk of a patent infringement action, and any related delay of FDA approval, if we file any future 505(b)(2) NDAs that contain a Paragraph IV certification.

***We are very early in our development efforts and have only two product candidates, KP201/APAP and KP201/IR (APAP-free), that have commenced clinical trials. All of our other product candidates are still in preclinical development. If we are unable to commercialize our product candidates, including KP201/APAP and KP201/IR (APAP-free), or experience significant delays in doing so, our business will be harmed.***

We are very early in our development efforts and have only two product candidates, KP201/APAP and KP201/IR (APAP-free), under clinical development. All of our other product candidates are still in preclinical development. We have not completed the

development of any product candidates, we generate no revenue from the sale of any prodrugs and we may never be able to develop a marketable prodrug product. We have invested substantially all of our efforts and financial resources in the development of our LAT platform technology, the identification of potential product candidates and the development of our product candidates. Our ability to generate revenue from our product candidates, which we do not expect will occur for at least 15 months, if ever, will depend heavily on their successful development and eventual commercialization. The success of our product candidates will depend on several factors, including:

- successful completion of preclinical studies and requisite clinical trials;
- successful completion and achievement of endpoints in our clinical trials;
- demonstration that the risks involved with our product candidates are outweighed by the benefits;
- successful development of our manufacturing processes for our product candidates, including entering into and maintaining arrangements with third-party manufacturers;
- successful completion of an FDA preapproval inspection of the facilities used to manufacture our product candidates, as well as select clinical trial sites;
- receipt of timely marketing approvals from applicable regulatory authorities, including the determination by the DEA, of the controlled substance schedule for a product candidate, taking into account the recommendation of the FDA;
- obtaining abuse-deterrent claims in the labels for our product candidates, including KP201/APAP;
- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for our product candidates and otherwise protecting our rights in our intellectual property portfolio;
- maintaining compliance with regulatory requirements, including cGMPs;
- launching commercial sales of product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our prodrug product candidates, if approved, by patients, the medical community and third-party payors;
- competing effectively with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement; and
- maintaining a continued acceptable safety and efficacy profile of the prodrug products following approval.

Whether regulatory approval will be granted is unpredictable and depends upon numerous factors, including the substantial discretion of the regulatory authorities. If, following submission, our NDA for a product candidate is not accepted for substantive review or approval, the FDA or other comparable foreign regulatory authorities may require that we conduct additional studies or clinical trials, provide additional data, take additional manufacturing steps or require other conditions before they will reconsider our application. If the FDA or other comparable foreign regulatory authorities require additional studies, clinical trials or data, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. In addition, the FDA or other comparable foreign regulatory authorities may not consider sufficient any additional required studies, clinical trials, data or information that we perform and complete or generate, or we may decide to abandon the program.

It is possible that none of our existing product candidates or any of our future product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would harm our business.

***Our ability to market and promote our products in the United States by describing their abuse-deterrent features will be determined by the FDA-approved labeling for them.***

The commercial success of KP201/APAP and most of our other product candidates will depend upon our ability to obtain FDA-approved labeling describing their abuse-deterrent features. Our failure to achieve FDA approval of product labeling containing such information will prevent our advertising and promotion of the abuse-deterrent features of our product candidates in order to differentiate them from other similar products. This would make our products less competitive in the market.

FDA approval is required in order to make claims that a product has an abuse-deterrent effect. In January 2013, the FDA published draft guidance with regard to the evaluation and labeling of abuse-deterrent opioids. This guidance was published in final form in April 2015. The FDA guidance provides direction as to the studies and data required for obtaining abuse-deterrent claims in a product label. The guidance describes four categories of label claims for abuse-deterrent products. Depending on product and study data, a combination of categories can be included in the label claims. The FDA guidance lists the following theoretical examples:

- Category 1—in vitro data demonstrate the product has physical and chemical properties that are expected to deter intravenous abuse. However, abuse is still possible by the oral and nasal routes.
- Category 1 and 2—in vitro data demonstrate that the product has physical and chemical properties that are expected to deter oral, nasal and intravenous abuse. However, abuse of intact product is still possible by the oral route.
- Category 2 and 3—pharmacokinetic and clinical abuse potential studies indicate that the product has properties that are expected to deter abuse via the oral, intranasal and intravenous routes. However, abuse of product by these routes is still possible.
- Category 4—data demonstrated a reduction in the abuse of the product in the community setting compared to the levels of abuse, overdose, and death that occurred when only formulations of the same opioid without abuse-deterrent properties were available. This reduction in abuse appears to be attributable to the product's formulation, which deters abuse by injection or snorting of the manipulated product. However, such abuse of this product is still possible, and the product's abuse deterrence properties do not deter abuse associated with swallowing the intact formulation.

If a product is approved by the FDA to include such claims in its label, the applicant may use information about the abuse-deterrent features of the product in its marketing efforts to physicians.

Although we conducted trials intended to support approval by the FDA of Category 1, 2 and potentially 3 labeling claims for KP201/APAP, there can be no assurance that KP201/APAP or any of our other product candidates will receive FDA-approved labeling that describes the abuse-deterrent features of such products. The FDA may find that our trials do not support abuse-deterrent labeling or that our product candidates do not provide substantial abuse deterrence because, for example, their deterrence mechanisms do not address the way they are most likely to be abused. For instance, during our May 2015 pre-NDA meeting, the FDA had questions about the relevance of the intranasal route of administration based on the agency's experience. The agency stated that it would likely address this issue in a future advisory committee meeting. The agency also observed that while there is epidemiological evidence that hydrocodone/APAP products are abused via intranasal and intravenous routes of administration, the most common abuse route of administration is oral. The agency further expressed concern that, if injected, KP201/APAP may precipitate in the blood posing a safety concern and requested that we characterize the solubility of the drug in the blood. The results of our KP201.T02 study, which was designed to evaluate the properties of KP201 that could reduce the likelihood of intravenous abuse of KP201/APAP, indicated that preparation of KP201/APAP for intravenous use resulted in a cloudy substance with excipient particles, which may have been APAP. Upon review of our NDA, the FDA will weigh a number of factors, including the most common route of abuse, information showing that hydrocodone/APAP is abused via the nasal and intravenous routes, information suggesting a risk for harm by intravenous abuse as compared to existing products, and results of testing concerning abuse deterrent characteristics.

As with all claims, we will be required to provide adequate substantiation. For example, we will need to demonstrate that KP201/APAP has abuse-deterrent properties sufficient to achieve Category 1, 2 and potentially 3 abuse-deterrent labeling.

Further, the FDA is not required to follow its guidance and could change this guidance, which could require us to conduct additional trials. If the FDA does not approve abuse-deterrent labeling, we will not be able to promote such products based on their abuse-deterrent features and may not be able to differentiate such products from other similar products.

Even if we do receive FDA approval for abuse-deterrent claims, the claims may not be broad enough to demonstrate a substantial benefit to health care providers and patients. For instance, the claims may not encompass the more common forms of abuse for products like our product candidates. Moreover, continued investigation in Phase 4 studies following product approval may not support the continued use of abuse-deterrent claims. We have proposed certain post-marketing studies and observations to the FDA in our NDA for KP201/APAP.



***If the FDA does not conclude that our product candidates are sufficiently bioequivalent, or have comparable bioavailability, to approved drugs, or if the FDA does not allow us to pursue the 505(b)(2) NDA pathway as anticipated, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and the FDA may not ultimately approve our product candidates.***

A key element of our strategy is to seek FDA approval for most of our product candidates, including KP201/APAP, through the 505(b)(2) NDA pathway. 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. 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 505(b)(2) NDA pathway as anticipated, 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. Moreover, even if the FDA does allow us to pursue the 505(b)(2) NDA pathway, depending on the product candidate, we may still need to conduct additional clinical trials, including clinical trials to assess product safety or efficacy. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates, and complications and risks associated with our product candidates, would likely substantially increase.

Moreover, our inability to pursue the 505(b)(2) NDA pathway could result in new competitive products reaching the market more quickly than our product candidates, which could hurt our competitive position and our business prospects. Even if we are allowed to pursue the 505(b)(2) NDA pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization on a timely basis, if at all. Other companies may achieve product approval of similar products before we do, which would delay our ability to obtain product approval, expose us to greater competition, and would require that we seek approval via alternative pathways, such as an ANDA, which is used for the development of generic drug products.

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

Even if our product candidates are approved under 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed, including more limited subject populations than we request, may require that contraindications, warnings or precautions be included in the product labeling, including a black box warning, may be subject to other conditions of approval, or may contain requirements for costly post-marketing clinical trials, testing and surveillance to monitor the safety or efficacy of the products, or other post-market requirements, such as a REMS. The FDA also may not approve a product candidate with a label that includes the labeling claims necessary or desirable for the successful commercialization of that product candidate. Based upon currently approved products, we anticipate that we will be required to conduct Phase 4 studies and to implement a REMS and will have a black box warning for at least some of our product candidates.

***The FDA may determine that any NDA we may submit under the 505(b)(2) regulatory pathway for any of our product candidates in the future is not sufficiently complete to permit a substantive review.***

If we were to file an NDA under the 505(b)(2) regulatory for any of our product candidates, within 60 days of the agency's receipt of our NDA, the FDA will make a threshold determination of whether the NDA is sufficiently complete to permit a substantive review. This 60-day review period is referred to as the filing review. If the NDA is sufficiently complete, the FDA will file the NDA. If the agency refuses to file the NDA, it will notify us and state the reason(s) for the refusal. The FDA may refuse to file our NDA for various reasons, including but not limited to, if:

- the NDA is incomplete because it does not on its face contain the information required under the FDCA or the FDA's regulations;
- the NDA does not contain a statement that each nonclinical laboratory study was conducted in compliance with the GLP requirements, or for each study not so conducted, a brief statement of the reason for the noncompliance;
- the NDA does not contain a statement that each clinical trial was conducted in compliance with the IRB regulations or was not subject to those regulations, and the agency's informed consent regulations or a brief statement of the reason for noncompliance; or

- the drug is a duplicate of a listed drug approved before receipt of the NDA and is eligible for approval under an ANDA for generic drugs.

In its procedures, the FDA has stated that it could find an NDA submitted under the Section 505(b)(2) regulatory pathway incomplete and refuse to file it if the NDA, among other reasons:

- fails to include appropriate literature or a listed drug citation to support the safety or efficacy of the drug product;
- fails to include data necessary to support any aspects of the proposed drug that represent modifications to the listed drug(s) relied upon;
- fails to provide a bridge, for example by providing comparative bioavailability data, between the proposed drug product and the listed drug product to demonstrate that such reliance is scientifically justified;
- uses an unapproved drug as a reference product for the bioequivalence study; or
- fails to provide a patent certification or statement as required by the FDA's regulations where the 505(b)(2) NDA relies on one or more listed drugs.

Additionally, the FDA will refuse to file an NDA if an approved drug with the same active moiety is entitled to five years of exclusivity, unless the exclusivity period has elapsed or unless four years of the five-year period have elapsed and the NDA contains a certification of patent invalidity or non-infringement. An active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bond) or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the therapeutic activity of the drug substance.

If the FDA refuses to file an NDA submitted by us, we may amend the NDA and resubmit it. In such a case, the FDA will again review the NDA and determine whether it may be filed. There can be no assurance that the FDA will file any NDA submitted by us in the future. If the agency refuses to file an NDA, we will need to address the deficiencies cited by the FDA, which could substantially delay the review process.

***Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.***

The risk of failure for our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Interpretation of results from early, usually smaller, studies that suggest positive trends in some subjects, requires caution. Results from later stages of clinical trials enrolling more subjects may fail to show the desired safety and efficacy results or otherwise fail to be consistent with the results of earlier trials of the same product candidates. Later clinical trial results may not replicate earlier clinical trials for a variety of reasons, including differences in trial design, different trial endpoints, or lack of trial endpoints in exploratory studies, subject population, number of subjects, subject selection criteria, trial duration, drug dosage and formulation and lack of statistical power in the earlier studies. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site or amend clinical trial protocols as needed;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and CROs;

- clinical trials of our product candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance in cases where that is required, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon prodrug development programs;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or trial protocols, or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate, including if we are not able to pursue the 505(b)(2) NDA pathway for approval of our product candidates;
- we will need to pay substantial application user fees, which we may not be able to afford;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- we may abandon our development program or programs based on the changing regulatory or commercial environment;
- regulatory authorities may not agree with our trial design or implementation; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval but without the claims necessary for us to successfully commercialize our product candidates;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing, surveillance, or other requirements, such as REMS; or
- have the product removed from the market after obtaining marketing approval.

Our prodrug development costs may also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates.

***Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.***

As product candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, various aspects of the development program, such as manufacturing methods and formulation, may be altered

along the way in an effort to optimize processes and results. Such changes may not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence product sales and generate revenue.

***We anticipate that most of our product candidates, if approved by the FDA, may be subject to mandatory REMS programs, which could increase the cost, burden and liability associated with the commercialization of these product candidates.***

The FDA has indicated that some opioid drugs formulated with the active ingredients hydrocodone, fentanyl, hydromorphone, methadone, morphine, oxycodone, oxymorphone and others will be required to have a REMS to ensure that the benefits of the drugs continue to outweigh the risks. The FDA has already approved a REMS for ER and long-acting opioids as part of a federal initiative to address inappropriate prescribing and prescription drug abuse and misuse, which the FDA continually updates. The REMS introduces new safety measures designed to reduce risks and improve the safe use of ER and long-acting opioids, while ensuring access to needed medications for patients in pain. The ER and long-acting opioid REMS affects more than 25 companies that manufacture these opioid analgesics. Under the new REMS, companies are required to make education programs available to prescribers. It is expected that companies will meet this obligation by taking specific steps to ensure that health care providers are aware of the availability of the training and by providing educational grants to continuing education providers, who will develop and deliver the training. The REMS also requires companies to make available FDA-approved patient education materials on the safe use of these drugs. The companies must perform periodic assessments of the implementation of the REMS and the success of the program in meeting its goals. The FDA will review these assessments and may require additional elements to achieve the goals of the program. Independent audits must also be conducted of the educational efforts.

We anticipate that most of our product candidates, including KP201/APAP, if approved by the FDA, may be subject to a 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 a REMS requirement, which could increase the costs to us and reduce the commercial benefits to us from the sale of these product candidates.

***Our product candidates contain controlled substances, the manufacture, use, sale, importation, exportation, prescribing and distribution of which are subject to regulation by the DEA.***

Before we can commercialize our product candidates, the DEA will need to determine the controlled substance schedule, taking into account the recommendation of the FDA. This may be a lengthy process that could delay our marketing of a product candidate and could potentially diminish any regulatory exclusivity periods for which we may be eligible. Most of our product candidates, including KP201/APAP, KP201/IR (APAP-free), KP511/ER, KP415, KP606/IR and KP746, if approved, will be regulated as “controlled substances” as defined in the CSA and the implementing regulations of the DEA, which establish registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA. These requirements are applicable to us, to our contract manufacturers and to distributors, prescribers and dispensers of our product candidates. The DEA regulates the handling of controlled substances through a closed chain of distribution. This control extends to the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce. A number of states and foreign countries also independently regulate these drugs as controlled substances.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Schedule II drugs are those that meet the following characteristics:

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

We expect that most of our product candidates may be listed by the DEA as Schedule II controlled substances under the CSA. Consequently, the manufacturing, shipping, storing, selling and using of the products will be subject to a high degree of regulation. However, we have requested in our NDA that KP201/APAP be listed as a Schedule III controlled substance based on its differential abuse potential when compared to other Schedule II controlled substances, such as IR hydrocodone combination products. None of the

previously approved abuse deterrent formulations of opioids have received Schedule III designation. In 2014, the DEA rescheduled hydrocodone combination products into Schedule II from Schedule III. If our product candidates are ultimately listed as Schedule II controlled substances, then the importation of the APIs for our product candidates, as well as the manufacture, shipping, storage, sales and use of the products, will be subject to a high degree of regulation. In addition to maintaining an importer and/or exporter registration, importers and exporters of controlled substances must obtain a permit for every import of a Schedule I or II substance and a narcotic substance in Schedule III, IV and V, as well as every export of a Schedule I or II substance and a narcotic substance in Schedule III and IV. For all other drugs in Schedule III, IV and V, importers and exporters must submit an import or export declaration. Schedule II drugs are subject to the strictest requirements for registration, security, recordkeeping and reporting. Also, distribution and dispensing of these drugs are highly regulated. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription. Electronic prescriptions may also be permissible depending on the state, so long as the prescription complies with the DEA's requirements for electronic prescriptions.

Controlled substances classified in Schedule III, IV, and V are also subject to registration, recordkeeping, reporting and security requirements. For example, Schedule III drug prescriptions must be authorized by a physician and may not be refilled more than six months after the date of the original prescription or more than five times. A prescription for controlled substances classified in Schedules III, IV and V issued by a physician, may be communicated either orally, in writing or by facsimile to the pharmacies. Controlled substances that are also classified as narcotics, such as hydrocodone, oxycodone and hydromorphone, are also subject to additional DEA requirements, such as manufacturer reporting of the import of narcotic raw material.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized. Similarly, separate registrations are also required for separate facilities. Acquisition and distribution transactions must also be reported for Schedule I and II controlled substances, as well as Schedule III narcotic substances.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Because most of our product candidates may be regulated as Schedule II controlled substances, they may be subject to the DEA's production and procurement quota scheme. The DEA establishes annually an aggregate quota for how much of a controlled substance may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. Manufacturers of Schedule I and II controlled substances are required to apply for quotas on an annual basis. If we or our contract manufacturers or suppliers do not obtain a sufficient quota from DEA, 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.

Because of their restrictive nature, these laws and regulations could limit commercialization of our product candidates containing controlled substances. States may also have their own controlled substance laws that may further restrict and regulate controlled substances. Failure to comply with these laws and regulations could also result in withdrawal of our DEA registrations, disruption in manufacturing and distribution activities, consent decrees, criminal and civil penalties and state actions, among other consequences.

***If we experience delays or difficulties in the enrollment of subjects in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.***

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible subjects to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. We cannot predict how successful we will be at enrolling subjects in future clinical trials. If we are not successful at enrolling subjects in one clinical trial, it may effect when we are able to initiate our next clinical trial, which could result in significant delays in our efforts to pursue regulatory approval of and commercialize our product candidates. In addition, some of our competitors have ongoing clinical trials to treat the same indications as our product candidates, and subjects who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors. Subject enrollment is affected by other factors including:

- the size and nature of the subject population specified in the trial protocol;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the fact that the product candidate is a controlled substance;
- severe or unexpected drug-related adverse events experienced by subjects in a clinical trial;

- the availability of drugs approved to treat the diseases or conditions under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the severity of the disease or condition under investigation;
- the ability to obtain and maintain subject informed consent;
- the ability to retain subjects in the clinical trial and their return for follow-up;
- the clinical trial design, including required tests, procedures and follow-up;
- the ability to monitor subjects adequately during and after treatment;
- delays in adding new investigators and clinical sites;
- withdrawal of clinical trial sites from clinical trials; and
- the proximity and availability of clinical trial sites for prospective subjects.

Our inability to enroll a sufficient number of subjects for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which could cause our value to decline and limit our ability to obtain additional financing.

***Our clinical trials may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates.***

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety and efficacy of the product candidate studied for the target indication.

If our product candidates are associated with side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The FDA or an institutional review board may also require that we suspend, discontinue, or limit our clinical trials based on safety information. Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates. Many product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the product candidate.

Clinical trials of our most advanced product candidate KP201/APAP have thus far found adverse events, such as dizziness, euphoria, drug withdrawal syndrome and nausea and other adverse events consistent with other opioid products.

***We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and management resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product

candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

***Social issues around the abuse of opioids and stimulants, including law enforcement concerns over diversion 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, stimulants and other controlled substances are commonplace. Law enforcement and regulatory agencies may apply policies that seek to limit the availability of opioids and stimulants. Such efforts may inhibit our ability to commercialize our product candidates. Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of hydrocodone or other opioid drugs, the limitations of abuse-deterrent formulations, public inquiries and investigations into prescription drug abuse, litigation or regulatory activity, sales, marketing, distribution or storage of our products could harm our reputation. Such negative publicity could reduce the potential size of the market for our product candidates and decrease the revenue we are able to generate from their sale, if approved. Similarly, to the extent prescription drug abuse becomes a less prevalent or less urgent public health issue, regulators and third-party payors may not be willing to pay a premium for abuse-deterrent formulations of opioids or stimulants.

Additionally, efforts by the FDA and other regulatory bodies to combat abuse of opioids and stimulants may negatively impact the market for our product candidates. For example, in April 2014, the FDA approved class-wide labeling changes to the indications for use of all approved ER and long-acting opioids so that ER and 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. 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. The FDA also held a public meeting in October 2014, on the development and regulation of abuse-deterrent formulations of opioid medications. Further, the Centers for Disease Control and Prevention recently issued draft guidelines for the prescribing of opioids for chronic pain, providing recommendations for primary care providers prescribing opioids for chronic pain on when to initiate or continue opioids, opioid selection and discontinuation, and the assessment of the risk and addressing harms of opioid use, among other areas. It is possible that FDA, or other regulatory bodies, will announce new regulatory initiatives at any time that may increase the regulatory burden or decrease the commercial opportunity for our product candidates.

***We are party to non-competition restrictions that may prevent us from investigating, developing or commercializing specified amphetamine-based product candidates.***

On March 21, 2012, we entered into an asset purchase agreement with Shire, pursuant to which we sold assets and intellectual property to Shire. As partial consideration for this sale, we and our chief executive officer, Travis C. Mickle, Ph.D., agreed not to compete with Shire in the development, commercialization, production or distribution of amphetamine amino acid conjugate products until March 21, 2017. As a result, we have not engaged in any development efforts for such product candidates and will not engage in any such development efforts until the expiration of this non-competition provision, if at all. Prior to such time, our competitors may make substantial development progress regarding similar product candidates and even obtain FDA or other regulatory approval for similar product candidates. This could result in our competitors establishing a strong market position before we are able to enter the market or begin our development process, which may prevent us from entering such market altogether.

#### **Risks Related to Our Dependence on Third Parties**

***We rely on and expect to continue to rely on third parties to conduct our clinical trials for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.***

We have engaged and expect to continue to engage CROs for our planned clinical trials of our product candidates. We rely on and expect to continue to rely on CROs, as well as other third parties, such as clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. Agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our drug development activities would be delayed.

Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, investigators and trial sites. We also are required to register specified ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. In

addition, we must conduct our clinical trials with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process. Failure to comply with the applicable requirements related to clinical investigations by us, our CROs or clinical trial sites can also result in clinical holds and termination of clinical trials, debarment, FDA refusal to approve applications based on the clinical data, warning letters, withdrawal of marketing approval if the product has already been approved, fines and other monetary penalties, delays, adverse publicity and civil and criminal sanctions, among other consequences.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

In addition, investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any NDA we submit by the FDA. Any such delay or rejection could prevent us from commercializing our product candidates. Further, our arrangements with investigators are also subject to scrutiny under other health care regulatory laws, such as the federal Anti-Kickback Statute.

We also rely on and expect to continue to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

If the third parties with whom we contract do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, we may need to conduct additional trials, 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 and our ability to generate revenue could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be adversely affected.

***We contract with a third party for the manufacture of KP201/APAP used in our clinical trials and with a sole source supplier for the manufacture of bulk quantities of KP201 used in KP201/APAP and we expect to continue to do so. This reliance on third-party manufacturers increases the risk that we will not have sufficient quantities of KP201 or KP201/APAP or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.***

We do not have any manufacturing facilities or personnel. We procure KP201 bulk drug substance from a sole source, third-party manufacturer and the KP201/APAP used in our clinical trials from another third party. We anticipate we will continue to do so for the foreseeable future. We also expect to continue to rely on third parties as we proceed with preclinical and clinical testing of our other product candidates, as well as for commercial manufacture if any of our product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of KP201, other bulk drug substances or our product candidates, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our ability to timely conduct our clinical trials or our other development or commercialization efforts.

We may be unable to establish any future agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to maintain our existing third-party relationships or establish any such agreements with other third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for FDA and DEA regulatory compliance and quality assurance;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- disruption and costs associated with changing suppliers, including additional regulatory filings;
- the possible breach, termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;



- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our product candidates in a timely fashion, in sufficient quantities or under acceptable terms; and
- carrier disruptions or increased costs that are beyond our control.

Any of these events could lead to clinical trial delays, failure to obtain regulatory approval or impact our ability to successfully commercialize our products. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production.

***The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our marketing application to the FDA, and these facilities could fail to obtain FDA approval.***

While we are ultimately responsible for the manufacture of our product candidates, we do not, other than through our contractual arrangements, control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we will not be able to secure and maintain regulatory approval for their manufacturing facilities. In addition, other than through our contractual agreements, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved.

Further, if our product candidates are approved, our suppliers will be subject to regulatory requirements, covering manufacturing, testing, quality control and record keeping relating to our product candidates, and subject to ongoing inspections by the regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions to our manufacturing capacity while we seek to secure another supplier that meets all regulatory requirements, as well as market disruption related to any necessary recalls or other corrective actions.

Third-party manufacturers may not be able to comply with current cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including warning letters, clinical holds or termination of clinical trials, fines, injunctions, restitution, disgorgement, civil penalties, delays, suspension or withdrawal of approvals or other permits, FDA refusal to approve pending applications, product detentions, FDA or DEA consent decrees placing significant restrictions on or suspending manufacturing and distribution operations, debarment, refusal to allow import or export, product detentions, adverse publicity, dear-health-care-provider letters or other warnings, license revocation, seizures or recalls of product candidates, operating restrictions, refusal of government contracts or future orders under existing contracts and civil and criminal liability, including False Claims Act liability, exclusion from participation in federal health care programs, and corporate integrity agreements among other consequences, any of which could significantly and adversely affect supplies of our prodrugs.

***Our product candidates and any prodrugs that we may develop may compete with other product candidates and drugs for access to manufacturing facilities, and we may be unable to obtain access to these facilities on favorable terms.***

There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for KP201 bulk drug substance. If

our current contract manufacturer for KP201 bulk drug substance cannot perform as agreed, we may be required to replace such manufacturer and we may incur added costs and delays in identifying and qualifying any such replacement.

***We may seek collaborations with third parties for the development or 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 seek third-party collaborators for the development and commercialization of our product candidates, including for the commercialization of any of our product candidates that are approved for marketing outside the United States. Our likely collaborators include large and mid-size pharmaceutical companies, regional, national and international pharmaceutical companies and biotechnology companies. If we do enter into any collaboration arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create 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 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;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise 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 present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

***If we are not able to establish collaborations, we may have to alter our development and commercialization plans.***

Our prodrug development programs and the potential commercialization of our product candidates will require substantial additional capital. For some of our product candidates, we may need to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally.

The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of product candidates, reduce or delay one or more of our development programs, delay potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

***Provisions in our agreements with Shire and MonoSol may inhibit our ability to enter into future collaborations with third parties.***

Under our asset purchase agreement with Shire, we granted Shire a right of first refusal to acquire, license or commercialize KP415. The right of first refusal may be exercised by Shire for a period of 30 business days following Shire's receipt of written notice from us of the existence of a bona fide offer from a third party to acquire, license or commercialize KP415.

We are also party to a termination agreement with MonoSol that may limit the value of any sale, license or commercialization of KP415. Under this termination agreement, MonoSol has the right to receive an amount equal to a percentage in the low teens of any value generated by KP415, and any product candidates arising therefrom, including royalty payments on any license of KP415, the sale of KP415 to a third party or the commercialization of KP415.

***Provisions in our facility agreement with Deerfield Private Design Fund III, L.P. may inhibit our ability to enter into specified transactions, including any joint venture, partnership or any other profit sharing arrangement.***

Pursuant to our credit facility agreement with Deerfield Private Design Fund III, L.P., or Deerfield, dated June 2, 2014, or the Deerfield facility, we may not enter into specified transactions, including any joint venture, partnership or any other profit sharing arrangement, without the prior approval of Deerfield. Deerfield's interests may not always coincide with our corporate interests or the interests of our other stockholders, and Deerfield may act in a manner with which you may not agree or that may not be in the best interests of our other stockholders. If Deerfield does not approve our entry into specified transactions, it could significantly delay or inhibit the commercialization of our product candidates.

## **Risks Related to Our Intellectual Property**

***If we are unable to obtain and maintain trade secret protection or patent protection for our technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.***

Our success depends in large part on our ability to obtain and maintain trade secret protection of our LAT platform technology as well as patent protection in the United States and other countries with respect to our product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product technology and product candidates.

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 our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents, licensed to third parties by us.

Further, we may also not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents, licensed from third parties to us. Therefore, any such patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If such licensors or licensees fail to maintain such patents, or lose rights to those patents, the rights we have in- or out-licensed may be reduced or eliminated.

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. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States or visa-versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and utility, or equivalent, patent applications in the United States and other jurisdictions are typically not published until 18 months after the filing date of such patent applications, or in some cases not at all. Therefore, we cannot know with certainty whether 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 are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and drugs. 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.

Our patent position is subject to numerous additional risks, including the following:

- we may fail to seek patent protection for inventions that are important to our success;
- our pending patent applications may not result in issued patents;
- we cannot be certain that we are the first to invent the inventions covered by pending patent applications or that we are the first to file such applications and, if we are not, we may be subject to priority disputes or lose rights;
- we may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications;
- we may file patent applications but have claims restricted or we may not be able to supply sufficient data to support our claims and, as a result, may not obtain the original claims desired or we may receive restricted claims; alternatively, it is possible that we may not receive any patent protection from an application;
- even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, and may not be of sufficient scope or strength to provide us with any commercial advantage;
- our competitors may be able to design around our owned or licensed patents by developing similar or alternative technologies or drugs without infringing on our intellectual property rights;
- we could inadvertently abandon a patent or patent application, resulting in the loss of protection of intellectual property rights in a particular country, and we, our collaborators or our patent counsel may take action resulting in a patent or patent application becoming abandoned which may not be able to be reinstated or if reinstated, may suffer patent term adjustments;
- the claims of our issued patents or patent applications when issued may not cover our product candidates;

- no assurance can be given that our patents would be declared by a court to be valid or enforceable or that a competitor's technology or product would be found by a court to infringe our patents and our patents or patent applications may be challenged by third parties in patent litigation or in proceedings before the USPTO or its foreign counterparts, and may ultimately be declared invalid or unenforceable or narrowed in scope;
- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim and there may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim;
- third parties may develop products that have the same or similar effect as our products without infringing our patents;
- third parties may intentionally circumvent our patents by means of alternate designs or processes or file applications or be granted patents that would block or hurt our efforts;
- there may be dominating patents relevant to our product candidates of which we are not aware;
- obtaining regulatory approval for pharmaceutical products is a lengthy and complex process, and as a result, any patents covering our product candidates may expire before or shortly after such product candidates are approved and commercialized;
- the patent and patent enforcement laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions; and
- we may not develop additional proprietary technologies that are patentable.

Any of these factors could hurt our ability to gain full patent protection for our products. Registered trademarks and trademark applications in the United States and other countries are subject to similar risks as described above for patents and patent applications, in addition to the risks described below.

Further, a third party may misappropriate or reverse engineer our LAT platform technology, which could limit our ability to stop others from using or commercializing similar or identical technology and resultant product candidates, product technology or prodrugs, or limit the duration of the trade secret protection of our LAT platform technology.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, nullity, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drugs and compete directly with us, without payment to us or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to seek patent protection or to license, develop or commercialize current or future product candidates.

In addition, the issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts, patent offices and tribunals in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, or limit the duration of the patent protection of our product technology, product candidates and prodrugs.

***Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.***

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted in the United States, redefine prior art and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first-to-file provisions, only became effective on March 16, 2013.

Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, 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. For instance, the Leahy-Smith Act established the inter partes review and post grant review procedures that has lowered the burden of proof for invalidity challenges to issued patents and limited the ability to amend patent claims in response to such challenges. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our owned and licensed patents and/or patent applications.

***We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke those parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology or its prior use by a third party. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which would undermine our competitive position.

***Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm business.***

Our commercial success depends upon our ability, and the ability of any collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. In particular, we are focused on developing product candidates based on widely used therapeutic agents or drugs, many of which may be protected by proprietary rights of third parties.

Although we seek to develop proprietary prodrug formulations that do not infringe the intellectual property rights of others, we may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our prodrugs or other aspects of our technology, including, for example, interference or derivation proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

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 and marketing our technology and drugs. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could 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, 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 or all of our business operations.

Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit alleging our infringement of a competitor's patent, we could be prevented from marketing our products in one or more foreign countries. As a result, our ability to grow our business and compete in the market may be harmed.

***Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.***

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities.

In addition, there could 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 hurt the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

***We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.***

A third party may hold intellectual property rights, including patent rights, which are important or necessary to the development of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed.

***We may be required to reduce the scope of our intellectual property due to third-party intellectual property claims.***

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours that claims priority to an application filed prior to March 16, 2013, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions. In addition, changes enacted on March 16, 2013 to the U.S. patent laws under the Leahy-Smith Act resulted in the United States changing from a “first to invent” country to a “first to file” country. As a result, we may lose the ability to obtain a patent if a third party files with the USPTO first and could become involved in proceedings before the USPTO to resolve disputes related to inventorship. We may also become involved in similar proceedings in other jurisdictions.

Furthermore, recent changes in U.S. patent law under the Leahy-Smith Act allows for post-issuance challenges to U.S. patents, including *ex parte* re-examinations, *inter partes* reviews and post-grant reviews. There is significant uncertainty as to how the new laws will be applied. If our U.S. patents are challenged using such procedures, we may not prevail, possibly resulting in altered or diminished claim scope or loss of patent rights altogether. Similarly, some countries, notably Europe, also have post-grant opposition proceedings that can result in changes in scope or cancellation of patent claims.

***We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.***

Many of our employees were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees do not use the proprietary information, show-how or know-how of others in their work for us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee’s former employer. For example, in March 2012, we settled litigation regarding similar matters with Shire. We may also in the future be subject to claims that we have caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these potential claims.

In addition, 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 such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, 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. A court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and could be a distraction to management. In addition, any litigation or threat thereof may adversely affect our ability to hire employees or contract with independent service providers. Moreover, a loss of key personnel or their work product could hamper or prevent our ability to commercialize our products.

***Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.***

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet solicited trademarks for our product candidates and have not yet begun the process

of applying to register trademarks for our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

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

In addition to seeking patent and trademark protection for our product candidates, we also rely on trade secrets, including unpatented show-how, know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our 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. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets.

Monitoring unauthorized uses and disclosures of our intellectual property, including our trade secrets, is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any 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 inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, our competitors may independently develop or reverse engineer knowledge, methods, show-how and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate such trade secrets, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

***Outside of the U.S. we cannot be certain that any country's patent or trademark office will not implement new rules that could seriously affect how we draft, file, prosecute and maintain patents, trademarks and patent and trademark applications.***

We cannot be certain that the patent or trademark offices of countries outside the United States will not implement new rules that increase costs for drafting, filing, prosecuting and maintaining patents, trademarks and patent and trademark applications or that any such new rules will not restrict our ability to file for patent protection. For example, we may elect not to seek patent protection in some jurisdictions or for some inventions in order to save costs. We may be forced to abandon or return the rights to specific patents due to a lack of financial resources.

#### **Risks Related to the Commercialization of Our Product Candidates**

***If we are unable to establish sales, marketing and distribution capabilities for our product candidates, we may not be successful in commercializing those product candidates in the United States, if and when they are approved.***

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product candidate for which we may obtain marketing approval in the United States, we will need to enter into collaborations with one or more parties or establish our own sales and marketing organization. We have not yet determined our commercialization strategy for KP201/APAP or any of our other product candidates. Should we decide to establish our own sales, marketing and distribution capabilities, we would encounter a number of risks. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.



Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- our inability to access government and commercial health plan formularies or secure preferred coverage and reimbursement levels;
- the inability of sales personnel to obtain access to physicians or achieve adequate numbers of physicians to prescribe any future prodrug products;
- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- liability for personnel, including sales personnel, failing to comply with applicable legal requirements; and
- costs associated with maintaining compliance with the FDA's marketing and promotional requirements, including ongoing training and monitoring, as well as unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we decide not to or are unable to establish our own sales, marketing and distribution capabilities and, instead, enter into arrangements with third parties to perform these services, our product revenue and our profitability, if any, are likely to be lower than if we were to sell, market and distribute any product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us, including as a result of restrictions in the Deerfield facility. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. Further, we may be liable for conduct of third parties acting on our behalf, including failure to comply with legal requirements applicable to sales and marketing of our products. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

***Even if any of our product candidates receives marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.***

If any of our product candidates receives marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of market acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments, including less expensive generic treatments;
- the ability to obtain abuse-deterrent claims in the labels for KP201/APAP and most of our other product candidates;
- our ability to offer our prodrug products for sale at competitive prices;
- the clinical indications for which our product candidates are approved;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the cost of treatment in relation to alternative treatments;
- the steps that prescribers and dispensers must take, since most of our product candidates are controlled substances, as well as the perceived risks based upon their controlled substance status;
- the ability to manufacture our product in sufficient quantities and yields;
- the strength of marketing and distribution support;

- the availability of third-party coverage and adequate reimbursement or willingness of patients to pay out of pocket in the absence of third-party coverage;
- the prevalence and severity of any side effects;
- any potential unfavorable publicity;
- any restrictions on the use, sale or distribution of our product candidates, including through REMS; and
- any restrictions on the use of our prodrug products together with other medications.

***We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.***

Our industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We will face competition and potential competition from a number of sources, including pharmaceutical and biotechnology companies, specialty pharmaceutical companies, generic drug companies, drug delivery companies and academic and research institutions. Our competitors may develop or market drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

If approved, our abuse-deterrent opioid product candidates will face competition from commercially available branded and generic opioid drugs including hydrocodone, hydromorphone and oxycodone, fentanyl, morphine, oxymorphone and methadone, as well as other marketed non-opioid products for the treatment of pain, and potential competition from opioid and non-opioid products for the treatment of pain that are currently in clinical development. In addition, our product candidates will face competition from approved and abuse-deterrent labeled opioid drugs and potential competition from abuse-deterrent opioid drugs that are currently in clinical development. We may compete with multiple companies that have developed and are developing abuse-deterrent technologies that may be applied to a variety of drugs, including those being developed for the treatment of acute moderate to moderately severe pain as well as for other indications that we are pursuing or may pursue in the future. If approved, our abuse-deterrent opioid product candidates may face competition from opioid products or abuse-deterrent technologies from companies including Allergan plc, Acura Pharmaceuticals, Inc., Cara Therapeutics, Inc., Collegium Pharmaceutical, Inc., Depomed, Inc., DURECT Corporation, Egalet Corporation, Elite Pharmaceuticals, Inc., Endo International plc, Inspiron Delivery Technologies, LLC, Grünenthal Group, IntelliPharmaceutics International Inc., Mallinckrodt plc, Mylan Inc., Nektar Therapeutics, Pain Therapeutics, Inc., Pfizer Inc., Purdue Pharma L.P., Signature Pharmaceuticals, Teva Pharmaceutical Industries Ltd., Trevena Inc. and UCB S.A.

If approved, KP201/APAP will compete against currently marketed, branded and generic, IR hydrocodone/APAP combination products indicated for the short-term management of acute pain. Some of these currently marketed products include AbbVie's Vicodin, Allergan's Norco, Shionogi's Xodol and UCB Pharma's Lortab, in addition to multiple other branded and generic hydrocodone/APAP combination products marketed by companies including Allergan plc, Endo International plc, and Mallinckrodt plc. In addition, if approved, KP201/APAP will face potential competition from any abuse-deterrent or other IR hydrocodone/APAP combination products for the treatment of acute moderate to moderately severe pain that are currently in or may enter into clinical development.

If approved, KP415 will compete against currently marketed, branded and generic methylphenidate products for the treatment of ADHD. Some of these currently marketed products include Johnson & Johnson's Concerta, Novartis AG's Ritalin, Ritalin LA, Focalin and Focalin XR, UCB S.A.'s Metadate CD, and Noven Pharmaceuticals' Daytrana, in addition to multiple other branded and generic methylphenidate products marketed by companies including Allergan plc and Mallinckrodt plc. In addition, if approved, KP415 will face potential competition from any abuse-deterrent or other methylphenidate products for the treatment of ADHD that are currently in or which may enter into clinical development.

If approved, KP511/ER will compete against currently marketed, branded and generic, IR and ER hydromorphone products approved for use in opioid-tolerant patients 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. Some of these currently marketed products include Purdue Pharma L.P.'s Dilaudid and Mallinckrodt plc's Exalgo, in addition to multiple other branded and generic IR and ER hydromorphone products marketed by companies including Allergan plc, Mallinckrodt plc, Rhodes Pharmaceuticals L.P. and Roxanne Laboratories, Inc. In addition, if approved, KP511/ER will face potential competition from any abuse-deterrent or other IR and ER hydromorphone products for the treatment of pain that are currently in or which may enter into clinical development.

If approved, KP606/IR will compete against currently marketed, branded and generic abuse-deterrent and other IR and ER oxycodone products approved for the management of moderate to severe pain where the use of an opioid analgesic is appropriate for use in opioid-tolerant patients for the treatment of acute pain and pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Some of these currently marketed products include Purdue Pharma L.P.'s OxyContin and Mallinckrodt plc's Roxicodone, in addition to multiple other branded and generic, abuse-deterrent and other, IR and ER oxycodone products marketed by companies including Allergan plc, Endo International plc, and Mallinckrodt plc. In addition, if approved, KP606/IR will face potential competition from any abuse-deterrent or other IR and ER oxycodone products that are currently in or which may enter into clinical development.

If approved, KP746 will compete against currently marketed, branded and generic oxymorphone products for the management of moderate to severe pain where the use of an opioid analgesic is appropriate. Some of these currently marketed products include Endo International plc's Opana ER, in addition to other generic oxymorphone products marketed by companies including CorePharma, LLC, Impax Laboratories Inc., Mallinckrodt Inc., Roxane Laboratories, Inc. and Teva Pharmaceuticals USA, Inc. In addition, if approved, KP746 will face potential competition from any abuse-deterrent and other IR and ER oxymorphone products that are currently in or which may enter into clinical development.

We believe the key competitive factors that will affect the development and commercial success of our product candidates include their potential degree of abuse deterrence, onset of action, bioavailability, therapeutic efficacy, convenience of dosing, safety, tolerability and cost. Many of our potential competitors have substantially greater financial, technical and human resources than we do, as well as more experience in the development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Consequently, our competitors may develop abuse-deterrent or other products for the short-term management of acute pain, or for other indications we are pursuing or may pursue in the future, and such competitors' products may be more effective, better tolerated and less costly than our product candidates. Our competitors may also be more successful in manufacturing and marketing their products than we are. We will also face competition in recruiting and retaining qualified personnel and establishing clinical trial sites and patient enrollment in clinical trials.

Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. If the competitor's product were similar to our product candidates, we may be required to seek approval via alternative pathways, such as the ANDA, which is used for the development of generic drug products. We may also be blocked from product marketing by periods of patent protection or regulatory exclusivity.

In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic drugs or giving abuse deterrence sufficient weight in a comparative clinical cost effectiveness analysis. For some of the indications that we are pursuing, drugs used off-label serve as cheaper alternatives to our product candidates. Their lower prices could result in significant pricing pressure, even if our product candidates are otherwise viewed as a preferable therapy. Additional drugs may become available on a generic basis over the coming years.

Many of our potential competitors have substantially greater financial, technical and human resources than we do, as well as more experience in the development of product candidates, obtaining FDA and other regulatory approvals of products, and the commercialization of those products. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Consequently, our competitors may develop abuse-deterrent or other products for the treatment of pain or ADHD or for other indications we may pursue in the future, and such competitors' products may be more effective, better tolerated and less costly than our product candidates. Our competitors may also be more successful in manufacturing and marketing their products than we are. We will also face competition in recruiting and retaining qualified personnel and establishing clinical trial sites and subject enrollment in clinical trials.

***We may not be able to obtain either five-year FDA regulatory exclusivity as an NCE or three-year FDA regulatory exclusivity.***

The FDA provides periods of regulatory exclusivity following their approval of an NDA, which provide the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug. Five-year exclusivity precludes approval of 505(b)(2) applications or ANDAs by delaying the submission or approval of the application, while three-year exclusivity precludes the approval of the application. We intend to seek NCE status for KP415, and we may seek NCE for other prodrug product candidates as appropriate. Five years of exclusivity are available to NCEs following the approval of an NDA by the FDA. An NCE is a drug that contains no active moiety that has been approved by the FDA in any other NDA. If a product is not eligible for the NCE exclusivity, it may be eligible for three years of exclusivity. Three-year exclusivity is available to

the holder of an NDA, including a 505(b)(2) NDA, for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials, other than bioavailability or bioequivalence trials, were essential to the approval of the application and were conducted or sponsored by the applicant.

There is a risk that the FDA may disagree with any claim that we may make that KP415 or any of our prodrug product candidates are NCEs and therefore entitled to five-year exclusivity. The FDA may also take the view that the studies that we are conducting are not clinical trials, other than bioavailability and bioequivalence studies, that are essential to approval and therefore do not support three-year exclusivity. Further, to the extent that the basis for exclusivity is not clear, the FDA may determine to defer a decision until it receives an application which necessitates a decision.

If we do obtain either five or three years of exclusivity, such exclusivity will not block all potential competitors from the market. Competitors may be able to obtain approval for similar products with different forms of abuse-deterrent mechanisms or may be able to obtain approval for similar products without an abuse-deterrent mechanism.

***Even if we are able to commercialize any product candidates, they may be subject to unfavorable pricing regulations, third-party coverage and reimbursement policies or healthcare reform initiatives.***

Our ability to commercialize any product candidates successfully will depend, in part, on the extent to which coverage and adequate reimbursement for our product candidates will be available from government payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers, managed care plans and other third-party payors. Government authorities and other third-party payors decide which medical products they will pay for and establish reimbursement levels, including co-payments. A 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 medical products. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs and products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Inadequate reimbursement levels may adversely affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our prodrug products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. Moreover, the trend has been for government and commercial health plans and their pharmacy benefit managers to commoditize drug products through therapeutic equivalence determinations, making formulary decisions based on cost. If coverage and adequate reimbursement are not available or reimbursement is available only at limited levels, we may not be able to successfully commercialize any product candidates for which marketing approval is obtained.

There may be significant delays in obtaining coverage and reimbursement for newly approved prodrug products, and coverage may be more limited than the indications for which the product is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new prodrug products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product 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 prodrug products 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. Private third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Except for certain government health care programs, such as the Department of Defense's TRICARE Uniform Formulary, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Even state Medicaid programs have their own preferred drug lists that may disadvantage non-preferred brand drugs. Therefore, coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained at all. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved prodrug products that we develop could significantly harm our operating results, our ability to raise capital needed to commercialize prodrugs and our overall financial condition.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs 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 product 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 commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue able to be generated from the sale of the product in that 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.

There can be no assurance that our product candidates, if they are approved for sale in the United States or in other countries, will be considered medically reasonable and necessary for a specific indication, that they will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available, or that third-party payors' reimbursement policies will not adversely affect our ability to sell our product candidates profitably if they are approved for sale.

***We may be subject to enforcement action if we engage in improper marketing or promotion of our products.***

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 claims, the FDA may object to our marketing claims and product advertising campaigns. Failure to comply with the FDA's promotional, marketing and advertising laws and regulations could lead to the issuance of warning letters, cyber letters, or untitled letters, adverse publicity, the requirement for dear-health-care-provider letters or other corrective information, fines and other monetary penalties, civil or criminal prosecution, including False Claims Act liability, restrictions on our operations and other operating requirements through consent decrees or corporate integrity agreements, debarment, exclusion from participation in federal health care programs and refusal of government contracts or future orders under existing contracts, among other consequences. Any of these consequences would harm the commercial success of our products.

Further, our promotional materials, statements and training methods must comply with the FDA's prohibition of the promotion of unapproved, or off-label, use. Physicians may use our products off-label, as the FDA does not restrict or regulate a physician's independent choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials, statements or training constitutes promotion of an off-label use, it could request that we modify our promotional materials, statements or training methods or subject us to regulatory or enforcement actions, such as the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine, disgorgement of money, operating restrictions or criminal penalties. We may also be subject to actions by other governmental entities or private parties, such as false claims act, civil whistleblower or "qui tam" actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products could be impaired. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us and harm our reputation.

***Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.***

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercialize any prodrug products that we may develop. This includes the risk that our products may be misused. For example, we anticipate that, if approved, our products may carry boxed warnings regarding lethality if our oral tablets are prepared for injection and hepatotoxicity, as is commonly done by abusers of opioids. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- termination of clinical trial sites or entire trial programs;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- significant costs to defend the related litigation;
- a diversion of management's time and our resources;

- substantial monetary awards paid to trial participants or patients;
- product recalls, withdrawals or labeling revisions and marketing or promotional restrictions;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any prodrug products that we may develop.

We currently hold \$10.0 million in product liability insurance coverage in the aggregate, with a per incident limit of \$10.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. 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.

***A variety of risks associated with international operations could materially adversely affect our business.***

We expect to engage in significant cross-border activities, and we will be subject to risks related to international operations, including:

- different regulatory requirements for maintaining approval of drugs in foreign countries;
- reduced protection for contractual and intellectual property rights in some countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in North America;
- tighter restrictions on privacy and the collection and use of patient data; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

**Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters**

***Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.***

In order to market and sell our products in the European Union and any other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States 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. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA 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 regulatory authorities in other countries or jurisdictions or by the FDA. However, failure to obtain approval in one jurisdiction may impact our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

***A variety of risks associated with marketing our product candidates internationally could affect our business.***

We may seek regulatory approval for our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market with low or lower prices rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may compromise our ability to achieve or maintain profitability.

***Any product candidate for which we obtain marketing approval could be subject to post-marketing restrictions or recall or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.***

Any product candidate for which we obtain marketing approval will be subject to a comprehensive regulatory scheme, which includes the regulation of manufacturing processes, post-approval clinical data, labeling, advertising, marketing, distribution and promotional activities for such product, by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, payment of substantial annual product and establishment fees, labeling requirements, promotional, marketing and advertising requirements, requirements related to further development, packaging, storage and distribution requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. If there are any modifications to the drug, including changes in indications, labeling, manufacturing processes or facilities, or new safety issues arise, a new or supplemental NDA, a post-implementation notification or other reporting may be required or requested depending on the change, which may require additional data or additional preclinical studies and clinical trials.

Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a REMS, which could involve requirements for, among other things, a medication guide, special training for prescribers and dispensers, and patient registries. If any of our product candidates receives marketing approval, the accompanying label may limit its approved uses, including more limited subject populations, than we request, and regulatory authorities may require that contraindications,

warnings or precautions be included in the product labeling, including a black box warning, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, which could limit sales of the product.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of products to ensure products are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our prodrug products, if any, for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the FDCA relating to the promotion of prescription drugs may lead to a number of actions and penalties, including warning letters, cyber letters, or untitled letters, adverse publicity, the requirement for dear-health-care-provider letters or other corrective information, fines and other monetary penalties, civil or criminal prosecution, including False Claims Act liability, restrictions on our operations and other operating requirements through consent decrees or corporate integrity agreements, debarment, exclusion from participation in federal health care programs and refusal of government contracts or future orders under existing contracts, among other consequences.

In addition, later discovery of previously unknown adverse events or other problems with our prodrug products, including those related to manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may have negative consequences, including:

- adverse inspectional findings;
- restrictions on such prodrug products, distribution, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a drug;
- additional warnings or otherwise restrict the product's indicated use, label, or marketing;
- issuance of safety alerts, dear-healthcare-provider letters, press releases or other communications containing warnings regarding the product;
- requirement to establish or modify a REMS;
- requirement to conduct post-marketing studies or surveillance;
- restrictions on drug distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- recall or withdrawal of the prodrug products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit and other delays;
- clinical holds, or the suspension or termination of ongoing clinical trials;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals or other permits or voluntary suspension of marketing;
- refusal to permit the import or export of our prodrug products;
- reputational harm;
- refusal of government contracts or future orders under existing contracts, exclusion from participation in federal health care programs, and corporate integrity agreements;



- product seizure or detention; or
- injunctions or the imposition of civil or criminal penalties, including False Claims Act liability.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of drugs for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

***Our employees, independent contractors, principal investigators, CROs, consultants, commercial collaborators, contract manufacturers, service providers and other vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.***

We are exposed to the risk of misconduct by employees and independent contractors, such as principal investigators, CROs, consultants, commercial collaborators, contract manufacturers, service providers and other vendors. Such misconduct could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards that we have established or that are established by regulation, to comply with federal and state contracting and healthcare fraud and abuse laws, to report drug pricing, financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including, but not limited to, research, manufacturing, distribution, pricing, discounting, marketing, advertising and promotion, sales commissions, customer incentive programs and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct and self-disclose credible evidence of False Claims Act violations. It is not always possible to identify and deter employee and independent contractor misconduct, and any precautions we take to detect and prevent improper activities 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. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of warning letters, untitled letters, cyber letters, seizure or recall of products, injunctions, withdrawal of product approval or other permits, clinical holds and termination of clinical trials, FDA refusal to approve pending applications, product detentions, FDA or DEA consent decrees, restriction or suspension of manufacturing and distribution, debarment, refusal to allow product import or export, adverse publicity, refusal of government contracts or future orders under existing contracts, dear-health-care-provider letters or other warnings or corrective information, recalls, delays, civil, criminal and administrative penalties including False Claims Act liability, damages, monetary fines, disgorgement, restitution, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, corporate integrity agreements, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, among other consequences, any of which could adversely affect our ability to operate.

***Our current and future relationships with healthcare professionals, principal investigators, consultants, customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to penalties.***

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and patient privacy and security regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or arranging for the purchase, lease or order of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid;
- federal civil and criminal false claims laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making or using a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government, including erroneous pricing information on which mandatory rebates, discounts and reimbursement amounts are based, or in the case of the civil False Claims Act, for violations of the Anti-Kickback Statute in connection with a claim for payment or for conduct constituting reckless disregard for the truth;
- the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;
- HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations, which impose obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Open Payments program, created under Section 6002 of the ACA, and its implementing regulations, which imposes new annual reporting requirements for certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, to annually report certain payments and transfers of value provided to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, and to report annually certain ownership and investment interests held by physicians and their immediate family members; and
- comparable state and foreign laws, which may be broader in scope than the analogous federal laws and may differ from each other in significant ways.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. 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, or that our compliance systems are inadequate to detect and report such conduct or to report accurate pricing information to the government. 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, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could significantly harm our business. If any of the physicians or other healthcare providers or entities with whom we currently, or expect to, do business, including future collaborators, is found not to be in compliance with applicable laws, they and we may be subject to penalties and potential exclusion from participation in healthcare programs as a result of their non-compliance.

***Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.***

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, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, President Obama signed into law the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our potential product candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded drugs and generic drugs, respectively;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;
- establishment of a new and distinct methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices (generally as negotiated between the Medicare Part D plan and the pharmacy) of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations and extension of the inflation percentage applicable to existing branded drugs to new formulations for purposes of computing the inflation penalty component of Medicaid rebates;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- the new requirements under the federal Open Payments program and its implementing regulations;

- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013, and will stay in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could negatively impact customers for our product candidates, if approved, and, accordingly, our financial operations.

There have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. We continue to evaluate the effect that the ACA has on our business. Final regulations, guidance, amendments and judicial orders are anticipated in the near future and we will continue to assess the ACA's impact on us as final regulations, guidance, amendments and judicial orders are issued.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may, among other things, result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. 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 prevent us from being able to generate revenue, attain profitability, or commercialize our prodrug product candidates.

Legislative and regulatory proposals and enacted statutes have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. For instance, the Drug Supply Chain Security Act imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this new legislation, manufacturers are required to provide specified information regarding the drug products they produce to individuals and entities to which product ownership is transferred, label drug products with a product identifier and keep specified records regarding the drug products. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers are also required to verify that purchasers of products are appropriately licensed. Further, under this legislation, manufacturers have drug product investigation, quarantine, disposition and FDA and trading-partner notification responsibilities related to counterfeit, diverted, stolen and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

***Governments outside the United States tend to impose strict price controls, which may affect our revenue, if any.***

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our prodrug products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste

products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

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 do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

***Our business and operations would suffer in the event of computer system failures.***

Despite the implementation of security measures, our internal computer systems, and those of our CROs 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. 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 or planned 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 Employee Matters and Managing Our Growth**

***Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.***

We are highly dependent on the management, research and development, clinical, financial and business development expertise of Travis C. Mickle, Ph.D., our president and chief executive officer, Gordon K. Johnson, our chief business officer, Tracy Woody, our chief commercial officer, R. LaDuane Clifton, our chief financial officer, Christal M.M. Mickle, our vice president product development, Sven Guenther, Ph.D., our executive vice president research and development, and Christopher M. Lauderback, our vice president commercial operations, as well as the other members of our scientific and clinical teams. Although we have employment agreements with each of our executive officers, these agreements do not obligate them to continue working for our company and they may terminate their employment with us at any time. Dr. Mickle also has consulting obligations to Shire Pharmaceuticals, LLC in addition to his duties as our president and chief executive officer, which may limit his availability to us.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our product pipeline toward scaling up for commercialization, manufacturing and sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our prodrug product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

***We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

As of December 31, 2015, we had 26 full-time employees. As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, drug development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our

facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

### **Risks Related to Ownership of Our Common Stock and Our Status as a Public Company**

***An active trading market for our common stock may not develop and you may not be able to resell your shares of our common stock for a profit, if at all.***

Prior to our initial public offering, there had been no public market for our common stock. An active trading market for our shares may never develop or be sustained. If an active market for our common stock does not develop or is not sustained, it may be difficult for you to sell our shares at an attractive price or at all.

***The trading price of the shares of our common stock is likely to be volatile, and purchasers of our common stock could incur substantial losses.***

Our stock price has been, and is likely to continue to be, volatile. Since shares of our common stock were sold in our initial public offering in April 2015 at a price of \$11.00 per share, our stock price has ranged from \$10.16 to \$26.15 through March 11, 2016. In addition, the stock market in general and the market for pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- actual or anticipated variations in our operating results;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the pharmaceutical industry;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- capital commitments;
- investors' general perception of us and our business;
- recruitment or departure of key personnel; and
- sales of our common stock, including sales by our directors and officers or specific stockholders.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business. Further, companies listed on The NASDAQ Global Market, and biotechnology and pharmaceutical 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.

***If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.***

The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. If one or more of the

analysts who cover us downgrade our shares or change their opinion of our shares, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

***A significant portion of our outstanding warrants are entitled to certain anti-dilution protections which, if triggered, may cause substantial dilution to your investment.***

As of December 31, 2015, we had outstanding immediately exercisable warrants to purchase 266,179 shares of our common stock at a weighted average exercise price of \$5.67 per share that include anti-dilution provisions pursuant to which the exercise price of such warrants will be adjusted downward if we issue any shares of our common stock or any securities convertible into our common stock at a price per share or with an exercise or conversion price less than the exercise price of such warrants. Upon such an event, the exercise price of these warrants will be automatically adjusted to equal the price per share paid for, the conversion price of or the exercise price of such securities, as applicable, and the number of shares of common stock issuable upon exercise of each warrant will be proportionately increased.

Additionally, in June 2014, we issued to Deerfield a warrant to purchase 14,423,076 shares of Series D redeemable convertible preferred stock at an exercise price of \$0.78 per share, which is exercisable until June 2, 2024, or the Deerfield Warrant. Upon completion of our initial public offering, the Deerfield Warrant automatically converted into a warrant to purchase 1,923,077 shares of our common stock at an exercise price of \$5.85 per share. The Deerfield Warrant includes an exercise price protection provision, pursuant to which the exercise price of the warrant will be adjusted downward on a broad-based weighted-average basis if we issue or sell any shares of common stock, convertible securities, warrants or options at a sale or exercise price per share less than the greater of the warrant's exercise price or the closing sale price of our common stock as reported on The NASDAQ Global Market on the last trading date immediately prior to such issuance or, in the case of a firm commitment underwritten offering, on the date of execution of the underwriting agreement between us and the underwriters for such offering. Each time we borrow a tranche under the Deerfield facility, we are obligated to issue to Deerfield a warrant with substantially the same terms and conditions.

***Future sales and issuances of equity and debt securities could result in additional dilution to our stockholders.***

We expect that we will need significant additional capital in the future to fund our planned operations, including to complete potential clinical trials for our product candidates. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. We may also borrow additional tranches under the Deerfield facility if the necessary conditions are satisfied. Each time we borrow a tranche under the Deerfield facility, we will simultaneously issue to Deerfield a warrant exercisable for a specified number of shares of our common stock. If we exercise our option to borrow the second tranche under the Deerfield facility, we will issue to Deerfield a warrant to purchase 1,282,052 shares of our common stock at an initial exercise price of \$5.85 per share. Similarly, if we exercise our option to borrow the third and fourth tranches, in each instance, we will issue to Deerfield a warrant exercisable for the number of shares of our common stock equal to 60% of the principal amount of such disbursement divided by 115% of the volume weighted average sales price of our common stock for the 20 consecutive trading days immediately prior to the date of such disbursement with an exercise price per share equal to 115% of such weighted average sales price. Each of these future Deerfield warrants, if issued, will be dilutive to your ownership interest.

Additionally, we previously issued to Deerfield a secured convertible note, or the Deerfield Note, in the principal amount of \$10.0 million. The Deerfield Note bears interest at 9.75% per annum. Deerfield may convert all or any portion of the outstanding principal and any accrued but unpaid interest on the Deerfield Note into shares of our common stock at a conversion price of \$5.85 per share. According to the terms of the Deerfield Note, in no event may Deerfield convert the Deerfield Note to the extent such conversion would result in Deerfield beneficially owning more than 9.985% of the then issued and outstanding shares of our common stock. This conversion limitation may not be waived and any purported conversion that is inconsistent with this conversion limitation will be null and void. This conversion limitation will not apply to any conversion made immediately prior to a change of control transaction. If Deerfield is only able to convert the Deerfield Note into a limited number of shares due to this conversion limitation, the Deerfield Note could subsequently become convertible into the remainder of the shares as a result of a variety of events. This could occur, for example, if we issue more shares or Deerfield sells some of its existing shares. Without regard to this conversion limitation, the Deerfield Note is convertible into 1,991,219 shares of our common stock, assuming a conversion date of December 31, 2015. The conversion price of the Deerfield Note will be adjusted downward if we issue or sell any shares of common stock, convertible securities, warrants or options at a sale or exercise price per share less than the greater of the Deerfield Note's conversion price or the closing sale price of our common stock as reported on The NASDAQ Global Market on the last trading date immediately prior to such issuance, or, in the case of a firm commitment underwritten offering, on the date of execution of the underwriting agreement between us and the underwriters for such offering.

Additionally, in February 2016, we issued the 2021 Notes. The 2021 Notes are convertible at an initial conversion rate of 58.4454 shares of our common stock per \$1,000 principal amount of the 2021 Notes, subject to adjustment under the indenture governing the 2021 Notes, which is equal to an initial conversion price of approximately \$17.11 per share of our common stock. Upon conversion, the 2021 Notes will be settled in shares of our common stock, together with a cash payment in lieu of delivering any fractional shares. The conversion rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date, we will increase the conversion rate for a holder who elects to convert its 2021 Notes in connection with such a corporate event in certain circumstances. Holders who convert on or after the date that is one year after the last date of original issuance of the 2021 Notes may also be entitled to receive, under certain circumstances, an interest make-whole payment payable in shares of common stock.

If Deerfield or the holders of the 2021 Notes elect to convert the Deerfield Note or the 2021 Notes, or in the event that the Deerfield Note automatically converts pursuant to its terms into shares of our common stock, your ownership interest will be diluted and the market price of our common stock may be materially and adversely effected.

Pursuant to our equity incentive plan, we may grant equity awards and issue additional shares of our common stock to our employees, directors and consultants, and the number of shares of our common stock reserved for future issuance under this plan will be subject to automatic annual increases in accordance with the terms of the plans. To the extent that new options are granted and exercised or we issue additional shares of common stock in the future, our stockholders may experience additional dilution, which could cause our stock price to fall.

***Our substantial indebtedness, and the conditions we must satisfy in order to make further draws on our credit facility, may limit cash flow available to invest in the ongoing needs of our business.***

In June 2014, we entered into the Deerfield facility, pursuant to which Deerfield agreed to loan to us up to \$60.0 million, subject to specified conditions. In June 2014, we drew down \$25.0 million against the facility. Under the terms of the Deerfield facility, Deerfield is obligated to provide three additional tranches in the principal amounts of \$10.0 million, \$12.5 million and \$12.5 million, respectively, upon our request and after the satisfaction of specified conditions, including the FDA's acceptance of an NDA for KP201/APAP and, for the final two tranches, the subsequent approval for the commercial sale thereof. If these conditions do not occur, we may not be able to borrow any further tranches under the Deerfield facility, which would limit our cash flow and our ability to invest in the ongoing needs of our business.

All loans issued under the Deerfield facility bear interest at 9.75% per annum. Interest accrued on outstanding debt under the Deerfield facility is due quarterly in arrears. Upon notice to Deerfield, we may choose to have one or more of the first eight of such scheduled interest payments added to the outstanding principal amount of the debt issued under the Deerfield facility, provided that all such interest will be due on July 1, 2016. We must repay one-third of the outstanding principal amount of all debt issued under the Deerfield facility on the fourth and fifth anniversaries of the Deerfield facility. We are then obligated to repay the balance of the outstanding principal amount on February 14, 2020. We used approximately \$18.6 million of the net proceeds from the offering of our 2021 Notes to repay in full the \$15.0 million original principal amount on the term note issued under Deerfield facility plus all accrued but unpaid interest on the term note, a make whole interest payment on the term note and a prepayment premium on the term note. If we are required to pay additional outstanding amounts due under the Deerfield facility prior to maturity or otherwise incur unanticipated monetary obligations under the Deerfield facility, our cash flow available to invest in the ongoing needs of our business may be limited.

In February 2016, we issued the 2021 Notes. Our ability to make payments on, and to refinance, the 2021 Notes, and to fund planned capital expenditures, sales and marketing efforts, research and development efforts, working capital and other general corporate purposes depends on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, legislative, regulatory and other factors, some of which are beyond our control. If we do not ever generate sufficient cash flow from operations or if future borrowings are not available to us in an amount sufficient to repay our indebtedness, including any amounts due under the 2021 Notes at their maturity, or to fund our liquidity needs, we may be forced to refinance all or a portion of the 2021 Notes, on or before the maturity thereof, sell assets, reduce or delay capital expenditures, seek to raise additional capital or take other similar actions. We may not be able to affect any of these actions on commercially reasonable terms or at all. Our ability to refinance our indebtedness will depend on our financial condition at the time, the restrictions in the instruments governing our present and potential future indebtedness and other factors, including market conditions. In addition, in the event of a default with respect to the 2021 Notes, the holders of the 2021 Notes and/or the trustee under the indenture governing the 2021 Notes may accelerate the payment of our obligations under 2021 Notes, which could have a material adverse effect on our business, financial condition and results of operations. A default under the indenture governing the 2021 Notes could also lead to a default under agreements governing future indebtedness, which could also have a material adverse effect on our business, financial condition and results of operations. Our inability to generate sufficient cash flow to satisfy our debt service obligations, or to refinance or restructure



our obligations on commercially reasonable terms or at all, would likely have a material adverse effect on our business, financial condition and results of operations.

***Despite our current debt levels, we may still incur substantially more debt or take other actions which would intensify the risks discussed above.***

Despite our current debt levels, we and our future subsidiaries may be able to incur substantial additional debt in the future, subject to the restrictions contained in our debt instruments, some of which may be secured debt. We are not restricted under the terms of the indenture governing the 2021 Notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing the 2021 Notes that could have the effect of diminishing our ability to make payments on the notes when due. The Deerfield facility restricts our ability to incur additional indebtedness, including secured indebtedness, subject to certain exceptions, but if the facility matures or is repaid, we may not be subject to such restrictions under the terms of any subsequent indebtedness.

***The accounting method for the 2021 Notes could have a material effect on our reported financial results.***

We may be required to account for certain features of the 2021 Notes as one or more embedded derivatives, which could require mark-to-market accounting treatment and result in the requirement to record gain or loss on a quarterly basis with regards to the mark-to-market value of that feature. Such accounting treatment could have a material impact on, and could potentially result in significant volatility in, our quarterly results of operations. Additionally, certain features of the 2021 Notes may result in the yield on the 2021 Notes not being deductible by us.

***Sales of a substantial number of shares of our common stock in the public market could cause the market price of our common stock to drop significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

Certain holders of shares of our common stock and shares of our common stock issuable upon the exercise of outstanding warrants, including Deerfield, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

***Anti-takeover provisions in our certificate of incorporation and bylaws, as well as provisions of Delaware law and the terms of some of our contracts, might discourage, delay or prevent a change in control of our company or changes in our board of directors or management and, therefore, depress the price of our common stock.***

Our certificate of incorporation and bylaws and Delaware law contain provisions that may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock or transactions that our stockholders might otherwise deem to be in their best interests. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove members of our board of directors or our management. Therefore, these provisions could adversely affect the price of our stock. Our corporate governance documents include provisions:

- establishing a classified board of directors with staggered three-year terms so that not all members of our board of directors are elected at one time;
- providing that directors may be removed by stockholders only for cause;
- preventing the ability of our stockholders to call and bring business before special meetings and to take action by written consent in lieu of a meeting;
- requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our board of directors;
- permitting the board of directors to issue up to 10,000,000 shares of preferred stock with any rights, preferences and privileges they may designate;

- limiting the liability of, and providing indemnification to, our directors and officers;
- providing that vacancies may be filled by remaining directors;
- preventing cumulative voting; and
- providing for a supermajority requirement to amend our bylaws.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the General Corporation Law of the State of Delaware, which prohibits a Delaware corporation from engaging in a broad range of business combinations with any “interested” stockholder for a period of three years following the date on which the stockholder became an “interested” stockholder.

In addition, the provisions of our termination agreement with MonoSol and our agreements with Deerfield and the holders of our 2021 Notes may discourage, delay or prevent a change in control of our company. For example, if we enter into a merger, an asset sale or any other change of control transaction, then MonoSol will be entitled to a percentage in the low teens of the price being paid to us and our stockholders in such transaction which is attributable to the value of KP415. Pursuant to the Deerfield facility, we may not enter into any major transaction without the prior approval of Deerfield, including a merger, asset sale or change of control transaction, and Deerfield has the option to demand repayment of all outstanding principal, and any unpaid interest accrued thereon, of all notes previously issued under the Deerfield facility immediately prior to consummation of such event. Further, under each warrant issued pursuant to the Deerfield facility, Deerfield has the right to demand that we redeem the warrant for a cash amount equal to the Black-Scholes value of a portion of the warrant upon the occurrence of specified events, including a merger, an asset sale or any other change of control transaction. Furthermore, the indenture governing the 2021 Notes requires us to repurchase the 2021 Notes for cash if we undergo certain fundamental changes. A takeover of us may trigger the requirement that we repurchase the 2021 Notes, which could make it more costly for a potential acquirer to engage in a business combination transaction with us.

Any provision of our certificate of incorporation, bylaws or Delaware law or any term of our contracts that has the effect of discouraging, delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

***Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.***

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, any action asserting a claim against us arising pursuant to any provisions of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

***We are an “emerging growth company” and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.***

We are an “emerging growth company” as defined in the JOBS Act and we take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;

- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least \$1.0 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

***We might not be able to utilize a significant portion of our net operating loss carryforwards, which could adversely affect our profitability.***

As of December 31, 2015, we had federal net operating loss carryforwards of approximately \$62.4 million, due to prior period losses, which if not utilized will begin to expire in 2027. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities, which could adversely affect our profitability. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” which is 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 net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have not determined if we have experienced Section 382 ownership changes in the past and if a portion of our net operating loss carryforwards are subject to an annual limitation under Section 382. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, including as a result of our initial public offering, the conversion of our outstanding convertible debt or as a result of future changes in our stock ownership. If we determine that an ownership change has occurred and our ability to use our historical net operating loss carryforwards is materially limited, it would harm our future operating results by increasing our future tax obligations.

***If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.***

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Commencing with our fiscal year ending December 31, 2016, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We have never been required to test our internal controls within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the Securities and Exchange Commission, or the SEC, or other regulatory authorities.

***Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.***

You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of the Deerfield facility, and any future debt agreements may, preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

***We incur increased costs and demands upon management as a result of being a public company.***

As a public company listed in the United States, we incur significant additional legal, accounting and other costs, which we anticipate could be between \$1.0 million and \$2.0 million annually, that we did not incur as a private company. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and The NASDAQ Stock Market, may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

#### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

#### **ITEM 2. PROPERTIES**

We occupy 7,800 square feet of headquarters office and laboratory space in Coralville, Iowa under a lease that expires in September 2016 and we have the right to extend the term of the lease for an additional three years. We also maintain additional leased spaces in several locations, including Celebration, Florida; Durham, North Carolina and Blacksburg, Virginia. We believe that our facilities are adequate for our current needs.

#### **ITEM 3. LEGAL PROCEEDINGS**

In January 2016 we settled our lawsuit against DeWaay Financial Network, L.L.C., or DFN, a financial advisor. We instituted the lawsuit by filing a declaratory judgment action against DFN on September 13, 2013, in the Iowa District Court for Johnson County, Iowa. The lawsuit was subsequently transferred to the Iowa District Court for Polk County, Iowa.

On June 6, 2011, we entered into an agreement with DFN, or the DFN agreement, pursuant to which we granted to DFN a purported right of first refusal to serve as our exclusive financial advisor for specified strategic transactions, including a sale of our company, private and public capital raising transactions, and joint ventures, licenses or similar transactions with respect to our product candidates. Pursuant to the DFN agreement we also granted a purported right to receive, subject to specified conditions including non-exercise of such right of first refusal, a cash fee equal to the greater of \$250,000 and 1.5% of the total consideration received by us, our affiliates and our equity owners and related to any such strategic transaction, in each case, irrespective of whether any such strategic transaction occurred during or after the term of the DFN agreement.

In the lawsuit, we sought a declaratory judgment finding invalid and unenforceable such purported right of first refusal or right to receive a cash fee related to any such strategic transaction. DFN filed an answer requesting that the court declare that such rights were valid and survive termination of the DFN agreement and counterclaims requesting that the court award damages to DFN, including a fee based upon the total consideration that we have received and in the future would receive under the Deerfield facility. Two former members of our board of directors joined the lawsuit as intervenors based on DFN's purported assignment of its rights, or a portion thereof, under the DFN agreement to the intervenors. In September 2015, the court granted summary judgment in our favor.

with respect to our declaratory judgment action and DFN's counterclaims and we separately entered into settlement agreements with each of the intervenors. DFN subsequently filed a notice of appeal of the court's ruling with the Supreme Court of Iowa. On January 6, 2016, we entered into a settlement agreement and mutual release with DFN and Donald DeWaay, Jr. pursuant to which, among other things, DFN, agreed, in exchange for the consideration described therein, to dismiss with prejudice the appeal t. DFN's appeal was subsequently dismissed by the Supreme Court of Iowa on January 7, 2016.

From time to time, we may be involved in routine legal proceedings, as well as demands, claims and threatened litigation, which arise in the normal course of our business. We believe there is no litigation pending that could, individually or in the aggregate, have a material adverse effect on our results of operations or financial condition.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. MARKET PRICE OF COMMON STOCK****Price Range of Common Stock**

Our common stock has been listed on The NASDAQ Global Market under the symbol “KMPH” since April 16, 2015. Prior to that date, there was no public trading market for our common stock. Our initial public offering was priced at \$11.00 per share on April 15, 2015. The following table sets forth for the periods indicated the high and low sales prices per share of our common stock as reported on The NASDAQ Global Market:

	<u>Low</u>	<u>High</u>
<b>Year ended December 31, 2015</b>		
Second Quarter (beginning April 16, 2015)	\$ 10.90	\$ 20.08
Third Quarter	\$ 14.60	\$ 26.15
Fourth Quarter	\$ 12.79	\$ 21.30

**Holders of our Common Stock**

As of March 11, 2016, we had 211 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

**Dividend Policy**

We have never declared or paid any cash dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. The terms of the Deerfield facility limit our ability to pay dividends.

**Securities Authorized for Issuance under Equity Compensation Plans**

The information regarding securities authorized for issuance under equity compensation plans is included in Part III of this report.

**Recent Sales of Unregistered Securities**

Between October 13, 2015 and February 18, 2016, we issued an aggregate of 24,224 shares of our common stock pursuant to the net-exercise provisions of outstanding warrants. We did not receive any cash or other consideration as the warrants were “net exercised” in full.

Between October 13, 2015 and February 10, 2016, we issued an aggregate of 76,074 shares of our common stock pursuant to the exercise of outstanding warrants for an aggregate cash purchase price of \$355,843.79.

The offers, sales and issuances of the securities described above were exempt from registration under Section 4(a)(2) of the Securities Act, or, in the case of shares of common stock issued upon the net-exercise of outstanding warrants, were exempt from registration pursuant to Section 3(a)(9) of the Securities Act. For those securities issued pursuant to Section 4(a)(2) of the Securities Act, we reasonably believed that the recipients of these shares acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. We also reasonably believed that such recipients were accredited investors as defined in Rule 501 promulgated under the Securities Act.

**Issuer Purchases of Equity Securities**

Not applicable.

**Use of Proceeds**

On April 21, 2015, we closed our initial public offering, in which we issued and sold 5,090,909 shares of common stock at a public offering price of \$11.00 per share. Subsequently, on May 12, 2015, we sold an additional 763,636 shares of our common stock.

pursuant to the underwriters' option to purchase additional shares. In the aggregate, the gross proceeds of our initial public offering, including gross proceeds from the underwriters' exercise of their option to purchase additional shares, were \$64.4 million. All of the shares issued and sold in our initial public offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-202660), which was declared effective by the SEC on April 15, 2015. Cowen and Company, LLC, RBC Capital Markets, LLC, Canaccord Genuity Inc. and Oppenheimer & Co. Inc. acted as the underwriters. The offering commenced on April 15, 2015, and did not terminate before all of the securities registered in the registration statement were sold.

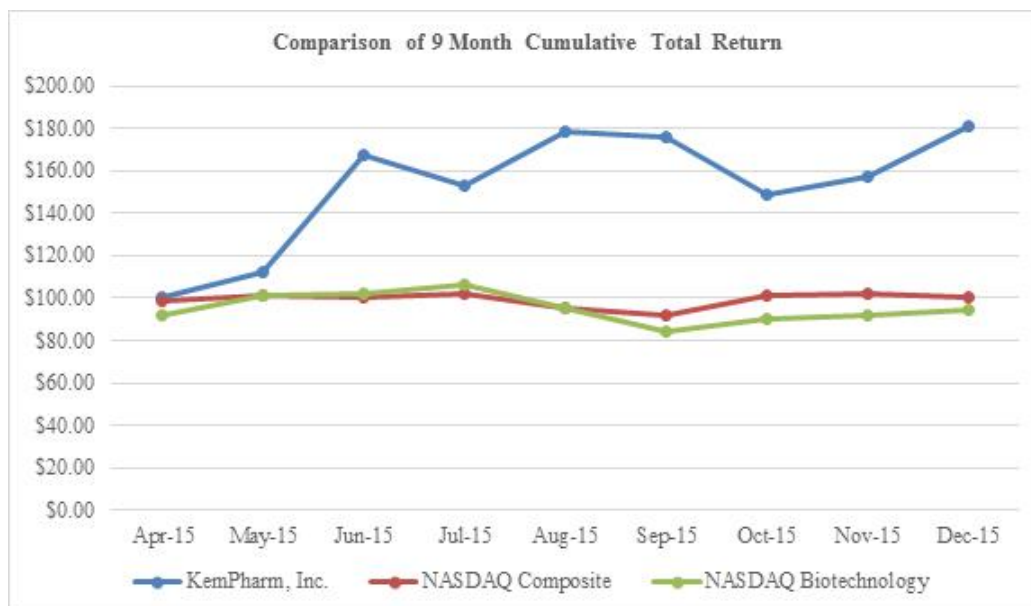
The net offering proceeds to us were \$59.9 million, after deducting underwriting discounts and commissions totaling \$4.5 million. In addition, offering expenses totaled \$2.8 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. There has been no material change in the planned use of proceeds from our initial public offering as described in our prospectus dated April 15, 2015, and filed with the SEC on April 16, 2015, pursuant to Rule 424(b) of the Securities Act. Through December 31, 2015, \$9.4 million of the net proceeds had been used to fund the development of KP201/APAP and our other product candidates and for working capital and other general corporate purposes.

### Stock Performance Graph

The following shall not be deemed "soliciting material" or to be "filed" for purposes of Section 18 of the Exchange Act, or incorporated by reference into any of our other filings under the Exchange Act or the Securities Act, except to the extent we specifically incorporate it by reference into such filing.

The following graph shows a comparison from April 16, 2015 (the date our common stock commenced trading on the NASDAQ Global Market) through December 31, 2015 of the cumulative total return for our common stock, the Nasdaq Composite Index, or NASDAQ Composite, and the Nasdaq Biotechnology Index, or NASDAQ Biotechnology. The graph assumes that \$100 was invested at the market open on April 16, 2015 in our common stock, the NASDAQ Composite and the NASDAQ Biotechnology. The data for the NASDAQ Composite and the NASDAQ Biotechnology assumes reinvestments of dividends.

The comparison in the following graph are based upon historical data and are not necessarily indicative of future stock price performance.



### ITEM 6. SELECTED FINANCIAL DATA

The following tables set forth our selected financial data for the periods indicated (in thousands, except for share and per share data). The following selected statement of operations data for the years ended December 31, 2015, 2014 and 2013, and the selected balance sheet data as of December 31, 2015 and 2014 are derived from our audited financial statements appearing elsewhere in this Annual Report on Form 10-K. The following selected balance sheet data as of December 31, 2013 is derived from our audited

financial statements not included in this Annual Report on Form 10-K. The data should be read together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and in conjunction with the financial statements, related notes and other financial information included elsewhere in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results to be expected in the future.

	Year Ended December 31, 2015	Year Ended December 31, 2014	Year Ended December 31, 2013
<b>Statement of operations data:</b>			
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	13,931	11,917	3,367
General and administrative	8,883	4,526	1,351
Total operating expenses	22,814	16,443	4,718
Loss from operations	(22,814)	(16,443)	(4,718)
Other expenses	(31,824)	(8,034)	(528)
Loss before income taxes	(54,638)	(24,477)	(5,246)
Income tax (expense) benefit	(26)	22	20
Net loss	<u>\$ (54,664)</u>	<u>\$ (24,455)</u>	<u>\$ (5,226)</u>
Net loss per share:			
Basic and diluted	<u>\$ (7.42)</u>	<u>\$ (10.27)</u>	<u>\$ (2.20)</u>
Weighted average common shares outstanding:			
Basic and diluted	7,368,681	2,381,041	2,381,041
<b>Balance sheet data:</b>			
Cash and cash equivalents	\$ 32,318	\$ 10,255	\$ 1,969
Marketable securities	19,002	—	—
Total assets	55,723	13,714	2,429
Convertible notes, net of discount (current and noncurrent)	9,234	7,560	3,846
Term notes, net of discount (current and noncurrent)	13,839	11,335	—
Derivative and warrant liability	37,839	15,966	2,813
Total liabilities	65,844	38,015	8,149
Redeemable convertible preferred stock	—	24,207	18,547
Total stockholders' deficit	(10,121)	(48,508)	(24,267)



## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

### Overview

We are a clinical-stage specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs that we believe will be improved versions of widely prescribed, approved drugs. We employ our LAT platform technology to create our prodrugs, which in some cases may be eligible for composition-of-matter patent protection. Our most advanced product candidate is KP201/APAP, which we are developing as an IR product candidate for the short-term management of acute pain. In December 2015, we submitted a 505(b)(2) NDA for KP201/APAP to the FDA. The FDA subsequently accepted this NDA for priority review in February 2016. The FDA has set a target action date for review of the NDA under PDUFA of June 9, 2016. We are also building a pipeline of additional prodrug product candidates that target large market opportunities in pain and ADHD. We own worldwide commercial rights for all of our product candidates, including KP201/APAP, except that Shire has a right of first refusal to acquire, license or commercialize KP415.

We are a development stage company and have not generated any revenue. We have incurred losses since our inception and, as of December 31, 2015, had an accumulated deficit of \$104.8 million. Our net losses for the years ended December 31, 2015, 2014 and 2013 were \$54.7 million, \$24.5 million and \$5.2 million, respectively.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, and those expenses and losses may fluctuate significantly from quarter-to-quarter and year-to-year. We anticipate that our expenses will increase substantially as we:

- continue our ongoing preclinical studies, clinical trials and our product development activities for our pipeline of product candidates;
- seek regulatory approvals for KP201/APAP and for any other product candidates that successfully complete clinical trials;
- continue research and preclinical development and initiate clinical trials of our other product candidates;
- seek to discover and develop additional product candidates;
- potentially establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, manufacturing and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our prodrug development and planned future commercialization efforts; and
- incur additional legal, accounting and other expenses in operating as a public company.

Our commercial revenue, if any, will be derived from sales of prodrug products that we do not expect to be commercially available for approximately 15 months, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, or exercise our right to borrow additional tranches under the

Deerfield facility, the terms of these securities or this debt may restrict our ability to operate. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

### **Third-Party Agreements**

In November 2009, we entered into a Supply Agreement with JMI pursuant to which JMI has agreed to supply us with all of the KP201 necessary for clinical trials and commercial sale for a price equal to JMI's manufacturing cost and to provide process optimization and development services for KP201. In exchange, we issued shares of our common stock to JMI, provided that the commercial supply arrangement for KP201 would be exclusive to JMI in the United States and agreed to pay JMI royalties on the net sales of KP201/APAP, if approved by the FDA. The percentage royalty rate ranges from the high teens at low volumes to the mid-single digits at higher volumes.

We are responsible for all costs of any KP201 manufactured during a specified validation process for KP201. After completion of the validation process, but prior to the commercial launch of KP201, JMI will manufacture batches of KP201 at a price to be negotiated. Failure to agree upon this pricing would result in JMI supplying these batches to us free of charge and we would pay JMI an additional royalty payment on such batches. The percentage royalty rate ranges from the low teens at low volumes to the low single digits at higher volumes and is additive to any minimum royalty we may owe JMI on such batch. After the commercial launch of KP201/APAP, JMI will manufacture and supply KP201 at a price equal to JMI's fully allocated manufacturing cost.

We must purchase all of our U.S. KP201 needs from JMI and JMI cannot supply KP201 to other companies. After the commercial launch of KP201, JMI is required to identify a secondary manufacturing site and qualify and validate that site for the production of KP201.

The term of the Supply Agreement extends as long as we hold a valid and enforceable patent for KP201 or until the tenth anniversary of KP201's commercial launch, whichever date is later. Upon the expiration of such term, the agreement will automatically renew for a period of two years unless either party provides 12 months' prior notice of its intent not to renew.

Under our March 2012 asset purchase agreement with Shire, Shire has a right of first refusal to acquire, license or commercialize KP415.

Under our March 2012 termination agreement with MonoSol, MonoSol has the right to receive an amount equal to a percentage in the low teens of any value generated by KP415, and any product candidates arising therefrom, including royalty payments on any license of KP415, the sale of KP415 to a third party, the commercialization of KP415 and the portion of any consideration that is attributable to the value of KP415 and paid to us or our stockholders in a change of control transaction.

### **Components of our Results of Operations**

#### ***Revenue***

To date, we have not generated any revenue. We do not expect to generate revenue for at least 15 months. If we fail to complete the development of our product candidates in a timely manner or fail to obtain their regulatory approval, our ability to generate future revenue would be compromised.

#### ***Operating Expenses***

We classify our operating expenses into two categories: research and development and general and administrative expenses. Salaries and personnel-related costs, including benefits, bonuses and stock-based compensation expense, comprise a significant component of each of these expense categories. We allocate expenses associated with our facilities, information technology costs and depreciation and amortization between these two categories based on employee headcount and the nature of work performed by each employee.

## Research and Development Expense

Research and development expense consists of expenses incurred while performing research and development activities to discover and develop potential product candidates. This includes conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for product candidates. We recognize research and development expenses as they are incurred. Our research and development expense primarily consists of:

- salaries and personnel-related costs, including benefits and any stock-based compensation, for our scientific personnel performing research and development activities;
- costs related to executing preclinical studies and clinical trials;
- fees paid to consultants and other third parties who support our product candidate development;
- other costs in seeking regulatory approval of our products; and
- allocated facility-related costs and overhead.

We typically use our employee, consultant and infrastructure resources across our development programs. We track outsourced development costs by product candidate or development program, but we do not allocate personnel costs, other internal costs or external consultant costs to specific product candidates or development programs.

Prior to January 1, 2012, our research and development costs were split between two of our product candidates, KP106 and KP201/APAP. Early in 2012, we sold our rights to KP106, and for the year ended December 31, 2012 and all subsequent periods, most of our research and development expenses related to the development of our product candidate KP201/APAP. The following table summarizes our research and development expenses for the years ended December 31, 2015, 2014 and 2013 (in thousands):

	Year Ended December 31, 2015	Year Ended December 31, 2014	Year Ended December 31, 2013
Outsourced development costs directly identified to programs:			
KP201/APAP	\$ 7,342	\$ 9,049	\$ 1,428
KP415	111	—	—
KP511	1,564	—	2
Total costs directly identified to programs	<u>9,017</u>	<u>9,049</u>	<u>1,430</u>
Costs not directly allocated to programs:			
Employee expenses including cash compensation, benefits and share-based compensation	3,655	1,861	1,457
Facilities	197	160	108
Other	1,062	847	372
Total costs not directly allocated to programs	<u>4,914</u>	<u>2,868</u>	<u>1,937</u>
Total research and development expenses	<u>\$ 13,931</u>	<u>\$ 11,917</u>	<u>\$ 3,367</u>

We plan to increase our research and development expense for the foreseeable future as we continue our efforts to commercialize, if approved, and further advance the development of our product candidates, subject to the availability of additional funding.

The successful commercialization, if approved, and development of product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs required to commercialize, if approved, and complete the remaining development of any product candidates. This is due to the numerous risks and uncertainties associated with the development of product candidates.

## General and Administrative Expense

General and administrative expense consists primarily of salaries and personnel-related costs, including employee benefits and any stock-based compensation, for employees performing functions other than research and development. This includes personnel in

executive, finance, human resources and administrative support functions. Other general and administrative expenses include facility-related costs not otherwise allocated to research and development expense, professional fees for auditing, tax and legal services, expenses associated with obtaining and maintaining patents, consulting costs and costs of our information systems.

We expect that our general and administrative expense will increase as we continue to operate as a public reporting company and continue to develop and commercialize KP201/APAP, if approved, and our other product candidates. We believe that these increases will likely include increased costs for director and officer liability insurance, costs related to the hiring of additional personnel and increased fees for outside consultants, lawyers and accountants. We also expect to incur increased costs to comply with corporate governance, internal controls, investor relations, disclosure and similar requirements applicable to public reporting companies.

### **Other (Expense) Income**

Other (expense) income consists primarily of non-cash costs associated with fair value adjustments to our derivative and warrant liability and amortization of debt issuance costs and debt discount to interest expense. Other (expense) income also includes interest expense incurred on our outstanding borrowings. Additionally, during the year ended December 31, 2014, we recognized a gain on extinguishment of debt upon the conversion of our 2013 convertible notes. These items are unrelated to our core business and thus are recognized as other (expense) income in our statements of operations.

From 2008 through 2012, we issued warrants to purchase 554,454 shares of common stock to the placement agent in our private placement offerings of redeemable convertible preferred stock as payment for services. We accounted for the warrants issued in connection with the private placement offerings as a derivative liability, which is adjusted to fair value at each reporting period.

From June 2013 through October 2013, we issued \$3.8 million of convertible notes together with warrants to purchase equity securities. The warrants allowed the holders to purchase shares of the same class and series of equity securities to be issued in specified future financings. In connection with the closing of the Deerfield facility in June 2014 described below, these warrants became warrants to purchase 1,079,453 shares of our Series D redeemable convertible preferred stock at a price of \$0.78 per share. The fair value of the warrants at issuance was \$0.4 million, and we recorded the warrant fair value as a debt discount. We concluded that the warrants qualified as a derivative liability and accordingly that the fair value of the warrants should be adjusted at each reporting period. We also concluded that embedded features in the convertible notes should be valued separately from the notes and adjusted to fair value at each reporting period. The amortization of the debt discount is recorded in interest expense and any change in the derivative and warrant liability is recorded in fair value adjustment.

On June 2, 2014, we entered into a \$60.0 million multi-tranche credit facility agreement with Deerfield. At the time we entered into the Deerfield facility, we borrowed the first tranche, which consisted of a \$15.0 million term note and a \$10.0 million senior secured convertible note. All borrowings under the Deerfield facility bear interest at 9.75% per annum. When we borrowed the first tranche, we issued to Deerfield a warrant to purchase 14,423,076 shares of Series D redeemable convertible preferred stock at an exercise price of \$0.78 per share, which upon the completion of our initial public offering became exercisable for 1,923,077 shares of our common stock at an exercise price of \$5.85 per share. This warrant is exercisable until June 2, 2024. The fair value of the warrant was accounted for as a debt discount and we are amortizing it over the stated term of the Deerfield facility. We concluded that the warrant qualified as a derivative liability and accordingly that the fair value of the warrant should be adjusted at each reporting period. We also concluded that an embedded feature in the warrant should be valued separately and adjusted to fair value at each reporting period. The amortization of debt issuance costs and debt discount is recorded in interest expense and the change in the derivative and warrant liability is recorded in fair value adjustment.

In February 2016, we used approximately \$18.6 million of the net proceeds from the offering of our 2021 Notes to repay in full the \$15.0 million original principal amount on the term note issued under Deerfield facility plus all accrued but unpaid interest on the term note, a make whole interest payment on the term note and a prepayment premium on the term note.

### **Income Tax Benefit**

Income tax benefit consists of refundable state income tax credits. To date, we have not been required to pay U.S. federal or state income taxes because we have not generated taxable income. We have received state income tax credits related to our qualified research activities in Iowa.

## Results of Operations

### Comparison of the Years Ended December 31, 2015 and 2014 (in thousands):

	Year Ended December 31, 2015	Year Ended December 31, 2014	Period-to- Period Change
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	13,931	11,917	2,014
General and administrative	8,883	4,526	4,357
Total operating expenses	22,814	16,443	6,371
Loss from operations	(22,814)	(16,443)	(6,371)
Other income (expenses):			
Gain on extinguishment of debt	—	1,900	(1,900)
Interest expense related to amortization of debt issuance costs and discount	(1,909)	(1,114)	(795)
Interest expense on principal	(2,671)	(1,605)	(1,066)
Fair value adjustment	(27,276)	(7,223)	(20,053)
Interest and other income	32	8	24
Total other expenses	(31,824)	(8,034)	(23,790)
Loss before income taxes	(54,638)	(24,477)	(30,161)
Income tax (expense) benefit	(26)	22	(48)
Net loss	\$ (54,664)	\$ (24,455)	\$ (30,209)

### Research and Development

Research and development expenses increased by \$2.0 million, from \$11.9 million for the year ended December 31, 2014, to \$13.9 million for the year ended December 31, 2015. This increase was primarily attributable to a \$1.7 million increase in contracted third-party research and development spending on KP511 and KP415, which was offset by a decrease of \$1.7 million in contracted third-party research and development spending on KP201/APAP, as well as a \$1.3 million increase in salaries and personnel-related costs due to increased headcount, a \$0.2 million increase in miscellaneous research and development costs related to overhead and a \$0.5 million increase in stock-based compensation expense related to the vesting of stock awards during the year ended December 31, 2015.

### General and Administrative

General and administrative expenses increased by \$4.4 million, from \$4.5 million for the year ended December 31, 2014, to \$8.9 million for the year ended December 31, 2015. This increase was primarily attributable to a \$1.9 million increase in salaries and personnel-related costs due to increased headcount, a \$1.6 million increase in stock-based compensation expense related to the vesting of stock awards, a \$0.2 million increase in miscellaneous general and administrative costs related to overhead, a \$0.4 million increase in marketing expenses and a \$0.3 million increase in accounting expenses and professional fees.

### Other Expenses

Other expenses increased by \$23.8 million, from \$8.0 million for the year ended December 31, 2014, to \$31.8 million for the year ended December 31, 2015. This was primarily attributable to the \$20.1 million increase in the fair value adjustment related to our derivative and warrant liability, and a \$1.9 million decrease in the gain on extinguishment of debt recognized in the second quarter of 2014 related to the conversion of our 2013 convertible notes into shares of our Series D redeemable convertible preferred stock. In addition, there was a \$0.8 million increase in the amortization of the debt issuance costs and debt discount and a \$1.0 million increase in interest expense related to the Deerfield facility during the year ended December 31, 2015.

## Comparison of the Years Ended December 31, 2014 and 2013 (in thousands)

	Year Ended December 31, 2014	Year Ended December 31, 2013	Period-to- Period Change
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	11,917	3,367	8,550
General and administrative	4,526	1,351	3,175
Total operating expenses	16,443	4,718	11,725
Loss from operations	(16,443)	(4,718)	(11,725)
Other income (expenses):			
Gain on extinguishment of debt	1,900	-	1,900
Interest expense related to amortization of debt issuance costs and discount	(1,114)	(1,560)	446
Interest expense on principal	(1,605)	(157)	(1,448)
Fair value adjustment	(7,223)	1,137	(8,360)
Interest and other income	8	52	(44)
Total other expenses	(8,034)	(528)	(7,506)
Loss before income taxes	(24,477)	(5,246)	(19,231)
Income tax benefit	22	20	2
Net loss	\$ (24,455)	\$ (5,226)	\$ (19,229)

### Research and Development

Research and development expense increased by \$8.5 million, from \$3.4 million for the year ended December 31, 2013 to \$11.9 million for the year ended December 31, 2014. This increase was primarily attributable to a \$7.6 million increase in contracted third-party research and development spending on KP201/APAP.

### General and Administrative

General and administrative expense increased by \$3.2 million, from \$1.3 million for the year ended December 31, 2013 to \$4.5 million for the year ended December 31, 2014. This increase was primarily attributable to a \$1.2 million increase in legal expenses associated with the Deerfield facility and patent-related and general corporate legal fees. In addition, we experienced a \$0.9 million increase in accounting expenses, primarily related to our initial public offering, a \$0.5 million increase in professional fees associated with our increased marketing and recruiting efforts, and a \$0.5 million increase in salaries and personnel-related costs due to increased headcount.

### Other (Expense) Income

Other expenses increased by \$7.5 million, from \$0.5 million for the year ended December 31, 2013 to \$8.0 million for the year ended December 31, 2014. This change was primarily attributable to a \$1.5 million increase in interest expense, offset by a \$0.5 million decrease in amortization of debt discount. Additionally, we experienced an \$8.4 million increase in the fair value adjustment related to our derivative and warrant liability. These increases were partially offset by a \$1.9 million gain on extinguishment of debt recognized upon the conversion of our 2013 convertible notes.

### Liquidity and Capital Resources

#### Sources of Liquidity

Through December 31, 2015, we have funded our research and development and operating activities primarily through the issuance of \$29.6 million of debt, \$23.1 million of private placements of redeemable convertible preferred stock and the sale of common stock in our initial public offering. As of December 31, 2015, we had cash and cash equivalents of \$32.3 million and marketable securities of \$19.0 million. We completed the initial closing of our initial public offering in April 2015, with a subsequent closing in May 2015, pursuant to which we received net proceeds, including net proceeds from the underwriters' exercise of their option to purchase additional shares, of \$59.9 million, after deducting underwriting discounts and commissions of \$4.5 million. In addition, we incurred offering expenses totaling \$2.8 million.

We have incurred losses since our inception and, as of December 31, 2015, had an accumulated deficit of \$104.8 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may obtain through one or more equity offerings, debt financings or other third-party funding, including potential strategic alliances and licensing or collaboration arrangements.

As of December 31, 2015, the outstanding principal balance under the Deerfield facility was \$28.4 million. In February 2016, we used approximately \$18.6 million of the net proceeds from the offering of our 2021 Notes to repay in full the \$15.0 million original principal amount on the term note issued under Deerfield facility plus all accrued but unpaid interest on the term note, a make whole interest payment on the term note and a prepayment premium on the term note.

As of December 31, 2014, we had cash and cash equivalents of \$10.3 million.

### ***Deerfield Facility***

In June 2014, we entered into the \$60.0 million multi-tranche credit facility with Deerfield. At the time we entered into the Deerfield facility, we borrowed the first tranche, which consisted of a \$15.0 million term note and a \$10.0 million senior secured convertible note. Under the terms of the Deerfield facility, Deerfield is obligated to provide three additional tranches in the principal amounts of \$10.0 million, \$12.5 million and \$12.5 million, respectively, upon our request and after the satisfaction of specified conditions, including the FDA's acceptance of our NDA for KP201/APAP and, for the final two tranches, the approval of KP201/APAP for the commercial sale in the United States. Deerfield's obligation to provide such disbursements terminates on June 30, 2016. All loans issued under the Deerfield facility bear interest at 9.75% per annum. Interest accrued on outstanding debt under the Deerfield facility is due quarterly in arrears. Upon notice to Deerfield, we may choose to have one or more of the first eight of such scheduled interest payments added to the outstanding principal amount of the debt issued under the Deerfield facility, provided that all such interest will be due on July 1, 2016. We have elected this option on all six of the scheduled interest payments through December 31, 2015. We must repay one-third of the outstanding principal amount of all debt issued under the Deerfield facility on the fourth and fifth anniversaries of the Deerfield facility. We are then obligated to repay the balance of the outstanding principal amount on February 14, 2020.

Prepayment of the outstanding balance is not allowed without written consent of Deerfield.

Pursuant to the Deerfield facility, we issued to Deerfield 1,923,077 shares of our Series D redeemable convertible preferred stock as consideration for the loans provided to us thereunder. Upon closing of our initial public offering, these shares of Series D redeemable convertible preferred stock reclassified into 256,410 shares of our common stock.

We also issued to Deerfield a warrant to purchase 14,423,076 shares of our Series D redeemable convertible preferred stock at an initial exercise price of \$0.78 per share. Upon closing of our initial public offering, this warrant converted into a warrant exercisable for 1,923,077 shares of our common stock at an exercise price of \$5.85 per share. If we exercise our option to borrow the second tranche, then we will issue to Deerfield a warrant to purchase 1,282,052 shares of our common stock at an initial exercise price of \$5.85 per share. Similarly, if we borrow the third and fourth tranches, in each instance, we will issue to Deerfield a warrant exercisable for the number of shares equal to 60% of the principal amount of such disbursement divided by 115% of the volume weighted average sales price of our common stock for the 20 consecutive trading days immediately prior to the date of such disbursement with an exercise price per share equal to 115% of such weighted average sales price.

Pursuant to the Deerfield facility, we may not enter into specified transactions, including a debt financing in the aggregate value of \$750,000 or more, a merger, an asset sale or any other change of control transaction or any joint venture, partnership or other profit sharing arrangement, without the prior approval of Deerfield. Additionally, if we were to enter into a major transaction, including a merger, consolidation, sale of substantially all of our assets or other change of control transaction, Deerfield would have the ability to demand that prior to consummation of such transaction we repay all outstanding principal and accrued interest of any notes issued under the Deerfield facility. Under each warrant issued pursuant to the Deerfield facility, Deerfield has the right to demand that we redeem the warrant for a cash amount equal to the Black-Scholes value of a portion of the warrant upon the occurrence of specified events, including a merger, an asset sale or any other change of control transaction.

The Deerfield facility also includes high yield discount obligation protections which go into effect in June 2019. After this time, if at any interest payment date our outstanding indebtedness under the Deerfield facility would qualify as an "applicable high yield discount obligation" under the Internal Revenue Code, as amended, or the Code, then we are obligated to prepay in cash on each such date the amount necessary to avoid such classification.

## 2021 Notes

In February 2016, we issued the 2021 Notes in aggregate principal amount of \$86.25 million. The 2021 Notes were originally issued to Cowen and Company, LLC and RBC Capital Markets, LLC as representatives of the several initial purchasers, who subsequently resold the 2021 Notes to qualified institutional buyers in reliance on the exemption from registration provided by Rule 144A under the Securities Act.

The 2021 Notes were issued pursuant to an indenture, dated as of February 9, 2016, or the indenture, between the Company and U.S. Bank National Association, as trustee. Interest on the 2021 Notes will be payable semi-annually in cash in arrears on February 1 and August 1 of each year, beginning on August 1, 2016, at a rate of 5.50% per year. The 2021 Notes mature on February 1, 2021 unless earlier converted or repurchased.

The 2021 Notes are not redeemable prior to the maturity date, and no sinking fund is provided for the 2021 Notes. The 2021 Notes are convertible at an initial conversion rate of 58.4454 shares of our common stock per \$1,000 principal amount of the 2021 Notes, subject to adjustment under the indenture, which is equal to an initial conversion price of approximately \$17.11 per share of our common stock. Upon conversion, the 2021 Notes will be settled in shares of our common stock, together with a cash payment in lieu of delivering any fractional shares. The conversion rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date, we will increase the conversion rate for a holder who elects to convert its 2021 Notes in connection with such a corporate event in certain circumstances.

If we undergo a “fundamental change” (as defined in the indenture), holders may require that we repurchase for cash all or any portion of their 2021 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2021 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

Holders who convert on or after the date that is one year after the last date of original issuance of the 2021 Notes may also be entitled to receive, under certain circumstances, an interest make-whole payment payable in shares of our common stock.

The indenture includes customary terms and covenants, including certain events of default after which the 2021 Notes may be due and payable immediately.

### Cash Flows (in thousands):

#### Comparison of the Years Ended December 31, 2015 and 2014 (in thousands)

	Year Ended December 31, 2015	Year Ended December 31, 2014	Period-to- Period Change
Net cash used in operating activities	\$ (20,268)	\$ (14,671)	\$ (5,597)
Net cash used in investing activities	(19,137)	(47)	(19,090)
Net cash provided by financing activities	61,468	23,004	38,464
Net increase in cash and cash equivalents	<u>\$ 22,063</u>	<u>\$ 8,286</u>	<u>\$ 13,777</u>

### Operating Activities

For the year ended December 31, 2015, net cash used in operating activities of \$20.3 million consisted of a net loss of \$54.7 million, primarily attributable to our spending on research and development, offset by \$34.3 million in adjustments for non-cash items and increased by \$0.1 million of cash provided by changes in working capital. Adjustments for non-cash items primarily consisted of changes in fair value of our derivative and warrant liabilities of \$27.3 million, non-cash interest expense of \$2.7 million, stock-based compensation expense of \$2.4 million, and amortization of debt issuance costs and debt discount of \$1.9 million.

For the year ended December 31, 2014, net cash used in operating activities of \$14.7 million consisted of a net loss of \$24.5 million, primarily attributable to our spending on research and development, offset by \$8.3 million in adjustments for non-cash items and \$1.5 million of cash provided by changes in working capital. Adjustments for non-cash items primarily consisted of changes in fair value of our derivative and warrant liabilities of \$7.2 million, non-cash interest expense of \$1.6 million, amortization of debt issuance costs and debt discount of \$1.1 million and stock-based compensation expense of \$0.2 million, partially offset by a \$1.9 million gain on extinguishment of debt.



## Investing Activities

For the year ended December 31, 2015, net cash used in investing activities was \$19.1 million, which was primarily attributable to the purchase of marketable securities of \$19.0 million and property and equipment of \$0.1 million.

For the year ended December 31, 2014, net cash used in investing activities was \$47,000, which was primarily attributable to the purchase of property and equipment.

## Financing Activities

For the year ended December 31, 2015, net cash provided by financing activities was \$61.5 million. Net cash consisted of (i) \$59.9 million in proceeds, net of underwriter's discounts, from our initial public offering, in which we issued and sold 5,090,909 shares of our common stock at a public offering price of \$11.00 per share in April 2015, and subsequently sold an additional 763,636 shares of our common stock pursuant to the underwriters' option to purchase additional shares in May 2015, and (ii) proceeds of \$4.0 million from the issuance of our Series D-1 convertible redeemable preferred stock in February 2015 and \$0.5 million of proceeds related to the exercise of stock options and warrants, offset by payment of deferred offering costs of \$0.3 million and payment of debt and stock issuance costs of \$2.5 million.

For the year ended December 31, 2014, net cash provided by financing activities consisted of \$25.0 million in proceeds from the issuance of a \$15.0 million term note and a \$10.0 million senior secured convertible promissory note under the Deerfield facility. These amounts were partially offset by \$1.8 million in payments of deferred offering costs, \$0.2 million in payments of debt issuance costs and \$0.1 million in repayments of debt and capital leases.

## Comparison of the Years Ended December 31, 2014 and 2013 (in thousands)

	Year Ended December 31, 2014	Year Ended December 31, 2013	Period-to- Period Change
Net cash used in operating activities	\$ (14,671)	\$ (4,327)	\$ (10,344)
Net cash used in investing activities	(47)	(34)	(13)
Net cash provided by financing activities	23,004	3,788	19,216
Net increase (decrease) in cash and cash equivalents	\$ 8,286	\$ (573)	\$ 8,859

## Operating Activities

For the year ended December 31, 2014, net cash used in operating activities of \$14.7 million consisted of a net loss of \$24.5 million, primarily attributable to our spending on research and development, offset by \$8.3 million in adjustments for non-cash items and \$1.5 million of cash provided by changes in working capital. Adjustments for non-cash items primarily consisted of changes in fair value of our derivative and warrant liabilities of \$7.2 million, non-cash interest expense of \$1.6 million, amortization of debt issuance costs and debt discount of \$1.1 million and stock-based compensation expense of \$0.2 million, partially offset by a \$1.9 million gain on extinguishment of debt.

For the year ended December 31, 2013, net cash used in operating activities of \$4.3 million consisted of a net loss of \$5.2 million, primarily attributable to our spending on research and development, offset by \$0.8 million in adjustments for non-cash items and \$0.1 million of cash provided by changes in working capital. Adjustments for non-cash items primarily consisted of amortization of debt issuance costs and debt discount of \$1.6 million, stock-based compensation expense of \$0.1 million, non-cash interest expense of \$0.2 million and depreciation and amortization expense of \$0.1 million, offset by changes in fair value of our derivative and warrant liabilities of \$1.1 million.

## Investing Activities

For the year ended December 31, 2014, net cash used in investing activities was \$47,000, which was primarily attributable to the purchase of property and equipment.

For the year ended December 31, 2013, net cash used in investing activities was \$34,000, which was primarily attributable to the purchase of property and equipment.

## ***Financing Activities***

For the year ended December 31, 2014, net cash provided by financing activities consisted of \$25.0 million in proceeds from the issuance of a \$15.0 million term note and a \$10.0 million senior secured convertible promissory note under the Deerfield facility. These amounts were partially offset by \$1.8 million in payments of deferred offering costs, \$0.2 million in payments of debt issuance costs and \$0.1 million in repayments of debt and capital leases.

For the year ended December 31, 2013, net cash provided by financing activities consisted of \$3.8 million in proceeds from the issuance of convertible notes, partially offset by \$0.1 million in repayments of debt and capital leases.

## ***Future Funding Requirements***

To date, we have not generated any revenue. We do not know when, or if, we will generate any revenue. We do not expect to generate significant revenue unless and until we obtain regulatory approval of and commercialize KP201/APAP. In addition, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, product candidates. We also expect to incur additional costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Based upon our current operating plan, we believe that our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements through at least the next 21 months. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of product candidates.

Our future capital requirements will depend on many factors, including:

- the progress and results of our preclinical studies, clinical trials and other product development and commercialization activities;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the ability to obtain abuse-deterrent claims in the labels for our product candidates, including KP201/APAP;
- the number and development requirements of other product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the efforts necessary to institute post-approval regulatory compliance requirements;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval, which may be affected by market conditions, including obtaining coverage and adequate reimbursement of our product candidates from third-party payors, including government programs and managed care organizations, and competition within the therapeutic class to which our product candidates are assigned;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the extent to which we acquire or in-license other product candidates and technologies.

Our commercial revenue, if any, will be derived from sales of prodrug products that we do not expect to be commercially available for at least 15 months, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business

objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, or exercise our right to borrow additional tranches under the Deerfield facility, the terms of these securities or this debt may restrict our ability to operate. The Deerfield facility includes, and any future debt financing and equity financing, if available, may involve agreements that include, covenants limiting and restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, entering into profit-sharing or other arrangements or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

### Contractual Obligations, Commitments and Contingencies

Our principal commitments consist of obligations under our outstanding debt obligations, non-cancelable leases for our office space and certain equipment, capital leases for various equipment and vendor contracts to provide research services. The following table summarizes these contractual obligations at December 31, 2015 (in thousands):

	Total	Less Than 1 year	1 to 3 Years	3 to 5 Years	More Than 5 Years
<b>Debt:</b>					
Principal payments	\$ 25,000	\$ —	\$ 8,333	\$ 16,667	\$ —
Interest payments	13,044	6,854	4,465	1,725	—
Operating lease commitments	7,691	440	984	913	5,354
Capital lease obligations	26	26	—	—	—
Total contractual obligations	<u>\$ 45,761</u>	<u>\$ 7,320</u>	<u>\$ 13,782</u>	<u>\$ 19,305</u>	<u>\$ 5,354</u>

The contractual obligations table does not include any potential royalty payments we may be required to make under our Supply Agreement because the amount and timing of when these payments will actually be made is uncertain and the payments are contingent upon the initiation and completion of future activities.

In February 2016, we issued the 2021 Notes in aggregate principal amount of \$86.25 million pursuant to the indenture. Interest on the 2021 Notes will be payable semi-annually in cash in arrears on February 1 and August 1 of each year, beginning on August 1, 2016, at a rate of 5.50% per year. The 2021 Notes mature on February 1, 2021 unless earlier converted or repurchased. The 2021 Notes are not redeemable prior to the maturity date, and no sinking fund is provided for the 2021 Notes. Upon conversion, the 2021 Notes will be settled in shares of our common stock, together with a cash payment in lieu of delivering any fractional shares. The conversion rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date, we will increase the conversion rate for a holder who elects to convert its 2021 Notes in connection with such a corporate event in certain circumstances.

If we undergo a “fundamental change” (as defined in the indenture), holders may require that we repurchase for cash all or any portion of their 2021 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2021 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

Holders who convert on or after the date that is one year after the last date of original issuance of the 2021 Notes may also be entitled to receive, under certain circumstances, an interest make-whole payment payable in shares of our common stock.

We used approximately \$18.6 million of the net proceeds from the offering of our 2021 Notes to repay in full the \$15.0 million original principal amount on the term note issued under Deerfield facility plus all accrued but unpaid interest on the term note, a make whole interest payment on the term note and a prepayment premium on the term note.

### Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

### Critical Accounting Policies and Significant Judgments and Estimates

This management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, as well as the reported revenues and expenses

during the reported periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note B to our audited financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements and understanding and evaluating our reported financial results.

### **Stock-Based Compensation**

We record the fair value of stock options issued as of the grant date as compensation expense. We recognize compensation expense over the requisite service period, which is equal to the vesting period. Stock-based compensation expense has been reported in our statements of operations as follows (in thousands):

	Year Ended December 31, 2015	Year Ended December 31, 2014	Year Ended December 31, 2013
Research and development	\$ 610	\$ 62	\$ 29
General and administrative	1,759	152	105
	<u>\$ 2,369</u>	<u>\$ 214</u>	<u>\$ 134</u>

### **Determination of the Fair Value of Stock-Based Compensation Grants**

We calculate the fair value of stock-based compensation arrangements using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the use of subjective assumptions, including the expected volatility of our common stock, the assumed dividend yield, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and the fair value of the underlying common stock on the date of grant. In applying these assumptions, we considered the following factors:

- we do not have sufficient history to estimate the volatility of our common stock. We calculate expected volatility based on reported data for selected similar publicly traded companies for which the historical information is available. For the purpose of identifying peer companies, we consider characteristics such as industry, length of trading history, similar vesting terms and in-the-money option status. We plan to continue to use the guideline peer group volatility information until the historical volatility of our common stock is sufficient to measure expected volatility for future option grants;
- the assumed dividend yield is based on our expectation of not paying dividends for the foreseeable future;
- we determine the average expected life of “plain vanilla” stock options based on the simplified method in accordance with SEC Staff Accounting Bulletin Nos. 107 and 110, as our common stock to date has been publicly traded for a limited amount of time. We expect to use the simplified method until we have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term. For options that are not considered “plain vanilla,” such as those with exercise prices in excess of the fair market value of the underlying stock, we use an expected life equal to the contractual term of the option;
- we determine the risk-free interest rate by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant; and
- we estimate forfeitures based on our historical analysis of actual stock option forfeitures.

We account for stock-based compensation arrangements with directors and consultants which contain only service conditions for vesting using a fair value approach. The fair value of these options is measured using the Black-Scholes option pricing model reflecting the same assumptions as applied to employee options in each of the reported periods, other than the expected life, which is assumed to be the remaining contractual life of the option. For director and consultant options subject to vesting, the compensation costs of these arrangements are subject to re-measurement over the vesting period.

The following summarizes the assumptions used for estimating the fair value of stock options granted to employees for the periods indicated:

	Year Ended December 31, 2015	Year Ended December 31, 2014	Year Ended December 31, 2013
Risk-free interest rate	1.40% - 1.99%	0.91% - 2.70%	0.52% - 2.80%
Expected term (in years)	4.33 - 6.25	7.00 - 10.00	4.04 - 10.00
Expected volatility	68.79% - 86.84%	86.00% - 95.00%	58.55% - 92.00%
Expected dividend yield	0%	0%	0%

Based upon the stock price of \$19.86 per share, which is the last sale price of our common stock reported on The NASDAQ Global Market as of December 31, 2015, the aggregate intrinsic value of outstanding options to purchase shares of our common stock as of December 31, 2015 and December 31, 2014 was \$9.2 million and \$5.7 million, respectively, of which \$5.1 million as of December 31, 2015 and \$2.6 million as of December 31, 2014 related to vested options and \$4.1 million as of December 31, 2015 and \$3.1 million as of December 31, 2014 related to unvested options.

#### ***Determination of Exercise Price of Stock Options and the Fair Value of Common Stock on Grant Dates Prior to Our Initial Public Offering***

The following table summarizes by grant date the number of shares of common stock subject to stock options granted between January 1, 2013 and March 2, 2015, as well as the associated per-share exercise price and the estimated fair value per share of our common stock on the grant date:

Grant Date	Number of Shares Underlying Options Granted	Exercise Price Per Share	Estimated Fair Value Per Share
January 13, 2013	2,000	\$ 5.85	\$ 5.85
April 4, 2013	3,333	5.85	5.85
July 10, 2013	80,000	5.85	3.60
January 1, 2014	14,664	5.85	3.90
June 2, 2014	13,333	5.85	5.48
June 9, 2014	666	5.85	5.48
June 18, 2014	6,400	5.85	5.48
July 9, 2014	77,199	5.85	5.48
January 20, 2015	8,640	8.63	8.63
March 2, 2015	145,199	8.63	8.63

In setting the exercise price of the stock options at each of the grant dates through July 9, 2014, management and the board of directors used the \$5.85 per-share pricing of our latest private placement of Series C redeemable convertible preferred stock in 2012 without taking into consideration any of the rights and preferences of our redeemable convertible preferred stock over our common stock. Beginning with the January 20, 2015 grant date through the March 2, 2015 grant date, management and the board of directors considered a third-party valuation in determining the exercise price of the stock options.

In the fall of 2014 we undertook third-party valuations of the fair value of our common stock as of July 10, 2013, December 31, 2013 and June 2, 2014 for financial reporting purposes. The estimated fair values per share of our common stock in the table above, as determined by the third-party valuations beginning with July 10, 2013 stock option grants, were used to measure the stock-based compensation expense for options granted during these periods.

There is inherent uncertainty in these estimates and, if we had made different assumptions than those described, the fair value of the underlying common stock and amount of our stock-based compensation expense, net loss and net loss per share amounts would have differed.

### ***Common Stock Valuation Methodology—Third-Party Valuations***

In estimating the fair value of our common stock at July 10, 2013, December 31, 2013, June 2, 2014 and December 31, 2014, given the absence of a public trading market for our common stock, and in accordance with the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, management and our third-party valuation specialists utilized the probability weighted expected return method, or PWERM, approach to allocate equity value to our common stock. The PWERM approach employs various market, income or cost approach calculations depending on the likelihood of various liquidation scenarios. For each of the various scenarios, an equity value is estimated and the rights and preferences for each class of stock are then considered to allocate the equity value to common stock. The common stock value is then multiplied by a discount factor reflecting the calculated discount rate and the timing of the event. Lastly, the common share value is multiplied by an estimated probability for each scenario. The probability and timing of each scenario are based on discussions between our board of directors and our management team. Under the PWERM, the value of our common stock was estimated based on four possible future events for our company:

- an earlier or later initial public offering, or IPO;
- a strategic merger or sale;
- our remaining a private company; and
- the dissolution of our company.

We used the market approach in determining the equity value of our business for use in the early and late IPO, strategic merger or sale and remaining private scenarios. We used the cost approach to value our net assets available to common stockholders if we were forced to liquidate our assets and dissolve the company. The cost approach involves identifying our significant tangible assets and liabilities, estimating the individual current market values of each and then totaling them to derive the value of the business as a whole.

The market approach estimates the fair value of a company by applying market multiples of comparable publicly traded companies and publicly disclosed data from arm's-length strategic merger or sale transactions involving similar companies in the marketplace. We reviewed recent precedent biopharmaceutical IPOs and merger or sale transactions to develop equity value estimates for application at each measurement date. We gave consideration to differences between us and the selected guideline public companies in terms of size, anticipated profitability, market size and other critical characteristics that generally reflect an investor's assessment of the business and financial risks inherent in our industry. In particular, we gave consideration to the fact that we had only one clinical-stage product candidate under development and that the product candidate is a chemically modified form of an existing approved drug with potential, but as yet unproven, differentiation. We also considered that this product candidate is intended to compete in a large existing market characterized by intense competition, low generic pricing and a challenging third-party reimbursement environment. In addition, we considered the size of the transaction, anticipated debt outstanding at IPO and number of employees as possible valuation proxies when comparing us with the guideline companies.

#### ***Determination of Exercise Price of Stock Options made at Our Initial Public Offering***

For the grants made on April 15, 2015, management and the board of directors relied on our initial public offering price to determine the exercise price of the stock options.

#### ***Determination of Exercise Price of Stock Options after Our Initial Public Offering***

After completion of our initial public offering, management and the board of directors have relied on the closing sale price of our common stock as reported on The NASDAQ Global Market on the date of grant to determine the exercise price of stock options.

#### ***Fair Value of Financial Instruments***

We have common stock warrants and, for the period ended December 31, 2014, had preferred stock warrants that meet the definition of derivative financial instruments and are accounted for as derivatives. The fair value of these warrant derivatives is based on either a Black-Scholes valuation model or a Monte Carlo simulation model at each reporting period.

The derivative liability for the common stock warrants was \$3.9 million at December 31, 2015 and \$2.7 million at December 31, 2014. The derivative liability for the preferred stock warrants was \$34.0 million at December 31, 2015 and \$13.2 million at December 31, 2014.

Upon exercise of the warrants, we will adjust the derivative liability to fair value with any changes recorded in other (expense) income. At such time, the derivative liability will also be reclassified to additional paid-in capital, and no further revaluations will be necessary.

#### ***Utilization of Net Operating Loss Carryforwards and Research and Development Credits***

As of December 31, 2015, we had federal net operating loss, or NOL, carryforwards of approximately \$62.0 million with expiration dates from 2027 to 2035. We also had research and development credit carryforwards of \$2.5 million with expiration dates ranging from 2027 to 2035.

In accordance with Section 382 of the Code, a change in equity ownership of greater than 50% within a three-year period results in an annual limitation on a company's ability to utilize its NOL carryforwards created during the tax periods prior to the change in ownership. We have not determined if we have experienced Section 382 ownership changes in the past and if a portion of our NOL carryforwards are subject to an annual limitation under Section 382 of the Code. If we experience a Section 382 ownership change in connection with our initial public offering, the conversion of our outstanding convertible debt or as a result of future changes in our stock ownership, the tax benefits related to the NOL carryforwards may be further limited or lost.

#### ***Emerging Growth Company Status***

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

#### ***Recent Accounting Pronouncements***

On April 5, 2012, President Obama signed the Jump-Start Our Business Startups Act (the JOBS Act) into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an emerging growth company. As an emerging growth company, the Company may elect to adopt new or revised accounting standards when they become effective for non-public companies, which typically is later than public companies must adopt the standards. The Company has elected not to take advantage of the extended transition period afforded by the JOBS Act and, as a result, 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.

In July 2013, the Financial Accounting Standards Board, or FASB issued Accounting Standard Update ("ASU") No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exist* ("ASU 2013-11"). ASU 2013-11 amends the presentation requirements of ASC Topic 740 Income Taxes and requires an unrecognized tax benefit to be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, similar tax loss, or a tax credit carryforward. To the extent the tax benefit is not available at the reporting date under the governing tax law or if the entity does not intend to use the deferred tax asset for such purpose, the unrecognized tax benefit should be presented as a liability and not combined with deferred tax assets. ASU 2013-11 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The amendments are to be applied to all unrecognized tax benefits that exist as of the effective date and may be applied retrospectively to each prior reporting period presented. The adoption of ASU 2013-11 in 2014 did not have a material impact on its financial statements as no uncertain tax positions existed for the years ended December 31, 2015 and 2014.

In May 2014, the FASB issued guidance codified in ASC Topic 606, *Revenue Recognition—Revenue from Contracts with Customers*, which amends the guidance in former ASC 605, *Revenue Recognition*, and becomes effective beginning January 1, 2018. The Company is currently evaluating the impact of the provisions of ASC 606 on its financial statements and disclosures.

In June 2014, the FASB issued ASU 2014-12, *Compensation-Stock Compensation (Topic 718): Accounting for Share-Based Payments when the Terms of an Award Provide that a Performance Target Could Be Achieved After the Requisite Service Period* ("ASU 2014-12"). The amendments require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. ASU 2014-12 is effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Earlier adoption is permitted. Entities may apply ASU 2014-12 either (a) prospectively to all awards granted or modified after the effective date or (b) retrospectively to all awards with performance targets

that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. If retrospective transition is adopted, the cumulative effect of applying this ASU as of the beginning of the earliest annual period presented in the financial statements should be recognized as an adjustment to the opening retained earnings balance at that date. Additionally, if retrospective transition is adopted, an entity may use hindsight in measuring and recognizing the compensation cost. The Company expects this standard to have a minimal impact on its financial statements upon adoption.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15"), which amends ASC Subtopic 205-40 to provide guidance about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related disclosures. Specifically, the amendments (1) provide a definition of the term "substantial doubt," (2) require an evaluation every reporting period, (3) provide principles for considering the mitigating effect of management's plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated and (6) require an assessment for a period of one year after the date that financial statements are issued. ASU 2014-15 is effective for fiscal years ending after December 15, 2016, and for annual periods and interim periods thereafter. The Company is currently evaluating the impact of the adoption of ASU 2014-15 on its financial statements and disclosures.

In January 2015, the FASB issued ASU No. 2015-01, *Income Statement - Extraordinary and Unusual Items (Subtopic 225-20); Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items* ("ASU 2015-01"), which eliminates from GAAP the concept of extraordinary items, stating that the concept causes uncertainty because (1) it is unclear when an item should be considered both unusual and infrequent and (2) users do not find the classification and presentation necessary to identify those events and transactions. ASU 2015-01 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015, with early adoption permitted provided the guidance is applied from the beginning of the fiscal year of adoption. The Company does not expect this standard to have an impact on its financial statements upon adoption.

In April 2015, the FASB issued ASU 2015-03, *Interest - Imputation of Interest (Subtopic 835-30)* ("ASU 2015-03"), which requires the debt issuance costs related to a recognized debt liability be presented in the balance sheet as direct deduction from the carrying amount of that debt liability, consistent with the presentation of debt discounts. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Adoption of ASU 2015-03 will reduce assets and liabilities by the amount of the debt issuance costs, which are \$1.1 million and \$1.5 million at December 31, 2015 and 2014, respectively.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes: Balance Sheet Classification of Deferred Taxes (Topic 740)* ("ASU 2015-17"), which requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. This update applies to all entities that present a classified statement of financial position. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. The Company does not expect this standard to have a material impact on its financial statements upon adoption.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments Overall - Recognition and Measurement of Financial Assets and Liabilities (Topic 825-10)* ("ASU 2016-01"), which provides several updates related to Topic 825-10. This update applies to all entities that hold financial assets or owe financial liabilities. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company does not expect this standard to have a material impact on its financial statements upon adoption.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* (ASU 2016-02), which requires lessees to recognize assets and liabilities for operating leases with lease terms greater than twelve months in the balance sheet. The update also requires improved disclosures to help users of financial statements better understand the amount, timing and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the impact of the adoption of ASU 2016-02 on its financial statements and disclosures.

## **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our primary exposure to market risk for our cash and cash equivalents is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. As of December 31, 2015, we had cash and cash equivalents of \$32.3 million and marketable securities of \$19.0 million. We currently do not hedge interest rate exposure. Because of the fixed rate of interest on our outstanding debt, an immediate 10% increase in interest rates would not have a material effect on our results of operations.



We are not subject to interest rate risk in connection with borrowings under the Deerfield facility because borrowings bear a fixed rate of interest.

In February 2016, we completed a private placement of our 2021 Notes. The 2021 Notes have a fixed annual interest rate of 5.50% and we, therefore, do not have economic interest rate exposure on the 2021 Notes. However, the fair value of the 2021 Notes will be exposed to interest rate risk. Generally, the fair value of the 2021 Notes will increase as interest rates fall and decrease as interest rates rise. The fair value of the 2021 Notes will also be affected by volatility in our stock price.

#### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The financial statements required by this item are set forth beginning in Item 15 of this report and are incorporated herein by reference.

#### **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

Not applicable.

#### **ITEM 9A. CONTROLS AND PROCEDURES**

##### ***Evaluation of Disclosure Controls and Procedures***

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our chief executive officer and our chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2015. Based on the evaluation of our disclosure controls and procedures as of December 31, 2015, our chief executive officer and our chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

##### ***Management's Report on Internal Control over Financial Reporting***

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

##### ***Changes in Internal Control over Financial Reporting***

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the most recent fiscal quarter that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

##### ***Inherent Limitations on Effectiveness of Controls***

Our management, including our chief executive officer and our chief financial officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a 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 management override

of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

**ITEM 9B. OTHER INFORMATION**

None.

## PART III

### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required by this Item 10 will be set forth under the headings “Proposal 1 Election of Directors,” “Executive Officers,” “Information Regarding the Board of Directors and Corporate Governance” and “Section 16(a) Beneficial Ownership Compliance” in our definitive proxy statement for our 2016 annual meeting of stockholders, or the proxy statement, and, is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. The Code of Conduct is available on our website at [www.kempharm.com](http://www.kempharm.com). The nominating and corporate governance committee of our board of directors is responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors. We intend to post any amendments to the Code of Conduct or any waivers of its requirements on our website.

### **ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item 11 will be set forth under the headings “Executive Compensation” and “Information Regarding the Board of Directors and Corporate Governance” in our proxy statement and is incorporated herein by reference.

### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.**

The information required by this Item 12 will be set forth under the headings “Security Ownership of Certain Beneficial Owners and Management” and “Securities Authorized for Issuance under the Equity Compensation Plans” in the proxy statement and is incorporated herein by reference.

### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by this Item 13 will be set forth under the headings “Information Regarding the Board of Directors and Corporate Governance” and “Transactions with Related Persons” in the proxy statement and is incorporated herein by reference.

### **ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

The information required by this Item 14 will be set forth under the headings “Proposal 2 Ratification of Selection of Independent Registered Public Accounting Firm” in the proxy statement and is incorporated herein by reference.

## ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

(1) *Index list to Financial Statements:*

	<b>Page</b>
Report of Independent Registered Public Accounting Firm	101
Balance Sheets as of December 31, 2015 and 2014	102
Statements of Operations for the years ended December 31, 2015, 2014 and 2013	103
Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Deficit for the years ended December 31, 2015, 2014, 2013	104
Statements of Cash Flows for the years ended December 31, 2015, 2014 and 2013	105
Notes to Financial Statements	106

(2) *Financial Statement Schedules*

All other schedules are omitted because they are not required or the required information is included in the financial statements or notes thereto.

(3) *Exhibits*

The exhibits listed in the accompanying Exhibit Index are filed or incorporated by reference as part of this report.

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders of KemPharm, Inc.:

We have audited the accompanying balance sheets of KemPharm, Inc. as of December 31, 2015 and 2014, and the related statements of operations, changes in redeemable convertible preferred stock and stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of KemPharm, Inc. at December 31, 2015 and 2014, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP  
Minneapolis, Minnesota  
March 15, 2016

**KEMPHARM, INC.**  
**BALANCE SHEETS**  
(in thousands, except share and par value amounts)

	December 31, 2015	December 31, 2014
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 32,318	\$ 10,255
Marketable securities	19,002	—
Prepaid expenses and other current assets	2,758	23
Total current assets	54,078	10,278
Debt issuance costs, net	1,133	1,468
Property and equipment, net	403	352
Other long-term assets	109	1,616
Total assets	<u>\$ 55,723</u>	<u>\$ 13,714</u>
<b>Liabilities, redeemable convertible preferred stock, and stockholders' deficit</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,906	\$ 3,096
Current portion of convertible notes	1,369	325
Current portion of term notes	2,041	482
Current portion of capital lease obligation	26	32
Total current liabilities	8,342	3,935
Convertible notes, net	7,865	7,235
Term notes, net	11,798	10,853
Derivative and warrant liability	37,839	15,966
Capital lease obligation, net	-	26
Total liabilities	65,844	38,015
Commitments and contingencies (Note G)		
Redeemable convertible preferred stock:		
Series A redeemable convertible preferred stock, \$0.0001 par value; no shares authorized, issued or outstanding as of December 31, 2015; 1,294,000 shares authorized, 1,293,838 issued and outstanding as of December 31, 2014	—	3,343
Series B redeemable convertible preferred stock, \$0.0001 par value; no shares authorized, issued or outstanding as of December 31, 2015; 829,234 shares authorized, issued and outstanding as of December 31, 2014	—	3,313
Series C redeemable convertible preferred stock, \$0.0001 par value; no shares authorized, issued or outstanding as of December 31, 2015; 2,474,400 shares authorized, 2,474,122 shares issued and outstanding as of December 31, 2014	—	11,892
Series D redeemable convertible preferred stock, \$0.0001 par value; no shares authorized, issued or outstanding as of December 31, 2015; 10,000,000 shares authorized, 967,359 issued and outstanding as of December 31, 2014	—	5,659
Total redeemable convertible preferred stock	—	24,207
Stockholders' deficit:		
Common stock, \$0.0001 par value, 250,000,000 shares authorized, 14,490,954 shares issued and outstanding as of December 31, 2015; 18,666,666 shares authorized, 2,381,041 shares issued and outstanding as of December 31, 2014	1	—
Additional paid-in capital	94,702	1,652
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of December 31, 2015; no shares authorized, issued or outstanding as of December 31, 2014	—	—
Accumulated deficit	(104,824)	(50,160)
Total stockholders' deficit	(10,121)	(48,508)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	<u>\$ 55,723</u>	<u>\$ 13,714</u>

*See accompanying notes to financial statements*

**KEMPHARM, INC.**  
**STATEMENTS OF OPERATIONS**  
(in thousands, except share and per share amounts)

	Year ended December 31,		
	2015	2014	2013
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	13,931	11,917	3,367
General and administrative	8,883	4,526	1,351
Total operating expenses	<u>22,814</u>	<u>16,443</u>	<u>4,718</u>
Loss from operations	<u>(22,814)</u>	<u>(16,443)</u>	<u>(4,718)</u>
Other (expense) income:			
Gain on extinguishment of debt	—	1,900	—
Interest expense related to amortization of debt issuance costs and discount	(1,909)	(1,114)	(1,560)
Interest expense on principal	(2,671)	(1,605)	(157)
Fair value adjustment	(27,276)	(7,223)	1,137
Interest and other income	32	8	52
Total other expenses	<u>(31,824)</u>	<u>(8,034)</u>	<u>(528)</u>
Loss before income taxes	(54,638)	(24,477)	(5,246)
Income tax (expense) benefit	(26)	22	20
Net loss	<u>\$ (54,664)</u>	<u>\$ (24,455)</u>	<u>\$ (5,226)</u>
Net loss per share:			
Basic and diluted	<u>\$ (7.42)</u>	<u>\$ (10.27)</u>	<u>\$ (2.20)</u>
Weighted average common shares outstanding:			
Basic and diluted	<u>7,368,681</u>	<u>2,381,041</u>	<u>2,381,041</u>

*See accompanying notes to financial statements*

KEMPHARM, INC.

STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT  
(in thousands)

	Redeemable Convertible Preferred Stock						Common Stock	Additional Paid-in Capital	Preferred Stock	Accumulated Deficit	Total Stockholders' Equity
	Series					Total					
	A	B	C	D	D-1						
Balance as of January 1, 2013	\$ 3,343	\$ 3,313	\$ 11,892	\$ —	\$ —	\$ 18,548	\$ 1,304	\$ —	\$ —	\$ (20,479)	\$ (19,175)
Net loss	—	—	—	—	—	—	—	—	—	(5,226)	(5,226)
Stock-based compensation expense	—	—	—	—	—	—	134	—	—	—	134
Balance as of December 31, 2013	\$ 3,343	\$ 3,313	\$ 11,892	\$ —	\$ —	\$ 18,548	\$ 1,438	\$ —	\$ —	\$ (25,705)	\$ (24,267)
Net loss	—	—	—	—	—	—	—	—	—	(24,455)	(24,455)
Stock-based compensation expense	—	—	—	—	—	—	—	214	—	—	214
Change in par value	—	—	—	—	—	—	(1,438)	1,438	—	—	—
Conversion of 2013 convertible notes into Series D preferred stock	—	—	—	4,159	—	4,159	—	—	—	—	—
Issuance of Series D preferred stock as financing fee	—	—	—	1,500	—	1,500	—	—	—	—	—
Balance as of December 31, 2014	\$ 3,343	\$ 3,313	\$ 11,892	\$ 5,659	\$ —	\$ 24,207	\$ —	\$ 1,652	\$ —	\$ (50,160)	\$ (48,508)
Net loss	—	—	—	—	—	—	—	—	—	(54,664)	(54,664)
Stock-based compensation expense	—	—	—	—	—	—	—	2,369	—	—	2,369
Exercise of stock options and warrants	—	—	—	—	—	—	—	4,749	—	—	4,749
Issuance of Series D-1 preferred stock	—	—	—	—	4,000	4,000	—	—	—	—	—
Issuance of common stock in connection with IPO, net of discounts and commissions	—	—	—	—	—	—	1	59,891	—	—	59,892
Conversion of 2013 warrants to equity classification	—	—	—	—	—	—	—	1,110	—	—	1,110
Conversion of preferred stock into common stock upon IPO	(3,343)	(3,313)	(11,892)	(5,659)	(4,000)	(28,207)	—	28,207	—	—	28,207
Offering expenses charged to equity	—	—	—	—	—	—	—	(3,276)	—	—	(3,276)
Balance as of December 31, 2015	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 1	\$ 94,702	\$ —	\$ (104,824)	\$ (10,121)

See accompanying notes to financial statements



**KEMPHARM, INC.**  
**STATEMENTS OF CASH FLOWS**  
(in thousands)

	2015	Year ended December 31, 2014	2013
<b>Cash flows from operating activities:</b>			
Net loss	\$ (54,664)	\$ (24,455)	\$ (5,226)
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on extinguishment of debt	—	(1,900)	—
Stock-based compensation expense	2,369	214	134
Non-cash interest expense	2,671	1,602	152
Amortization of debt issuance costs and debt discount	1,909	1,114	1,560
Depreciation and amortization expense	84	75	68
Fair value adjustment	27,276	7,223	(1,137)
Change in assets and liabilities:			
Prepaid expenses and other current assets	(1,228)	523	(4)
Accounts payable and accrued expenses	1,315	933	126
Net cash used in operating activities	<u>(20,268)</u>	<u>(14,671)</u>	<u>(4,327)</u>
<b>Cash flows from investing activities:</b>			
Proceeds from sale of assets	—	2	17
Purchases of property and equipment	(135)	(49)	(51)
Purchases of marketable securities	(19,002)	—	—
Net cash used in investing activities	<u>(19,137)</u>	<u>(47)</u>	<u>(34)</u>
<b>Cash flows from financing activities:</b>			
Proceeds from initial public offering, net of discounts and commissions	59,892	—	—
Proceeds from issuance of Series D-1 preferred stock	4,000	—	—
Payment of deferred offering costs	(315)	(1,767)	—
Proceeds from issuance of debt	—	25,000	3,846
Repayment of line of credit	—	(35)	(5)
Payment of debt and stock issuance costs	(2,533)	(163)	—
Repayment of obligations under capital lease	(32)	(31)	(53)
Proceeds from exercise of Series D preferred stock warrants	43	—	—
Proceeds from exercise of common stock options and warrants	413	—	—
Net cash provided by financing activities	<u>61,468</u>	<u>23,004</u>	<u>3,788</u>
Increase (decrease) in cash and cash equivalents	22,063	8,286	(573)
Cash and cash equivalents, beginning of year	10,255	1,969	2,542
Cash and cash equivalents, end of year	<u>\$ 32,318</u>	<u>\$ 10,255</u>	<u>\$ 1,969</u>
<b>Supplemental cash flow information:</b>			
Cash paid for interest	\$ —	\$ 3	\$ 5
Conversion feature on 2013 convertible notes and put option	—	—	1,150
Issuance of 2013 warrants and Deerfield warrant	—	7,610	410
Fixed assets financed by capital lease	—	—	94
Embedded Deerfield put option on Deerfield warrant	—	220	—
Issuance of Series D preferred stock as transaction fee	—	1,500	—
Conversion of 2013 convertible notes and interest into Series D preferred stock	—	4,159	—
Deferred offering costs included in accounts payable and accrued expenses	428	315	—
Conversion of preferred stock into common stock upon IPO	28,207	—	—
Offering expenses charged to equity	3,276	—	—
Reclassification of 2013 warrants to equity	1,110	—	—
Transfer of warrants to equity upon exercise	4,293	—	—

*See accompanying notes to financial statements*

**A. Description of Business and Basis of Presentation**

KemPharm, Inc. (the “Company”) is a clinical-stage specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs. Through the use of its Ligand Activated Therapy (“LAT”) platform technology, the Company is able to initiate and pursue the development of improved versions of widely prescribed, approved drugs. The Company was formed on October 30, 2006, and incorporated in Iowa, and reorganized in Delaware on May 30, 2014.

The Company has experienced recurring losses from operations and negative operating cash flows due to its ongoing research and development of its potential product candidates. The Company also has a stockholders’ deficit at December 31, 2015. Various internal and external factors will affect whether and when the candidates become approved drugs and how significant their market share will be. The length of time and cost of developing and commercializing these candidates and/or failure of them at any stage of the drug approval process will materially affect the Company’s financial condition and future operations. Based upon our current operating plan, we believe that our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements through at least the next 21 months.

***Reverse Stock Split***

On April 2, 2015, the Company effected a 1-for-7.5 reverse stock split of its issued common stock. All applicable share data, per share amounts and related information in the financial statements and notes thereto have been adjusted retroactively to give effect to the 1-for-7.5 reverse stock split.

***Initial Public Offering***

In April 2015, the Company completed an initial public offering (“IPO”) of its common stock. In connection with the initial closing of the IPO, the Company sold an aggregate of 5,090,909 shares of common stock at a price to the public of \$11.00 per share. In May 2015, the underwriters in the IPO exercised their option to purchase additional shares pursuant to which the Company sold an additional 763,636 shares of common stock at a price equal to the public price of \$11.00 per share. In the aggregate, net proceeds from the IPO including net proceeds from the underwriters’ exercise of their option to purchase additional shares, were \$59.9 million, after deducting underwriting discounts and commissions of \$4.5 million. In addition, offering expenses totaled \$2.8 million. Upon completion of the IPO, all outstanding shares of the Company’s redeemable convertible preferred stock were converted or reclassified into 5,980,564 shares of common stock and all outstanding warrants to acquire shares of the Company’s redeemable convertible preferred stock became warrants to acquire the Company’s common stock. In connection with the IPO, the Company amended and restated its Amended and Restated Certificate of Incorporation to change the authorized capital stock to 250,000,000 shares, designated as common stock, and 10,000,000 shares, designated as preferred stock, each with a par value of \$0.0001 per share.

***Reclassifications***

Certain prior year amounts have been reclassified to conform to the current year presentation. These reclassifications had no effect on previously reported net loss.

**B. Summary of Significant Accounting Policies**

***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires the Company to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

On an ongoing basis, the Company evaluates its estimates, including those related to the useful lives of property and equipment, the fair value of the Company’s common stock and assumptions used for purposes of determining stock-based compensation, income taxes, and the fair value of the derivative and warrant liability, among others. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable, the results of which form the basis for making judgments about the carrying value of assets and liabilities.

***Concentration of Credit Risk***

**KEMPHARM, INC.**  
**NOTES TO FINANCIAL STATEMENTS**

Financial instruments that potentially expose the Company to concentrations of credit risk consist principally of cash on deposit with multiple financial institutions, the balances of which frequently exceed insured limits.

***Cash and Cash Equivalents***

The Company considers any highly liquid investments with an original maturity of three months or less to be cash and cash equivalents.

***Marketable Securities***

The Company maintains investment securities that are classified as trading securities. These securities are carried at fair value with unrealized gains and losses included in other income on the statement of operations. The securities primarily consist of certificates of deposit and government bonds.

***Property and Equipment***

The Company records property and equipment at cost less accumulated depreciation and amortization. Costs of renewals and improvements that extend the useful lives of the assets are capitalized. Maintenance and repairs are expensed as incurred. Depreciation is determined on a straight-line basis over the estimated useful lives of the assets, which generally range from three to fifteen years. Leasehold improvements are amortized over the shorter of the useful life of the asset or the term of the related lease. Upon retirement or disposition of assets, the costs and related accumulated depreciation and amortization are removed from the accounts with the resulting gains or losses, if any, reflected in results of operations.

***Debt Issuance Costs***

Debt issuance costs incurred in connection with financing arrangements are amortized over the life of the respective financing arrangement using the effective interest method.

***Supply Arrangements***

The Company enters into supply arrangements for the supply of components of its product candidates. These arrangements also may include a share of future revenue if related product candidates reach commercialization. Costs under these supply arrangements, if any, are expensed as incurred (Note H).

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

Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets may not be recoverable. When such events occur, the Company compares the carrying amounts of the assets to their undiscounted expected future cash flows. If the undiscounted cash flows are insufficient to recover the carrying values, an impairment loss is recorded for the difference between the carrying values and fair values of the asset. No such impairment occurred for the years ended December 31, 2015 and 2014.

***Fair Value of Financial Instruments***

The accounting standard for fair value measurements provides a framework for measuring fair value and requires disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, based on the Company's principal or, in absence of a principal, most advantageous market for the specific asset or liability.

The Company uses a three-tier fair value hierarchy to classify and disclose all assets and liabilities measured at fair value on a recurring basis, as well as assets and liabilities measured at fair value on a non-recurring basis, in periods subsequent to their initial measurement. The hierarchy requires the Company to use observable inputs when available, and to minimize the use of unobservable inputs, when determining fair value. The three tiers are defined as follows:

- Level 1—Observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets;
- Level 2—Observable inputs other than quoted prices in active markets that are observable either directly or indirectly in the marketplace for identical or similar assets and liabilities; and
- Level 3—Unobservable inputs that are supported by little or no market data, which require the Company to develop its own assumptions.

### ***Research and Development***

Major components of research and development costs include cash compensation, stock-based compensation, depreciation and amortization expense on research and development property and equipment, costs of preclinical studies, clinical trials and related clinical manufacturing, costs of drug development, costs of materials and supplies, facilities cost, overhead costs, regulatory and compliance costs, and fees paid to consultants and other entities that conduct certain research and development activities on the Company's behalf. Costs incurred in research and development are expensed as incurred.

The Company records nonrefundable advance payments it makes for future research and development activities as prepaid expenses. Prepaid expenses are recognized as expense in the statements of operations as the Company receives the related goods or services.

### ***Patent Costs***

Patent costs, including related legal costs, are expensed as incurred and recorded within general and administrative expenses on the statements of operations.

### ***Income Taxes***

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial reporting and tax basis of assets and liabilities, as well as for operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using the tax rates that are expected to apply to taxable income for the years in which those tax assets and liabilities are expected to be realized or settled. Valuation allowances are recorded to reduce deferred tax assets to the amount the Company believes is more likely than not to be realized.

Uncertain tax positions are recognized only when the Company believes it is more likely than not that the tax position will be upheld on examination by the taxing authorities based on the merits of the position. The Company recognizes interest and penalties, if any, related to unrecognized income tax uncertainties in income tax expense. The Company did not have any accrued interest or penalties associated with uncertain tax positions for the years ended December 31, 2015 and 2014.

The Company files income tax returns in the United States for federal and various state jurisdictions. With few exceptions, the Company is no longer subject to U.S. federal and state and local income tax examinations for years prior to 2010, although carryforward attributes that were generated prior to 2012 may still be adjusted upon examination by the Internal Revenue Service if used in a future period. No income tax returns are currently under examination by taxing authorities.

### ***Stock-Based Compensation***

The Company measures and recognizes compensation expense for all stock-based payment awards made to employees, officers and directors based on the estimated fair values of the awards as of the grant date. The Company records the value of the portion of the award that is ultimately expected to vest as expense over the requisite service period. The Company also accounts for equity instruments issued to non-employees using a fair value approach under Accounting Standards Codification (ASC) subtopic 505-50. The Company values equity instruments and stock options granted using the Black-Scholes option pricing model. The value of non-employee stock-based compensation is subject to periodic adjustments as the underlying equity instruments vest and is recognized as an expense over the term of the related financing or the period over which services are received.

### ***Basic and Diluted Net Loss per Share of Common Stock***

The Company uses the two-class method to compute net loss per common share because the Company has issued securities, other than common stock, that contractually entitle the holders to participate in dividends and earnings of the Company. The two-class method requires earnings for the period to be allocated between common stock and participating securities based upon their respective rights to receive distributed and undistributed earnings. Holders of each series of the Company's redeemable convertible preferred stock are entitled to participate in distributions, when and if declared by the board of directors, that are made to common stockholders and, as a result, are considered participating securities.

### ***Segment and Geographic Information***

Operating segments are defined as components of an enterprise (business activity from which it earns revenue and incurs expenses) for which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker (CODM) is its Chief Executive Officer. The Company views its operations and manages its business as a single operating and reporting segment. All assets of the Company were held in the United States for the years ended December 31, 2015 and 2014.

### ***Application of New or Revised Accounting Standards—Adopted***

From time to time, the Financial Accounting Standards Board (the "FASB") or other standard-setting bodies issue accounting standards that are adopted by the Company as of the specified effective date.

On April 5, 2012, President Obama signed the Jump-Start Our Business Startups Act (the JOBS Act) into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an emerging growth company. As an emerging growth company, the Company may elect to adopt new or revised accounting standards when they become effective for non-public companies, which typically is later than public companies must adopt the standards. The Company has elected not to take advantage of the extended transition period afforded by the JOBS Act and, as a result, 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.

In July 2013, the FASB issued Accounting Standard Update ("ASU") No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exist* ("ASU 2013-11"). ASU 2013-11 amends the presentation requirements of ASC Topic 740 Income Taxes and requires an unrecognized tax benefit to be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, similar tax loss, or a tax credit carryforward. To the extent the tax benefit is not available at the reporting date under the governing tax law or if the entity does not intend to use the deferred tax asset for such purpose, the unrecognized tax benefit should be presented as a liability and not combined with deferred tax assets. ASU 2013-11 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The amendments are to be applied to all unrecognized tax benefits that exist as of the effective date and may be applied retrospectively to each prior reporting period presented. The adoption of ASU 2013-11 in 2014 did not have a material impact on its financial statements as no uncertain tax positions existed for the years ended December 31, 2015 and 2014.

### ***Application of New or Revised Accounting Standards—Not Yet Adopted***

In May 2014, the FASB issued guidance codified in ASC Topic 606, *Revenue Recognition—Revenue from Contracts with Customers*, which amends the guidance in former ASC 605, *Revenue Recognition*, and becomes effective beginning January 1, 2018. The Company is currently evaluating the impact of the provisions of ASC 606 on its financial statements and disclosures.

In June 2014, the FASB issued ASU 2014-12, *Compensation-Stock Compensation (Topic 718): Accounting for Share-Based Payments when the Terms of an Award Provide that a Performance Target Could Be Achieved After the Requisite Service Period* ("ASU 2014-12"). The amendments require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. ASU 2014-12 is effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Earlier adoption is permitted. Entities may apply ASU 2014-12 either (a) prospectively to all awards granted or modified after the effective date or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. If retrospective transition is adopted, the cumulative effect of applying this ASU as of the beginning of the earliest annual period presented in the financial statements should be recognized as an adjustment to the opening retained earnings balance at that date. Additionally, if retrospective transition is adopted, an entity may use hindsight in measuring and recognizing the compensation cost. The Company expects this update to have a minimal impact on its financial statements upon adoption.

**KEMPHARM, INC.**  
**NOTES TO FINANCIAL STATEMENTS**

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15"), which amends ASC Subtopic 205-40 to provide guidance about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related disclosures. Specifically, the amendments (1) provide a definition of the term "substantial doubt," (2) require an evaluation every reporting period, (3) provide principles for considering the mitigating effect of management's plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated and (6) require an assessment for a period of one year after the date that financial statements are issued. ASU 2014-15 is effective for fiscal years ending after December 15, 2016, and for annual periods and interim periods thereafter. The Company is currently evaluating the impact of the adoption of ASU 2014-15 on its financial statements and disclosures.

In January 2015, the FASB issued ASU No. 2015-01, *Income Statement - Extraordinary and Unusual Items (Subtopic 225-20); Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items* ("ASU 2015-01"), which eliminates from GAAP the concept of extraordinary items, stating that the concept causes uncertainty because (1) it is unclear when an item should be considered both unusual and infrequent and (2) users do not find the classification and presentation necessary to identify those events and transactions. ASU 2015-01 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015, with early adoption permitted provided the guidance is applied from the beginning of the fiscal year of adoption. The Company does not expect this standard to have an impact on its financial statements upon adoption.

In April 2015, the FASB issued ASU 2015-03, *Interest - Imputation of Interest (Subtopic 835-30)* ("ASU 2015-03"), which requires the debt issuance costs related to a recognized debt liability be presented in the balance sheet as direct deduction from the carrying amount of that debt liability, consistent with the presentation of debt discounts. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Adoption of ASU 2015-03 will reduce assets and liabilities by the amount of the debt issuance costs, which are \$1.1 million and \$1.5 million at December 31, 2015 and 2014, respectively.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes: Balance Sheet Classification of Deferred Taxes (Topic 740)* ("ASU 2015-17"), which requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. This update applies to all entities that present a classified statement of financial position. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. The Company does not expect this standard to have a material impact on its financial statements upon adoption.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments Overall - Recognition and Measurement of Financial Assets and Liabilities (Topic 825-10)* ("ASU 2016-01"), which provides several updates related to Topic 825-10. This update applies to all entities that hold financial assets or owe financial liabilities. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company does not expect this standard to have a material impact on its financial statements upon adoption.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* (ASU 2016-02), which requires lessees to recognize assets and liabilities for operating leases with lease terms greater than twelve months in the balance sheet. The update also requires improved disclosures to help users of financial statements better understand the amount, timing and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the impact of the adoption of ASU 2016-02 on its financial statements and disclosures.

**C. Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31, 2015	December 31, 2014
Other receivables	\$ 2,375	\$ —
Prepaid insurance	290	—
Other prepaid expenses and current assets	93	23
Total	<u>\$ 2,758</u>	<u>\$ 23</u>

**KEMPHARM, INC.**  
**NOTES TO FINANCIAL STATEMENTS**

**D. Property and Equipment**

Property and equipment consists of the following (in thousands):

	December 31, 2015	December 31, 2014
Laboratory equipment	\$ 530	\$ 530
Computers and hardware	176	73
Furniture and office equipment	169	137
Leasehold improvements	6	6
Total property and equipment	881	746
Less: accumulated depreciation and amortization	(478)	(394)
Property and equipment, net	<u>\$ 403</u>	<u>\$ 352</u>

The Company leases various equipment under capital lease agreements. The assets under capital leases are included in property and equipment as follows (in thousands):

	December 31, 2015	December 31, 2014
Furniture and office equipment	\$ 94	\$ 94
Less: accumulated depreciation and amortization	(22)	(12)
	<u>\$ 72</u>	<u>\$ 82</u>

The estimated useful lives of property and equipment are as follows:

<u>Asset Category</u>	<u>Useful Life (in years)</u>
Laboratory equipment	10
Computers and hardware	3-7
Furniture and office equipment	5-10
Leasehold improvements	15

Depreciation and amortization expense, including amounts pertaining to assets held under capital leases, was approximately \$84,000, \$75,000 and \$68,000 for the years ended December 31, 2015, 2014 and 2013, respectively.

**E. Accounts Payable and Accrued Expenses**

Accounts payable and accrued expenses consist of the following (in thousands):

	December 31, 2015	December 31, 2014
Accounts payable	\$ 1,252	\$ 1,582
Accrued interest	698	631
Accrued banking fees	700	700
Accrued payroll	947	183
Other accrued expenses	1,309	-
Total	<u>\$ 4,906</u>	<u>\$ 3,096</u>

**F. Debt Obligations**

***Deerfield Facility Agreement***

On June 2, 2014, the Company entered into a \$60.0 million facility agreement (the "Deerfield Facility Agreement") with Deerfield Private Design Fund III, LP ("Deerfield"). The first payment to the Company under the terms of the Deerfield Facility Agreement consisted of a term loan of \$15.0 million (the "Term Notes") and a senior secured loan of \$10.0 million (the "Deerfield

Convertible Notes”). All loans issued under the Deerfield Facility Agreement bear interest at 9.75% per annum. Deerfield may convert any portion of the outstanding principal and any accrued but unpaid interest on the Deerfield Convertible Notes into shares of the Company’s common stock at an initial conversion price of \$5.85 per share.

The Company also issued to Deerfield a warrant to purchase 14,423,076 shares of Series D redeemable convertible preferred stock (“Series D preferred stock”) at an exercise price of \$0.78 per share, which is exercisable until June 2, 2024 (the “Deerfield Warrant”). Upon completion of the IPO, the Deerfield Warrant automatically converted into a warrant to purchase 1,923,077 shares of the Company’s common stock at an exercise price of \$5.85 per share. In the event that a Major Transaction occurs, as defined below, Deerfield may require the Company redeem the Deerfield Warrant for a cash amount equal to the Black-Scholes value of the portion of the Deerfield Warrant to be redeemed (the “Put Option”). A Major Transaction is (i) a consolidation, merger, exchange of shares, recapitalization, reorganization, business combination or other similar event; (ii) the sale or transfer in one transaction or a series of related transactions of all or substantially all of the assets of the Company; (iii) a third-party purchase, tender or exchange offer made to the holders of outstanding shares, such that following such purchase, tender or exchange offer a change of control has occurred; (iv) the liquidation, bankruptcy, insolvency, dissolution or winding-up affecting the Company; (v) the shares of the Company’s common stock cease to be listed on any eligible market; and (vi) at any time, the shares of the Company’s common stock cease to be registered under Section 12 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”).

In addition, the Company issued to Deerfield 1,923,077 shares of Series D preferred stock as consideration for the loans provided to the Company under the Deerfield Facility Agreement. Upon completion of the IPO, these shares automatically reclassified into 256,410 shares of the Company’s common stock. The Company recorded the fair value of the shares of Series D preferred stock of \$1.5 million, to debt issuance costs on the date of issuance. The Company recorded the fair value of the Deerfield Warrant of \$7.6 million and the fair value of the embedded Put Option of \$0.2 million to debt discount on the date of issuance. The debt issuance costs and debt discount are amortized over the term of the related debt and the expense is recorded as interest expense in the statements of operations.

The Company must repay one-third of the outstanding principal amount of all debt issued under the Deerfield Facility Agreement on the fourth and fifth anniversaries of the Deerfield Facility Agreement. The Company is then obligated to repay the balance of the outstanding principal amount on February 14, 2020.

Interest accrued on outstanding debt under the Deerfield facility is due quarterly in arrears. Upon notice to Deerfield, the Company may choose to have one or more of the first eight of such scheduled interest payments added to the outstanding principal amount of the debt issued under the Deerfield Facility Agreement, provided that all such interest will be due on July 1, 2016. The Company has elected this option on all six of the scheduled interest payments to date. The accrued interest added to outstanding principal is reflected in the balance sheets as current portion of convertible notes and current portion of term notes.

Deerfield is obligated to provide three additional tranches upon the Company’s request and after the satisfaction of specified conditions, including the FDA’s acceptance of a new drug application (“NDA”) for KP201/APAP and, for the final two tranches, the subsequent approval for commercial sale thereof.

As of December 31, 2015, borrowings available to the Company under the Deerfield Facility Agreement were \$35.0 million. Under the terms of the Deerfield Facility Agreement, future tranches to the Company are as follows:

- The second tranche consists of a \$10.0 million term loan that bears interest at 9.75% and a warrant to purchase 1,282,052 shares of the Company’s common stock at an exercise price of \$5.85 per share.
- The third and fourth tranches each consist of a \$12.5 million term loan that bears interest at 9.75% and a warrant exercisable for the number of shares equal to 60% of the principal amount of such disbursement divided by 115% of the volume weighted average sales price of the Company’s common stock for the 20 consecutive trading days immediately prior to the date of such disbursement with an exercise price per share equal 115% of such weighted average sales price.

***Second Amendment to Senior Secured Convertible Note and Warrant***

On January 6, 2016, the Company, entered into a Second Amendment (the “Second Amendment”) to the Deerfield Convertible Notes and Deerfield Warrant, by and between the Company and Deerfield. The Second Amendment, among other things, clarified the calculation of an anti-dilution adjustment of the conversion price and exercise price of the Deerfield Convertible Notes and Deerfield Warrant, respectively, in the event that the Company effects a firm commitment underwritten public offering of its securities. Except



as modified by the Second Amendment and Third Amendment (as described below), all terms and conditions of the Deerfield Convertible Notes and Deerfield Warrant remain in full force and effect.

***Issuance of 5.50% Senior Convertible Notes and Third Amendment to Senior Secured Convertible Note and Warrant***

On February 9, 2016, the Company issued \$86.25 million aggregate principal amount of its 5.50% Senior Convertible Notes due 2021 (the “2021 Notes”) to Cowen and Company, LLC and RBC Capital Markets, LLC, as representatives of the several initial purchasers (the “Initial Purchasers”), who subsequently resold the 2021 Notes to qualified institutional buyers (the “Note Offering”) in reliance on the exemption from registration provided by Rule 144A under the Securities Act of 1933, as amended (the “Securities Act”).

The net proceeds from the Note Offering were approximately \$82.8 million, after deducting the Initial Purchasers’ discount and estimated offering expenses. Concurrent with the Note Offering, the Company used approximately \$18.6 million of the net proceeds from the Note Offering to repay in full the Term Notes, plus all accrued but unpaid interest on the Term Notes, a make whole interest payment on the term note and a prepayment premium on the term note.

The 2021 Notes were issued pursuant to an Indenture, dated as of February 9, 2016 (the “Indenture”), between the Company and U.S. Bank National Association, as trustee. Interest on the 2021 Notes will be payable semi-annually in cash in arrears on February 1 and August 1 of each year, beginning on August 1, 2016, at a rate of 5.50% per year. The 2021 Notes mature on February 1, 2021 unless earlier converted or repurchased. The 2021 Notes are not redeemable prior to the maturity date, and no sinking fund is provided for the 2021 Notes.

The 2021 Notes are convertible at an initial conversion rate of 58.4454 shares of the Company’s common stock per \$1,000 principal amount of the 2021 Notes, subject to adjustment under the Indenture, which is equal to an initial conversion price of approximately \$17.11 per share of common stock. Upon conversion, the 2021 Notes will be settled in shares of the Company’s common stock, together with a cash payment in lieu of delivering any fractional share. The conversion rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date, the Company will increase the conversion rate for a holder who elects to convert its 2021 Notes in connection with such a corporate event in certain circumstances.

In connection with the Note Offering, on February 3, 2016, the Company entered into a Third Amendment (the “Third Amendment”) to the Deerfield Facility Agreement, Deerfield Convertible Notes and Deerfield Warrant with Deerfield. The Third Amendment, among other things, eliminated the Company’s ability to require Deerfield to convert the Deerfield Convertible Notes into Company common stock. In addition, pursuant to the Third Amendment, Deerfield consented to the prepayment of the Term Notes and the issuance of the 2021 Notes. Except as modified by the Third Amendment, all terms and conditions of the Deerfield Facility Agreement remain in full force and effect.

***Conversion of 2013 Convertible Notes into Series D Preferred Stock***

From June 2013 through October 2013, the Company issued 10.0% unsecured convertible promissory notes (the “2013 Convertible Notes”) for gross proceeds of \$3.8 million. The 2013 Convertible Notes accrued interest from the date of issuance through the maturity date, with such interest payable in cash upon maturity. The 2013 Convertible Notes did not have a stated maturity date and instead matured under various scenarios, such as the sale of substantially all of the assets of the Company, dissolution of the Company, failure to observe covenants, and voluntary or involuntary bankruptcy. In accordance with the terms of the 2013 Convertible Notes, and effected by the written consent of the holders of a majority of the outstanding principal of such notes, on June 2, 2014, the principal amount of the 2013 Convertible Notes of \$3.8 million and all accrued interest of \$0.3 million converted into 5,332,348 shares of Series D preferred stock at \$0.78 per share. Upon the conversion of the 2013 Convertible Notes, the embedded conversion feature of the 2013 Convertible Notes and Put Option was marked to fair value and the balance of \$1.9 million was recorded as a gain on extinguishment of debt.

***Line of Credit***

The Company has a \$50,000 credit agreement with a financial institution (the “Line of Credit Agreement”). As of December 31, 2015 and 2014, the Company had \$50,000 available under the Line of Credit Agreement. The Line of Credit Agreement is collateralized by all of the Company’s business assets. The Line of Credit Agreement contains no financial covenants. Borrowings under the Line of Credit Agreement carry interest at a rate equal to the prime rate plus 1.75% per annum. The Company is required to

make interest only payments on any draws under the Line of Credit Agreement. The interest rate under the Line of Credit Agreement was 5% as of December 31, 2015 and 2014.

During the fourth quarter of 2015, the Company entered into an additional \$100,000 credit agreement with the same financial institution (the "Second Line of Credit Agreement"). As of December 31, 2015, the Company had \$100,000 available under the Second Line of Credit Agreement. The Second Line of Credit Agreement is uncollateralized and contains no financial covenants. Borrowings under the Second Line of Credit Agreement carry interest at a rate equal to the prime rate plus 9.99% per annum. The Company is required to make interest only payments on any draws under the Second Line of Credit Agreement. The interest rate under the Second Line of Credit Agreement was 13.24% as of December 31, 2015.

## **G. Commitments and Contingencies**

### ***Legal Matters***

From time to time, the Company is involved in various legal proceedings arising in the normal course of business. For some matters, a liability is not probable or the amount cannot be reasonably estimated, and therefore an accrual has not been made. However, for such matters when it is probable that the Company has incurred a liability and can reasonably estimate the amount, the Company accrues and discloses such estimates.

In 2014, a former financial advisor of the Company filed a request with the Iowa District Court to declare valid a purported right of first refusal to serve as the Company's exclusive financial advisor for specified strategic transactions and to receive fees for the specified strategic transactions irrespective of whether any such specified transaction occurred during or after the term of the financial advisor's service agreement. This filing by the former financial advisor was made in response to an action initiated by the Company in 2013 seeking a declaratory judgement finding that such purported right was invalid and unenforceable. Two former members of the Company's board of directors (the "Board") joined the lawsuit as intervenors based on the former financial advisor's purported assignment of its rights, or a portion thereof, under the agreement to the intervenors. In September 2015, the court granted summary judgement in favor of the Company with respect to the Company's declaratory judgement action and the former financial advisor's counterclaims and the Company separately entered into settlement agreements with each of the intervenors. The settlements reached with the intervenors did not differ from the accrual previously recorded by the Company by a material amount. The former financial advisor subsequently filed a notice of appeal of the court's ruling with the Supreme Court of Iowa. On January 6, 2016, the Company entered into a Settlement Agreement and Mutual Release (the "Settlement Agreement") with the former financial advisor and Donald DeWaay, Jr. pursuant to which, among other things, the former financial advisor agreed, in exchange for the consideration described therein, to dismiss with prejudice its pending appeal. DFN's appeal was subsequently dismissed by the Supreme Court of Iowa on January 7, 2016. The settlement amount was commiserate with the contingency recorded in the books and records of the Company. The consideration in the settlement agreement did not differ from the accrual previously recorded by the Company by a material amount.

### ***Lease Agreements***

#### ***Iowa***

The Company leases office and laboratory facilities in Iowa under a long-term non-cancelable operating lease. The Company's lease for its Iowa facilities expires in September 2016 and includes a renewal option that could extend the lease for an additional three years.

#### ***Florida***

The Company leases office space in Florida under a long-term non-cancelable operating lease. In April 2015, the Company signed a first amendment to the lease to expand the amount of office space in the current facility. In December 2015, the Company signed a second amendment to the lease to move from one facility to an adjacent facility with more office space. The adjacent facility requires build out and is anticipated to be ready by mid-2016. The expiration date on the Company's lease for its Florida facility is dependent on the adjacent facility's build out completion date. Currently the lease is expected to expire in mid-2025 and includes renewal options that could extend the lease for two additional five year terms.

#### ***Virginia***

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The Company leases office and laboratory facilities in Virginia under a short-term non-cancelable operating lease. The Company's lease for its Virginia facilities expires in August 2016. The Company anticipates, based on historical experience, extending the lease term for a period of 12 months upon expiration.

**North Carolina**

The Company leases office space in North Carolina under a long-term non-cancelable operating lease. The expiration date of the Company's lease is May 2020 and includes renewal options that could extend the lease for an additional three years.

**Capital Lease**

The Company leases various laboratory, computer and other office equipment that are accounted for as capital leases and that require ongoing payments including interest expense. The capital leases are financed through various financial institutions and are collateralized by the underlying assets. As of December 31, 2015, the interest rate for assets under remaining capital leases was 0.67%.

Rent expense for non-cancelable operating leases was \$0.3 million, \$0.2 million and \$0.1 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Future minimum lease payments under capital leases and non-cancelable operating leases as of December 31, 2015 were as follows (in thousands):

<u>Year Ending December 31,</u>	<u>Capital Leases</u>	<u>Operating Leases</u>
2016	\$ 27	\$ 440
2017	—	487
2018	—	497
2019	—	485
2020	—	428
Thereafter	—	5,354
<b>Total minimum lease payments</b>	<b>27</b>	<b>\$ 7,691</b>
Less: amounts representing interest	(1)	
<b>Total</b>	<b>\$ 26</b>	

**H. Supply Arrangement**

As of December 31, 2015, the Company has one manufacturing arrangement that involves potential future expenditures related to research and development.

In November 2009, the Company entered into a supply agreement (the "Supply Agreement") with Johnson Matthey Inc. ("JMI") whereby JMI has agreed to supply the Company with all of the KP201 necessary for clinical trials and commercial sale for a price equal to JMI's manufacturing cost and to provide process optimization and development services for KP201. The Company's most advanced product candidate, KP201/APAP, is a combination of KP201 and acetaminophen ("APAP") and is under development to treat acute moderate to moderately severe pain. The Company submitted an NDA for KP201/APAP in the second half of 2015 under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act. No expense was recorded under this agreement for the years ended December 31, 2015 and 2014. The Company must purchase all of its U.S. KP201 needs from JMI and JMI cannot supply KP201 to other companies. The term of the Supply Agreement extends as long as the Company holds a valid and enforceable patent for KP201 or until the tenth anniversary of KP201's commercial launch, whichever date is later. Upon the expiration of such term, the agreement will automatically renew for a period of two years unless either party provides 12 months prior notice of its intent not to renew. Under the agreement, JMI will receive a tiered-based royalty share on the net sales on the commercial sale of a FDA approved drug incorporating KP201. No reliable estimate of the future payments can be made at this time.

**I. Preferred Stock and Warrants**

**Authorized, Issued, and Outstanding Preferred Stock**

In April 2015, the Company amended and restated its Certificate of Incorporation to decrease the number of its authorized shares of preferred stock to 10,000,000 shares with a par value of \$0.0001 per share. As described in Note A, in April 2015, the Company completed an IPO of its common stock. Upon completion of the IPO, all outstanding shares of the Company's redeemable convertible preferred stock were automatically converted or reclassified into an aggregate of 5,980,564 shares of the Company's common stock. As of December 31, 2015, the Company had 10,000,000 shares of authorized and undesignated preferred stock, and did not have any preferred stock outstanding.

**Preferred Stock Activity**

The following table summarizes redeemable convertible preferred stock activity for the years ended December 31, 2015 and 2014:

	Shares of					Total
	Series A Preferred	Series B Preferred	Series C Preferred	Series D Preferred	Series D-1 Preferred	
Balance, January 1, 2013	9,704,215	6,220,000	18,557,408	—	—	34,481,623
Balance, December 31, 2013	9,704,215	6,220,000	18,557,408	—	—	34,481,623
Shares issued upon conversion of 2013 Convertible Notes	—	—	—	5,332,348	—	5,332,348
Shares issued for financing fee to Deerfield	—	—	—	1,923,077	—	1,923,077
Balance, December 31, 2014	9,704,215	6,220,000	18,557,408	7,255,425	—	41,737,048
Issuance of Series D-1 preferred stock	—	—	—	—	3,200,000	3,200,000
Exercise of Series D preferred warrants	—	—	—	3,205	—	3,205
Effect of reverse stock-split	(8,410,377)	(5,390,766)	(16,083,286)	(6,290,844)	(2,784,416)	(38,959,689)
Less: Conversion of preferred stock into common stock upon IPO	(1,293,838)	(829,234)	(2,474,122)	(967,786)	(415,584)	(5,980,564)
Balance, December 31, 2015	—	—	—	—	—	—

**Series D-1 Redeemable Convertible Preferred Stock**

In February 2015, the Company entered into a stock purchase agreement with Cowen KP Investment LLC in which Cowen KP Investment LLC agreed to purchase and the Company agreed to sell 3,200,000 shares of the Company's Series D-1 redeemable convertible preferred stock for \$1.25 per share, or an aggregate of \$4.0 million. Upon completion of the IPO, these shares automatically converted into 415,584 shares of the Company's common stock.

**Warrants**

As described in Note A, in April 2015, the Company completed an IPO of its common stock. Upon completion of the IPO, and as of December 31, 2015, warrants to purchase 15,499,324 shares of Series D preferred stock were reclassified into warrants to purchase 2,066,543 shares of the Company's common stock. As of December 31, 2014, the Company had pre-split outstanding warrants to purchase 15,502,529 shares of Series D preferred stock at an exercise price of \$0.78 per share. During the year ended December 31, 2015, warrants to purchase 3,205 shares of Series D preferred stock were exercised.

During 2013, the Company issued \$3.8 million of convertible notes and the warrants (the "2013 Warrants") to purchase 1,079,453 shares of equity securities in a future financing meeting specified criteria (a "Qualified Financing") (Note F). The 2013 Warrants allow the holders to purchase shares of the same class and series of equity securities issued in the Qualified Financing for an exercise price equal to the per share price paid by the purchasers of such equity securities in the Qualified Financing. When the Company entered into the Deerfield Facility Agreement, the 2013 Warrants became warrants to purchase 1,079,453 shares of Series D preferred stock. Upon completion of the IPO, the 2013 Warrants automatically converted into warrants to purchase 143,466 shares of the Company's common stock at an exercise price of \$5.85 per share. The 2013 Warrants, if unexercised, expire on the earlier of June 2, 2019, or upon a liquidation event.

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On June 2, 2014, pursuant to the terms of the Deerfield Facility Agreement, the Company issued the Deerfield Warrant to purchase 14,423,076 shares of Series D preferred stock (Note F). The Company recorded the fair value of the Deerfield Warrant as a debt discount and a warrant liability. The Deerfield Warrant, if unexercised, expires on the earlier of June 2, 2024, or upon a liquidation event. Upon completion of the IPO, the Deerfield Warrant automatically converted into a warrant to purchase 1,923,077 shares of the Company's common stock at an exercise price of \$5.85 per share. The Company is amortizing the debt discount to interest expense over the term of the Term Notes and the Deerfield Convertible Notes.

The Company determined that the 2013 Warrants and Deerfield Warrant should be recorded as a liability and stated at fair value at each reporting period upon inception. As stated above, upon completion of the IPO, the 2013 Warrants and the Deerfield Warrant automatically converted into warrants to purchase the Company's common stock. The Company marked the 2013 Warrants to fair value and reclassified them to equity upon closing of the IPO. The Deerfield Warrant remains classified as a liability and is recorded at fair value at each reporting period since it can be settled in cash. Changes to the fair value of the warrant liability are recorded through the statements of operations as a fair value adjustment (Note L).

**J. Common Stock and Warrants**

***Authorized, Issued, and Outstanding Common Shares***

In April 2015, the Company amended its Certificate of Incorporation to increase the number of its authorized shares of common stock to 250,000,000 shares. Of the authorized shares, 14,490,954 and 2,381,041 shares of common stock were issued and outstanding at December 31, 2015 and 2014, respectively.

At December 31, 2015 and 2014, the Company had reserved authorized shares of common stock for future issuance as follows:

	<b>December 31, 2015</b>	<b>December 31, 2014</b>
Conversion of Series A redeemable convertible preferred stock	—	1,293,838
Conversion of Series B redeemable convertible preferred stock	—	829,234
Conversion of Series C redeemable convertible preferred stock	—	2,474,122
Conversion of Series D redeemable convertible preferred stock	—	967,359
Conversion of Series D-1 redeemable convertible preferred stock	—	—
Conversion of Deerfield Convertible Notes	1,991,219	1,808,353
Outstanding awards under equity incentive plans	1,397,511	395,185
Outstanding common stock warrants	2,325,383	595,920
Outstanding Series D redeemable convertible preferred stock warrants	—	2,066,970
Possible future issuances under equity incentive plans	1,410,848	365,706
<b>Total common shares reserved for future issuance</b>	<b><u>7,124,961</u></b>	<b><u>10,796,687</u></b>

***Common Stock Activity***

The following table summarizes common stock activity during the year ended December 31, 2015 (there was no common stock activity during the years ended December 31, 2014 and 2013):

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	<b>Shares of Common Stock</b>
Balance at December 31, 2014	2,381,041
Issuance of common stock in connection with the IPO	5,854,545
Conversion of preferred stock to common stock in connection with the IPO	5,980,564
Common stock warrants exercised	270,038
Common stock options exercised	4,766
Balance at December 31, 2015	14,490,954

The Company calculates the fair value of common stock warrants using a Monte Carlo simulation. There were warrants exercised for an aggregate of 270,038 shares of common stock during the year ended December 31, 2015 and there were no warrants exercised during the year ended December 31, 2014. From 2008 through 2012, the Company issued warrants to purchase 595,920 shares of common stock in its private placement offerings of Series A redeemable convertible preferred stock, Series B redeemable convertible preferred stock and Series C redeemable convertible preferred stock (the “Underwriter Warrants”) and for leasing laboratory space. The Company accounts for the Underwriter Warrants as a derivative liability, which is adjusted to fair value at each reporting period, with the change in fair value recorded within other expenses in the statements of operations.

**K. Stock-Based Compensation**

The Company maintains a stock-based compensation plan (the “Incentive Stock Plan”) that governs stock awards made to employees and directors prior to completion of the IPO.

In November 2014, the Board, and in April 2015, the Company’s stockholders, approved the Company’s 2014 Equity Incentive Plan (the “2014 Plan”) which became effective in April 2015. The 2014 Plan provides for the grant of stock options, other forms of equity compensation, and performance cash awards. The maximum number of shares of common stock that may be issued under the 2014 Plan is 2,266,666, as of December 31, 2015. In addition, the number of shares of common stock reserved for issuance under the 2014 Plan will automatically increase on January 1 of each year, beginning on January 1, 2016 and ending on and including January 1, 2024, by 4% of the total number of shares of the Company’s capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Board. Pursuant to the terms of the 2014 Plan, on January 1, 2016, the common stock reserved for issuance under the 2014 Plan automatically increased by 579,638 shares.

During the year ended December 31, 2015, stock options to acquire 4,766 shares of common stock were exercised with an intrinsic value of \$54,000. No stock options were exercised during the years ended December 31, 2014 and 2013.

Stock-based compensation expense recorded under the Incentive Stock Plan and the 2014 Plan is included in the following line items in the accompanying statements of operations (in thousands):

	<b>Year ended December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
Research and development	\$ 610	\$ 62	\$ 29
General and administrative	1,759	152	105
	\$ 2,369	\$ 214	\$ 134

**Stock Option Awards**

The Company estimates the fair value of stock options using the Black-Scholes option-pricing model, which requires the use of subjective assumptions, including the expected term of the option, the expected stock price volatility, expected dividend yield and the risk-free interest rate for the expected term of the option. The expected term represents the period of time the stock options are expected to be outstanding. Due to the lack of sufficient historical exercise data to provide a reasonable basis upon which to otherwise estimate the expected term of the stock options, the Company uses the simplified method to estimate the expected term for its “plain vanilla” stock options. Under the simplified method, the expected term of an option is presumed to be the mid-point between the vesting date and the end of the contractual term. Some options, for example those that have exercise prices in excess of the fair value of the underlying stock, are not considered “plain vanilla” stock options. For these options, the Company uses an expected term equal to the contractual term of the option. Expected volatility is based on historical volatilities for publicly traded stock of comparable

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companies over the estimated expected term of the stock options. The Company assumes no dividend yield because dividends are not expected to be paid in the near future, which is consistent with the Company's history of not paying dividends.

The Company recognizes compensation expense related to stock-based payment transactions upon satisfaction of the requisite service or vesting requirements. Forfeitures are estimated at the time of grant and revised based on actual forfeitures, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Using the Black-Scholes option-pricing model, the weighted-average fair value of awards granted during the years ended December 31, 2015, 2014 and 2013 fair value was \$10.63, \$4.50 and \$3.00 per share, respectively. The assumptions used to estimate fair value are as follows:

	December 31, 2015	December 31, 2014	December 31, 2013
Risk-free interest rate	1.40% - 1.99%	0.91% - 2.70%	0.52% - 2.80%
Expected term (in years)	4.33 - 6.25	7.00 - 10.00	4.04 - 10.00
Expected volatility	68.79% - 86.84%	86.00% - 95.00%	58.55% - 92.00%
Expected dividend yield	0%	0%	0%

The activity under the Incentive Stock Plan and the 2014 Plan for the year ended December 31, 2015 is summarized as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding balance at January 1, 2015	395,185	\$ 5.40	7.24	\$ 1,275,980
Granted	1,010,457	\$ 16.30		
Exercised	(4,766)	\$ 5.85		
Forfeited	(3,365)	\$ 5.85		
Outstanding balance at December 31, 2015	<u>1,397,511</u>	\$ 13.28	8.58	\$ 9,204,403
Exercisable at December 31, 2015	<u>384,087</u>	\$ 6.71	6.55	\$ 5,057,062
Vested and expected to vest at December 31, 2015	<u>1,254,325</u>	\$ 13.00	8.49	\$ 8,614,743

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Information regarding currently outstanding and exercisable options as of December 31, 2015 is as follows:

Exercise Price	Options Outstanding		Options Exercisable	
	Number of Shares	Weighted Average Remaining Contractual Term (in years)	Number of Shares	Weighted Average Remaining Contractual Term (in years)
\$0.75	12,000	1.50	12,000	1.50
\$3.00	20,666	2.54	20,666	2.54
\$4.65	49,327	2.61	49,327	2.61
\$5.85	305,061	7.23	207,428	6.91
\$8.63	154,639	9.03	6,666	8.57
\$11.00	21,333	9.30	—	—
\$11.41	170,035	9.41	88,000	9.41
\$16.61	11,250	9.94	—	—
\$18.29	205,000	9.49	—	—
\$18.61	38,400	9.65	—	—
\$19.02	62,000	9.65	—	—
\$20.45	335,000	9.68	—	—
\$21.37	6,400	9.70	—	—
\$22.12	6,400	9.71	—	—
	<u>1,397,511</u>	<u>8.58</u>	<u>384,087</u>	<u>6.55</u>

The total fair value of stock options vested during the years ended December 31, 2015, 2014 and 2013, was \$1.1 million, \$0.2 million and \$0.2 million, respectively.

Unvested stock options as of December 31, 2015 and 2014 were as follows:

Exercise Price	Number of Unvested Shares	
	December 31, 2015	December 31, 2014
\$5.85	97,633	225,018
\$8.63	147,973	—
\$11.00	21,333	—
\$11.41	82,035	—
\$16.61	11,250	—
\$18.29	205,000	—
\$18.61	38,400	—
\$19.02	62,000	—
\$20.45	335,000	—
\$21.37	6,400	—
\$22.12	6,400	—
	<u>1,013,424</u>	<u>225,018</u>

As of December 31, 2015, there was \$9.0 million of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under the 2014 Plan and the Company's 2007 stock incentive plan. That compensation cost is expected to be recognized over a weighted-average period of 2.77 years.

During the year ended December 31, 2015, the Company recognized \$0.7 million of stock-based compensation expense related to performance-based awards included in general and administrative expenses and \$0.2 million of stock-based compensation expense related to performance-based awards included in research and development expenses. These awards were in connection with the grant of fully vested stock options exercisable for an aggregate of 163,998 shares of common stock during the year ended December 31, 2015. The Company did not recognize any stock-based compensation expense related to performance-based incentive awards during



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the years ended December 31, 2014 or 2013, since the strategic initiatives set for the awards were not achieved or probable of achievement.

**L. Fair Value of Financial Instruments**

The carrying amounts of certain financial instruments, including cash and cash equivalents and accounts payable, approximate their respective fair values due to the short-term nature of such instruments.

The fair value of the Deerfield Convertible Notes and the Term Notes was \$42.0 million and \$14.1 million, respectively, at December 31, 2015. Both the Deerfield Convertible Notes and Term Notes fall within Level 3 of the fair value hierarchy as their value is based on the credit worthiness of the Company, which is an unobservable input.

**Assets and Liabilities Measured at Fair Value on a Recurring Basis**

The Company evaluates its financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level in which to classify them for each reporting period. This determination requires significant judgments to be made. The following table summarizes the conclusions reached regarding fair value measurements as of December 31, 2015 and 2014 (in thousands):

	Balance at December 31, 2015	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Underwriter warrant liability	\$ 3,877	\$ —	\$ —	\$ 3,877
Deerfield warrant liability	33,750	—	—	33,750
Embedded put option	212	—	—	212
Total liabilities	<u>\$ 37,839</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 37,839</u>
<b>Trading securities:</b>				
Certificates of deposit	8,951	8,951	—	—
Government bonds	10,051	10,051	—	—
Total assets	<u>\$ 19,002</u>	<u>\$ 19,002</u>	<u>\$ —</u>	<u>\$ —</u>

	Balance at December 31, 2014	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Underwriter warrant liability	\$ 2,746	\$ —	\$ —	\$ 2,746
2013 warrant liability	520	—	—	520
Deerfield warrant liability	12,560	—	—	12,560
Embedded put option	140	—	—	140
Total liabilities	<u>\$ 15,966</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 15,966</u>

The Company's Underwriter Warrant liability, Deerfield Warrant liability and the embedded Put Option on the Deerfield Warrant are measured at fair value on a recurring basis. The 2013 Warrant liability was recorded at fair value on a recurring basis through the completion of the IPO. As of December 31, 2015 and 2014, the Underwriter Warrant liability, the Deerfield Warrant liability and the embedded Put Option are reported on the balance sheet in derivative and warrant liability. Upon closing of the IPO in April 2015, the 2013 Warrant liability was marked to fair value and then reclassified to equity. The Company used a Monte Carlo simulation to value the Underwriter Warrant liability and the embedded Put Option at December 31, 2015 and 2014. The Company used a Monte Carlo simulation to value the 2013 Warrant liability as of December 31, 2014, and the closing date of the IPO. Significant unobservable inputs used in measuring the fair value of these financial instruments included the Company's estimated enterprise value, an estimate of the timing of a liquidity event, a present value discount rate and an estimate of the Company's stock volatility using the volatilities of guideline peer companies. Changes in the fair value of the Underwriter Warrant liability, the 2013 Warrant liability, the Deerfield

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Warrant liability and the embedded Put Option are reflected in the statements of operations as a fair value adjustment. A 10% increase in the enterprise value would result in an increase of \$0.4 million in the estimated fair value of the Underwriter Warrant liability, an increase of \$1.9 million in the estimated fair value of the Deerfield Warrant liability, and no change in the estimated fair value of the embedded Put Option at December 31, 2015.

A reconciliation of the beginning and ending balances for the derivative and warrant liability measured at fair value on a recurring basis using significant unobservable inputs (Level 3) is as follows (in thousands):

	2015	2014
Balance at beginning of period	\$ 15,966	\$ 2,813
Issuance of Deerfield warrant	—	7,610
Embedded put option	—	220
Conversion of 2013 Convertible Notes	—	(1,900)
Reclassification of 2013 warrants to equity	(1,110)	—
Exercise of warrants	(4,293)	—
Adjustment to fair value	27,276	7,223
Balance at end of period	<u>\$ 37,839</u>	<u>\$ 15,966</u>

**M. Income Taxes**

The Company's financial statements include a total state tax benefit of \$15,000, \$22,000 and \$20,000 on a loss before income taxes of \$54.6 million, \$24.5 million and \$5.2 million for the years ended December 31, 2015, 2014 and 2013, respectively. A reconciliation of the difference between the benefit for income taxes and income taxes at the statutory U.S. federal income tax rate is as follows (in thousands):

	Year ended December 31,		
	2015	2014	2013
Federal statutory rate	34.00 %	34.00 %	34.00 %
Effect of:			
Change in valuation allowance	(19.25)	(32.88)	(38.38)
State tax benefit (net of federal)	4.06	5.96	7.53
Warrant liability	(15.28)	(9.39)	6.08
State research and development credit	0.03	0.09	0.37
Federal research and development credit	0.84	3.29	2.53
Conversion feature and put option on 2013 convertible notes	(1.68)	(1.26)	(8.81)
Interest expense	—	0.21	(0.99)
Stock-based compensation	(1.28)	—	—
Other	(1.42)	0.07	(1.95)
Federal income tax provision effective rate	<u>0.02 %</u>	<u>0.09 %</u>	<u>0.38 %</u>

**KEMPHARM, INC.**  
**NOTES TO FINANCIAL STATEMENTS**

The components of deferred tax assets and liabilities are as follows (in thousands):

	December 31, 2015	December 31, 2014	December 31, 2013
Deferred tax assets relating to:			
Net operating loss carryforwards	\$ 26,617	\$ 16,390	\$ 9,606
Research and development tax carryforward	2,254	1,793	899
Compensation	232	83	76
Total gross deferred tax assets	<u>29,103</u>	<u>18,266</u>	<u>10,581</u>
Deferred tax liabilities relating to:			
Property and equipment	80	170	176
Total gross deferred tax liabilities	<u>80</u>	<u>170</u>	<u>176</u>
Deferred tax assets less liabilities	29,023	18,096	10,405
Valuation allowance	(29,023)	(18,096)	(10,405)
Net deferred tax asset (liability)	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. Based upon the level of historical taxable income and projections for future taxable income over the periods in which the deferred tax assets are deductible, management believes it is more likely than not that the Company will not realize the benefits of these deductible differences in the future.

The Company had the following federal net operating loss carryforward and research activities credits as of December 31, 2015 (in thousands):

Year Incurred	Net Operating Loss Carryforwards	Research Activities Credit	Expiration
2007	\$ 454	\$ 30	2027
2008	1,178	65	2028
2009	3,060	176	2029
2010	3,423	149	2030
2011	9,929	176	2031
2012	—	170	2032
2013	4,353	133	2033
2014	15,819	894	2034
2015	24,189	461	2035
	<u>\$ 62,405</u>	<u>\$ 2,254</u>	

The Company also has certain state net operating loss carryforwards totaling \$59.7 million that expire between 2027 and 2035. Due to potential ownership changes that may have occurred or would occur in the future, IRC Section 382 may place additional limitations on the Company's ability to utilize the net operating loss carryforward.

Financial Interpretation No. 48 ("FIN 48"), *Accounting for Uncertainty in Income Taxes*, uses the term "more likely than not" to evaluate whether or not a tax position will be sustained upon examination. The Company has not identified any tax positions that do not meet the more likely than not threshold.

**N. Net Loss Per Share**

Under the two-class method, for periods with net income, basic net income per common share is computed by dividing the net income attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Net income attributable to common stockholders is computed by subtracting from net income the portion of current year

**KEMPHARM, INC.**  
**NOTES TO FINANCIAL STATEMENTS**

earnings that participating securities would have been entitled to receive pursuant to their dividend rights had all of the year's earnings been distributed. No such adjustment to earnings is made during periods with a net loss as the holders of the participating securities have no obligation to fund losses. Diluted net loss per common share is computed under the two-class method by using the weighted average number of shares of common stock outstanding plus, for periods with net income attributable to common stockholders, the potential dilutive effects of stock options and warrants. In addition, the Company analyzes the potential dilutive effect of the outstanding participating securities under the if-converted method when calculating diluted earnings per share in which it is assumed that the outstanding participating securities convert into common stock at the beginning of the period. The Company reports the more dilutive of the approaches (two-class or if-converted) as its diluted net income per share during the period.

The following table summarizes the computation of basic and diluted net loss and net loss per share of the Company (in thousands, except share and per share amounts):

	Year ended December 31,		
	2015	2014	2013
Net loss - basic and diluted	\$ (54,664)	\$ (24,455)	\$ (5,226)
Weighted-average number of common shares - basic and diluted	7,368,681	2,381,041	2,381,041
Net loss per share - basic and diluted	<u>\$ (7.42)</u>	<u>\$ (10.27)</u>	<u>\$ (2.20)</u>

Diluted net loss per share is the same as basic net loss per share for all periods presented because the effects of potentially dilutive items were anti-dilutive given the Company's net loss. The following securities, presented on a common stock equivalent basis, have been excluded from the calculation of weighted average common shares outstanding because their effect is anti-dilutive:

	December 31, 2015	December 31, 2014	December 31, 2013
Redeemable convertible preferred stock:			
Series A	—	1,293,838	1,293,838
Series B	—	829,234	829,234
Series C	—	2,474,122	2,474,122
Series D	—	967,359	—
Total redeemable convertible preferred stock	—	5,564,553	4,597,194
Warrants to purchase common stock	2,325,383	595,920	595,920
Warrants to purchase Series D preferred stock	—	2,066,970	143,893
Awards under equity incentive plans	1,397,511	395,185	296,255
2013 Convertible Notes	—	—	683,417
Deerfield Convertible Notes	1,991,219	1,808,353	—

**O. Employee Benefit Plan**

The Company has a 401(k) retirement plan (the "401(k) Plan") that covers all employees. The Company may provide a discretionary match with a maximum amount of 4% of the participant's compensation, which vests immediately. The Company made matching contributions under the 401(k) Plan of \$113,000, \$69,000 and \$50,000 for the years ended December 31, 2015, 2014 and 2013, respectively.

The Company has a discretionary profit sharing plan (the "Profit Sharing Plan") that covers all employees. Employees become eligible participants in the Profit Sharing Plan once they have provided three years of service to the Company. The Company made no contributions to the Profit Sharing Plan in 2015, 2014 or 2013.

**P. Subsequent Events (unaudited)**

***Second Amendment to Senior Secured Convertible Note and Warrant***

On January 6, 2016, the Company, entered into a Second Amendment (the "Second Amendment") to the Deerfield Convertible Notes and Deerfield Warrant, by and between the Company and Deerfield. The Second Amendment, among other things, clarified the calculation of an anti-dilution adjustment of the conversion price and exercise price of the Deerfield Convertible Notes and the

**KEMPHARM, INC.**  
**NOTES TO FINANCIAL STATEMENTS**

Deerfield Warrant, respectively, in the event that the Company effects a firm commitment underwritten public offering of its securities. Except as modified by the Second Amendment and Third Amendment (as described below), all terms and conditions of the Deerfield Convertible Notes and Deerfield Warrant remain in full force and effect.

***Withdrawal of Registration Statement on Form S-1***

On February 3, 2016, the Company requested that the Securities and Exchange Commission (the “Commission”) consent to the withdrawal of the Company’s Registration Statement on Form S-1 filed with the Commission on December 18, 2015.

***Issuance of 5.50% Senior Convertible Notes and Third Amendment to Senior Secured Convertible Note and Warrant***

On February 9, 2016, the Company issued \$86.25 million aggregate principal amount of the 2021 Notes to Initial Purchasers, who subsequently resold the 2021 Notes to qualified institutional buyers in reliance on the exemption from registration provided by Rule 144A under the Securities Act.

The net proceeds from the Note Offering were approximately \$82.8 million, after deducting the Initial Purchasers’ discount and estimated offering expenses. Concurrent with the Note Offering, the Company used approximately \$18.6 million of the net proceeds from the Note Offering to repay in full the Term Notes, plus all accrued but unpaid interest on the Term Notes, a make whole interest payment on the term note and a prepayment premium on the Term Notes.

The 2021 Notes were issued pursuant to the Indenture. Interest on the 2021 Notes will be payable semi-annually in cash in arrears on February 1 and August 1 of each year, beginning on August 1, 2016, at a rate of 5.50% per year. The 2021 Notes mature on February 1, 2021 unless earlier converted or repurchased. The 2021 Notes are not redeemable prior to the maturity date, and no sinking fund is provided for the 2021 Notes.

The 2021 Notes are convertible at an initial conversion rate of 58.4454 shares of the Company’s common stock per \$1,000 principal amount of the 2021 Notes, subject to adjustment under the Indenture, which is equal to an initial conversion price of approximately \$17.11 per share of common stock. Upon conversion, the 2021 Notes will be settled in shares of the Company’s common stock, together with a cash payment in lieu of delivering any fractional share. The conversion rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date, the Company will increase the conversion rate for a holder who elects to convert its 2021 Notes in connection with such a corporate event in certain circumstances. The 2021 Notes contain an embedded derivative that will be bifurcated and marked to market each period.

In connection with the Note Offering, on February 3, 2016, the Company entered into the Third Amendment to the Deerfield Facility Agreement, Deerfield Convertible Notes and Deerfield Warrant with Deerfield. The Third Amendment, among other things, eliminated the Company’s ability to require Deerfield to convert the Deerfield Convertible Notes into Company common stock. In addition, pursuant to the Third Amendment, Deerfield consented to the prepayment of the Term Notes and the issuance of the 2021 Notes. Except as modified by the Third Amendment, all terms and conditions of the Deerfield Facility Agreement remain in full force and effect.

**KEMPHARM, INC.**  
**NOTES TO FINANCIAL STATEMENTS**

**Q. Quarterly Results of Operations (unaudited)**

The following tables set forth unaudited quarterly statements of operations data for each of the quarters indicated. The financial statements for each of these quarters have been prepared on the same basis as the audited financial statements included herein and, in the opinion of management, include all adjustments, consisting only of normal recurring adjustments, necessary for the fair statement of the results of operations for these periods. You should read this information together with our financial statements and related notes included herein. These quarterly operating results are not necessarily indicative of the results for any future period.

	Three-Months Ended							
	Dec 31, 2015	Sep 30, 2015	Jun 30, 2015	Mar 31, 2015	Dec 31, 2014	Sep 30, 2014	Jun 30, 2014	Mar 31, 2014
Revenue	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Operating expenses:								
Research and development	4,716	4,328	2,768	2,119	5,911	3,253	1,715	1,038
General and administrative	2,566	2,152	3,188	977	1,577	1,086	1,330	534
Total operating expenses	7,282	6,480	5,956	3,096	7,488	4,339	3,045	1,572
Loss from operations	(7,282)	(6,480)	(5,956)	(3,096)	(7,488)	(4,339)	(3,045)	(1,572)
Other income (expenses):								
Gain on extinguishment of debt	—	—	—	—	—	—	1,900	—
Amortization of debt discount	(475)	(479)	(477)	(477)	(478)	(477)	(159)	—
Interest expense	(698)	(687)	(654)	(632)	(631)	(173)	(704)	(96)
Fair value adjustment	(764)	(2,089)	(22,661)	(1,762)	(3,221)	(2,189)	(1,570)	(242)
Interest and other income	15	11	5	—	4	3	—	—
Total other expenses	(1,922)	(3,244)	(23,787)	(2,871)	(4,326)	(2,836)	(533)	(338)
Loss before income taxes	(9,204)	(9,724)	(29,743)	(5,967)	(11,814)	(7,175)	(3,578)	(1,910)
Income tax (expense) benefit	1	(20)	—	(7)	(27)	38	6	5
Net loss	\$(9,203)	\$(9,744)	\$(29,743)	\$(5,974)	\$(11,841)	\$(7,137)	\$(3,572)	\$(1,905)
Net loss per share:								
Basic and diluted	\$ (0.64)	\$ (0.68)	\$ (2.45)	\$ (2.50)	\$ (4.97)	\$ (3.00)	\$ (1.50)	\$ (0.80)

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

KEMPHARM, INC.

Dated: March 15, 2016

By: /s/ Travis C. Mickle  
Travis C. Mickle, Ph.D.  
President and Chief Executive Officer  
(Principal Executive Officer)

Dated: March 15, 2016

By: /s/ R. LaDuane Clifton  
R. LaDuane Clifton  
Chief Financial Officer and Secretary  
(Principal Financial Officer and Principal Accounting  
Officer)

## POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitute and appoint Travis C. Mickle and R. LaDuane Clifton, and each of them (with full power to each of them to act alone), as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution in each of them for him and in his name, place and stead, and in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Travis C. Mickle</u> Travis C. Mickle, Ph.D.	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 15, 2016
<u>/s/ R. LaDuane Clifton</u> R. LaDuane Clifton	Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	March 15, 2016
<u>/s/ Danny L. Thompson</u> Danny L. Thompson	Director	March 15, 2016
<u>/s/ Matthew R. Plooster</u> Matthew R. Plooster	Director	March 15, 2016
<u>/s/ Richard W. Pascoe</u> Richard W. Pascoe	Director	March 15, 2016
<u>/s/ Joseph B. Saluri</u> Joseph B. Saluri	Director	March 15, 2016
<u>/s/ David S. Tierney</u> David S. Tierney	Director	March 15, 2016



## EXHIBIT INDEX

Exhibit No.	Description
2.1+	Asset Purchase Agreement, by and between Shire LLC and Travis C. Mickle, Ph.D. and the Registrant, dated as of March 21, 2012 (incorporated herein by reference to the Registrant's Amendment No. 1 to Registration Statement on Form S-1/A (File No. 333-202660) as filed with the SEC on April 3, 2015).
3.1	Amended and Restated Certificate of Incorporation of KemPharm, Inc. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on April 21, 2015).
3.2	Amended and Restated Bylaws, as currently in effect, of KemPharm, Inc. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on April 21, 2015).
4.1	Reference is made to Exhibits 3.1 and 3.2 hereof.
4.2	Specimen stock certificate evidencing shares of Common Stock (incorporated herein by reference to the Registrant's Amendment No. 2 to Registration Statement on Form S-1/A (File No. 333-202660) as filed with the SEC on April 9, 2015).
4.3	Indenture, by and between the Registrant and U.S. Bank National Association, dated as of February 9, 2016 (incorporated herein by reference to the Registrant's Current Report on Form 8-K filed with the SEC on February 9, 2016).
4.4	Form of Note representing the Company's 5.50% Senior Convertible Notes due 2021 (included as Exhibit A to the Indenture filed hereto as Exhibit 4.3) (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on February 9, 2016).
10.1+	Material Supply Agreement, by and between the Registrant and Johnson Matthey, Inc., dated as of November 2, 2009 (incorporated by reference Registrant's Amendment No. 1 to Registration Statement on Form S-1/A (File No. 333-202660) as filed with the SEC on April 3, 2015).
10.2	Facility Agreement, by and between the Registrant and Deerfield Private Design Fund III, L.P., dated as of June 2, 2014 (incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.2.1	First Amendment to Facility Agreement, Senior Secured Convertible Note and Warrant, by and between Registrant and Deerfield Private Design Fund III, L.P., dated March 6, 2015 (incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.2.2	Second Amendment to Facility Agreement by and between Registrant and Deerfield Private Design Fund III, L.P., dated December 17, 2015 (incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-208633) as filed with the SEC on December 18, 2015).
10.2.3	Third Amendment to Facility Agreement, Senior Secured Convertible Note and Warrant, by and between Registrant and Deerfield Private Design Fund III, L.P., dated February 3, 2016 (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on February 9, 2016).
10.3	Senior Secured Convertible Note issued to Deerfield Private Design Fund III, L.P., dated as of June 2, 2014 (incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.3.1	Second Amendment to Senior Secured Convertible Note and Warrant, by and between Registrant and Deerfield Private Design Fund III, L.P., dated January 6, 2016 (incorporated by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on January 11, 2016).
10.4	Amended and Restated Investors' Rights Agreement, dated as of February 19, 2015, by and among the Registrant and certain of its stockholders (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.5	Warrant to Purchase Shares of Series D Preferred Stock issued to Deerfield Private Design Fund III, L.P., dated as of June 2, 2014 (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.6	Form of Stock Purchase Warrant to purchase shares of Series D Convertible Preferred Stock issued in bridge financing, along with a schedule of warrant holders (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.7.1	Form of Common Stock Purchase Warrants issued by KemPharm, Inc., an Iowa corporation, along with a schedule of warrant holders (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.7.1	Form of Common Stock Purchase Warrants issued by KemPharm, Inc., a Delaware corporation, along with a schedule of warrant holders (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).

Exhibit No.	Description
10.8	Lease Agreement, by and between the Registrant and the Board of Regents, State of Iowa for the Use and Benefit of the University of Iowa, dated as of September 6, 2013 (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.9+	Agreement to Terminate CLA, by and between MonoSol Rx, LLC and the Registrant, dated as of March 20, 2012 (incorporated herein by reference to the Registrant's Amendment No. 1 to Registration Statement on Form S-1/A (File No. 333-202660) as filed with the SEC on April 3, 2015).
10.10#	Incentive Stock Plan, as amended to date (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.11#	Form of Incentive Stock Option Agreement under Incentive Stock Plan (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.12#	Form of Nonqualified Stock Option Agreement under Incentive Stock Plan (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.13#	Form of 2014 Equity Incentive Plan (incorporated herein by reference to Registrant's Amendment No. 1 to Registration Statement on Form S-1/A (File No. 333-202660) as filed with the SEC on April 3, 2015).
10.14#	Form of Stock Option Grant Notice and Stock Option Agreement under 2014 Equity Incentive Plan (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 File No. 333-202660) as filed with the SEC on March 11, 2015).
10.15#	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under 2014 Equity Incentive Plan (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 File No. 333-202660) as filed with the SEC on March 11, 2015).
10.16#*	Non-Employee Director Compensation Policy.
10.17#	Form of Indemnification Agreement with the Registrant's directors and executive officers (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.18#	Amended and Restated Employment Agreement by and between the Registrant and R. LaDuane Clifton, dated as of June 25, 2015 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 14, 2015).
10.18.1#	Amendment to Amended and Restated Employment Agreement by and between the Registrant and R. LaDuane Clifton, dated as of October 13, 2015 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on November 13, 2015).
10.19#	Employment Agreement by and between the Registrant and Christal M.M. Mickle, dated as of May 30, 2014 (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.19.1#	Amendment to Employment Agreement by and between the Registrant and Christal M.M. Mickle, dated as of October 13, 2015 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2015).
10.20#	Amended and Restated Employment Agreement by and between the Registrant and Gordon K. Johnson, dated as of June 25, 2015 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 14, 2015).
10.20.1#	Amendment to Amended and Restated Employment Agreement by and between the Registrant and Gordon K. Johnson, dated as of October 13, 2015 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on November 13, 2015).
10.21#	Employment Agreement by and between the Registrant and Travis C. Mickle, Ph.D., dated as of May 30, 2014 (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.21.1#	Amendment to Employment Agreement by and between the Registrant and Travis C. Mickle, Ph.D., dated as of October 13, 2015 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2015).
10.22#	Employment Agreement by and between the Registrant and Tracy Woody, dated as of March 30, 2015 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on May 29, 2015).
10.22.1#	Amendment to Employment Agreement by and between the Registrant and Tracy M. Woody, dated as of September 4, 2015 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on November 13, 2015).
10.23#	Acceleration Provisions of Stock Options Letter by and between the Registrant and Sven Guenther, Ph.D., dated as of October 13, 2015 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2015).

Exhibit No.	Description
10.24	Board of Directors Services Agreement by and between Registrant and Richard W. Pascoe, dated as of January 1, 2014 (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.25	Board of Directors Services Agreement by and between Registrant and Joseph B. Saluri, dated as of January 1, 2014 (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
23.1*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (included on signature page).
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (1)
32.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (1)
101.INS**	XBRL Instance Document.
101.SCH**	XBRL Taxonomy Extension Schema Document.
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document.

\* Filed herewith

\*\* Attached as Exhibit 101 to this Annual Report on Form 10-K for the year ended December 31, 2015, formatted in XBRL (Extensible Business Reporting Language): (i) Balance Sheets, (ii) Statements of Operations, (iii) Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Deficit, (iv) Statements of Cash Flows, and (v) Notes to Financial Statements, tagged as blocks of text and including detailed tags.

# Indicates management contract or compensatory plan.

+ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a grant for confidential treatment and have been separately filed with the Securities and Exchange Commission.

(1) This certification accompanies the Annual Report on Form 10-K to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Registrant under the Securities Act or the Exchange Act (whether made before or after the date of the Annual Report on Form 10-K), irrespective of any general incorporation language contained in such filing.

**KemPharm, Inc.**  
**Non-Employee Director Compensation Policy**

Each member of the board of director (the “**Board**”) of KemPharm, Inc. (the “**Company**”) who is not also an employee of the Company or any subsidiary of the Company shall be entitled to the following compensation for service on the Board and its committees:

Cash Compensation

Cash compensation shall be paid in the following annual amounts. Payments shall be made in quarterly installments in arrears on the last day of each calendar quarter in which service occurred, and shall be *prorated* as appropriated for a director who does not serve for the full quarter.

1. Annual Board Service Retainer:
  - a. All non-employee directors: \$35,000
  - b. Chairman of the Board, if not an employee, or lead independent director, if any (in addition to the retainer for all non-employee directors): \$15,000
  
2. Annual Committee Member Service Retainer:
  - a. Member of the Audit Committee: \$7,500
  - b. Member of the Compensation Committee: \$5,000
  - c. Member of the Nominating and Corporate Governance Committee: \$5,000
  
3. Annual Committee Chair Service Retainer (in addition to Committee Member Service Retainer):
  - a. Chairman of the Audit Committee: \$15,000
  - b. Chairman of the Compensation Committee: \$10,000
  - c. Chairman of the Nominating and Corporate Governance Committee: \$7,500

Equity Compensation

The equity compensation set forth below will be granted under the Company’s 2014 Equity Incentive Plan (the “**Plan**”). All stock options granted under this policy will be nonqualified stock options using the Company’s standard form of Nonqualified Stock Option Agreement under the Plan, with an exercise price per share equal to the last reported sale price of the Company’s common stock on the NASDAQ Capital Market on the date of grant or, if such grant date is not a trading date, on the last trading date prior to the grant date, and with a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).

Annual Grant: On the date of each annual stockholders meeting of the Company, each director who continues to serve as a non-employee member of the Board following such stockholders meeting will be automatically, and without further action by the Board or the Compensation Committee of the Board, be granted a stock option for 10,000 shares of common stock. The stock options will vest and become exercisable in full on the earlier of (1) the first anniversary of the grant date, (2) the day before the first annual stockholders meeting occurring after the grant date or (3) immediately prior to a “Change in Control” as defined in the Plan, subject in each case to the director’s continued service on such vesting date.

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-203703) pertaining to the Incentive Stock Plan, as amended, and the 2014 Equity Incentive Plan of KemPharm, Inc. of our report dated March 15, 2016, with respect to the financial statements of KemPharm, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2015.

/s/ Ernst & Young LLP  
Minneapolis, Minnesota  
March 15, 2016

## CERTIFICATIONS

I, Travis C. Mickle, certify that:

1. I have reviewed this Annual Report on Form 10-K of KemPharm, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 15, 2016

/s/ Travis C. Mickle

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Name: Travis C. Mickle, Ph.D.  
Title: President and Chief Executive Officer  
(Principal Executive Officer)

## CERTIFICATIONS

I, R. LaDuane Clifton, certify that:

1. I have reviewed this Annual Report on Form 10-K of KemPharm, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 15, 2016

/s/ R. LaDuane Clifton

Name: R. LaDuane Clifton

Title: Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of KemPharm, Inc., (the "Company") for the fiscal year ended December 31, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Travis C. Mickle, Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 15, 2016

/s/ Travis C. Mickle

Name: Travis C. Mickle, Ph.D.

Title: President and Chief Executive Officer  
(Principal Executive Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350, is not being "filed" by the Company as part of the Report or as a separate disclosure document and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.



CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of KemPharm, Inc., (the "Company") for the fiscal year ended December 31, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, R. LaDuane Clifton, Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 15, 2016

/s/ R. LaDuane Clifton

Name: R. LaDuane Clifton

Title: Chief Financial Officer

(Principal Financial Officer and Principle Accounting Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350, is not being "filed" by the Company as part of the Report or as a separate disclosure document and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.