Filed Pursuant to Rule 424(b)(4)
Registration No. 333-202660

PROSPECTUS **Dated April 15, 2015**

5,090,909 Shares

Common Stock

This is an initial public offering of shares of our common stock. We are offering 5,090,909 shares of our common stock. Prior to this offering, there has been no public market for our common stock. Our common stock has been approved for listing on The NASDAQ Global Market under the symbol "KMPH." The initial public offering price is $11.00 per share.

We are an "emerging growth company" under applicable Securities and Exchange Commission Rules and will be subject to reduced public company reporting requirements for this prospectus and future filings.

We have reserved up to 5% of the shares of common stock offered by this prospectus for sale, at the initial public offering price, to our directors, officers, employees, investors and their affiliated entities, and other individuals associated with us and members of their respective families. See "Underwriting—Directed Share Program."

Our business and an investment in our common stock involve significant risks. These risks are described under the caption "Risk Factors" beginning on page 12 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	*Total*
Public Offering Price	**$ 11.00**	**$ 55,999,999**
Underwriting Discount(1)	**$ 0.77**	**$ 3,920,000**
Proceeds to KemPharm (Before Expenses)	**$ 10.23**	**$ 52,079,999**

(1) See "Underwriting" in this prospectus for a description of compensation payable to the underwriters.

The underwriters may also purchase up to an additional 763,636 shares from us at the public offering price, less the underwriting discount, within 30 days from the date of this prospectus to cover overallotments.

An entity affiliated with Deerfield Private Design Fund III, L.P., one of our existing stockholders, has agreed to purchase 500,000 shares of our common stock in this offering.

The underwriters expect to deliver the shares against payment in New York, New York on April 21, 2015.

Cowen and Company **RBC Capital Markets**

Canaccord Genuity **Oppenheimer & Co.**

April 15, 2015

TABLE OF CONTENTS

You should rely only on the information contained in this prospectus and any free writing prospectus prepared by or on behalf of us or to which we have referred you. We have not authorized anyone to provide you with information that is different from that contained in such prospectuses. We are offering to sell shares of our common stock, and seeking offers to buy shares of our common stock, only in jurisdictions where such offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock.

Until and including May 10, 2015, 25 days after the date of this prospectus, all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to unsold allotments or subscriptions.

For investors outside of the United States: neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our financial statements and the related notes thereto and the information set forth under the sections "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case included in this prospectus. Unless the context otherwise requires, we use the terms "KemPharm," "company," "we," "us" and "our" in this prospectus to refer to KemPharm, Inc.

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, each of which is a new molecular entity, or NME. We believe our prodrugs, as NMEs, will be eligible for composition-of-matter patent protection. We intend to employ the regulatory pathway under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, otherwise known as 505(b)(2),to reduce the time, risk and expense associated with drug development. 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. A new molecular entity is an active ingredient that has not been marketed in the United States in any form.

Our most advanced product candidate, KP201/APAP, consists of KP201, our NME prodrug of hydrocodone, formulated in combination with acetaminophen, or APAP. We are developing KP201/APAP as an immediate release, or IR, product candidate for the treatment of acute moderate to moderately severe pain. 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 other commonly employed extraction techniques. We believe this approach to abuse-deterrence at the molecular level may be more effective than many formulation-based abuse-deterrence technologies, which combine the opioid drug with another drug or use an abuse-deterrent capsule or physical matrix.

We designed KP201/APAP with abuse-deterrent properties to address the epidemic of opioid abuse in the United States. 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. The increasing negative social consequences and costs of prescription drug abuse led the U.S. Food and Drug Administration, or FDA, to publish draft guidance in January 2013 and final guidance in April 2015 with regard to the evaluation and labeling of abuse-deterrent opioids. The FDA has approved abuse-deterrent labeling language in the product labels for four abuse-deterrent opioids: OxyContin, Targiniq ER, Embeda and Hysingla.

We believe that KP201/APAP has the potential to be the first FDA-approved IR product for the treatment of pain with the efficacy of hydrocodone/APAP combination products and abuse-deterrent labeling. We have completed a bioavailability trial comparing KP201/APAP to Norco, an approved hydrocodone/APAP combination product, and based on this trial, the FDA confirmed at our October 2013 End-of-Phase 2 meeting that the results of the trial support a finding that KP201/APAP is bioequivalent to Norco. Bioavailability refers to the rate and total amount of a drug that reaches the target in the body after administration, and two drugs are said to be bioequivalent if there is no clinically significant difference in their bioavailability. We are conducting clinical trials that are designed with the goal of obtaining abuse-deterrent claims in our product label for KP201/APAP. We intend to submit a new drug application, or NDA, under 505(b)(2), otherwise known as a 505(b)(2) NDA, for KP201/APAP to the FDA in the second half of 2015. We believe our NDA will receive priority review like other abuse-deterrent opioids.

We are also building a pipeline of additional NME prodrug product candidates that target large market opportunities in pain, attention deficit hyperactivity disorder, or ADHD, and other central nervous system indications. We anticipate reporting human proof-of-concept, or POC, data for three additional product candidates in 2016 and 2017.

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 was acquired by Shire plc in 2007 and Vyvanse generated over $1.2 billion in sales in 2013.

As of March 10, 2015, our patent portfolio consisted of 28 granted patents and 87 pending patent applications worldwide, including a granted U.S. composition-of-matter patent covering KP201, a pending U.S. patent application covering KP201-related compositions-of-matter and a granted U.S. composition-of-matter patent covering the prodrug underlying one of our other product candidates.

Our LAT Prodrug Platform Technology

We use our LAT platform technology to discover and develop NME prodrugs that improve one or more of the attributes of approved drugs, such as susceptibility to abuse, bioavailability and safety. We create our NME prodrugs by chemically attaching one or more molecules, referred to as ligands, to an FDA-approved drug, referred to as the parent drug. When the prodrug is administered to a patient as intended, human metabolic processes, such as those in the gastrointestinal, or GI, tract, separate the ligand from the prodrug and release the parent drug, which can then exert its therapeutic effect. We believe that our LAT platform technology offers the following potential benefits:

- ***Improved drug properties***. We seek to develop NME 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.
- ***505(b)(2) NDA pathway*.** Our NME prodrugs may be eligible to use the 505(b)(2) NDA pathway if we are able to demonstrate the bioequivalence of one of our product candidates to an appropriate approved drug. This may allow us to avoid the significant time and expense of conducting large clinical trials.

Our Pipeline of NME 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:

Indication / Parent Drug	Product Candidate	Development Status	Key Milestone
Pain			
Hydrocodone (IR)	KP201/APAP	Clinical Trials	NDA Filing – 2H 2015
Hydromorphone (extended release)	KP511/ER	Preclinical	Human POC Data – 2016
Oxycodone (extended release)	KP606/ER	Preclinical	Human POC Data – 2017
ADHD			
Methylphenidate (controlled release)	KP415	Preclinical	Human POC Data – 2016
Multiple CNS Disorders			
Quetiapine	KP303	Preclinical	Preclinical Development

KP201/APAP

We are developing KP201/APAP for the treatment of acute moderate to moderately severe 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. IMS Health Incorporated, or IMS, a healthcare information firm, estimates that IR hydrocodone bitartrate formulated in combination with APAP, or hydrocodone/APAP, products accounted for 127 million prescriptions in the United States in 2013.

KP201/APAP employs our molecular-based approach to abuse deterrence and is designed not to release its hydrocodone component until it is metabolized in the GI tract following oral administration. We believe the KP201 prodrug does not release hydrocodone effectively upon intranasal administration and has very poor solubility in blood, water and other solvents, thus rendering it unsuitable for intravenous, or IV, administration. We believe KP201/APAP is highly tamper-resistant and is stable under conditions that can potentially defeat many other abuse-deterrent technologies.

We plan to seek 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 and, based on this trial, the FDA confirmed at our October 2013 End-of-Phase 2 meeting that the results of the trial support a finding that KP201/APAP is bioequivalent to Norco.

To rely on the 505(b)(2) NDA pathway for KP201/APAP, we are also required to establish the safety and effectiveness of APAP and the safety and effectiveness of hydrocodone separately through other methods. We recently completed a bridging bioavailability trial of KP201/APAP and Ultracet, an FDA-approved tramadol/APAP combination product. The data from this trial suggests comparable bioavailability between the APAP in KP201/APAP and the APAP in Ultracet. We intend to reference the FDA's prior findings of safety and effectiveness for the APAP component of Ultracet in our 505(b)(2) NDA. We also plan to reference in our 505(b)(2) NDA published medical and scientific literature that establish the safety and effectiveness of hydrocodone. Based on our October 2013 End-of-Phase 2 meeting with the FDA, we believe that no additional efficacy trials will be required for KP201/APAP.

We are also conducting two human abuse liability trials that will generate additional data that we expect to include in our 505(b)(2) NDA submission. We designed these trials with the goal of obtaining abuse-deterrent claims in our product label for KP201/APAP. We expect data from the first of these trials, an oral human abuse liability trial, in the second quarter of 2015 and data from the second trial, an intranasal human abuse liability trial, in the third quarter of 2015.

We anticipate submitting our 505(b)(2) NDA for KP201/APAP to the FDA in the second half of 2015 and we expect that KP201/APAP, like other abuse-deterrent opioids, will receive priority review.

Additional NME Prodrug Product Candidates

KP511/ER

KP511/ER is our extended release, or ER, formulation of KP511, our NME prodrug of hydromorphone, which we are developing for the treatment of moderate to severe pain. KP511/ER is designed to be an abuse-deterrent opioid product that offers equivalent efficacy to approved ER hydromorphone products, such as Exalgo. 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.

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 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. We anticipate reporting human proof-of-concept data for KP511/ER in 2016.

KP415

KP415 is our NME 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 abuse-deterrent methylphenidate product. 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 $1.1 billion in 2014.

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. 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.

Other Product Candidates

We are using our LAT platform technology to develop other product candidates in pain and CNS indications. One example is KP606/ER, an ER formulation of KP606, our NME prodrug of oxycodone, which we are developing for the treatment of moderate to severe pain. KP606/ER is designed to be an ER abuse-deterrent opioid product that offers equivalent efficacy to OxyContin. We plan to seek approval of KP606/ER under the 505(b)(2) FDA pathway. We anticipate reporting human proof-of-concept data for KP606/ER in 2017.

Another example is KP303, our NME prodrug of quetiapine, which is currently in preclinical development and which we are developing for the potential treatment of CNS disorders such as schizophrenia, bipolar disorder and major depressive disorder.

Our Strategy

Our goal is to be a leading specialty pharmaceutical company focused on the discovery, development and commercialization of our novel and proprietary NME 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 plan to submit an NDA to the FDA in the second half of 2015. We expect that the approval process will be conducted according to the 505(b)(2) NDA pathway and will be subject to priority review, with potential approval as early as mid-2016. Prior to product launch, 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 would occur as early as 2017.
- ***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.
- ***Advance the development of our other pipeline product candidates.*** We plan to advance KP511/ER, KP415 and KP606/ER through human proof-of-concept trials to evaluate their bioequivalence to appropriate FDA-approved drugs, and we expect to report data from these trials in 2016 and 2017.
- ***Leverage our LAT platform technology to develop additional product candidates.*** We plan to employ our LAT platform technology to develop additional NME prodrugs that have improved properties over approved drugs and address unmet medical needs in large, established markets.
- ***Continue to build a global intellectual property portfolio.*** We intend to vigorously pursue composition-of-matter patent protection for our NME prodrugs in markets covering a majority of the global commercial opportunity.

Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks are discussed more fully in the “Risk Factors” section of this prospectus. These risks include the following:

- We are very early in our development efforts and have only one product candidate, KP201/APAP, that has 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, or experience significant delays in doing so, our business will be harmed.
- 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.
- We have incurred significant losses since our inception. We expect to incur losses for the next several years and may never achieve or maintain profitability.
- 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 NME prodrug development programs or commercialization efforts.
- We contract with a third party for the manufacture of KP201/APAP and with a sole source supplier for the manufacture of bulk quantities of KP201. 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.

- If we are unable to obtain and maintain patent protection for our technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, our ability to successfully commercialize our technology and product candidates may be impaired.
- 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.
- 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.
- 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.
- 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.

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*. The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock.

We have proprietary rights to a number of trademarks used in this prospectus which are important to our business, including KemPharm® and the KemPharm logo. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus 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.

Implications of Being an Emerging Growth Company

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of relief from certain reporting requirements and other burdens that are otherwise applicable generally to public companies. These provisions include:

- presentation of only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- exemption from the auditor attestation requirement on the effectiveness of our internal controls over financial reporting;
- reduced disclosure about our executive compensation arrangements; and
- no requirements for non-binding advisory votes on executive compensation or golden parachute arrangements.

We may take advantage of these provisions for up to five years or such earlier time that we no longer qualify as an emerging growth company. We would cease to be an emerging growth company if

we have more than $1.0 billion in annual revenue, have more than $700 million in market value of our capital stock held by non-affiliates or issue more than $1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced burdens. For example, we have taken advantage of the reduced reporting requirements with respect to disclosure regarding our executive compensation arrangements, have presented only two years of audited financial statements, have presented reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure and have taken advantage of the exemption from auditor attestation on the effectiveness of our internal controls over financial reporting. To the extent that we take advantage of these reduced burdens, the information that we provide stockholders may be different than you might obtain from other public companies in which you hold equity interests.

In addition, under 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.

The Offering	
Common stock offered by us	5,090,909 shares
Common stock to be outstanding immediately after this offering	13,462,674 shares
Option to purchase additional shares	We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase up to 763,636 additional shares of our common stock.
Use of proceeds	We estimate that the net proceeds to us from this offering, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately $49.3 million, or approximately $57.1 million if the underwriters exercise their option to purchase additional shares. We anticipate that the net proceeds from this offering will be used to complete our planned clinical trials and seek regulatory approval of KP201/APAP, to fund the research and development of the other preclinical NME prodrug product candidates in our pipeline, and for working capital and general corporate purposes. See “Use of Proceeds” for additional information.
Risk factors	You should read the “Risk Factors” section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Directed share program	At our request, the underwriters have reserved up to 5% of the shares of common stock offered by this prospectus for sale, at the initial public offering price, to our directors, officers, employees, investors and their affiliated entities, and other individuals associated with us and members of their respective families. The sales will be made by RBC Wealth Management, a selected dealer affiliated with RBC Capital Markets, LLC, an underwriter of this offering, through a directed share program. We do not know if these persons will choose to purchase all or any portion of these reserved shares, but any purchases they do make will reduce the number of shares available to the general public. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares of common stock. Any shares of common stock sold to our directors or executive officers

	pursuant to the directed share program will be subject to the 180-day lock-up restrictions described in “Underwriting.”
NASDAQ Global Market symbol	KMPH

An entity affiliated with Deerfield Private Design Fund III, L.P., one of our existing stockholders, has agreed to purchase 500,000 shares of our common stock in this offering.

The number of shares of our common stock that will be outstanding after this offering is based on 8,371,765 shares of common stock outstanding as of March 10, 2015, and excludes:

- 549,824 shares of our common stock issuable upon the exercise of stock options outstanding under our existing incentive stock plan as of March 10, 2015, at a weighted average exercise price of $6.30 per share;
- 2,652,302 shares of our common stock issuable upon exercise of warrants outstanding as of March 10, 2015, at a weighted average exercise price of $5.73 per share;
- 1,841,683 shares of our common stock issuable upon conversion of principal and accrued interest underlying the convertible note outstanding as of March 10, 2015, assuming a conversion date of March 10, 2015;
- 2,266,666 shares of our common stock reserved for future issuance under our 2014 equity incentive plan, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan;
- 21,333 shares of our common stock issuable upon the exercise of stock options we have granted to an executive officer as of the date of this prospectus, at an exercise price equal to $11.00 per share; and
- 116,509 shares of our common stock issuable upon the exercise of stock options we expect to grant to our executive officers promptly following the closing date of this offering, which will have an exercise price equal to the per share fair market value of our common stock as of the grant date.

Except as otherwise indicated herein, all information in this prospectus, including the number of shares that will be outstanding after this offering, assumes or gives effect to:

- a 1-for-7.5 reverse stock split of our common stock completed on April 2, 2015;
- the conversion or reclassification of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 5,980,563 shares of our common stock, which will automatically occur upon the closing of this offering;
- the conversion of outstanding warrants to purchase shares of redeemable convertible preferred stock into warrants to purchase common stock upon the closing of this offering; and
- no exercise of the underwriters’ option to purchase additional shares of common stock.

Summary Financial Data

The tables below provide summary financial data for the periods indicated. We have derived the summary statement of operations data for the years ended December 31, 2013 and 2014 and the summary balance sheet data as of December 31, 2014 from our audited financial statements appearing elsewhere in this prospectus. You should read this summary financial data together with the historical financial statements and related notes to those statements, as well as "Management's Discussion and Analysis of Financial Condition and Results of Operations," which are included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future.

	Year Ended December 31,	
	2013	2014
Statement of operations data:		
Revenue	$ –	$ –
Operating expenses:		
Research and development	3,366,932	11,917,217
General and administrative	1,350,971	4,526,093
Total operating expenses	4,717,903	16,443,310
Loss from operations	(4,717,903)	(16,443,310)
Other (expense) income	(528,086)	(8,033,698)
Loss before income taxes	(5,245,989)	(24,477,008)
Income tax benefit	19,544	22,247
Net loss	$(5,226,445)	$(24,454,761)
Net loss per share:		
Basic and diluted	$ (2.20)	$ (10.27)
Basic and diluted, pro forma(1)		$ (3.13)
Weighted average common shares outstanding:		
Basic and diluted	2,381,041	2,381,041
Basic and diluted, pro forma(1)		7,823,352

(1) See Note 14 to our Financial Statements for an explanation of the method used to calculate the pro forma basic and diluted net loss per share and the pro forma basic and diluted weighted average common shares outstanding.

The following table presents our summary balance sheet data:

- on an actual basis as of December 31, 2014;
- on a pro forma basis to give effect to:
  - the issuance and sale of 3,200,000 shares of Series D-1 redeemable convertible preferred stock, or the Series D-1 shares, in February 2015 and our receipt of $3.9 million in net proceeds therefrom;
  - the conversion or reclassification of all outstanding shares of our redeemable convertible preferred stock, including the Series D-1 shares, into an aggregate of 5,980,136 shares of our common stock, which will automatically occur upon the closing of this offering; and
  - the conversion of outstanding warrants to purchase shares of redeemable convertible preferred stock into warrants to purchase common stock upon the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to our sale of 5,090,909 shares of common stock in this offering at the initial public offering price of $11.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	As of December 31, 2014		
	Actual	Pro Forma	Pro Forma As Adjusted
Balance sheet data:			
Cash and cash equivalents	$ 10,255,021	$ 14,155,021	$63,435,020
Working capital	6,343,052	10,243,052	59,523,051
Total assets	13,713,780	17,613,780	66,893,779
Convertible notes, net of discount	7,235,441	7,235,441	7,235,441
Term notes, net of discount	10,853,162	10,853,162	10,853,162
Derivative and warrant liability	15,965,891	15,965,891	15,965,891
Total liabilities	38,015,468	38,015,468	38,015,468
Redeemable convertible preferred stock	24,206,612	–	–
Total stockholders' (deficit) equity	(48,508,300)	(20,401,688)	28,878,311

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before you invest in our common stock, you should carefully consider the following risks, as well as general economic and business risks, and all of the other information contained in this prospectus. Any of the following risks could have a material adverse effect on our business, operating results and financial condition and cause the trading price of our common stock to decline, which would cause you to lose all or part of your investment. When determining whether to invest, you should also refer to the other information contained in this prospectus, including our financial statements and the related notes thereto.

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 incurred net losses of $5.2 million and $24.5 million for the years ended December 31, 2013 and 2014, respectively. As of December 31, 2014, we had an accumulated deficit of $50.2 million. We have financed our operations to date with $52.7 million raised in private placements of redeemable convertible preferred stock, convertible promissory notes and term debt.

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 studies and clinical trials evaluating, among other things, KP201/APAP's abuse-deterrent features;
- 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 potential 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 NME 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 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 the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 18 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 studies and clinical trials for KP201/APAP;
- 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, we receive from commercial sales of our product candidates for which we obtain 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 NME prodrug products that we do not expect to be

commercially available for a number of years, 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 our credit facility, or the Deerfield facility, with Deerfield Private Design Fund III, L.P., or Deerfield, 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. 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 NME 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.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this prospectus.

Our report from our independent registered public accounting firm for the year ended December 31, 2014 includes an explanatory paragraph stating that our recurring losses from operations and stockholders' deficit raise substantial doubt about our ability to continue as a going concern. While we believe that we will be able to raise the capital we need to continue our operations, there can be no assurances that we will be successful in these efforts or will be able to resolve our liquidity issues or eliminate our operating losses. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited consolidated financial statements, and it is likely that investors will

lose all or a part of their investment. After this offering, future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

Risks Related to the Development of Our Product Candidates

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

A key element of our strategy is to use our LAT platform technology to build a pipeline of NME 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 NME 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.

We are very early in our development efforts and have only one product candidate, KP201/APAP, that has 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, or experience significant delays in doing so, our business will be harmed.

We are very early in our development efforts and have only one product candidate, KP201/APAP, that has commenced clinical trials. 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 NME 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 a number of years, 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 current good manufacturing practices, or cGMPs;
- launching commercial sales of product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our NME 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 NME 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 intend to conduct trials to support approval by the FDA of Category 1, 2 and 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. 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 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, if required, may not support the continued use of abuse-deterrent claims.

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.

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. For KP201/APAP, because there are no approved NDAs for hydrocodone/APAP combination products, we are required to establish safety and efficacy of APAP and safety and efficacy of hydrocodone separately through other methods. We plan to reference published medical and scientific literature in our 505(b)(2) NDA to establish the safety and effectiveness of hydrocodone. If this literature is insufficient, we may need to conduct additional clinical trials and provide additional data and information regarding the safety and effectiveness of hydrocodone.

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 abbreviated new drug application, or 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 Risk Evaluation and Mitigation Strategy, or 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 may 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.

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 contract research organizations, or 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 risk evaluation and mitigation strategies, or 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.

Our decision to seek approval of KP201/APAP and other product candidates under 505(b)(2) may increase the risk that patent infringement suits are filed against us, which would delay the FDA's approval of such product candidates.

In connection with any NDA that we file under 505(b)(2), if there are patents that claim the approved drug contained in our product candidates and referenced in our 505(b)(2) NDA, we must certify to the FDA and notify the patent holder that any patents listed for the approved drug in the FDA's Orange Book publication are invalid, unenforceable or will not be infringed by the manufacture, use or sale of our prodrug. If a patent infringement lawsuit is filed against us within 45 days of its receipt of notice of our certification, the FDA is automatically prevented from approving our 505(b)(2) NDA until the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a court decision in the infringement case that is favorable to us, or such shorter or longer period as may be ordered by a court. Such actions are routinely filed by patent owners. Accordingly, we may invest significant time and expense in the development of our product candidates only to be subject to significant delay and patent litigation before our product candidates may be commercialized. We may not be successful in defending any patent infringement claim. Even if we are found not to infringe, or a

plaintiff's patent claims are found invalid or unenforceable, defending any such infringement claim would be expensive and time-consuming, and would delay launch of KP201/APAP or our other product candidates and distract management from their normal responsibilities.

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. 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 20 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, KP511/ER, KP415 and KP606/ER, if approved, will be regulated as "controlled substances" as defined in the Controlled Substances Act of 1970, or 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 will 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. Schedule II drugs are subject to the strictest requirements for registration, security, recordkeeping and reporting. Also, distribution, prescribing and dispensing of these drugs are highly regulated.

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.

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 are expected to be regulated as Schedule II controlled substances, they will 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. 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 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 payers 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. It is possible that FDA 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 LLC, or 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 expect 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 expect to engage CROs for our planned clinical trials of our product candidates. We expect 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 will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will 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 regulatory standards, commonly referred to as good clinical practices, or 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, principal 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, principal 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 principal investigators are also subject to scrutiny under other health care regulatory laws, such as the federal Anti-Kickback Statute.

We also expect 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 NME 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 NME 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 Rx, LLC 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 Rx, LLC, or MonoSol, which 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 the Deerfield facility may inhibit our ability to enter into specified transactions, including any joint venture, partnership or any other profit sharing arrangement.

Pursuant to 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. Additionally, if we were to enter into such a 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. 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 United States Patent and Trademark Office, or 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 preissuance 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. 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 NME 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, that 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* reexaminations, *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 NME 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. 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 NME 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 NME 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 also indirectly 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 products or technologies from companies including Actavis plc, Acura Pharmaceuticals, Inc., Cara Therapeutics, Inc., Collegium Pharmaceutical, Inc., Depomed, Inc., DURECT Corporation, Egalet Corporation, Elite Pharmaceuticals, Inc., Endo International plc, 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 treatment of acute moderate to moderately severe pain. Some of these currently marketed products include AbbVie's Vicodin, Actavis'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 Endo International plc, Actavis 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 Actavis 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, KP303 will compete against currently marketed, branded and generic quetiapine products for the treatment of CNS disorders such as schizophrenia, bipolar disorder and major depressive disorder. Some of these currently marketed products include Astrazeneca PLC's Seroquel and Seroquel XR, in addition to multiple other generic quetiapine products marketed by companies including Lupin Pharmaceuticals, Inc., Roxanne Laboratories, Inc. and Teva Pharmaceutical Industries Ltd. In addition, if approved, KP303 will face potential competition from any quetiapine products for the treatment of CNS disorders such as schizophrenia, bipolar disorder and major depressive disorder 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 Actavis 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 and 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/ER will compete against currently marketed, branded and generic abuse-deterrent and other IR and ER oxycodone 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 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 Actavis plc, Endo International plc, and Mallinckrodt plc. In addition, if approved, KP606/ER will face potential competition from any abuse-deterrent or other IR and ER oxycodone products for treatment of pain 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 treatment of acute moderate to moderately severe 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. 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 new chemical entity, or NCE, status for KP415, and we may seek NCE status for other NME 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. 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 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 NME 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 NME 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 NME 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 NME 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 NME 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 NME 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, civil whistleblower or "qui tam" actions, operating restrictions or criminal penalties. 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 NME 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 NME prodrug products that we may develop.

We currently hold $8.0 million in product liability insurance coverage in the aggregate, with a per incident limit of $8.0 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

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, advertising, marketing, promotion, sale, distribution, import, export, and reporting of safety and other post-market information, are subject to comprehensive regulation by the FDA, DEA and other regulatory agencies in the United States and by the European Medicines Agency, or EMA, and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. Through the prior experience of our management, we have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Prior to product launch, the DEA would then need to determine the controlled substance schedule of KP201/APAP, taking into account the recommendation of the FDA. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. If any of our product candidates receives marketing approval, the accompanying label may limit its approved use, which could limit sales of the product.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. We

may not gain approval of our product candidates, or even if we obtain regulatory approval for a product candidate, product candidates may be subject to fewer or more limited indications, 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, may grant approval contingent on the performance of costly post-marketing clinical trials or other post-market requirements, such as REMS, may require post-marketing surveillance 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. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. Regulatory authorities may further disagree with the study design, assessment tools or evaluations that we conducted. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be materially impaired.

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 NME prodrug products, if any, for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug and Cosmetic Act 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 NME 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 NME 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 NME 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 NME 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 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. 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 and customers 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 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;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, 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.

We continue to evaluate the effect that the ACA has on our business. Additionally, new litigation attempting to invalidate the ACA is currently pending before the U.S. Supreme Court that could affect our business. Final regulations, guidance, and judicial orders are anticipated in the near future and we will continue to assess the ACA's impact on us as final regulations and guidance 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 NME 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 recently enacted 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 will be 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 will also be required to verify that purchasers of products are

appropriately licensed. Further, under this new legislation, manufacturers will 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 NME 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 operating officer and chief financial officer, Christal M.M. Mickle, our vice president operations and 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. Additionally, Mr. Mickle 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 NME 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 March 10, 2015, we had 18 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 this Offering, 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 at or above the initial offering price, if at all.

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock has been determined through negotiations with the underwriters and may not be indicative of the price at which our common stock will trade upon completion of this offering. Although our common stock has been approved for listing on The NASDAQ Global Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop or is not sustained, it may be difficult for you to sell shares you purchased in this offering at an attractive price or at all.

The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price may be volatile. 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 will be influenced by the research and reports that equity research analysts publish about us and our business. We do not currently have and may never obtain research coverage by equity research analysts. Equity research analysts may elect not to provide

research coverage of our common stock after the completion of this offering, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

We may incur substantial costs as a result of ongoing litigation.

We are currently party to a lawsuit against DeWaay Financial Network, L.L.C., or DFN, a financial advisor, in the Iowa District Court for Polk County, Iowa to resolve whether DFN has a valid (i) 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 or (ii) right to a cash fee equal to the greater of $250,000 or 1.5% of the total consideration received by us, our affiliates and our equity owners related to any such strategic transaction, including this offering and future offerings and the Deerfield facility, under an engagement agreement between us and DFN.

In the lawsuit, we are seeking a declaratory judgment finding invalid and unenforceable such purported right of first refusal and right to receive a cash fee related to any such strategic transaction. DFN filed an answer requesting that the court declare that such rights are 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 will receive pursuant to the Deerfield facility. A trial date for the matter has been set for August 2015.

If it is finally determined that DFN has a valid right of first refusal or right to receive a cash fee related to any such strategic transaction, we could be required to pay to DFN a portion of the consideration received in any such strategic transaction, including this offering and future capital raising transactions. Such an outcome would increase our costs in entering into any such transaction and might prevent us from doing so altogether. Further, we cannot predict the timing or outcome of this litigation and irrespective of its outcome, this litigation may cause us to incur substantial costs in related legal fees and divert management's attention and resources from our business.

If you purchase shares of our common stock in this offering, you will suffer immediate dilution of your investment.

The initial public offering price of our common stock is substantially higher than the pro forma as adjusted net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our pro forma as adjusted net tangible book value per share after this offering. Based on the initial public offering price of $11.00 per share, you will experience immediate dilution of $9.08 per share, representing the difference between our pro forma as adjusted net tangible book value per share after this offering and the initial public offering price. After this offering, we will also have an outstanding convertible note issued to Deerfield with a conversion price lower than the initial public offering price and options and warrants to purchase common stock with exercise prices lower than the initial public offering price. To the extent the outstanding convertible note is converted or outstanding options and warrants are exercised, there will be further dilution to investors in this offering.

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 March 10, 2015, we had outstanding immediately exercisable warrants to purchase 544,293 shares of our common stock at a weighted average exercise price of $5.35 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 our Series D redeemable convertible preferred stock at an exercise price of $0.78 per share. Upon the closing of this offering, this warrant will become a warrant to purchase 1,923,077 shares of our common stock at an exercise price of $5.85 per share. Following completion of this offering, exercise price protection provisions in this warrant will go into effect, 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 on The NASDAQ Global Market on the last trading date immediately prior to such issuance. 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 Series D redeemable convertible preferred stock at a conversion price of $0.78 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, upon the consummation of this offering, the Deerfield Note will become convertible into 1,841,683 shares of our common stock, assuming a conversion date of March 10, 2015. At our option, the Deerfield Note will convert into shares of our common stock upon

the occurrence prior to June 30, 2016 of either (i) the FDA's approval of an NDA for KP201 for the treatment of acute pain without requiring the performance of an efficacy study or (ii) the FDA's acceptance of an NDA for KP201 for review and our consummation of an initial public offering of our common stock at price of at least $9.375 per share with at least $25.0 million in gross proceeds to us. Following completion of this offering, 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 on The NASDAQ Global Market on the last trading date immediately prior to such issuance.

If Deerfield elects to convert the Deerfield Note, 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.

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 these plans 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. If we are required to pay 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.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This 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 following this offering, the market price of our common stock could decline significantly.

Upon the closing of this offering, we will have outstanding 13,462,674 shares of common stock, assuming no conversion of outstanding convertible notes and no exercise of outstanding options or warrants. Of these shares, the 5,090,909 shares sold in this offering and 164,388 additional shares will be freely tradable (except that common stock sold to our directors or executive officers in this offering pursuant to the directed share program will be subject to the 180-day lock-up restrictions described below), and 8,207,377 additional shares of common stock will be available for sale in the public market beginning 180 days after the date of this prospectus following the expiration of lock-up or similar agreements between substantially all of our stockholders and us or the underwriters subject to the volume, manner of sale and other limitations under Rule 144 and Rule 701. The representatives of the underwriters may release stockholders from their lock-up agreements with the underwriters at any time and without notice, which would allow for earlier sales of shares in the public market.

In addition, promptly following the completion of this offering, we intend to file one or more registration statements on Form S-8 registering the issuance of 3,027,557 shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up or similar agreements described above and the restrictions of Rule 144 in the case of our affiliates.

Additionally, after this offering, the holders of an aggregate of 5,894,703 shares of our common stock and 2,277,533 shares of our common stock issuable upon the exercise of outstanding warrants, or their transferees, will 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 to be in effect upon the closing of this offering, as well as provisions of Delaware law and the terms of some or 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 to be in effect upon the closing of this offering 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 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.

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 to be in effect upon the closing of this offering will provide that the Court of Chancery of the State of Delaware will be 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 to be in effect upon the closing of this offering 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 to be in effect upon the closing of this offering, 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.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Upon completion of this offering, our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates will, in the aggregate, beneficially own 22.6% of our outstanding common stock. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets or other significant corporate transactions.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the price at which shares are being sold in this offering and have held their shares for a longer period, they may be more interested in our sale to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

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 intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- 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 this 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, 2014, we had federal net operating loss carryforwards of $38.4 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 this offering. 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.

After the completion of this offering, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, 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, 2015, 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 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. Prior to this offering, 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.

We will have broad discretion in the use of proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

We will have broad discretion over the use of proceeds from this offering. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. We expect to use the net proceeds to us from this offering to complete our planned clinical trials and seek regulatory approval of KP201/APAP, to fund the research and development of the other preclinical NME prodrug product candidates in our pipeline, and for working capital and general corporate purposes. Our failure to apply the net proceeds of this offering effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use our net proceeds from this offering.

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 will 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 will incur significant additional legal, accounting and other costs, which we anticipate could be between $1.0 million and $2.0 million annually. 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business” but are also contained elsewhere in this prospectus. In some cases, you can identify forward-looking statements by the words “may,” “might,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “objective,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue” and “ongoing,” or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Forward-looking statements include statements about:

- our plans to develop and commercialize our product candidates;
- our planned clinical trials for KP201/APAP and our other NME prodrug product candidates;
- the timing of the availability of data from our clinical trials;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates, including expectations about our ability to use the 505(b)(2) NDA pathway and expedited FDA review and the timing of DEA scheduling;
- the clinical utility of our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position;
- our ability to identify additional product candidates with significant commercial potential that are consistent with our commercial objectives; and
- our estimates regarding future revenue, expenses and needs for additional financing.

You should refer to the “Risk Factors” section of this prospectus for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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

MARKET AND INDUSTRY DATA

This prospectus 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 prospectus 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.

USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of 5,090,909 shares of our common stock in this offering will be approximately $49.3 million, or approximately $57.1 million if the underwriters exercise their option to purchase additional shares in full, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We currently estimate that we will use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately $20.0 million to complete our planned clinical trials and seek regulatory approval of KP201/APAP;
- approximately $10.0 million to fund continued research and development of KP511/ER, KP606/ER, KP415 and our other NME prodrug product candidates; and
- the remainder for working capital and other general corporate purposes.

In addition, we may be required to pay 1.5% of the proceeds of this offering and proceeds from the Deerfield transaction to DFN. See “Business—Legal Proceedings” for additional information regarding this potential payment.

This expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from clinical trials, as well as any collaborations that we may enter into with third parties for our product candidates, and any unforeseen cash needs.

As a result, our management will have broad discretion in the application of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering. Pending these uses, we plan to invest these net proceeds in short-term, interest bearing obligations, certificates of deposit or direct or guaranteed obligations of the United States.

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.

CAPITALIZATION

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

- on an actual basis;
- on a pro forma basis to give effect to:
  - the issuance and sale of 3,200,000 shares of Series D-1 redeemable convertible preferred stock in February 2015 and our receipt of $3.9 million in net proceeds therefrom;
  - the conversion or reclassification of all outstanding shares of our redeemable convertible preferred stock, including the Series D-1 shares, into an aggregate of 5,980,136 shares of our common stock, which will automatically occur upon the closing of this offering;
  - the conversion of outstanding warrants to purchase shares of redeemable convertible preferred stock into warrants to purchase common stock upon the closing of this offering; and
  - the filing of our amended and restated certificate of incorporation immediately following the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to our sale of 5,090,909 shares of common stock in this offering, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and the related notes appearing elsewhere in this prospectus.

	As of December 31, 2014		
	Actual	Pro Forma	Pro Forma As Adjusted
Cash and cash equivalents	$ 10,255,021	$ 14,155,021	$ 63,435,020
Convertible notes, net of discount	$ 7,235,441	$ 7,235,441	$ 7,235,441
Term notes, net of discount	10,853,162	10,853,162	10,853,162
Derivative and warrant liability	15,965,891	15,965,891	15,965,891
Redeemable convertible preferred stock:			
Series A redeemable convertible preferred stock, $0.0001 par value; 9,705,000 shares authorized, 9,704,215 shares issued and outstanding, actual; no shares designated, issued or outstanding, pro forma and pro forma as adjusted	3,342,849	–	–
Series B redeemable convertible preferred stock, $0.0001 par value; 6,220,000 shares authorized, 6,220,000 shares issued and outstanding, actual; no shares designated, issued or outstanding, pro forma and pro forma as adjusted	3,312,465	–	–
Series C redeemable convertible preferred stock, $0.0001 par value; 18,558,000 shares authorized, 18,557,408 shares issued and outstanding, actual; no shares designated, issued or outstanding, pro forma and pro forma as adjusted	11,892,066	–	–
Series D redeemable convertible preferred stock, $0.0001 par value; 75,000,000 shares authorized, 7,255,425 shares issued and outstanding, actual; no shares designated, issued or outstanding, pro forma and pro forma as adjusted	5,659,232	–	–
Series D-1 redeemable convertible preferred stock, $0.0001 par value; no shares authorized, no shares issued and outstanding, actual; no shares designated, issued or outstanding, pro forma and pro forma as adjusted	–	–	–
Stockholders’ (deficit) equity:			
Common stock, $0.0001 par value; 140,000,000 shares authorized, 2,381,041 shares issued and outstanding, actual; 250,000,000 shares authorized, 8,361,177 shares issued and outstanding, pro forma; 250,000,000 shares authorized, 13,452,086 shares issued and outstanding, pro forma as adjusted	238	837	1,346
Preferred stock, $0.0001 par value; no shares authorized, issued or outstanding, actual; 10,000,000 shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted	–	–	–
Additional paid-in-capital	1,651,822	29,757,835	79,037,325
Accumulated deficit	(50,160,360)	(50,160,360)	(50,160,360)
Total stockholders’ (deficit) equity	(48,508,300)	(20,401,688)	28,878,311
Total capitalization	$ 9,752,806	$ 13,652,806	$ 62,932,805

The number of shares of common stock outstanding in the table above does not include:

- 395,185 shares of our common stock issuable upon the exercise of stock options outstanding under our existing incentive stock plan as of December 31, 2014, at a weighted average exercise price of $5.40 per share;
- 2,662,890 shares of our common stock issuable upon exercise of warrants outstanding as of December 31, 2014, at a weighted average exercise price of $5.72 per share;
- 1,808,353 shares of our common stock issuable upon conversion of principal and accrued interest underlying the convertible note outstanding as of December 31, 2014, assuming a conversion date of December 31, 2014;
- 2,266,666 shares of our common stock reserved for future issuance under our 2014 equity incentive plan, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan;
- 21,333 shares of our common stock issuable upon the exercise of stock options we have granted to an executive officer as of the date of this prospectus, at an exercise price equal to $11.00 per share; and
- 116,509 shares of our common stock issuable upon the exercise of stock options we expect to grant to our executive officers promptly following the closing date of this offering, which will have an exercise price equal to the per share fair market value of our common stock as of the grant date.

DILUTION

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

As of December 31, 2014, we had a net tangible book deficit of $(51.5) million, or $(21.64) per share of common stock. On a pro forma basis, after giving effect to the issuance and sale of 3,200,000 shares of Series D-1 redeemable convertible preferred stock in February 2015 and our receipt of $3.9 million in net proceeds therefrom, and the conversion or reclassification of the outstanding shares of our redeemable convertible preferred stock into 5,980,136 shares of our common stock upon the closing of this offering, which will automatically occur upon the closing of this offering, and the conversion of outstanding warrants to purchase shares of redeemable convertible preferred stock into warrants to purchase common stock upon the closing of this offering, our pro forma net tangible book deficit would have been $(23.4) million, or $(2.80) per share of common stock.

After giving effect to the issuance and sale of 5,090,909 shares of our common stock in this offering at the initial public offering price of $11.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2014 would have been $13.5 million, or $1.92 per share of common stock. This represents an immediate increase in the pro forma net tangible book value of $4.72 per share to existing stockholders, and an immediate dilution in the pro forma net tangible book value of $9.08 per share to investors purchasing shares of our common stock in this offering. The following table illustrates this per share dilution:

Initial public offering price per share		$11.00
Actual net tangible book deficit per share as of December 31, 2014	$(21.64)	
Increase per share attributable to sale of Series D-1 redeemable convertible preferred stock and assumed conversion or reclassification of redeemable convertible preferred stock	18.84	
Pro forma net tangible book value per share before this offering	(2.80)	
Increase in pro forma net tangible book value per share attributable to this offering	4.72	
Pro forma as adjusted net tangible book value per share after this offering		1.92
Dilution per share to investors participating in this offering		$ 9.08

If the underwriters exercise their option in full to purchase 763,636 additional shares of common stock in this offering, the pro forma as adjusted net tangible book value per share after the offering would be $2.37 per share, the increase in the pro forma net tangible book value per share to existing stockholders would be $5.17 per share and the dilution to new investors purchasing common stock in this offering would be $8.63 per share.

The following table sets forth as of December 31, 2014, on the pro forma basis described above, the differences between the number of shares of common stock purchased from us, the total consideration paid and the weighted average price per share paid by existing stockholders and by investors purchasing shares of our common stock in this offering at the initial public offering price of $11.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares purchased		Total consideration		Weighted average price per share
	Number	Percent	Amount	Percent	
Existing stockholders	8,361,177	62%	$32,336,418	37%	$ 3.87
New investors	5,090,909	38	55,999,999	63	11.00
Total	13,452,086	100%	$88,336,417	100%	

The table above also excludes:

- 395,185 shares of our common stock issuable upon the exercise of stock options outstanding under our existing incentive stock plan as of December 31, 2014, at a weighted average exercise price of $5.40 per share;
- 2,662,890 shares of our common stock issuable upon exercise of warrants outstanding as of December 31, 2014, at a weighted average exercise price of $5.72 per share;
- 1,808,353 shares of our common stock issuable upon conversion of principal and accrued interest underlying the convertible note outstanding as of December 31, 2014, assuming a conversion date of December 31, 2014;
- 2,266,666 shares of our common stock reserved for future issuance under our 2014 equity incentive plan, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan;
- 21,333 shares of our common stock issuable upon the exercise of stock options we have granted to an executive officer as of the date of this prospectus, at an exercise price equal to $11.00 per share; and
- 116,509 shares of our common stock issuable upon the exercise of stock options we expect to grant to our executive officers promptly following the closing date of this offering, which will have an exercise price equal to the per share fair market value of our common stock as of the grant date.

After December 31, 2014, we issued additional stock options exercisable to purchase 154,639 shares of common stock at an exercise price of $8.63 per share, and warrants were exercised to purchase 10,161 shares of common stock and 3,205 shares of our Series D redeemable convertible preferred stock.

An entity affiliated with Deerfield Private Design Fund III, L.P., one of our existing stockholders, has agreed to purchase 500,000 shares of our common stock in this offering. The foregoing discussion and tables do not reflect any potential purchase by this entity.

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

SELECTED FINANCIAL DATA

The following tables set forth our selected financial data for the periods indicated. The following selected statement of operations data for the years ended December 31, 2013 and 2014 and the selected balance sheet data as of December 31, 2013 and 2014 are derived from our audited financial statements appearing elsewhere in this prospectus. 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 prospectus. Our historical results are not necessarily indicative of the results to be expected in the future.

	Year Ended December 31,	
	2013	2014
Statement of operations data:		
Revenue	$ –	$ –
Operating expenses:		
Research and development	3,366,932	11,917,217
General and administrative	1,350,971	4,526,093
Total operating expenses	4,717,903	16,443,310
Loss from operations	(4,717,903)	(16,443,310)
Other (expense) income	(528,086)	(8,033,698)
Loss before income taxes	(5,245,989)	(24,477,008)
Income tax benefit	19,544	22,247
Net loss	$(5,226,445)	$(24,454,761)
Net loss per share:		
Basic and diluted	$ (2.20)	$ (10.27)
Basic and diluted, pro forma(1)		$ (3.13)
Weighted average common shares outstanding:		
Basic and diluted	2,381,041	2,381,041
Basic and diluted, pro forma(1)		7,823,352

(1) See Note 14 to our Financial Statements included elsewhere in this prospectus for an explanation of the method used to calculate the pro forma basic and diluted net loss per share and the pro forma basic and diluted weighted average common shares outstanding.

	As of December 31,	
	2013	2014
Balance sheet data:		
Cash and cash equivalents	$ 1,968,632	$ 10,255,021
Total assets	2,428,984	13,713,780
Convertible notes (current and noncurrent)	3,846,000	7,235,441
Term notes, net of discount	–	10,853,162
Derivative and warrant liability	2,813,260	15,965,891
Total liabilities	8,148,901	38,015,468
Redeemable convertible preferred stock	18,547,380	24,206,612
Total stockholders' deficit	(24,267,297)	(48,508,300)

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 prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, 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 prospectus, 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, each of which is an NME and therefore 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 treatment of acute moderate to moderately severe pain. We intend to submit a 505(b)(2) NDA for KP201/APAP to the FDA in the second half of 2015. We are also building a pipeline of additional NME prodrug product candidates that target large market opportunities in pain, ADHD and other central nervous system indications. 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, 2014, had an accumulated deficit of $50.2 million. Our net losses for the years ended December 31, 2013 and 2014 were $5.2 million and $24.5 million, respectively.

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

- continue our ongoing studies and clinical trials evaluating, among other things, KP201/APAP's abuse-deterrent features;
- 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;
- ultimately 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 NME prodrug products that we do not expect to be commercially available for several years, 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 Johnson Matthey Inc., or 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 them in the United States and agreed to pay them 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 the registration batches of KP201 at a price to be negotiated. Failure to agree upon this pricing would result in JMI supplying the registration 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. 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 Rx, LLC, or 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 the next few years. 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, substantially all 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, 2013 and 2014 and the period from October 30, 2006 (date of inception) to December 31, 2012:

	Year Ended December 31,		Period From October 30, 2006 (Date of Inception) to December 31,
	2013	2014	2012
Outsourced development costs directly identified to programs:			
KP106	$ —	$ —	$ 1,608,214
KP201/APAP	1,427,719	9,048,507	1,965,259
KP415	—	—	6,069
KP511	2,600	—	110,616
Total costs directly identified to programs	1,430,319	9,048,507	3,690,158
Costs not directly allocated to programs:			
Employee expenses including cash compensation, benefits and share-based compensation	1,457,205	2,144,055	
Facilities	107,587	168,278	
Other	371,821	556,337	
Total costs not directly allocated to programs	1,936,613	2,868,710	
Total research and development expenses	$3,366,932	$11,917,217	

We plan to increase our research and development expense for the foreseeable future as we continue our effort to develop KP201/APAP and to further advance the development of our other product candidates, subject to the availability of additional funding.

The successful development of product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs required to 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 begin to operate as a public reporting company and continue to develop and potentially commercialize KP201/APAP 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, both of which 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. 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.

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, 2013 and 2014

	Year Ended December 31,		Period-to-Period Change
	2013	2014	
Revenue	$ –	$ –	$ –
Operating expenses:			
Research and development	3,366,932	11,917,217	8,550,285
General and administrative	1,350,971	4,526,093	3,175,122
Total operating expenses	4,717,903	16,443,310	11,725,407
Loss from operations	(4,717,903)	(16,443,310)	(11,725,407)
Other (expense) income:			
Gain on extinguishment of debt	–	1,900,000	1,900,000
Interest expense	(1,716,869)	(2,715,350)	(998,481)
Fair value adjustment	1,137,348	(7,222,631)	(8,359,979)
Interest and other income	51,435	4,283	(47,152)
Total other expense	(528,086)	(8,033,698)	(7,505,612)
Loss before income taxes	(5,245,989)	(24,477,008)	(19,231,019)
Income tax benefit	19,544	22,247	2,703
Net loss	$ (5,226,445)	$ (24,454,761)	$(19,228,316)

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 this 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 expense 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 $1.0 million increase in interest expense, predominantly related to amortization of debt issuance costs and 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 convertible notes.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have funded our research and development and operating activities primarily through the issuance of $29.6 million of debt and $23.1 million of private placements of redeemable convertible preferred stock. As of December 31, 2014, we had cash and cash equivalents of $10.3 million.

We have incurred losses since our inception and, as of December 31, 2014, had an accumulated deficit of $50.2 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.

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 an NDA for KP201/APAP and, for the final two tranches, the subsequent approval for the commercial sale thereof. 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 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.

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. 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 such a 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.

As of December 31, 2014, the outstanding principal balance under the Deerfield facility was $25.0 million.

Cash Flows

	Year Ended December 31,	
	2013	2014
Net cash used in operating activities	$(4,316,057)	$(14,674,086)
Net cash provided by (used in) investing activities	(45,968)	(43,723)
Net cash provided by financing activities	3,788,970	23,004,198
Net increase (decrease) in cash and cash equivalents	$ (573,055)	$ 8,286,389

Operating Activities

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.

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, 2013, net cash used in investing activities was $46,000, which was primarily attributable to the purchase of property and equipment.

For the year ended December 31, 2014, net cash used in investing activities was $44,000, which was primarily attributable to the purchase of property and equipment.

Financing Activities

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.

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.

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. Following the closing of this offering, we 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 the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements through at least the next 18 months. We intend to devote the majority of the net proceeds from this offering for clinical development and regulatory approval of KP201/APAP. 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 studies and clinical trials for KP201/APAP;
- 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 NME prodrug products that we do not expect to be commercially available for several years, 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, 2014:

Contractual Obligations	Total	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years
Debt:					
Principal payments	$25,000,000	$ –	$ –	$16,666,667	$8,333,333
Interest payments	12,431,582	–	9,212,747	3,118,664	100,171
Operating lease commitments	380,518	168,101	212,417	–	–
Capital lease obligations	58,281	31,789	26,492	–	–
Total contractual obligations	$37,870,381	$199,890	$9,451,656	$19,785,331	$8,433,504

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.

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 2 to our audited financial statements appearing elsewhere in this prospectus, 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:

	Year Ended December 31,	
	2013	2014
Research and development	$ 29,296	$ 61,467
General and administrative	104,449	152,291
	$133,745	$213,758

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 not been publicly traded. 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.

Employee Stock Options

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,	
	2013	2014
Risk-free interest rate	0.52% - 2.80%	0.91% - 2.70%
Expected term (in years)	4.04 - 10.00	7.00 - 10.00
Expected volatility	58.55% - 92.00%	86.00% - 95.00%
Expected dividend yield	0%	0%

Based upon the initial public offering price of $11.00 per share, the aggregate intrinsic value of outstanding options to purchase shares of our common stock as of December 31, 2014 was $2.2 million, of which $1.1 million related to vested options and $1.1 million to unvested options.

Determination of Exercise Price of Stock Options and the Fair Value of Common Stock on Grant Dates

The following table summarizes by grant date the number of shares of common stock subject to stock options granted between January 1, 2013 and the date of this prospectus, 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, management and the board of directors considered a third-party valuation in determining the exercise price of the stock options.

In connection with the preparation of the financial statements necessary for the filing of the registration statement of which this prospectus forms a part, 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. Following the

closing of this offering and the commencement of public trading of our common stock, the fair value per share of our common stock for purposes of determining stock-based compensation will be the closing price of our common stock as reported on the applicable grant date.

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 IPO 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 have 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.

Significant factors contributing to the determination of the fair value of our common stock at the date of each grant beginning on July 10, 2013 were as follows:

July 2013 Grants

In estimating the fair value of our common stock in July 2013, management used a third-party valuation as of July 10, 2013. The following assumptions were used to complete the valuation using the PWERM analysis:

- future net equity value of $60.0 million used for early IPO (March 31, 2014), late IPO (June 30, 2014) and stay-private scenarios, determined using the market approach;
- future net equity value of $2.5 million used for the dissolution scenario, determined using the cost approach; and
- weighting of liquidity events at 25% for an early IPO, 5% for a later IPO, 0% for a strategic merger or sale, 5% for a dissolution and 65% to the stay-private scenario.

January 2014 Grants

In estimating the fair value of our common stock in January 2014, management used a third-party valuation as of December 31, 2013. The following assumptions were used to complete the valuation using the PWERM analysis:

- future net equity value of $90.0 million used for early IPO (September 30, 2014), late IPO (December 31, 2014) and stay-private scenarios, determined using the market approach;
- future net equity value of $117.0 million used for the strategic merger or sale scenario, determined using the market approach;
- future net equity value of $2.5 million used for the dissolution scenario, determined using the cost approach; and
- weighting of liquidity events at 30% for an early IPO, 5% for a later IPO, 5% for a strategic merger or sale, 5% for a dissolution and 55% for the stay-private scenario.

The increase in valuation from July 2013 was driven by the generation of bioequivalence clinical data for KP201/APAP, the successful completion of an end-of-Phase 2 meeting with the FDA regarding KP201/APAP and changes in management's assumption regarding the probability of an IPO.

June and July 2014 Grants

In estimating the fair value of our common stock in June and July 2014, management used a third-party valuation as of June 2, 2014. The following assumptions were used to complete the valuation using the PWERM analysis:

- future net equity value of $130.0 million used for early IPO (March 31, 2015) and late IPO (June 30, 2015) scenarios, determined using the market approach;
- future net equity value of $110.0 million used for the stay-private scenario, determined using the market approach;
- future net equity value of $135.0 million used for the strategic merger or sale scenario, determined using the market approach;
- future net equity value of zero used for the dissolution scenario, determined using the cost approach; and
- weighting of liquidity events at 50% for an early IPO, 20% for a later IPO, 20% for a strategic merger or sale, 5% for a dissolution and 5% for the stay-private scenario.

The increase in valuation from January 2014 was driven by the successful closing of the Deerfield facility and changes in management's assumption regarding the probability of an IPO.

January and March 2015 Grants

In estimating the fair value of our common stock in January and March 2015, management used a third-party valuation as of December 31, 2014. The following assumptions were used to complete the valuation using the PWERM analysis:

- future net equity value of $129.3 million used for early IPO (March 31, 2015) and late IPO (June 30, 2015) scenarios, determined using the market approach;
- future net equity value of $109.3 million used for the stay-private scenario, determined using the market approach;
- future net equity value of $134.3 million used for the strategic merger or sale scenario, determined using the market approach;
- future net equity value of zero used for the dissolution scenario, determined using the cost approach; and
- weighting of liquidity events at 80% for an early IPO, 5% for a later IPO, 10% for a strategic merger or sale, 2.5% for a dissolution and 2.5% for the stay-private scenario.

The increase in valuation from July 2014 was driven by changes in management's assumption regarding the probability of an IPO.

Fair Value of Financial Instruments

We have common stock warrants and 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 $2.7 million at December 31, 2014. The derivative liability for the preferred stock warrants was $13.1 million at December 31, 2014. Estimating the fair value of the underlying shares is highly complex and subjective because our stock is not publicly traded.

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, 2014, we had federal net operating loss, or NOL, carryforwards of approximately $38.4 million with expiration dates from 2027 to 2034. We also had research and development credit carryforwards of $1.8 million with expiration dates ranging from 2027 to 2034.

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 this offering 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

In June 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-10, *Development Stage Entities* (Topic 915): *Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. This ASU removes all incremental financial reporting requirements for development stage entities, including the removal of Topic 915 from the FASB Accounting Standards Codification. The amendments in this ASU eliminate certain disclosure requirements to (1) present inception-to-date information in the statements of income, cash flows and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. The ASU clarifies that disclosures about risks and uncertainties required by Topic 275 also apply to entities that have not commenced planned principal operations. We elected to early adopt ASU 2014-10 in 2013. The amendments primarily relate to disclosure matters and, therefore, have no impact on our financial statements, other than the omission of previously required disclosures including inception-to-date financial information.

In July 2013, the FASB issued ASU No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exist*. ASU 2013-11 amends the presentation requirements of ASC 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 NOL 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 did not have a material impact on our 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.* The ASU requires 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. We are currently evaluating the impact of the adoption of ASU 2014-12 on our financial statements and disclosures.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, 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. We are currently evaluating the impact of the adoption of ASU 2014-15 on our financial statements and disclosures.

In May 2014, the FASB issued guidance codified in ASC 606, *Revenue Recognition—Revenue from Contracts with Customers*, which amends the guidance in former ASC 605, *Revenue Recognition*, and becomes effective beginning January 1, 2017. We are currently evaluating the impact of the provisions of ASC 606 on our 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*, 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. This ASU 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. We do not expect this standard to have an impact on our financial statements or disclosures upon adoption.

Quantitative and Qualitative Disclosure about Market Risk

Interest Rate Sensitivity

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. However, we do not believe a sudden change in the interest rates would have a material impact on our financial condition or results of operations. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

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

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, each of which is a new molecular entity, or NME, and therefore may be eligible for composition-of-matter patent protection. Our most advanced product candidate, KP201/APAP, consists of KP201, our NME prodrug of hydrocodone, formulated in combination with acetaminophen, or APAP. We are developing KP201/APAP as an immediate release, or IR, product candidate for the treatment of acute moderate to moderately severe pain. We designed KP201/APAP with abuse-deterrent properties to address the epidemic of opioid abuse in the United States. We intend to submit a new drug application 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 the second half of 2015. We are also building a pipeline of additional NME prodrug product candidates that target large market opportunities in pain, attention deficit hyperactivity disorder, or ADHD, and other central nervous system indications.

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. A new molecular entity is a drug containing an active ingredient that has not been approved or marketed in the United States.

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 $1.2 billion in sales in 2013.

We use our LAT platform technology to discover and develop NME prodrugs that improve one or more of the attributes of approved drugs, such as susceptibility to abuse, bioavailability and safety. We primarily seek to develop NME 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 are NMEs and may be eligible for composition-of-matter patent protection.

IMS Health Incorporated, or IMS, a healthcare information firm, estimates that IR hydrocodone bitartrate 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 does not release hydrocodone effectively upon intranasal administration and has very poor solubility in blood, water and other solvents, thus rendering it unsuitable for intravenous, or IV, administration.

Based on our KP201/APAP human bioavailability trials, the FDA confirmed at our October 2013 End-of-Phase 2 meeting that the results of the trial support a finding that KP201/APAP is bioequivalent to Norco, an approved hydrocodone/APAP combination product that we intend to cite in our 505(b)(2) NDA. Bioavailability refers to the rate and total amount of a drug that reaches the target in the body after administration, and 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 End-of-Phase 2 meeting with the FDA in October 2013, we received feedback on the bioequivalence findings to Norco, the sufficiency of our proposed preclinical and clinical data package to support NDA filing, the adequacy of our analytical methods and the design of required abuse liability studies.

We believe that KP201/APAP has the potential to be the first FDA-approved IR product for the treatment of pain with the efficacy of hydrocodone/APAP combination products and abuse-deterrent labeling. We are conducting clinical trials that are designed with the goal of obtaining abuse-deterrent claims in our product label for KP201/APAP. We are conducting 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 intend to submit our new drug application, or NDA, to the FDA in the second half of 2015 and we believe it will receive priority review like other abuse-deterrent opioids.

Additionally, we intend to advance our pipeline of other product candidates for the treatment of pain, ADHD and other central nervous system, or CNS, indications and we anticipate reporting human proof-of-concept, or POC, data for three product candidates in 2016 and 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 March 10, 2015, our patent portfolio consisted of 28 granted patents and 87 pending patent applications worldwide, including a granted U.S. composition-of-matter patent covering KP201, a pending U.S. patent application covering KP201-related compositions-of-matter and a granted U.S. composition-of-matter patent covering the prodrug underlying one 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 NME 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 to treat acute moderate to moderately severe pain. We plan to submit an NDA to the FDA in the second half of 2015. We expect that the approval process for KP201/APAP will be conducted according to the 505(b)(2) NDA pathway and will

be subject to priority review, with potential approval as early as mid-2016. Prior to product launch, the U.S. Drug Enforcement Administration, or DEA, would then need to determine the controlled substance schedule of KP201/APAP, taking into account the recommendation of the FDA, which we expect would occur as early as 2017.

- ***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 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 treatment of moderate to severe pain, and KP606/ER, our ER formulation of our prodrug of oxycodone, for the treatment of moderate to severe pain. We plan to advance all 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.
- ***Leverage our LAT platform technology to develop additional product candidates***. We plan to employ our LAT platform technology to develop additional NME prodrugs that have improved properties over approved drugs and address unmet medical needs in large, established markets. We intend to develop NME 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 NME prodrugs in markets covering a majority of the global commercial opportunity. As of March 10, 2015, our patent portfolio consisted of 28 granted patents and 87 pending patent applications worldwide, including a granted U.S. composition-of-matter patent covering KP201, a pending U.S. patent application covering KP201-related compositions-of-matter and a granted U.S. composition-of-matter patent covering KP511, the prodrug underlying our KP511/ER product candidate.

Our LAT Prodrug Platform Technology

We use our LAT platform technology to create NME 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 are 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 NME 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 NME 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 NME 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 one of our product candidates to an appropriate approved drug, we will then be able to reference the FDA's previous findings of safety and effectiveness for the approved drug 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 four abuse-deterrent opioids, OxyContin, Targiniq ER, Embeda and Hysingla. 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 February 2013, the STOPP Act would have required 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.
- ***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 NME 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 NME Prodrug Product Candidates

Indication / Parent Drug	Product Candidate	Development Status	Key Milestone
Pain			
Hydrocodone (IR)	KP201/APAP	Clinical Trials	NDA Filing – 2H 2015
Hydromorphone (extended release)	KP511/ER	Preclinical	Human POC Data – 2016
Oxycodone (extended release)	KP606/ER	Preclinical	Human POC Data – 2017
ADHD			
Methylphenidate (controlled release)	KP415	Preclinical	Human POC Data – 2016
Multiple CNS Disorders			
Quetiapine	KP303	Preclinical	Preclinical Development

KP201/APAP

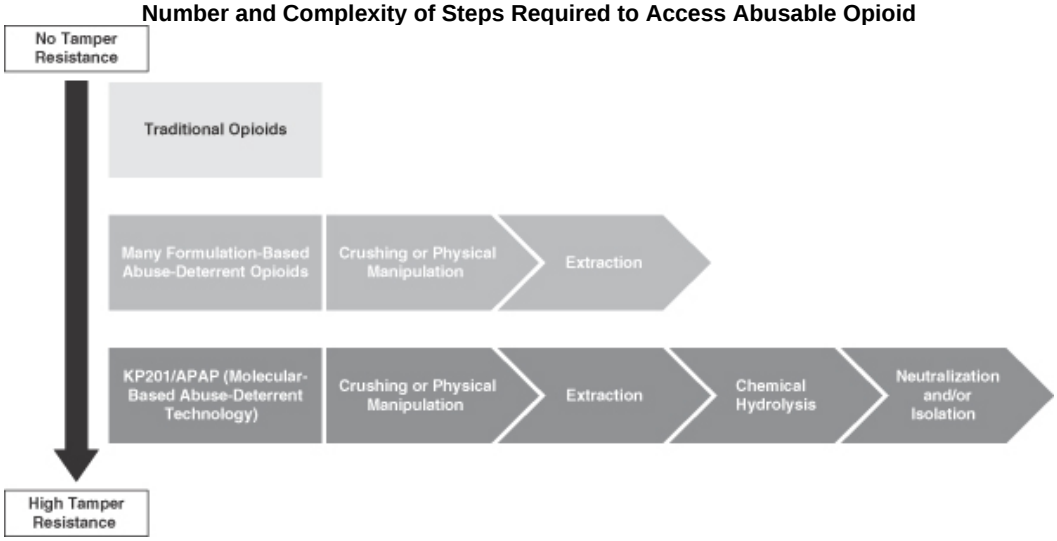
Overview

Our most advanced product candidate, KP201/APAP, is an IR combination of KP201, our NME prodrug of hydrocodone, and APAP. We are developing KP201/APAP for the treatment of acute moderate to moderately severe 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 an NME called 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 plan to seek 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 anticipate submitting our 505(b)(2) NDA for KP201/APAP to the FDA in the second half of 2015 and expect that KP201/APAP, like other abuse-deterrent opioids, will receive priority review, allowing for potential FDA approval as early as mid-2016. Prior to product launch, 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 would occur as early as 2017.

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. We believe the KP201 prodrug does not release hydrocodone effectively 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 March 10, 2015, KP201 had received granted, issued or allowed patent status in 12 foreign jurisdictions and patent applications covering KP201 were pending in an additional 18 foreign jurisdictions.
- ***No generic equivalent product.*** KP201 is an NME 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 plan to seek 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 October 2013 End-of-Phase 2 meeting that the results of the trial support a finding that KP201/APAP is bioequivalent to Norco. However, 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 APAP and the safety and effectiveness of hydrocodone separately through other methods. We recently 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 intend to reference the FDA's prior findings of safety and effectiveness for the APAP component of Ultracet in our 505(b)(2) NDA. We also plan to reference in our 505(b)(2) NDA published medical and scientific literature that establish the safety and effectiveness of hydrocodone. Based on communications with the FDA, we believe that no additional efficacy trials will be required for KP201/APAP.

We are also conducting two human abuse liability trials that will generate additional data that we expect to include in our 505(b)(2) NDA submission. We designed these trials with the goal of obtaining

abuse-deterrent claims in our product label for KP201/APAP in accordance with the FDA draft guidance. We expect data from the first of these trials, an oral human abuse liability trial, in the second quarter of 2015 and data from the second trial, an intranasal human abuse liability trial, in the third quarter of 2015.

We anticipate submitting our 505(b)(2) NDA for KP201/APAP to the FDA in the second half of 2015 and we expect that KP201/APAP, like other abuse-deterrent opioids, will receive priority review.

Completed Clinical Trials

KP201 Pilot Pharmacokinetics and Bioavailability Trial. We submitted our investigational new drug, or 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. There were no serious adverse events. We do not believe any of the adverse events were unusual or unexpected following the administration of opioid medication.

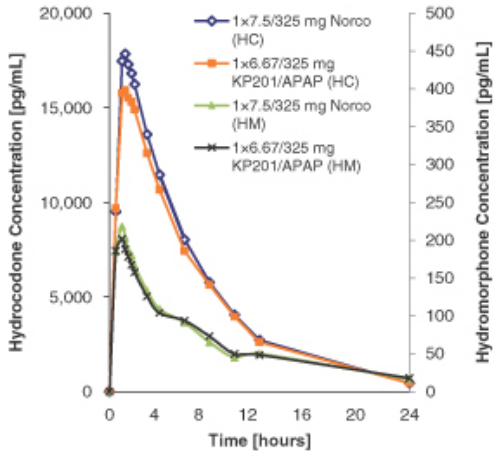
KP201/APAP Bioequivalence Trial. In August 2013, we conducted our second human clinical trial of KP201, an open-label, bioequivalence trial comparing KP201/APAP to Norco. The primary objective of this trial was to compare the pharmacokinetic profile and exposure of hydrocodone, hydromorphone and APAP 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 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 lower limit for one pharmacokinetic parameter for APAP was trivially outside of the statistical range for bioequivalence, but overall, KP201/APAP was still considered by the FDA to be bioequivalent to Norco with regard to APAP.

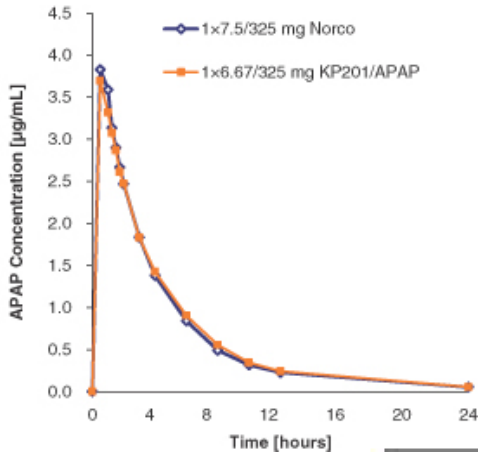
The following charts summarize the bioequivalence data from this trial.

KP201/APAP Bioequivalence Trial

Hydrocodone/Hydromorphone



Acetaminophen



Note: HC refers to hydrocodone and HM refers to hydromorphone.

In addition, systemic exposure to intact KP201 was below the measurement threshold in each subject at all of the measurement points. There were no unusual or unexpected adverse events.

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. There were no unusual or unexpected adverse events.

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 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. There were no unusual or unexpected adverse events.

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. In addition, there were no unusual or unexpected adverse events.

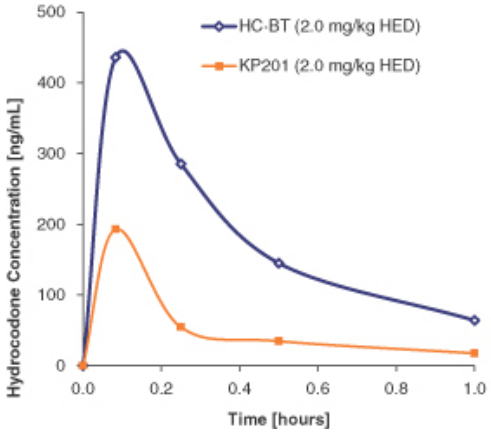
Preclinical Abuse Deterrence and Tamper-Resistant Extraction Studies

In order to evaluate the abuse-deterrent qualities of KP201, we conducted preclinical studies in rats to compare the exposure to hydrocodone following intranasal and IV administration of KP201 as compared to intranasal and IV administration of hydrocodone bitartrate, the form of hydrocodone in Norco. As shown in the charts below, we observed significantly lower plasma concentrations of hydrocodone following intranasal and IV administration of KP201 when compared to intranasal and IV administered hydrocodone bitartrate.

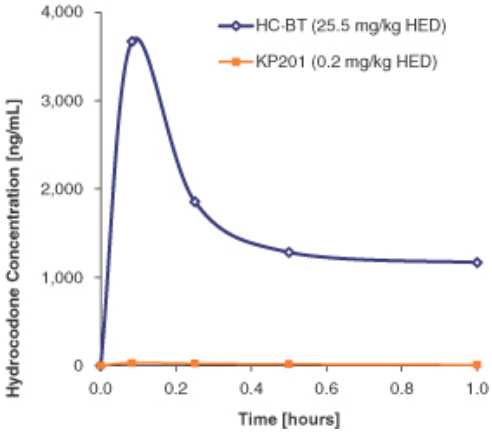
We believe we may see even better results, or lower plasma levels of hydrocodone, following KP201 intranasal administration in our ongoing intranasal human abuse liability trial because the rats we studied have the ability to metabolize KP201 much better than humans. For the IV administration of KP201 in rats, we used a fully saturated, buffered solution of KP201, but because KP201 is poorly soluble under these conditions, the maximum dose that could be dissolved and injected intravenously into the rats was only about 0.30 mg/kg (equal to 0.20 mg/kg of hydrocodone content). This amount was only about one percent of the hydrocodone contained in the comparative IV dose of hydrocodone bitartrate, which likewise reflected the maximum amount of hydrocodone bitartrate that could be dissolved and injected. We believe KP201's poor solubility in blood, water and other solvents renders it unsuitable for IV administration. The following charts summarize the data from this study.

KP201 Abuse-Deterrent Properties in Preclinical Study in Rats

Intranasal



Intravenous



Note: HC BT refers to hydrocodone bitartrate.
HED refers to human equivalent dose.

In order to evaluate the tamper-resistant properties of KP201, we conducted multiple tamper-resistant extraction studies. For example, we performed solvent extraction studies, and preliminary results of these studies suggested that, although KP201 is soluble in a number of solvents, dissolving KP201 in solution only yields the intact, inactive prodrug in solution and does not release hydrocodone. Preliminary results of these studies also suggested that KP201 is much less soluble in water than hydrocodone bitartrate and is poorly soluble in human blood.

We also conducted multiple solvent hydrolysis studies of KP201. The table below summarizes preliminary results of these studies suggesting that KP201 remains intact, and does not hydrolyze, or break down into its two components, hydrocodone and benzoic acid, in commonly available solvents at room temperature or even at their respective boiling points.

KP201 Solvent Hydrolysis Studies

	% Release of Hydrocodone					
	Ambient Temperature			At Boiling Point		
Solvent	**0.5 hours**	**1 hour**	**4 hours**	**0.5 hours**	**1 hour**	**4 hours**
Water	0	0	0	0	0	0
Ethanol	0	0	0	0	0	0
Methanol	0	0	0	0	0	0
Acetone	0	0	0	0	0	0
Ethyl acetate	0	0	0	0	0	0
Toluene	0	0	0	0	0	0
Xylene	0	0	0	0	0	0
Tetrahydrofuran	0	0	0	0	0	0
Methy ethyl ketone	0	0	0	0	0	0
Octane	0	0	0	0	0	0
Petrol ether	0	0	0	0	0	0

In addition, we conducted various harsh-chemical and real-world “kitchen” studies that used typical drug abuser-accessible solvents and methodologies, as well as a simulated smoking study. No hydrocodone release from the prodrug was observed in the simulated smoking study. In the other studies, we observed that only very harsh and extreme acidic or basic conditions can begin to hydrolyze KP201 and release its hydrocodone, but the resulting end product is toxic and not suitable for abuse. The toxic end product can only be made suitable for abuse by neutralizing it or isolating the hydrocodone using advanced chemistry and sophisticated laboratory equipment. As a result of our tamper-resistant extraction studies, we believe KP201/APAP is highly tamper-resistant and is stable under conditions that can potentially defeat many formulation-based abuse-deterrent technologies.

Ongoing Clinical Trials

In September 2014, we initiated two human abuse liability trials, each intended to generate data that we expect to include in our 505(b)(2) NDA submission. We believe the data from these trials, together with the data from the tamper-resistant extraction studies we are conducting, if the data is positive, will be instrumental in obtaining the FDA’s Category 1, 2 and 3 abuse-deterrent language in the KP201/APAP product label, if it is approved.

KP201/APAP Oral Human Abuse Liability Trial. The primary objective of this human abuse liability trial is to compare the pharmacodynamic, or drug likability, effects, exposure levels and safety of KP201/APAP compared to Norco after oral administration. 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. This is a single-center, randomized, double-blind, active- and placebo-controlled, crossover trial. Sixty-three subjects completed the study.

KP201/APAP Intranasal Human Abuse Liability Trial. The primary objective of this human abuse liability trial is to assess the relative pharmacodynamic, or drug likability, effects, exposure levels and safety of KP201/APAP compared to Norco after crushing and intranasal administration. This trial will include a dose selection phase and the main trial. The dose selection phase will evaluate escalating doses of each drug to identify the maximum tolerated dose of both KP201/APAP and Norco in order to select a dose that is well tolerated and produces robust responses on pharmacodynamic measures for use in the main trial. This is a single-center, randomized, double-blind trial. In the dose selection phase, subjects will be screened and qualified in order to enroll eight subjects per cohort with potentially up to six cohorts. The subjects will be randomized into the main trial with 40 assumed completers. We expect data from this trial in the third quarter of 2015.

Ongoing Tamper-Resistant Extraction Studies

In the fourth quarter of 2014, we will began two tamper-resistant extraction studies, each intended to generate data that we expect to include in our 505(b)(2) NDA submission. We believe the data from these two studies, if it is positive, together with the data from our two human abuse liability trials described above, will be instrumental in obtaining the FDA’s Category 1, 2 and 3 abuse-deterrent language in the KP201/APAP product label, if it is approved.

KP201/APAP In Vitro Extraction and Hydrolysis Study. This study is designed based on the FDA guidance. KP201/APAP tablets will be evaluated for the possibility and potential for individuals to extract KP201 from its tablet formulation and to convert extracted KP201 to hydrocodone by following a protocol we developed with input and advice from the FDA. The goal of the study is to evaluate the ease with which the abuse-deterrent properties of KP201 can be defeated or compromised as compared to Norco.

KP201/APAP IV Formulation Assessment Study. This study is also designed based on the FDA guidance. KP201/APAP tablets will be evaluated following a protocol we developed with input and advice from the FDA to determine the properties of KP201 that reduce the likelihood of IV abuse as

compared to Norco. The study will evaluate the amount of KP201, APAP and hydrocodone detected in an extract suitable for IV abuse that has been derived from KP201 tablets. KP201/APAP tablet extracts suitable for IV abuse will also be evaluated for their effects during simulated injections into human plasma and into whole blood.

KP511/ER

Overview

KP511/ER is our ER formulation of KP511, our NME prodrug of hydromorphone, which we are developing for the treatment of moderate to severe pain. 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 anticipate reporting human proof-of-concept data for KP511/ER in 2016.

Market Opportunity

Oral hydromorphone products are typically used to treat acute and chronic moderate to severe pain. 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 March 10, 2015, a composition-of-matter patent on KP511 was granted in Singapore and applications covering KP511 were pending in the United States and an additional 25 foreign jurisdictions.

- ***No generic equivalent product.*** KP511 is an NME 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 NME 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.

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 $1.1 billion in 2014.

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***. A composition-of matter-patent has been filed for KP415 with the United States Patent and Trademark Office, or USPTO. Our patent strategy is focused primarily on key geographic market opportunities, and, as of March 10, 2015, KP415 patent filings were pending in an additional 26 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 an NME 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 and CNS indications. One example is KP606/ER an ER formulation of KP606, our NME prodrug of oxycodone, which we are developing for the treatment of moderate to severe pain. KP606/ER is designed to be an ER abuse-deterrent opioid product that offers equivalent efficacy to OxyContin. KP606 combines oxycodone with one or more ligands. We have currently formulated an IR dosage of KP606 and plan to develop an ER dosage of KP606.

We plan to seek approval of KP606/ER under the 505(b)(2) FDA pathway. We anticipate reporting human proof-of-concept data for KP606/ER in 2017.

Another example is KP303, our NME prodrug of quetiapine, which is currently in preclinical development and which we are developing for the potential treatment of CNS disorders such as schizophrenia, bipolar disorder and major depressive disorder.

Our Intellectual Property

Our intellectual property strategy includes seeking composition-of-matter patents, among other patents, for our NME prodrugs and product candidates and conjugates of our NME 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 NME 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 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 March 10, 2015, we owned nine issued patents or allowed patent applications within the United States, and an additional 19 foreign patents covering our NME prodrugs or product candidates. The terms of the nine issued U.S. patents or allowed U.S. patent applications extend to various dates between 2030 and 2032. The term of our overall domestic and foreign patent portfolio related to our NME 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 March 10, 2015, we owned seven pending patent applications under active prosecution in the United States, and an additional 77 pending foreign patent applications covering our NME prodrugs and product candidates. Also, as of March 10, 2015, we owned three provisional patent applications in the United States.

Our issued and granted patents provide protection in jurisdictions that include the United States, Australia, Canada, China, Colombia, Japan, Kazakhstan, Mexico, New Zealand, Russia, Ukraine, Singapore, Indonesia and South Africa.

In 2013, 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, Columbia, Japan, Kazakhstan, Mexico, New Zealand, Russia, Ukraine, Indonesia and South Africa. In addition, three U.S. patent applications covering KP201-related compositions-of-matter are pending and patent applications covering KP201 are currently pending in the United Arab Emirates, Brazil, Belarus, Chile, Costa Rica, Cuba, Egypt, Europe, Hong Kong, Israel, India, South Korea, Malaysia, 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. 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, Colombia, 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 NME 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

Currently, we do not have any internal sales, marketing or distribution infrastructure. Because many of our product candidates 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.

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 treatment of acute moderate to moderately severe 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 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 Actavis plc, Acura Pharmaceuticals, Inc., Cara Therapeutics, Inc., Collegium Pharmaceutical, Inc., Depomed, Inc., DURECT Corporation, Egalet Corporation, Elite Pharmaceuticals, Inc., Endo International plc, 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 treatment of acute moderate to moderately severe pain. Some of these currently marketed products include AbbVie's Vicodin, Actavis'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 Endo International plc, Actavis 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 treatment of acute to 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 Actavis 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, KP303 will compete against currently marketed, branded and generic quetiapine products for the treatment of CNS disorders such as schizophrenia, bipolar disorder and major depressive disorder. Some of these currently marketed products include Astrazeneca PLC's Seroquel and Seroquel XR, in addition to multiple other generic quetiapine products marketed by companies including Lupin Pharmaceuticals, Inc., Roxanne Laboratories, Inc. and Teva Pharmaceutical Industries Ltd. In addition, if approved, KP303 will face potential competition from any quetiapine products for the treatment of CNS disorders such as schizophrenia, bipolar disorder and major depressive disorder 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 Actavis 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/ER will compete against currently marketed, branded and generic, abuse-deterrent and other IR and ER oxycodone 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 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 Actavis plc, Endo International plc, and Mallinckrodt plc. In addition, if approved, KP606/ER will face potential competition from any abuse-deterrent and other, IR and ER oxycodone products for the treatment of pain that are currently in or which may enter into clinical development.

Manufacturing

Our manufacturing strategy is to rely on contract manufacturers to produce our NME 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 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 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 them in the United States, and we agreed to pay them royalties 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 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 and KP201/APAP. We are responsible for product development, including formulation, preclinical studies and clinical trials, and for regulatory approval, quality assurance and commercialization. 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 active pharmaceutical ingredient, or 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 the registration batches of KP201 at a price to be negotiated. Failure to agree upon this pricing would result in JMI supplying the registration 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. 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.

Within the Medicare program, as self-administered drugs, KP201/APAP, KP415, KP511/ER and KP606/ER 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 reimbursed by Medicare or Medicaid, pricing and rebate programs must comply with, as applicable, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 as well as 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 to pay rebates on prescription drugs to state Medicaid programs and empowers states to negotiate rebates on pharmaceutical prices, which may result in prices for our future products that will likely be lower than the prices we might otherwise obtain. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply.

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 marketing application.

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 FFDCA. 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 FFDCA, 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 expect to be able 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 FFDCA 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 *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as 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 product 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.

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.

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.

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 are currently in discussions with the FDA regarding our PREA obligations.

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 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 FDA's NDA

review times 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 a 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 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 conditional 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.

Moreover, the recently enacted Drug Supply Chain Security Act imposes new obligations on manufacturers of pharmaceutical products related to product and tracking and tracing. Among the requirements of this new legislation, manufacturers will be required to provide information regarding the drug products to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this new legislation, manufactures will have drug

product investigation, quarantine, disposition, and 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.

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 will be listed by the DEA as Schedule II controlled substances under the CSA. Consequently, 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. 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.

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.

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 must also be accompanied by special order forms, with copies provided to the DEA. Because most of our product candidates are expected to be regulated as Schedule II controlled substances, they will 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 substance 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 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 new 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, 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." Covered manufacturers were required to begin collecting data on August 1, 2013 and submit reports on aggregate payment data to the government for the first reporting period (August 1, 2013—December 31, 2013) by March 31, 2014, and were required to report detailed payment data for the first reporting period and submit legal attestation to the completeness and accuracy of such data by June 30, 2014. Thereafter, manufacturers must submit reports by the 90th day of each subsequent 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. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes requirements 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, which has the potential to substantially change health care financing by both governmental and private insurers, and to significantly affect the U.S. pharmaceutical 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. We continue to evaluate the effect that the ACA has on our business. Additionally, new litigation attempting to invalidate the ACA is currently pending before the U.S. Supreme Court that could affect our business. Final regulations, guidance, and judicial orders are anticipated in the near future and we will continue to assess the ACA's impact on us as final regulations and guidance 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.

Facilities

We occupy 7,800 square feet of headquarters office and laboratory space in Coralville, Iowa under a lease that expires in 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 Blacksburg, Virginia and Celebration, Florida. We believe that our facilities are adequate for our current needs.

Employees

As of March 10, 2015, we employed 18 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.

Legal Proceedings

We are currently party to a 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 removed 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, and we 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 are seeking a declaratory judgment finding invalid and unenforceable such purported right of first refusal and right to receive a cash fee related to any such strategic transaction. DFN filed an answer requesting that the court declare that such rights are 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 will receive under the Deerfield facility. Two former members of our board of directors joined the lawsuit as intervenors and a trial date for the matter has been scheduled for August 2015. We cannot predict the timing or outcome of this litigation. However, if it is determined that such purported right of first refusal or right to receive a cash fee related to any such strategic transaction are valid, we could be required to pay to DFN a portion of the consideration received in any such strategic transaction, including this offering and future capital raising transactions.

From time to time we are involved in legal proceedings arising in the ordinary course of business. We believe there is no other litigation pending that could have, individually or in the aggregate, a material adverse effect on our results of operations or financial condition.

MANAGEMENT

Directors and Executive Officers

The following table sets forth information concerning our directors and executive officers, including their ages as of March 10, 2015:

Name	Age	Position
Executive Officers:		
Travis C. Mickle, Ph.D.	42	President, Chief Executive Officer and Chairman
Gordon K. Johnson	63	Chief Operating Officer and Chief Financial Officer
Sven Guenther, Ph.D(1).	43	Executive Vice President Research and Development
Christal M.M. Mickle(2)	36	Vice President Operations and Product Development
Tracy M. Woody	45	Chief Commercial Officer
R. LaDuane Clifton	42	Vice President of Finance and Corporate Controller
Other Key Employees:		
Christopher M. Lauderback	40	Vice President Commercial Operations
Non-Management Directors:		
Danny L. Thompson	51	Director
Matthew R. Plooster	33	Director
Richard W. Pascoe	51	Director
Joseph B. Saluri	48	Director
David S. Tierney	51	Director

(1) Dr. Guenther resigned from our board of directors as of the date of this prospectus.
(2) Ms. Mickle resigned from our board of directors as of the date of this prospectus.

Executive Officers

Travis C. Mickle, Ph.D.

Dr. Mickle is a co-founder of our company and has served as a member of our board of directors since our inception in 2006 and chairman of our board of directors since November 2014. Dr. Mickle served as our president and chief scientific officer from 2006 to October 2010, and has served as our president and chief executive officer since October 2010. Prior to founding our company, Dr. Mickle spent five years with New River Pharmaceuticals, a specialty pharmaceutical company, where he was a senior research scientist from 2001 to 2002, the director of chemistry from 2002 to 2003 and the director of drug discovery and CMC from 2003 to 2005. Dr. Mickle received his Ph.D. degree from the University of Iowa and his B.A. degree from Simpson College. Our board of directors believes that Dr. Mickle's leadership of our company since its inception, knowledge of our company as founder and experience with pharmaceutical companies provides him with the qualifications and skills to serve as a director of our company. Mr. Mickle is married to Christal M.M. Mickle.

Gordon K. Johnson

Mr. Johnson has served as our chief operating officer and chief financial officer since July 2013. Prior to joining our company, Mr. Johnson was the president and chief operating officer of Citius Pharmaceuticals, LLC, a specialty pharmaceutical company, from November 2012 to July 2013. From July 2012 to October 2012, Mr. Johnson was the executive vice president and chief business officer of

Direct Markets, Inc., a technology company. From June 2011 to July 2012, Mr. Johnson served as a managing director of Rodman & Renshaw, LLC. Prior to that, he was a managing director at Piper Jaffray & Co. from 2007 to March 2011. Mr. Johnson received his M.B.A. degree from Harvard Business School and his B.A. degree from the University of Missouri.

Sven Guenther, Ph.D.

Dr. Guenther joined our company as our group leader of research in 2007, served as a member of our board of directors from April 2012 to April 2015 and has served as our executive vice president of research and development since May 2014. Prior to joining our company, Dr. Guenther served as a research scientist for New River Pharmaceuticals from 2003 to 2007. Dr. Guenther received his Ph.D. degree from the University of Iowa.

Christal M.M. Mickle

Ms. Mickle is a co-founder of our company and served as a member of our board of directors from 2006 to April 2015. Ms. Mickle has held a variety of positions at our company, including vice president and group leader from 2006 to 2008, secretary from 2006 to 2014, vice president of corporate affairs from 2008 to October 2013 and vice president operations and product development from October 2013 to the present. Ms. Mickle received her M.A. degree from the University of Virginia and her B.A. and B.S. degrees from Virginia Polytechnic Institute and State University.

Tracy M. Woody

Ms. Woody has served as our chief commercial officer since February 2015. Prior to joining our company, Ms. Woody founded and served as managing director of TMW Consulting, Inc., a consulting firm working with emerging biotech and medical device companies, from 2013 to February 2015. As part of her consultancy work, Ms. Woody served as acting chief executive officer of RetroJect, Inc., a private ophthalmic medical device company, from 2013 to February 2015. Ms. Woody served as vice president of sales and marketing for NextWave Pharmaceuticals from 2010 to December 2012. She served as vice president of business development and vice president of sales and marketing at The Greer Labs Inc., an allergy immunotherapy company, from 2002 to 2010. From 1999 to 2001, Ms. Woody served as the director of marketing at ALZA Corporation, a research-based pharmaceutical company. Ms. Woody received a B.S. from East Carolina University.

R. LaDuane Clifton

Mr. Clifton has served as our vice president of finance and corporate controller since March 2015. Prior to joining our company, Mr. Clifton served in a variety of positions with The LGL Group Inc., a publicly held producer of industrial and commercial products and services, from August 2009 to February 2015, including chief financial officer, secretary and treasurer from December 2012 to February 2015, chief accounting officer and secretary from March 2010 to December 2012 and corporate controller from August 2009 to March 2010. From August 2008 to August 2009, Mr. Clifton served as chief financial officer of a21, Inc., a publicly held holding company with businesses in stock photography and the online retail and manufacture of framed art, and as its corporate controller from March 2007 to August 2008. Mr. Clifton was an auditor at KPMG LLP from August 2004 to March 2007. Mr. Clifton received his B.B.A. and M.B.A. from the University of North Florida.

Other Key Employees

Christopher M. Lauderback

Dr. Lauderback has served as our vice president commercial operations since September 2012. Prior to joining our company, Dr. Lauderback was the senior manager of CMC scientific affairs at Sigma-Tau Pharmaceuticals, Inc., a specialty pharmaceutical company, from June 2009 to September 2012. From 2008 to 2009, Dr. Lauderback worked as the associate director, CMC development at AirBase Therapeutics, LLC. Dr. Lauderback started his career at New River Pharmaceuticals, where he served as a senior scientist from 2001 to 2006 and as the associate director, CMC development from 2006 to 2007. Dr. Lauderback received his Ph.D. degree from the University of Kentucky and his B.S. degree from Emory and Henry College.

Non-Management Directors

Danny L. Thompson

Mr. Thompson has served as a director of our company since 2007. He has served as the president of Success Bank since 1998 and the vice president of Garrett Bancshares, LTD since 2006. From 1984 to 1997, he has held several positions at Davis County Savings Bank including executive vice president of operations, trust officer and commercial loan officer. Mr. Thompson received his M.B.A. degree from St. Ambrose University and his B.A. degree from Buena Vista College. Our board of directors believes that Mr. Thompson's business experience provides him with the qualifications and skills to serve as a director of our company.

Matthew R. Plooster

Mr. Plooster has served as a director of our company since March 2011. Mr. Plooster co-founded Bridgepoint Merchant Banking, a division of Bridgepoint Holdings, LLC, where he has served as a managing principal since March 2012. Mr. Plooster also currently serves as a manager of Bridgepoint Investment Partners I, LLLP, a position he has held since May 2012. Previously, Mr. Plooster worked as an investment banker at DeWaay Investment Banking from October 2010 to March 2012, Morgan Stanley from August 2009 to November 2009 and Deutsche Bank from 2004 to July 2009. Mr. Plooster received his Certificate in Business Excellence from Columbia Business School and his B.A. degree from the University of Chicago. Our board of directors believes that Mr. Plooster's experience as an investor in healthcare companies provides him with the qualifications and skills to serve as a director of our company.

Richard W. Pascoe

Mr. Pascoe has served as a director of our company since January 2014 and our lead independent director since November 2014. Since March 2013, Mr. Pascoe has served as the chief executive officer and on the board of directors of Apricus Biosciences, a specialty pharmaceutical company. From August 2008 to March 2013, Mr. Pascoe was the president and chief executive officer and a director of Pernix Sleep, Inc. (formerly known as Somaxon Pharmaceuticals, Inc.), a specialty pharmaceutical company. Prior to Pernix, from 2005 to 2008, Mr. Pascoe worked for ARIAD Pharmaceuticals, Inc., a specialty pharmaceutical company, where he was most recently senior vice president and chief operating officer. Mr. Pascoe received his B.S. degree from the United States Military Academy at West Point. Our board of directors believes that Mr. Pascoe's experience as a pharmaceutical company executive provides him with the qualifications and skills to serve as a director of our company.

Joseph B. Saluri

Mr. Saluri has served as a director of our company since January 2014. Mr. Saluri has served as vice president and general counsel for Stine Seed Company and its affiliates since July 1999. Prior to

his employment with Stine, Mr. Saluri was an attorney and solicitor at law with Nicholas Critelli Associates, PC, in Des Moines, Iowa and London, England. Since May 2010, Mr. Saluri has served as a director of Newlink Genetics Corp, a public biopharmaceutical company. Mr. Saluri received his J.D. degree from Drake University Law School and his B.S.B.A. degree from Drake University. Our board of directors believes that Mr. Saluri's extensive legal background and experience in corporate management, finance and investor relations provides him with the qualifications and skills to serve as a director of our company.

David S. Tierney

Dr. Tierney joined our board in March 2015. Since April 2014, Dr. Tierney has served as chief executive officer of Icon Bioscience, Inc., a privately held ophthalmic drug delivery company. From January 2013 until March 2014, Dr. Tierney was a venture partner at Signet Healthcare Partners, a New York City based life science private equity fund. Dr. Tierney served as president and chief operating officer and as a member of the board of directors of Oceana Therapeutics, Inc., a private specialty pharmaceutical company, from its organization in 2008 through its sale to Salix Pharmaceuticals, Ltd. in December 2011. Dr. Tierney served as the president and chief executive officer and as a member of the board of directors of Valera Pharmaceuticals, Inc., a specialty pharmaceutical company, between August 2000 and April 2007, when Valera completed a merger with Indevus Pharmaceuticals, Inc. From January 2000 to August 2000, Dr. Tierney served as president of Biovail Technologies, a division of Biovail Corporation, a Canadian drug delivery company. From March 1997 to January 2000, Dr. Tierney was senior vice president of drug development at Roberts Pharmaceutical Corporation and from December 1989 to March 1997, Dr. Tierney was employed by Élan Corporation, a pharmaceutical company, in a variety of management positions. Dr. Tierney is also a director of Catalyst Pharmaceutical Partners and Bioject Medical Technologies, Inc. Dr. Tierney received his medical degree from the Royal College of Surgeons in Dublin, Ireland and was subsequently trained in internal medicine. Our board of directors believes that Dr. Tierney's experience as a pharmaceutical company executive provides him with the qualifications and skills to serve as a director of our company.

Board Composition

Our board of directors currently consists of six members. Dr. Mickle is the chairman of our board of directors and Mr. Pascoe is the lead independent director of our board of directors. As lead independent director, Mr. Pascoe presides over periodic meetings of our independent directors, serves as a liaison between our chairman and the independent directors and performs additional duties as our board of directors may otherwise determine or delegate from time to time. Each director is currently elected to the board for a one-year term, to serve until the election and qualification of successor directors at the annual meeting of stockholders, or until the director's earlier removal, resignation or death.

Our directors were elected to and currently serve on the board pursuant to a voting agreement among us and several of our largest stockholders. Pursuant to the terms of this voting agreement, Messrs. Plooster and Thompson were designated by the holders of a majority of our Series C redeemable convertible preferred stock and Dr. Tierney was designated by Deerfield Private Design Fund III, L.P., or Deerfield. This voting agreement will terminate upon the completion of this offering, after which there will be no further contractual obligations regarding the election of our directors.

In accordance with our amended and restated certificate of incorporation, which will be in effect upon the closing of this offering, our board of directors will be divided into three classes, each of which will consist, as nearly as possible, of one-third of the total number of directors constituting our entire board and which will serve staggered three-year terms. At each annual meeting of stockholders, the

successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- Class I, which will consist of Travis C. Mickle, Ph.D. and Danny L. Thompson, and their term will expire at our first annual meeting of stockholders to be held after the completion of this offering;
- Class II, which will consist of Richard W. Pascoe and David S. Tierney, and their term will expire at our second annual meeting of stockholders to be held after the completion of this offering; and
- Class III, which will consist of Matthew R. Plooster and Joseph B. Saluri, and their term will expire at our third annual meeting of stockholders to be held after the completion of this offering.

Our amended and restated bylaws, which will become effective upon the closing of this offering, will provide that the authorized number of directors may be changed only by resolution approved by a majority of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Director Independence

Our board of directors has undertaken a review of the independence of the directors and considered whether any director has a material relationship with us that could compromise his ability to exercise independent judgment in carrying out his responsibilities. As a result of this review, our board of directors has determined that Messrs. Thompson, Plooster, Pascoe, Saluri and Tierney, representing five of our six current directors, are “independent directors” as defined under NASDAQ rules.

Committees of the Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and responsibilities described below. From time to time, the board may establish other committees to facilitate the management of our business. A copy of each committee’s charter will be posted on our website, *www.kempharm.com*.

Audit Committee

Our audit committee reviews our internal accounting procedures and consults with and reviews the services provided by our independent registered public accountants. Our audit committee consists of three directors, Danny L. Thompson, Richard W. Pascoe and Joseph B. Saluri. Mr. Thompson is the chairman of the audit committee and our board of directors has determined that Mr. Thompson is an “audit committee financial expert” as defined by SEC rules and regulations. Our board of directors has determined that each of Messrs. Thompson, Pascoe and Saluri are independent directors under NASDAQ listing rules and under Rule 10A-3 under Securities Exchange Act of 1934, as amended, or the Exchange Act. We intend to continue to evaluate the requirements applicable to us and we intend to comply with future requirements to the extent that they become applicable to our audit committee. The principal duties and responsibilities of our audit committee include:

- appointing and retaining an independent registered public accounting firm to serve as independent auditor to audit our financial statements, overseeing the independent auditor’s work and determining the independent auditor’s compensation;
- approving in advance all audit services and non-audit services to be provided to us by our independent auditor;

- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls, auditing or compliance matters, as well as for the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;
- reviewing and discussing with management and our independent auditor the results of the annual audit and the independent auditor's review of our quarterly financial statements; and
- conferring with management and our independent auditor about the scope, adequacy and effectiveness of our internal accounting controls, the objectivity of our financial reporting and our accounting policies and practices.

Compensation Committee

Our compensation committee reviews and determines the compensation of all our executive officers. Our compensation committee consists of three directors, Matthew R. Plooster, David S. Tierney and Richard W. Pascoe, each of whom is a non-employee member of our board of directors as defined in Rule 16b-3 under the Exchange Act. Mr. Plooster is the chairman of the compensation committee. Our board of directors has determined that the composition of our compensation committee satisfies the applicable independence requirements under, and the functioning of our compensation committee complies with the applicable requirements of, stock exchange listing rules and SEC rules and regulations. We intend to continue to evaluate and intend to comply with all future requirements applicable to our compensation committee. The principal duties and responsibilities of our compensation committee include:

- establishing and approving, and making recommendations to the board of directors regarding, performance goals and objectives relevant to the compensation of our chief executive officer, evaluating the performance of our chief executive officer in light of those goals and objectives and setting, or recommending to the full board of directors for approval, the chief executive officer's compensation, including incentive-based and equity-based compensation, based on that evaluation;
- setting the compensation of our other executive officers, based in part on recommendations of the chief executive officer;
- exercising administrative authority under our stock plans and employee benefit plans;
- establishing policies and making recommendations to our board of directors regarding director compensation;
- reviewing and discussing with management the compensation discussion and analysis that we may be required from time to time to include in SEC filings; and
- preparing a compensation committee report on executive compensation as may be required from time to time to be included in our annual proxy statements or annual reports on Form 10-K filed with the SEC.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee consists of three directors, Joseph B. Saluri, Matthew R. Plooster and David S. Tierney. Mr. Saluri is the chairman of the nominating and corporate governance committee. Our board of directors has determined that the composition of our nominating and corporate governance committee satisfies the applicable independence requirements under, and the functioning of our nominating and corporate governance committee complies with the applicable requirements of, stock exchange listing standards and SEC rules and regulations. We will continue to evaluate and will comply with all future requirements applicable to our nominating and corporate governance committee. The nominating and corporate governance committee's responsibilities include:

- assessing the need for new directors and identifying individuals qualified to become directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;
- assessing individual director performance, participation and qualifications;

- developing and recommending to the board corporate governance principles;
- monitoring the effectiveness of the board and the quality of the relationship between management and the board; and
- overseeing an annual evaluation of the board's performance.

Code of Business Conduct and Ethics for Employees, Executive Officers and Directors

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 will be available on our website at *www.kempharm.com*. The nominating and corporate governance committee of our board of directors will be responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors. We expect that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website.

Compensation Committee Interlocks and Insider Participation

None of our directors who currently serve as members of our compensation committee is, or has at any time during the past year been, one of our officers or employees. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any other entity that has one or more executive officers serving on our board of directors or compensation committee.

Non-Employee Director Compensation

We have not historically paid cash retainers or other compensation with respect to service on our board of directors, except for reimbursement of direct expenses incurred in connection with attending meeting of the board or committees. We have at times granted stock options to some of our non-employee directors under our existing incentive stock plan, or our 2007 Plan.

In addition, in March 2015, our board of directors approved a non-employee director cash stipend compensation policy to be effective upon completion of this offering. Under this policy we will pay each of our non-employee directors a cash stipend for service on our board of directors and, if applicable, on the audit committee, compensation committee and nominating and corporate governance committee. Each of our non-employee directors will receive an additional stipend if they serve as the chairman of our compensation committee or audit committee or serve as our lead independent director.

These stipends are payable in four equal quarterly installments on the last day of each quarter. The stipends paid to each of our non-employee directors for service on the board of directors and for service on the audit committee, the compensation committee and the nominating and corporate governance committee are as follows:

	Member Annual Service Stipend	Chairman Additional Annual Service Stipend
Board of directors	$ 25,000	$ –
Audit committee	7,500	2,500
Compensation committee	5,000	2,500
Nominating and corporate governance committee	5,000	–
Lead Independent Director	15,000	N/A

In January 2014 we entered into services agreements with each of Mr. Pascoe and Mr. Saluri upon their appointment to our board of directors. Pursuant to their services agreements, each of Messrs.

Pascoe and Saluri received an option to purchase 7,332 shares upon joining our board of directors at an exercise price of $5.85 per share. Further, on the date of each annual meeting of stockholders, each of Messrs. Pascoe and Saluri will receive an option to purchase 3,333 shares of our common stock. The exercise price of these options will equal the fair market value of our common stock on the date of grant. All shares subject to vesting under these option grants will vest in full and become immediately exercisable if the holder is removed without cause or resigns upon our request without cause. These services agreements also provide for the payment of cash stipends to each of Messrs. Pascoe and Saluri that were superseded by our non-employee director cash stipend compensation policy.

Following the closing of this offering, we may implement a formal policy pursuant to which all of our non-employee directors will be eligible to receive equity compensation for service on our board of directors.

2014 Director Compensation Table

The following table sets forth information regarding compensation earned for service on our board of directors during the year ended December 31, 2014 by our non-employee directors. Dr. Mickle, our president and chief executive officer, and Dr. Guenther, our executive vice president, research and development, were also directors during 2014, but did not receive any additional compensation for their service as directors. Dr. Mickle's and Dr. Guenther's compensation as executive officers is set forth below under "Executive Compensation—Summary Compensation Table." Ms. Mickle, our vice president operations and product development, was also a director during 2014, but is not a named executive officer. As Ms. Mickle did not receive any additional compensation for her service as a director, she is not included in the table below.

Name	Fees earned or paid in cash ($)	Option Awards[4] ($)
Danny L. Thompson	29,375[1]	–
Matthew R. Plooster	–	–
Richard W. Pascoe	27,500[2]	21,911
Joseph B. Saluri	26,375[3]	21,911
Jonathan S. Leff [5]	–	–

(1) Represents stipends awarded for Mr. Thompson's service on our board of directors during 2014, his service as the chairman of our compensation committee during the first three quarters of 2014 and his service as the chairman of our audit committee during the fourth quarter of 2014.

(2) Represents stipends awarded for Mr. Pascoe's service on our board of directors during 2014, his service as the chairman of our audit committee during the third quarter of 2014, his service as a member of our audit committee during the fourth quarter of 2014 and his service as a member of our compensation committee during 2014.

(3) Represents stipends awarded for Mr. Saluri's service on our board of directors during 2014, his service as a member of our audit committee during the third and fourth quarters of 2014 and his service as the chairman of our nominating and corporate governance committee during the fourth quarter of 2014.

(4) This column reflects the full grant date fair value for options granted during the year as measured pursuant to ASC Topic 718 as stock-based compensation in our financial statements. Unlike the calculations contained in our financial statements, this calculation does not give effect to any estimate of forfeitures related to service-based vesting but assumes that the director will perform the requisite service for the award to vest in full. The assumptions we used in valuing options are described in Note 11 to our audited financial statements included in this prospectus.

(5) Mr. Leff resigned from our board of directors in March 2015.

The table below shows the aggregate number of option awards outstanding for each of our non-employee directors as of December 31, 2014:

Name	Aggregate Option Awards Outstanding (#)
Danny L. Thompson	23,332(1)
Richard W. Pascoe	7,332(2)
Joseph B. Saluri	7,332(2)

(1) As of December 31, 2014, all shares underlying these options were vested.
(2) As of December 31, 2014, 666 shares underlying this option were vested. An additional 666 shares will vest upon the closing of this offering. The remaining 6,000 shares will vest in equal annual installments through January 1, 2017.

In March 2015, we granted Dr. Tierney an option exercisable for 7,332 shares of our common stock at an exercise price of $8.63 per share as compensation for Dr. Tierney's service as a member of our board of directors. 666 shares subject to this option will vest upon the closing of this offering and an additional 666 shares will vest upon the closing of a private financing with gross proceeds to us of at least $5.0 million. The remaining 6,000 shares will vest in equal annual installments through March 1, 2018.

EXECUTIVE COMPENSATION

Our chief executive officer and our two other most highly compensated executive officers for the year ended December 31, 2014 are listed below:

- Travis C. Mickle, Ph.D., our president and chief executive officer;
- Gordon K. Johnson, our chief operating officer and chief financial officer; and
- Sven Guenther, Ph.D., our executive vice president research and development.

We refer to these executive officers as our named executive officers.

Summary Compensation Table

The following table presents the compensation awarded to, earned by or paid to each of our named executive officers for the years ended December 31, 2013 and 2014.

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Option Awards ($)(2)	All Other Compensation ($)(3)	Total ($)
Travis C. Mickle, Ph.D.	2014	317,000	37,500	124,895	14,225	493,620
President and chief executive officer	2013	234,000	75,000	–	10,365	319,365
Gordon K. Johnson(4)	2014	300,000	200,000	62,806	12,285	575,091
Chief operating officer and chief financial officer	2013	107,938	–	241,508	7,662	357,108
Sven Guenther, Ph.D.	2014	166,150	9,500	93,671	7,086	276,407
Executive vice president research and development						

(1) The amounts reflect the discretionary bonus paid in June 2014 for performance during 2013 and the first six months of 2014, as discussed further below under "—Narrative to Summary Compensation Table—Annual Bonus." Our board of directors has not yet determined the bonus amounts payable to our executive officers for performance during the last six months of 2014. Bonus amounts for service during the last six months of 2014, if any, will be determined by our board of directors in 2015.

(2) The amounts reflect the full grant date fair value for awards granted during 2013. The grant date fair value was computed in accordance with ASC Topic 718, *Compensation—Stock Compensation*. Unlike the calculations contained in our financial statements, this calculation does not give effect to any estimate of forfeitures related to service-based vesting, but assumes that the executive will perform the requisite service for the award to vest in full. The assumptions we used in valuing options are described in note 11 to our audited financial statements included in this prospectus.

(3) See "—Narrative to Summary Compensation Table—Other Compensation" for a description of the items in this column.

(4) Mr. Johnson became an executive officer of our company in July 2013.

Narrative to Summary Compensation Table

We review compensation annually for all employees, including our executives. In setting executive base salaries and bonuses and granting equity incentive awards, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders, and a long-term commitment to our company. We do not target a specific competitive position or a specific mix of compensation among base salary, bonus or long-term incentives.

The compensation committee of our board of directors has historically determined our executives' compensation. Our compensation committee typically reviews and discusses management's proposed compensation with the chief executive officer for all executives other than the chief executive officer. Based on those discussions and its discretion, the compensation committee then recommends the compensation for each executive officer. Our compensation committee, without members of management present, discusses and ultimately approves the compensation of our executive officers.

Annual Base Salary

Our named executive officers' base salaries are reviewed periodically by our board of directors, and adjustments may be made upon the recommendations of the compensation committee. In July 2013, we entered into an employment agreement with Mr. Johnson under which his annual base salary was established at $275,000. Pursuant to their respective employment agreements, upon the closing of the Series D redeemable convertible preferred stock financing in June 2014, the annual base salaries for Dr. Mickle and Mr. Johnson increased to $400,000 and $325,000, respectively. In addition, pursuant to Mr. Johnson's employment agreement, Mr. Johnson's annual base salary will increase to $400,000 upon the completion of this offering. Our compensation committee approved an increase in Dr. Guenther's annual base salary, effective June 1, 2014, from $132,300 to $200,000.

Annual Bonus

Our board of directors and compensation committee may make special cash bonus awards in their discretion. In June 2014, our compensation committee awarded Dr. Guenther a discretionary cash bonus of $38,000 in recognition of his services provided in the last six months of 2012, the year ended December 31, 2013 and the first six months of 2014. In June 2014, our compensation committee recommended and, in July 2014, our board of directors approved, a discretionary cash bonus to Dr. Mickle of $150,000 in recognition of his services in the last six months of 2012, the year ended December 31, 2013 and the first six months of 2014. Pursuant to his employment agreement, upon the closing of the Deerfield facility, we awarded Mr. Johnson cash bonuses of $200,000. These bonus amounts, to the extent they were in recognition for Dr. Mickle's, Mr. Johnson's and Dr. Guenther's performance during the indicated year, are reflected in the "Bonus" column of the Summary Compensation Table above for the indicated year.

Long-Term Incentives

Our 2007 Plan authorizes us to make grants to eligible recipients of non-qualified stock options, incentive stock options and other stock-based awards. All of our awards under this plan have been in the form of stock options.

We typically grant stock options at the start of employment to each executive and our other employees. Through 2014, we have not maintained a practice of granting additional equity on an annual basis, but we have retained discretion to provide additional targeted grants in appropriate circumstances.

We award stock options on the date the compensation committee approves the grant. We set the option exercise price and grant date fair value based on our per-share valuation on the date of grant.

In July 2014, our compensation committee awarded to Dr. Guenther an option to purchase 20,000 shares of our common stock. In July 2014, our board of directors awarded to Dr. Mickle an option grant to purchase 26,666 shares of our common stock. Each of these options has an exercise price of $5.85 per share.

In July 2013, in connection with the commencement of Mr. Johnson's employment with us, our board of directors committee approved the grant of an option to Mr. Johnson to purchase 80,000 shares of our common stock. In June 2014, pursuant to Mr. Johnson's employment agreement, we

granted Mr. Johnson a fully vested option to purchase 13,333 shares of our common stock upon the closing of the Deerfield facility and a fully vested option to purchase 5,333 shares of our common stock upon the issuance and sale of the Series D-1 shares. Each of these options has an exercise price of $5.85 per share and $8.63 per share, respectively. All shares subject to vesting under these option grants will vest in full and become immediately exercisable upon the closing of a sale or other change in control of our company. In addition, pursuant to Mr. Johnson's employment agreement, we will grant Mr. Johnson (a) an option to purchase up to 48,000 shares of our common stock upon the closing of additional fundraising transactions, (b) an option to purchase up to 40,000 shares of our common stock upon the closing of this offering, (c) an option to purchase up to 66,666 shares of our common stock upon our receipt of a strategic partnership payment and (d) 40,000 shares of our common stock upon a sale or other change of control transaction.

Other Compensation

We provided a reimbursement of $3,500 for legal expenses incurred by Mr. Johnson during the negotiation of his employment agreement during 2013. We also provided a reimbursement of $3,000 for legal expenses incurred by Dr. Mickle during the negotiation of his employment agreement during 2014.

Other amounts shown in the "All Other Compensation" column in the Summary Compensation Table relate to company contributions to the 401(k) plan and premiums we paid for life insurance policies on behalf of the named executive officer.

Except for the benefits described above, we do not provide perquisites or personal benefits to our named executive officers. We do, however, pay the premiums for medical and dental insurance for all of our employees, including our named executive officers.

Employment Arrangements and Potential Payments upon Termination of Employment

In July 2013, we entered into an employment agreement with Mr. Johnson under which he serves as our chief operating officer and chief financial officer. Under this agreement, upon Mr. Johnson is eligible to receive severance benefits in specified circumstances.

In the event that we terminate Mr. Johnson without cause or he resigns for good reason, Mr. Johnson will be entitled to receive an amount equal to 12 months of his annual base salary, less applicable deductions, payable in accordance with our normal payroll schedule, except that we will pay such severance in a lump sum on the first pay day immediately following the effective date of termination if such termination of employment occurs upon or within one year following a sale that constitutes a "change in control event" as defined under Section 409A of the Internal Revenue Code of 1986, as amended, or the Code. In the event that we terminate Mr. Johnson without cause or he resigns for good reason, and a specified minimum debt raise, sale or a fundraising transaction occurs, or a specified strategic partnership payment is made within 60 days following the date of termination, Mr. Johnson will be entitled to receive a bonus payment and an option grant, as specified in his agreement. In the event that we terminate Mr. Johnson with cause, Mr. Johnson resigns without good reason, or the employment is terminated due to mutual agreement, death or disability, then Mr. Johnson will not be entitled to receive severance benefits.

The following definitions have been adopted in Mr. Johnson's employment agreement:

- "cause" means (a) Mr. Johnson performed an act or acts of willful and material malfeasance or misconduct with respect to the performance of his duties and responsibilities as an employee and executive officer or under the agreement that results in material harm to us that remains uncorrected for 15 days after receipt of written notice, (b) Mr. Johnson's continued failure to devote his full business time and attention and his best efforts to the faithful performance of his material duties and responsibilities (other than a failure resulting from disability) that remains

uncorrected for 15 days after receipt of written notice, (c) Mr. Johnson's material breach of any material provision of the agreement that remains uncorrected for 15 days after receipt of written notice, (d) the commission of an act of fraud, embezzlement, misappropriation, or personal dishonesty against us (which, if proven, would constitute a felony) or (e) the conviction, or plea of *nolo contendere*, to a crime constituting a felony; and

- "good reason" means (a) material diminution by us of Mr. Johnson's authority, duties or responsibilities the duration of which is greater than 15 days and which is not the result of his acts or omissions which constitute cause, (b) a material change in the geographic location at which Mr. Johnson must perform services under the agreement, (c) a material diminution in his base salary which is not the result of his acts or omissions which constitute cause or (d) any action or inaction that constitutes a material breach by us of the agreement, including our failure to pay any amounts due to Mr. Johnson or our failure to obtain from a successor the express assumption of the agreement.

We previously entered into an employment agreement with Dr. Mickle in March 2007, which did not contain any severance benefits. In May 2014, we entered into a new employment agreement with Dr. Mickle, under which Dr. Mickle serves as our president and chief executive officer. Under this agreement, upon the execution of a release of claims, Dr. Mickle is eligible to receive severance benefits in specified circumstances.

In the event that we terminate Dr. Mickle without cause or he resigns for good reason, Dr. Mickle will be entitled to receive (a) an amount equal to 18 months of his annual base salary, less applicable deductions, payable in accordance with our normal payroll schedule, (b) a pro rata bonus award payable on the first regularly scheduled pay day following the 60th day after his termination, (c) 18 months of continued health coverage and (d) full vesting of his outstanding equity awards, except that if such termination occurs within 60 days before, upon or within one year following a sale that constitutes a "change in control event" as defined under the Code, then Dr. Mickle will be entitled to receive his 18 month salary continuation and his target annual bonus in one lump sum payment on the first regularly scheduled pay day following the 60th day after his termination. In the event that we terminate Dr. Mickle with cause, Dr. Mickle resigns without good reason, or his employment is terminated due to mutual agreement, death or disability, then Dr. Mickle will not be entitled to receive severance benefits.

The following definitions have been adopted in Dr. Mickle's employment agreement:

- "cause" means (a) executive is convicted of, or pleads nolo contendere to, a crime constituting a misdemeanor involving dishonesty or moral turpitude or any crime constituting a felony, (b) executive neglects, refuses or fails to perform executive's material duties, (c) executive commits a material act of dishonesty or otherwise engages in or is guilty of gross negligence or willful misconduct in the performance of executive's duties or (d) executive materially breaches the provisions of any written non-competition, non-disclosure or non-solicitation agreement, or any other agreement with us; and
- "good reason" means (a) material diminution by us of the executive's authority, duties or responsibilities the duration of which is greater than 15 days and which is not the result of his acts or omissions which constitute cause, (b) a material change in the geographic location at which the executive must perform services under the agreement, (c) a material diminution in his base salary which is not the result of his acts or omissions which constitute cause or (d) any action or inaction that constitutes a material breach by us of the agreement, including our failure to pay any amounts due to the executive or our failure to obtain from a successor the express assumption of the agreement.

Outstanding Equity Awards at End of 2014

The following table provides information about outstanding stock options held by each of our named executive officers at December 31, 2014. All of these options were granted under our 2007 Plan.

	Option Awards				
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Travis C. Mickle, Ph.D.			53,333(1)(2)	$ 5.85	08/17/2022
	—	26,666(1)(3)		$ 5.85	07/29/2024
Gordon K. Johnson	40,000	40,000(4)		$ 5.85	07/09/2023
	13,333	—		$ 5.85	07/10/2023
Sven Guenther, Ph.D.	20,000	—		$ 4.65	07/01/2019
	—	20,000(5)		$ 5.85	07/08/2024

(1) All shares underlying these option grants will vest in full and become immediately exercisable in the event Dr. Mickle is terminated by us without cause or resigns for good reason.
(2) This option vests as follows: 40,000 shares will vest upon a liquidation event for stockholders and 13,333 shares will vest upon the completion of an opioid induced constipation study for KP201.
(3) The shares underlying this option will vest in four equal annual installments beginning on July 30, 2015 through July 30, 2018.
(4) This option vests as follows: 25% of the total shares underlying this option vested on each of July 10, 2013 and July 10, 2014 and the remaining 50% of the shares underlying the option vest thereafter in two equal annual installments through July 10, 2016. All shares subject to vesting under this option grant will vest in full and become immediately exercisable immediately upon the closing of a sale or other change in control of our company.
(5) The shares underlying this option will vest in four equal annual installments beginning on July 9, 2015 through July 9, 2018.

Pension Benefits

Our named executive officers did not participate in, or otherwise receive any benefits under, any pension or retirement plan sponsored by us during 2013 or 2014.

Nonqualified Deferred Compensation

Our named executive officers did not participate in, or otherwise receive any benefits under, any nonqualified deferred compensation plan sponsored by us during 2013 or 2014.

Equity Incentive Plans

2014 Equity Incentive Plan

Our board of directors adopted and our stockholders have approved our 2014 Equity Incentive Plan, or our 2014 Plan. Our board of directors has approved the grant of stock options to one of our executive officers under the 2014 Plan, effective as of the date of this prospectus. Our 2014 Plan provides for the grant of incentive stock options within the meaning of Section 422 of the Code to our employees and our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of stock compensation to our employees, including officers, consultants and directors. Our 2014 Plan also provides for the grant of performance cash awards to our employees, consultants and directors.

Authorized Shares

The maximum number of shares of our common stock that may be issued under our 2014 Plan is 2,266,666 shares. The number of shares of our common stock reserved for issuance under our 2014 Plan will automatically increase on January 1 of each year, for a period of ten years, from January 1, 2015 continuing through January 1, 2024, by 4.0% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares as may be determined by our board of directors. The maximum number of shares that may be issued pursuant to the exercise of incentive stock options under the 2014 Plan is 13,600,000. The aggregate maximum number of shares subject to awards granted during a single fiscal year to any non-employee director, taken together with any cash fees paid to such non-employee director during the fiscal year, cannot exceed $500,000 in total value, calculating the value of any such awards based on the grant date fair value of such awards for financial reporting purposes and excluding the value of any dividend equivalent payments paid pursuant to any award granted in a previous fiscal year.

Shares issued under our 2014 Plan may be authorized but unissued or reacquired shares of our common stock. Shares subject to stock awards granted under our 2014 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, will not reduce the number of shares available for issuance under our 2014 Plan. Additionally, shares issued pursuant to stock awards under our 2014 Plan that we repurchase or that are forfeited, as well as shares reacquired by us as consideration for the exercise or purchase price of a stock award or to satisfy tax withholding obligations related to a stock award, will become available for future grant under our 2014 Plan.

Administration

Our board of directors, or a duly authorized committee thereof, has the authority to administer our 2014 Plan. Our board of directors has delegated its authority to administer our 2014 Plan to our compensation committee under the terms of the compensation committee's charter. Our board of directors may also delegate to one or more of our officers the authority to (a) designate employees other than officers to receive specified stock awards and (b) determine the number of shares of our common stock to be subject to such stock awards. Subject to the terms of our 2014 Plan, the administrator has the authority to determine the terms of awards, including recipients, the exercise price or strike price of stock awards, if any, the number of shares subject to each stock award, the fair market value of a share of our common stock, the vesting schedule applicable to the awards, together with any vesting acceleration, the form of consideration, if any, payable upon exercise or settlement of the stock award and the terms and conditions of the award agreements for use under our 2014 Plan.

The administrator has the power to modify outstanding awards under our 2014 Plan. Subject to the terms of our 2014 Plan, the administrator has the authority to reprice any outstanding option or stock appreciation right, cancel and re-grant any outstanding option or stock appreciation right in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

Section 162(m) Limits

No participant may be granted stock awards covering more than 3,400,000 shares of our common stock under our 2014 Plan during any calendar year pursuant to stock options, stock appreciation rights and other stock awards whose value is determined by reference to an increase over an exercise price or strike price of at least 100% of the fair market value of our common stock on the date of grant. Additionally, no participant may be granted in a calendar year a performance stock award covering more than 3,400,000 shares of our common stock or a performance cash award having a maximum value in excess of $5,000,000 under our 2014 Plan. These limitations enable us to grant awards that will be exempt from the $1,000,000 limitation on the income tax deductibility of compensation paid per covered executive officer imposed by Section 162(m) of the Code.

Performance Awards

Our 2014 Plan permits the grant of performance-based stock and cash awards that may qualify as performance-based compensation that is not subject to the $1,000,000 limitation on the income tax deductibility of compensation paid per covered executive officer imposed by Section 162(m) of the Code. To enable us to grant performance-based awards that will qualify, our compensation committee can structure such awards so that the stock or cash will be issued or paid pursuant to such award only following the achievement of specified pre-established performance goals during a designated performance period.

Corporate Transactions

Our 2014 Plan provides that in the event of a specified corporate transaction, including a consolidation, merger, or similar transaction involving our company, the sale, lease or other disposition of all or substantially all of the assets of our company or the consolidated assets of our company and our subsidiaries, or a sale or disposition of at least 50% of the outstanding capital stock of our company, the administrator will determine how to treat each outstanding stock award. The administrator may:

- arrange for the assumption, continuation or substitution of an stock award by a successor corporation;
- arrange for the assignment of any reacquisition or repurchase rights held by us to a successor corporation;
- accelerate the vesting of the stock award and provide for its termination prior to the effective time of the corporate transaction;
- arrange for the lapse, in whole or in part, of any reacquisition or repurchase right held by us; or
- cancel the stock award prior to the transaction in exchange for a cash payment, which may be reduced by the exercise price payable in connection with the stock award.

The administrator is not obligated to treat all stock awards or portions of stock awards, even those that are of the same type, in the same manner. The administrator may take different actions with respect to the vested and unvested portions of a stock award.

Change in Control

The administrator may provide, in an individual award agreement or in any other written agreement between us and the participant, that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a change in control. In the absence of such a provision, no such acceleration of the stock award will occur.

Plan Amendment or Termination

Our board has the authority to amend, suspend, or terminate our 2014 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. No incentive stock options may be granted after the tenth anniversary of the date our board of directors adopts our 2014 Plan.

2007 Plan

Our 2007 Plan was adopted by our board of directors and approved by our stockholders in June 2007. Awards outstanding under our 2007 Plan following this offering will continue to be governed by their existing terms. Our board of directors has determined that no further grants will be made under the 2007 Plan following this offering.

Share Reserve

We have reserved 800,000 shares of our common stock under the 2007 Plan. As of March 10, 2015, options to purchase 549,824 shares of our common stock were outstanding under the 2007 Plan and 211,067 shares were available for future grant.

Administration

Our board of directors or the compensation committee of our board of directors act as the administrator of the 2007 Plan. The administrator has the complete discretion to make all decisions relating to the plan and outstanding awards.

Eligibility

Employees, non-employee directors and consultants are eligible to participate in our 2007 Plan however only employees are eligible for the grant of incentive stock options.

Types of Awards

Our 2007 Plan provides for the award of incentive and nonstatutory stock options and the award of incentive stock (including phantom stock credits to acquire incentive stock).

The administrator may (a) grant awards under the 2007 Plan conditional upon an election by a participant to defer payment of a portion of his or her salary, (b) give a participant a choice between two types of awards or combinations of awards, (c) grant awards in the alternative so that acceptance of or exercise of one award cancels the right of a participant to another and (d) grant awards in any combination or combinations and subject to any condition or condition consistent with the terms of the 2007 Plan that the administrator in its sole discretion may determine

Terms of Awards

Subject to the terms of the 2007 Plan, the administrator determines the terms of all awards. The exercise price for stock options granted under the 2007 Plan may not be less than 100% of the fair market value of our common stock on the grant date; however, the exercise price for an incentive stock option granted to a holder of more than 10% of our stock may not be less than 110% of such fair market value on the grant date. Options are generally transferable only by will or the laws of descent and distribution, and may be exercised during the holder's lifetime only by the holder or, in the case of a nonstatutory stock option, by the holder's guardian or legal representative.

The term of options granted under the 2007 Plan may not exceed ten years and will generally expire sooner if the optionee's service terminates. Options vest at the times determined by the administrator.

Shares may be awarded under the 2007 Plan in consideration for services rendered to us or sold under the 2007 Plan. Shares awarded or sold under the 2007 Plan may be fully vested at grant or subject to special forfeiture conditions or rights of repurchase as determined by the administrator.

Change in Control

Until June 2014, our form of incentive stock option agreement provided for acceleration of vesting upon a change of control for incentive stock option awards issued under our 2007 Plan. All unvested shares subject to such an incentive stock option award will vest in full and become immediately exercisable immediately prior to the effective date of a change of control transaction.

Our form of non-qualified stock option agreement provides for similar acceleration of vesting upon a change of control for non-qualified stock option awards issued under our 2007 Plan. All unvested shares subject to a non-qualified stock option award will vest in full and become immediately exercisable if the holder is terminated without cause within 24 months after the consummation of a change of control transaction.

Changes in Capitalization

If any change is made in the shares of the common stock by reason of any merger, consolidation, reorganization, recapitalization, stock dividend, split up, combination of shares, exchange of shares, change in corporate structure, or otherwise, appropriate adjustments will be made by the administrator to the kind and maximum number of shares subject to the 2007 Plan and the kind and number of shares and price per share of stock subject to each outstanding award. Any increase in the shares, or the right to acquire shares, as the result of such an adjustment will be subject to the same terms and conditions that apply to the award for which such increase was received. No fractional shares of common stock will be issued under the 2007 Plan on account of any such adjustment, and rights to shares always will be limited after such an adjustment to the lower full share.

Amendment and Termination

Our board of directors may at any time amend the 2007 Plan. However, our board of directors must obtain approval of our stockholders or any amendment requiring such approval under federal tax or federal securities laws, including an increase to the maximum number of shares of our common stock that may be issued under the 2007 Plan. In addition, our board of directors may not alter or impair any award previously granted under the 2007 Plan without the consent of the holder of such award. The 2007 Plan will terminate ten years after the earliest of the date the 2007 Plan was adopted by our board of directors, the date our stockholder approved the 2007 Plan or a date determined by our board of directors.

401(k) Plan

We maintain a tax-qualified retirement plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees are able to defer eligible compensation subject to applicable annual Code limits. Currently, we match 100% of each eligible employee's contributions up to 4% of total eligible compensation. Employees' pre-tax contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. Employees are immediately and fully vested in their contributions, and our matching contribution is also immediately and fully vested when made. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan.

Limitations on Liability and Indemnification Matters

Upon the closing of this offering, our amended and restated certificate of incorporation will contain provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

This limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation and our amended and restated bylaws will provide that we are required to indemnify our directors to the fullest extent permitted by Delaware law. Our amended and restated bylaws will also provide that, upon satisfaction of certain conditions, we are

required to advance expenses incurred by a director in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. Our amended and restated bylaws will also provide our board of directors with discretion to indemnify our officers and employees when determined appropriate by the board. We have entered into and expect to continue to enter into agreements to indemnify some of our directors and executive officers. With certain exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought and we are not aware of any threatened litigation that may result in claims for indemnification.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with the terms of our insider trading policy. Prior to 180 days after the date of this offering, subject to early termination, the sale of any shares under such plan would be prohibited by the lock-up agreement that the director or officer has entered into with the underwriters.

RELATED PARTY TRANSACTIONS

The following is a description of transactions since January 1, 2012 to which we have been a participant in which the amount involved exceeded or will exceed $120,000, and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or any members of their immediate family, had or will have a direct or indirect material interest, other than compensation arrangements which are described under “Management—Executive Compensation.”

March 2012 Asset Sale

On March 21, 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 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 and Dr. Mickle entered into a consulting agreement with Shire to provide litigation support services with respect to such sold assets. As compensation for his services provided under such consulting agreement, Shire is required to pay Dr. Mickle a monthly retainer of $10,000 and compensation of $750 per hour.

2013 Transfers of Series C Redeemable Convertible Preferred Stock and Common Stock

On January 14, 2013, we and some of the holders of our capital stock entered into a stock purchase agreement pursuant to which (a) we redeemed 83,333 shares of our Series C redeemable convertible preferred stock at a purchase price of $0.78 per share from the sellers for an aggregate consideration of $65,000, (b) the sellers sold to other holders of our capital stock an aggregate of 44,873 shares of our Series C redeemable convertible preferred stock at a purchase price of $0.78 per share for an aggregate consideration of $35,000 and (c) the sellers sold to other holders of our capital stock an aggregate of 4,444 shares of our common stock at a price of $4.65 per share for an aggregate consideration of $20,667. Participants in this stock purchase included Christal M.M. Mickle, a holder more than 5% of our capital stock and one of our officers and directors. The following table presents the aggregate number of shares purchased by Christal M.M. Mickle in this stock purchase:

	Shares of Common Stock Purchased	Shares of Series C Redeemable Convertible Preferred Stock Purchased	Aggregate Purchase Price
Christal M.M. Mickle	4,444	44,873	$55,667

2013 Bridge Financing

Between June 5, 2013 and October 18, 2013, we issued an aggregate of $3.8 million in unsecured convertible promissory notes, or the 2013 notes, in a private placement. In connection with the issuance of the 2013 notes, we issued warrants to purchase an aggregate of 1,079,453 shares of our Series D redeemable convertible preferred stock at an exercise price of $0.78 per share at the time we completed our Series D financing described below. For more information regarding these warrants, please refer to the section titled “Description of Capital Stock—Warrants.” Participants in this private placement of the 2013 notes included some of our officers, directors and holders of more than 5% of our capital stock or entities affiliated with them. The following table presents the aggregate principal amount of the 2013 notes and number of warrants to purchase Series D redeemable convertible preferred stock issued to these related parties in this bridge financing:

Name of Affiliate	Principal Amount of Unsecured Convertible Promissory Notes	Warrants to Purchase Series D Redeemable Convertible Preferred Stock Issued
Travis C. Mickle, Ph.D. and Christal M.M. Mickle(1)	$ 101,000	32,371
Matthew R. Plooster	6,000	384

(1) Beneficially owned by Travis C. Mickle, Ph.D. and Christal M.M. Mickle as joint tenants with right of survivorship.

All principal and interest under the 2013 notes was converted into 5,332,348 shares of our Series D redeemable convertible preferred stock in connection with our June 2014 financing described below.

Issuance of Series D Redeemable Convertible Preferred Stock and Senior Secured Convertible Promissory Notes

In June 2014, we issued an aggregate of 5,332,348 shares of our Series D redeemable convertible preferred stock pursuant to the conversion of the 2013 notes in the aggregate principal amount of $3.8 million. The purchase price for these shares took the form of conversion of principal and interest under the outstanding 2013 notes held by the respective investors at a conversion price of $0.78 per share. Participants in this financing included some of our officers, directors and holders of more than 5% of our capital stock or entities affiliated with them. The following table presents the aggregate number of our Series D redeemable convertible preferred stock issued to these related parties in this financing:

Name of Affiliate	Shares of Series D Redeemable Convertible Preferred Stock Issued	Aggregate Purchase Price (Note Conversion)
Travis C. Mickle, Ph.D. and Christal M.M. Mickle(1)	137,541	$ 107,282
Matthew R. Plooster	8,456	6,596

(1) Shares beneficially owned by Travis C. Mickle, Ph.D. and Christal M.M. Mickle as joint tenants with right of survivorship.

In addition, in connection with the Series D redeemable convertible preferred stock financing, we issued to Deerfield 1,923,077 shares of our Series D redeemable convertible preferred stock as consideration for a series of loans issued to us by Deerfield under the Deerfield facility. 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, or the initial Deerfield warrant, and a senior secured promissory note in the principal amount of $10.0 million, or the Deerfield Note.

Upon the closing of this offering, each share of Series D redeemable convertible preferred stock will be automatically reclassified into one share of common stock and the initial Deerfield warrant will become a warrant to purchase common stock and the number of shares and purchase price per share will be appropriately adjusted.

Deerfield Financing

Deerfield Facility

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, including a term loan of $15.0 million and a senior secured loan of $10.0 million. 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. 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 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. If we enter into any major transaction without the prior approval of Deerfield, including a debt financing in the aggregate value of $750,000 or more, merger, asset sale, change of control transaction, liquidation event or the delisting of our securities on a publicly traded market, 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.

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 Code, then we are obligated to prepay in cash on each such date the amount necessary to avoid such classification.

The Deerfield facility also limits our ability to enter into specified business transactions without the prior approval of Deerfield, including a debt financing in the aggregate value of $500,000 or more, a merger, a change of control, an asset sale or an underwritten public offering of our common stock. The Deerfield facility also provides Deerfield with the right to demand that we redeem in cash all outstanding principal, and any accrued interest thereon, of any note issued under the Deerfield facility upon the occurrence of specified events, including a merger, asset sale or other change of control transaction.

Deerfield Warrants

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, or the Deerfield warrants. When we borrowed the first tranche, we issued to Deerfield the initial Deerfield warrant. According to the terms of the initial Deerfield warrant, in no event may Deerfield exercise the initial Deerfield warrant if such exercise would result in Deerfield beneficially owning more than 9.985% of the then issued and outstanding shares of our common stock. This exercise limitation may not be

waived and any purported exercise that is inconsistent with this exercise limitation is null and void. This exercise limitation will not apply to any exercise made immediately prior to a change of control transaction. If Deerfield is only able to exercise the initial Deerfield warrant for a limited number of shares due to this exercise limitation, the initial Deerfield warrant could subsequently become exercisable to purchase 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 exercise limitation, the initial Deerfield warrant is exercisable for 14,423,076 shares of our Series D redeemable convertible preferred stock. The initial Deerfield warrant includes a net exercise provision and contains provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrant in the event of certain stock dividends, stock splits, recapitalizations, reclassifications and consolidations. Under the initial Deerfield warrant, Deerfield also has the right to demand upon the occurrence of specified events, including a merger, asset sale or other change of control transaction, that we redeem the initial Deerfield warrant for a cash amount equal to the Black-Scholes value of the portion of the initial Deerfield warrant to be redeemed. If Deerfield chooses not to redeem the initial Deerfield warrant upon the occurrence of such an event, we may not enter into any such transaction unless our successor entity assumes in writing all our obligations under both the initial Deerfield warrant and the Deerfield facility and provides Deerfield with registration rights.

Following completion of this offering, exercise price protection provisions in the initial Deerfield warrant will go into effect, pursuant to which the exercise price of the initial Deerfield 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 initial Deerfield warrant's exercise price or the closing sale price of our common stock on The NASDAQ Global Market on the last trading date immediately prior to such issuance. Without regard to the exercise limitation, upon completion of this offering, the initial Deerfield warrant will become exercisable for 1,923,077 shares of our common stock at an exercise price of $5.85 per share and is exercisable until its expiration on June 2, 2024.

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. For more information regarding the Deerfield warrants, please refer to the section titled "Description of Capital Stock — Warrants."

Deerfield Senior Secured Convertible Promissory Note

Pursuant to the Deerfield facility, we issued 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 of the Deerfield Note into shares of our Series D redeemable convertible preferred stock at a conversion price of $0.78 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, upon the consummation of this offering, the Deerfield Note will become convertible into 1,841,683 shares of our

common stock, assuming a conversion date of March 10, 2015. At our option, the Deerfield Note will convert into shares of our common stock upon the occurrence prior to June 30, 2016 of either (a) the FDA's approval of an NDA for KP201 for the treatment of acute pain without requiring the performance of an efficacy study or (b) the FDA's acceptance of an NDA for KP201 for review and our consummation of an initial public offering of our common stock at price of at least $9.375 per share with at least $25.0 million in gross proceeds to us. Following completion of this offering, 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 on The NASDAQ Global Market on the last trading date immediately prior to such issuance.

The Deerfield Note provides Deerfield with the right to demand that we redeem in cash all outstanding principal, and any accrued interest thereon, of the Deerfield Note upon the occurrence of specified events, including a merger, asset sale or other change of control transaction. If Deerfield chooses not to exercise this redemption right, then we may not enter into any such transaction unless the successor entity to us assumes in writing all our obligations under the Deerfield Note and provides Deerfield with registration rights.

Investors' Rights Agreement

We have entered into an investors' rights agreement with some of our stockholders, including Deerfield. The investors' rights agreement, among other things:

- grants these stockholders specified registration rights with respect to shares of our common stock, including shares of common stock issued or issuable upon conversion or reclassification of the shares of our redeemable convertible preferred stock, convertible notes and warrants held by them;
- obligates us to deliver periodic financial statements and provide certain inspection rights to Deerfield;
- grants a right of first refusal with respect to sales of our shares by us, subject to specified exclusions, which exclusions include the sale of the shares pursuant to this prospectus, to the stockholders who are parties to the investors' rights agreement and who hold a specified number of shares of registrable securities; and
- provides Deerfield with certain approval rights such that we may not enter into certain transactions, including the sale of some of our assets, without Deerfield's prior written consent.

For more information regarding the registration rights provided in this agreement, please refer to the section titled ''Description of Capital Stock—Registration Rights.'' The provisions of this agreement other than those relating to registration rights will terminate upon the closing of this offering.

Voting Agreement

We have entered into a voting agreement with some of our stockholders, including Deerfield. The voting agreement provides for, among other things, the voting of shares with respect to the constituency of our board of directors and the voting of shares in favor of specified transactions approved by our board of directors, Deerfield and the requisite majority of holders of our outstanding Series D redeemable convertible preferred stock. The voting agreement will terminate upon the closing of this offering.

Right of First Refusal and Co-Sale Agreement

We have entered into a right of first refusal and co-sale agreement with some of our stockholders, including Deerfield. The right of first refusal and co-sale agreement, among other things, grants our investors rights of first refusal and co-sale with respect to proposed transfers of our securities by

specified stockholders and grants us rights of first refusal with respect to proposed transfers of our securities by specified stockholders. The right of first refusal and co-sale agreement will terminate upon the closing of this offering.

Indemnification Agreements

Our amended and restated certificate of incorporation will contain provisions limiting the liability of directors, and our amended and restated bylaws will provide that we will indemnify each of our directors to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide our board of directors with discretion to indemnify our officers and employees when determined appropriate by the board.

In addition, we have entered into indemnification agreements with each of our directors and executive officers in connection with this offering. For more information regarding these agreements, see “Executive Compensation—Limitations on Liability and Indemnification Matters.”

Related Person Transaction Policy

Prior to this offering, we have not had a formal policy regarding approval of transactions with related parties. We have adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds $120,000. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our Code of Business Conduct and Ethics that we have adopted to be in effect upon the closing of this offering, our employees and directors will have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director’s independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.

PRINCIPAL STOCKHOLDERS

The following table sets forth the beneficial ownership of our common stock as of March 10, 2015 for:

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

The percentage ownership information shown in the table is based upon 8,371,765 shares of common stock outstanding as of March 10, 2015, after giving effect to the conversion or reclassification of all of our redeemable convertible preferred stock into 5,980,563 shares of common stock, which will occur automatically upon the closing of this offering.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before May 9, 2015, which is 60 days after March 10, 2015. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for persons listed in the table is c/o KemPharm, Inc., 2656 Crosspark Road, Suite 100, Coralville, Iowa 52241.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
Principal Stockholders:			
Deerfield Private Design Fund III, L.P.(1)	1,195,186	9.9%	9.9%
Bridgepoint Investment Partners I, LLLP(2)	428,304	5.1	3.2
Executive Officers and Directors:			
Travis C. Mickle, Ph.D.(3)	2,377,695	28.4	17.7
Gordon K. Johnson(4)	58,666	*	*
Sven Guenther, Ph.D.(5)	63,852	*	*
Christal M.M. Mickle(3)	2,377,695	28.4	17.7
Tracy M. Woody	–	*	*
R. LaDuane Clifton	–	*	*
Danny L. Thompson(6)	122,392	1.5	*
Matthew R. Plooster(7)	434,017	5.2	3.2
Richard W. Pascoe(8)	2,666	*	*
Joseph B. Saluri(9)	7,221	*	*
David S. Tierney	–	*	*
All current directors and executive officers as a group (11 persons)(10)	3,066,509	36.2	22.6

* Represents beneficial ownership of less than 1%.

(1) Consists of 256,410 shares of common stock issuable upon conversion or reclassification of shares of preferred stock held by Deerfield Private Design Fund III, L.P., or Deerfield, and additional shares of common stock issuable upon the conversion of a convertible promissory note and the exercise of a warrant held by Deerfield. In accordance with the terms of the note and warrant, Deerfield may not convert or exercise this note or warrant if such conversion or exercise 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 is null and void. Upon completion of this offering the number of shares beneficially owned by Deerfield, after giving effect to this conversion limitation, will be 1,705,515. But for this conversion limitation, Deerfield would also have the right to acquire 1,841,683 shares of common stock issuable upon the conversion of the note and 1,923,077 shares of common stock issuable upon exercise of the warrant within 60 days of March 10, 2015, and Deerfield would beneficially own 4,021,170 shares of common stock. The shares directly held by Deerfield are indirectly beneficially owned by Deerfield Mgmt III, L.P., its general partner, Deerfield Management Company, L.P., its investment manager, and James E. Flynn. As the sole member of the respective general partners of Deerfield Mgmt III, L.P. and Deerfield Management Company, L.P, Mr. Flynn is the sole natural person possessing beneficial ownership over such shares. The principal business address of Deerfield is 780 Third Avenue, 37th Floor, New York, NY 10017. An entity affiliated with Deerfield has agreed to purchase 500,000 shares of our common stock in this offering at the initial public offering price. The number of shares beneficially owned and the percentage of shares beneficially owned after this offering, as reflected in the table above, do not give effect to this potential purchase.

(2) Consists of 428,304 shares of common stock issuable upon conversion of shares of preferred stock held by Bridgepoint Investment Partners I, LLLP, or Bridgepoint. The shares directly held by Bridgepoint are indirectly held by its general partner, Bridgepoint Capital Partners, LLP, or BPCP. The individual managers of BPCP are Matthew R. Plooster, one of our directors, and Adam S. Claypool. Matthew R. Plooster and Adam S. Claypool share voting and dispositive power with regard to the shares directly held by Bridgepoint. The principal business address of Bridgepoint is 700 Locust Street, Suite 203, Des Moines, Iowa 50309.

(3) Consists of (a) 1,538,373 shares of common stock held directly by Dr. Mickle, (b) 271,111 shares of common stock held directly by Ms. Mickle, who is the spouse of Dr. Mickle, (c) 230,812 shares of common stock held by the TCM Family Trust u/d/p April 30, 2009, for which Dr. Mickle and Ms. Mickle serve as co-trustees, (d) 230,812 shares of common stock held by the Mickle Family Trust u/d/p April 30, 2009, for which Dr. Mickle and Ms. Mickle serve as co-trustees, (e) 5,983 shares of common stock issuable upon conversion of shares of preferred stock held directly by Ms. Mickle, (f) 96,288 shares of common stock issuable upon conversion or reclassification of shares of preferred stock held jointly by Dr. Mickle and Ms. Mickle and (g) 4,316 shares issuable upon exercise of an immediately exercisable warrant held jointly by Dr. Mickle and Ms. Mickle.

(4) Consists of 58,666 shares of common stock underlying options that are exercisable within 60 days of March 10, 2015. Promptly following the closing date of this offering, we expect to grant Mr. Johnson a stock option exercisable for 40,000 shares of our common stock which will be fully vested and immediately exercisable and have an exercise price equal to the per share fair market value of our common stock as of the grant date.

(5) Consists of 20,000 shares of common stock, 23,852 shares of common stock issuable upon conversion of shares of preferred stock and 20,000 shares of common stock underlying options that are exercisable within 60 days of March 10, 2015.

(6) Consists of (a) 7,373 shares of common stock issuable upon conversion of shares of preferred stock held jointly by Mr. Thompson and his spouse, Robyn A. Thompson, (b) 23,332 shares of common stock underlying options that are exercisable within 60 days of March 10, 2015 held directly by Mr. Thompson, and (c) 91,687 shares of common stock issuable upon conversion of shares of preferred stock held by Garrett Bancshares, LTD. Mr. Thompson is the Vice-President of Garrett Bancshares, LTD and may be deemed to have shared voting and dispositive power over,

and be deemed to be indirect beneficial owner of, the shares directly held by Garrett Bancshares, LTD. The address for Garrett Bancshares, LTD is 109 N. Madison Street, Bloomfield, IA 52537.

(7) Consists of (a) 4,545 shares of common stock issuable upon conversion or reclassification of shares of preferred stock held directly by Mr. Plooster, (b) 1,117 shares of common stock issuable upon conversion or reclassification of shares of preferred stock held by TD Ameritrade Clearing Inc. Custodian FBO Matthew Ryan Plooster Roth IRA, for which Mr. Plooster serves as trustee, (c) 51 shares of common stock issuable upon exercise of an immediately exercisable warrant and (d) the shares identified in footnote 2 above.

(8) Consists of 2,666 shares of common stock underlying options that are exercisable within 60 days of March 10, 2015.

(9) Consists of 4,555 shares of common stock issuable upon conversion of shares of preferred stock and 2,666 shares of common stock underlying options that are exercisable within 60 days of March 10, 2015.

(10) Consists of (a) 2,291,108 shares of common stock, (b) 663,704 shares of common stock issuable upon conversion or reclassification of shares of preferred stock, (c) 107,330 shares of common stock underlying options that are exercisable within 60 days of March 10, 2015 and (d) 4,367 shares of common stock issuable upon exercise of immediately exercisable warrants.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries. You should also refer to the amended and restated certificate of incorporation and the amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is part.

General

Upon the closing of this offering, our amended and restated certificate of incorporation will authorize us to issue up to 250,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share, all of which shares of preferred stock will be undesignated. Our board of directors may establish the rights and preferences of the preferred stock from time to time. As of March 10, 2015, we had outstanding 2,391,202 shares of common stock, held by eight stockholders of record. As of March 10, 2015, after giving effect to the conversion or reclassification of all outstanding preferred stock into 5,980,563 shares of common stock, which will automatically occur upon the closing of this offering, there would have been 8,371,765 shares of common stock issued and outstanding, held of record by 631 stockholders.

Common Stock

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Under our amended and restated certificate of incorporation and amended and restated bylaws, our stockholders will not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Rights and Preferences

Holders of common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Preferred Stock

As of March 10, 2015, there were outstanding 44,940,253 shares of redeemable convertible preferred stock, of which 9,704,215 shares of Series A redeemable convertible preferred stock were

outstanding, 6,220,000 shares of Series B redeemable convertible preferred stock were outstanding, 18,557,408 shares of Series C redeemable convertible preferred stock were outstanding, 7,258,630 shares of Series D redeemable convertible preferred stock were outstanding and 3,200,000 shares of Series D-1 redeemable convertible preferred stock. All currently outstanding shares of redeemable convertible preferred stock will be converted or reclassified into an aggregate of 5,980,563 shares of common stock, which will automatically occur upon the closing of this offering.

Following the closing of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of us and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of common stock until the board of directors determines the specific rights attached to that preferred stock.

We have no present plans to issue any shares of preferred stock following completion of this offering.

Options

As of March 10, 2015, under our 2007 Plan, options to purchase an aggregate of 549,824 shares of common stock were outstanding. For additional information regarding the terms of this plan, see “Executive Compensation—Equity Incentive Plans.”

Deerfield Note

On June 2, 2014, we issued to Deerfield 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 thereon, of the Deerfield Note into shares of our Series D redeemable convertible preferred stock at a price per share of $0.78. According to the terms of the Deerfield Note, in no event may Deerfield convert this note if 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 is 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, upon the consummation of this offering, the Deerfield Note will become convertible into 1,841,683 shares of our common stock, assuming a conversion date of March 10, 2015. The conversion price, and the number of shares issued upon conversion, of the Deerfield Note is subject to adjustment in the event of certain stock dividends, stock

splits, recapitalizations, reclassifications and consolidations. Following completion of this offering, 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 on The NASDAQ Global Market on the last trading date immediately prior to such issuance. For more information regarding the Deerfield Note, please refer to the section titled "Related Party Transactions—Issuance of Series D Redeemable Convertible Preferred Stock and Senior Secured Convertible Promissory Notes."

Warrants

As of March 10, 2015, we have outstanding immediately exercisable warrants to purchase 585,759 shares of our common stock at a weighted average exercise price of $5.30 per share and which expire between December 7, 2015 and the two year anniversary of the consummation of this offering. The warrants include a net exercise provision and contain provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of each warrant in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations. Additionally, some of these warrants include anti-dilution provisions pursuant to which the exercise price of the common stock warrants will be adjusted downward if we issue any shares of our common stock at price per share or any securities convertible into our common stock with an exercise price less than the exercise price of such warrants. Upon such an event, the exercise price of such warrants will be automatically adjusted to equal the price per share paid for, or 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 adjusted. We have also granted piggyback registration rights to certain common stock warrant holders, as more fully described below under "Description of Capital Stock—Registration Rights."

In June 2013, in connection with our sale of the 2013 notes, we issued warrants, or the 2013 warrants, for the purchase of a number of shares of our capital stock at a price per share to be determined upon the occurrence of specified events. Upon consummation of the Deerfield facility, the 2013 warrants became exercisable for an aggregate of 1,079,453 shares of Series D redeemable convertible preferred stock at a price per share of $0.78. The 2013 warrants include a net exercise provision and provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrants on a weighted-average basis in the event of certain stock dividends, stock splits, recapitalizations, reclassifications and consolidations.

In June 2014, in connection with our entering into the Deerfield facility, we issued the initial Deerfield warrant to Deerfield. According to the terms of the initial Deerfield warrant, in no event may Deerfield exercise this warrant if such exercise would result in Deerfield beneficially owning more than 9.985% of the then issued and outstanding shares of our common stock. This exercise limitation may not be waived and any purported exercise that is inconsistent with this exercise limitation is null and void. This exercise limitation will not apply to any exercise made immediately prior to a change of control transaction. If Deerfield is only able to exercise the initial Deerfield warrant for a limited number of shares due to this exercise limitation, the initial Deerfield warrant could subsequently become exercisable to purchase 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 exercise limitation, the initial Deerfield warrant is exercisable for 14,423,076 shares of our Series D redeemable convertible preferred stock. The initial Deerfield warrant includes a net exercise provision and contains provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrant in the event of certain stock dividends, stock splits, recapitalizations, reclassifications and consolidations. Under the initial Deerfield warrant, Deerfield also has the right to demand upon the occurrence of specified events, including a merger, asset sale or other change of control transaction, that we redeem the initial Deerfield warrant for cash amount equal to the Black-

Scholes value of the portion of the initial Deerfield warrant to be redeemed. If Deerfield chooses not to redeem the initial Deerfield warrant upon the occurrence of such an event, we may not enter into any such transaction unless our successor entity assumes in writing all our obligations under both the initial Deerfield warrant and the Deerfield facility and provides Deerfield with certain registration rights.

Following completion of this offering, exercise price protection provisions in the initial Deerfield warrant will go into effect, pursuant to which the exercise price of the initial Deerfield 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 initial Deerfield warrant's exercise price or the closing sale price of our common stock on The NASDAQ Global Market on the last trading date immediately prior to such issuance. Upon completion of this offering, the initial Deerfield warrant will become exercisable for 1,923,077 shares of our common stock at an exercise price of $5.85 per share and is exercisable until its expiration on June 2, 2024.

Pursuant to the Deerfield facility, we are obligated to issue to Deerfield warrants with substantially the same terms as the initial Deerfield warrant if Deerfield makes any additional disbursements under the Deerfield facility. For more information regarding the Deerfield facility, please refer to the section titled "Related Party Transactions—Issuance of Series D Redeemable Convertible Preferred Stock and Senior Secured Convertible Promissory Notes."

Registration Rights

We and the holders of our existing redeemable convertible preferred stock have entered into an investors' rights agreement. The registration rights provisions of this agreement provide (i) some of these holders with demand and Form S-3 registration rights, and (ii) all holders with piggyback registration rights with respect to the shares of our common stock currently held by them and issuable to them upon exercise of warrants and upon conversion or reclassification of our redeemable convertible preferred stock in connection with this offering.

Demand Registration Rights

At any time beginning six months following the date of this prospectus, Deerfield has the right to demand that we file a Form S-1 registration statement, as long as the anticipated aggregate offering price, net of underwriting discounts and commissions, would exceed $15.0 million. Upon receipt of this demand, the holders of shares of common stock that are issued upon conversion or reclassification of our redeemable convertible preferred stock and some holders of shares of our common stock would be entitled to participate in this registration. These registration rights are subject to specified conditions and limitations, including the right of the underwriters, if any, to limit the number of shares included in any such registration under specified circumstances. Upon such a request, we are required to effect the registration as soon as reasonably possible. An aggregate of 5,894,703 shares of common stock and 2,277,533 shares issuable upon the exercise of warrants will be entitled to these demand registration rights.

Piggyback Registration Rights

At any time after the completion of this offering, if we propose to register any of our securities under the Securities Act of 1933, as amended, or the Securities Act, either for our own account or for the account of other stockholders, the holders of shares of common stock that are issued upon conversion or reclassification of our redeemable convertible preferred stock, some holders of shares of our common stock and our currently outstanding common stock warrants will each be entitled to notice of the registration and will be entitled to include their shares of common stock in the registration statement, provided that the holders of our common stock warrants may include their shares of common stock in such registration only if the aggregate value of such shares would be equal to or greater than $5.0 million in the offering or if such shares constitute all the shares of our common stock

held by such holder. These piggyback registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under specified circumstances. An aggregate of 5,894,703 shares of common stock and 2,610,836 shares issuable upon the exercise of warrants will be entitled to these piggyback registration rights.

Registration on Form S-3

At any time after we become eligible to file a registration statement on Form S-3, Deerfield will be entitled, upon their written request, to have such shares registered by us on a Form S-3 registration statement at our expense, subject to other specified conditions and limitations. Upon receipt of this demand, the holders of shares of common stock that are issued upon conversion or reclassification of our redeemable convertible preferred stock and some holders of shares of our common stock would be entitled to participate in this registration. An aggregate of 5,894,703 shares of common stock and 2,277,533 shares issuable upon the exercise of warrants will be entitled to these Form S-3 registration rights.

Expenses of Registration

We will pay all expenses relating to any demand, piggyback or Form S-3 registration, other than underwriting discounts and commissions, subject to specified conditions and limitations.

Termination of Registration Rights

The registration rights granted under the investors' rights agreement will terminate upon the written consent of Deerfield and the stockholders holding a majority of the registrable securities then outstanding.

Anti-Takeover Provisions

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a "business combination" to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Certificate of Incorporation and Bylaws to be in Effect Upon the Closing of this Offering

Our amended and restated certificate of incorporation to be in effect upon the closing of this offering, or our restated certificate, will provide for our board of directors to be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors. Our restated certificate and our amended and restated bylaws to be effective upon the closing of this offering, or our restated bylaws, will also provide that directors may be removed by the stockholders only for cause upon the vote of 66 2/3% or more of our outstanding common stock. Furthermore, the authorized number of directors may be changed only by resolution of the board of directors, and vacancies and newly created directorships on the board of directors may, except as otherwise required by law or determined by the board, only be filled by a majority vote of the directors then serving on the board, even though less than a quorum.

Our restated certificate and restated bylaws will also provide that all stockholder actions must be effected at a duly called meeting of stockholders and will eliminate the right of stockholders to act by written consent without a meeting. Our restated bylaws will also provide that only our chairman of the board, chief executive officer or the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors may call a special meeting of stockholders.

Our restated bylaws will also provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing, and will specify requirements as to the form and content of a stockholder's notice.

Our restated certificate and restated bylaws will provide that the stockholders cannot amend many of the provisions described above except by a vote of 66 2/3% or more of our outstanding common stock.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Choice of Forum

Our restated certificate will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our restated certificate, or our amended and restated bylaws; or
- any action asserting a claim against us that is governed by the internal affairs doctrine.

The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any action, a court could find the choice of forum provisions contained in our restated certificate to be inapplicable or unenforceable in such action.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent's address is 144 Fernwood Avenue, Edison, NJ 08837.

NASDAQ Global Market Listing

Our common stock has been approved for listing on The NASDAQ Global Market under the trading symbol "KMPH."

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market existed for our common stock. Future sales of shares of our common stock in the public market after this offering, or the perception that these sales could occur, could adversely affect prevailing market prices for our common stock and could impair our future ability to raise equity capital.

Based on the number of shares outstanding as of March 10, 2015, upon the closing of this offering and assuming no exercise of the underwriters' option to purchase additional shares, 13,462,674 shares of common stock will be outstanding, assuming no outstanding options or warrants are exercised. All of the shares of common stock sold in this offering will be freely tradable without restrictions or further registration under the Securities Act, except for any shares sold to our "affiliates," as that term is defined under Rule 144 under the Securities Act. The remaining 8,371,765 shares of common stock held by existing stockholders are "restricted securities," as that term is defined in Rule 144 under the Securities Act. Restricted securities may be sold in the public market only if registered or if their resale qualifies for exemption from registration described below under Rule 144 promulgated under the Securities Act.

As a result of contractual restrictions described below and the provisions of Rules 144 and 701, the shares sold in this offering and the restricted securities will be available for sale in the public market as follows:

- the 5,090,909 shares sold in this offering and 164,388 of the existing restricted shares will be eligible for immediate sale upon the completion of this offering (except that common stock sold to our directors or executive officers in this offering pursuant to the directed share program will be subject to the 180-day lock-up restrictions described below);
- the remaining 8,207,377 restricted shares will be eligible for sale in the public market upon expiration of lock-up agreements 180 days after the date of this prospectus, subject in certain circumstances to the volume, manner of sale and other limitations under Rule 144 and Rule 701.

Rule 144

In general, persons who have beneficially owned restricted shares of our common stock for at least six months, and any of our affiliates who own either restricted or unrestricted shares of our common stock, are entitled to sell their securities without registration with the SEC under an exemption from registration provided by Rule 144 under the Securities Act.

Non-Affiliates

Any person who is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale may sell an unlimited number of restricted securities under Rule 144 if:

- the restricted securities have been held for at least six months, including the holding period of any prior owner other than one of our affiliates;
- we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale; and
- we are current in our Exchange Act reporting at the time of sale.

Any person who is not deemed to have been an affiliate of ours at the time of, or at any time during the three months preceding, a sale and has held the restricted securities for at least one year, including

the holding period of any prior owner other than one of our affiliates, will be entitled to sell an unlimited number of restricted securities without regard to the length of time we have been subject to Exchange Act periodic reporting or whether we are current in our Exchange Act reporting.

Affiliates

Persons seeking to sell restricted securities who are our affiliates at the time of, or any time during the three months preceding, a sale, would be subject to the restrictions described above. They are also subject to additional restrictions, by which such person would be required to comply with the manner of sale and notice provisions of Rule 144 and would be entitled to sell within any three-month period only that number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 135,000 shares immediately after the completion of this offering based on the number of shares outstanding as of March 10, 2015; or
- the average weekly trading volume of our common stock on The NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Additionally, persons who are our affiliates at the time of, or any time during the three months preceding, a sale may sell unrestricted securities under the requirements of Rule 144 described above, without regard to the six month holding period of Rule 144, which does not apply to sales of unrestricted securities.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and in the section of this prospectus titled “Underwriting” and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Form S-8 Registration Statements

As soon as practicable after the completion of this offering, we intend to file with the SEC one or more registration statements on Form S-8 under the Securities Act to register the shares of our common stock that are issuable pursuant to our 2007 Plan and 2014 Plan. These registration statements will become effective immediately upon filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to vesting restrictions, any applicable lock-up agreements described below and Rule 144 limitations applicable to affiliates.

Lock-Up Agreements

We and the holders of substantially all of our common stock outstanding on the date of this prospectus, including each of our executive officers and directors, have entered into lock-up agreements with the underwriters or otherwise agreed, subject to certain exceptions, that we and they will not, directly or indirectly, offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale, or otherwise dispose of or hedge any of our shares of common stock, any options or warrants to purchase shares of our common stock, or any securities convertible into, or exchangeable for or that represent the right to receive shares of our common stock, without the prior written consent of the representatives of the underwriters for a period of 180 days from the date of this prospectus.

MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following is a general discussion of the material U.S. federal income and estate tax considerations applicable to non-U.S. holders with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. All prospective non-U.S. holders of our common stock should consult their own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock. In general, a non-U.S. holder means a beneficial owner of our common stock (other than a partnership or an entity or arrangement treated as a partnership for U.S. federal income tax purposes) that is not, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or an entity treated as a corporation for U.S. federal income tax purposes, created or organized in the United States or under the laws of the United States or of any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust if (1) a U.S. court can exercise primary supervision over the trust's administration and one or more U.S. persons have the authority to control all of the trust's substantial decisions or (2) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing U.S. Treasury Regulations promulgated thereunder, published administrative rulings and judicial decisions, all as in effect as of the date of this prospectus. These laws are subject to change and to differing interpretation, possibly with retroactive effect. Any change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus.

We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, for investment). This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances, nor does it address any aspects of U.S. state, local or non-U.S. taxes. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as holders that own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below), corporations that accumulate earnings to avoid U.S. federal income tax, tax-exempt organizations, banks, financial institutions, insurance companies, brokers, dealers or traders in securities, commodities or currencies, tax-qualified retirement plans, holders subject to the alternative minimum tax or the Medicare contribution tax, holders who hold or receive our common stock pursuant to the exercise of employee stock options or otherwise as compensation, holders holding our common stock as part of a hedge, straddle or other risk reduction strategy, conversion transaction or other integrated investment, holders deemed to sell our common stock under the constructive sale provisions of the Code, controlled foreign corporations, passive foreign investment companies and certain former U.S. citizens or long-term residents.

In addition, this discussion does not address the tax treatment of partnerships (or entities or arrangements that are treated as partnerships for U.S. federal income tax purposes) or persons that hold their common stock through such partnerships. If a partnership, including any entity or arrangement treated as a partnership for U.S. federal income tax purposes, holds shares of our common stock, the U.S. federal income tax treatment of a partner in such partnership will generally

depend upon the status of the partner and the activities of the partnership. Such partners and partnerships should consult their own tax advisors regarding the tax consequences of the purchase, ownership and disposition of our common stock.

There can be no assurance that the Internal Revenue Service, which we refer to as the IRS, will not challenge one or more of the tax consequences described herein, and we have not obtained, nor do we intend to obtain, a ruling with respect to the U.S. federal income or estate tax consequences to a non-U.S. holder of the purchase, ownership or disposition of our common stock.

Distributions on Our Common Stock

Distributions, if any, on our common stock generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's adjusted tax basis in the common stock. Any remaining excess will be treated as capital gain from the sale or exchange of such common stock, subject to the tax treatment described below in "Gain on Sale, Exchange or Other Disposition of Our Common Stock." Any such distribution will also be subject to the discussion below under the heading "Foreign Accounts."

Dividends paid to a non-U.S. holder will generally be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to U.S. persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

Gain on Sale, Exchange or Other Disposition of Our Common Stock

Subject to the discussion below regarding backup withholding and foreign accounts, in general, a non-U.S. holder will not be subject to any U.S. federal income tax on any gain realized upon such holder's sale, exchange or other disposition of shares of our common stock unless:

- the gain is effectively connected with a U.S. trade or business of the non-U.S. holder and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a

fixed base maintained in the United States by such non-U.S. holder, in which case the non-U.S. holder generally will be taxed at the graduated U.S. federal income tax rates applicable to U.S. persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "Distributions on Our Common Stock" also may apply;

- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the net gain derived from the disposition, which may be offset by U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States); or
- our common stock constitutes a U.S. real property interest because we are, or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation." Even if we are or become a U.S. real property holding corporation, provided that our common stock is regularly traded on an established securities market, our common stock will be treated as a U.S. real property interest only with respect to a non-U.S. holder that holds more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. In such case, such non-U.S. holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to U.S. persons (as defined in the Code). Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

U.S. Federal Estate Tax

Shares of our common stock that are owned or treated as owned at the time of death by an individual who is not a citizen or resident of the United States, as specifically defined for U.S. federal estate tax purposes, are considered U.S. situs assets and will be included in the individual's gross estate for U.S. federal estate tax purposes. Such shares, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax or other treaty provides otherwise.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of the dividends on our common stock paid to such holder and the tax withheld, if any, with respect to such dividends. Non-U.S. holders will have to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Dividends paid to non-U.S. holders subject to the U.S. withholding tax, as described above in "Distributions on Our Common Stock," generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with

substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder may be allowed as a credit against the non-U.S. holder's U.S. federal income tax liability, if any, and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

Foreign Accounts

The Code generally imposes a U.S. federal withholding tax of 30% on dividends and the gross proceeds of a disposition of our common stock paid to a "foreign financial institution" (as specifically defined for this purpose), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). A U.S. federal withholding tax of 30% also applies to dividends and the gross proceeds of a disposition of our common stock paid to a non-financial foreign entity, unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding substantial direct and indirect U.S. owners of the entity. The withholding provisions described above currently apply to dividends paid on our common stock and will generally apply with respect to gross proceeds of a sale or other disposition of our common stock on or after January 1, 2017. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes.

UNDERWRITING

We and the underwriters for the offering named below have entered into an underwriting agreement with respect to the common stock being offered. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase from us the number of shares of our common stock set forth opposite its name below. Cowen and Company, LLC and RBC Capital Markets, LLC are the representatives of the underwriters.

Underwriter	Number of Shares
Cowen and Company, LLC	2,163,637
RBC Capital Markets, LLC	1,654,546
Canaccord Genuity Inc.	636,363
Oppenheimer & Co. Inc.	636,363
Total	5,090,909

The underwriting agreement provides that the obligations of the underwriters are conditional and may be terminated at their discretion based on their assessment of the state of the financial markets. The obligations of the underwriters may also be terminated upon the occurrence of the events specified in the underwriting agreement. The underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased, other than those shares covered by the overallotment option described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act of 1933, and to contribute to payments the underwriters may be required to make in respect thereof. The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Underwriters' Option to Purchase Additional Shares. We have granted to the underwriters an option to purchase up to 763,636 additional shares of common stock at the public offering price, less the underwriting discount. This option is exercisable for a period of 30 days. The underwriters may exercise this option solely for the purpose of covering overallotments, if any, made in connection with the sale of common stock offered hereby. To the extent that the underwriters exercise this option, the underwriters will purchase additional shares from us in approximately the same proportion as shown in the table above.

Discounts and Commissions. The following table shows the public offering price, underwriting discount and proceeds, before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares. We estimate that the total expenses of the offering, excluding underwriting discount, will be approximately $2.8 million and are payable by us.

		Total	
	Per Share	Without Over-Allotment	With Over-Allotment
Public offering price	$ 11.00	$55,999,999	$64,399,995
Underwriting discount	$ 0.77	$ 3,920,000	$ 4,508,000
Proceeds, before expenses, to us	$ 10.23	$52,079,999	$59,891,995

The underwriters propose to offer the shares of common stock to the public at the public offering price set forth on the cover of this prospectus. The underwriters may offer the shares of common stock to securities dealers at the public offering price less a concession not in excess of $0.47 per share. If all of the shares are not sold at the public offering price, the underwriters may change the offering price and other selling terms.

We have agreed to reimburse the underwriters for legal fees of up to $40,000 incurred in qualification of the offering with the Financial Industry Regulatory Authority (FINRA), which amount is deemed by FINRA to be underwriting compensation.

Discretionary Accounts. The underwriters do not intend to confirm sales of the shares to any accounts over which they have discretionary authority.

Market Information. Prior to this offering, there has been no public market for shares of our common stock. The initial public offering price has been determined by negotiations between us and the representatives of the underwriters.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

Our common stock has been approved for listing on The NASDAQ Global Market under the trading symbol “KMPH.”

Stabilization. In connection with this offering, the underwriters may engage in stabilizing transactions, overallotment transactions, syndicate covering transactions, penalty bids and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase shares of common stock so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the common stock while the offering is in progress.
- Overallotment transactions involve sales by the underwriters of shares of common stock in excess of the number of shares the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the overallotment option. In a naked short position, the number of shares involved is greater than the number of shares in the overallotment option. The underwriters may close out any short position by exercising their overallotment option and/or purchasing shares in the open market.
- Syndicate covering transactions involve purchases of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared with the price at which they may purchase shares through exercise of the overallotment option. If the underwriters sell more shares than could be covered by exercise of the overallotment option and, therefore, have a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.
- Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the common stock originally sold by that syndicate member is purchased in stabilizing or syndicate covering transactions to cover syndicate short positions. These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock in

the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on The NASDAQ Global Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Lock-Up Agreements. Pursuant to certain ‘‘lock-up’’ agreements, we and our executive officers, directors and substantially all of our other stockholders, have agreed, subject to certain exceptions, not to lend, offer, sell, contract to sell, announce any intention to sell, pledge or otherwise dispose of, enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of, directly or indirectly, or file with the SEC a registration statement under the Securities Act relating to, any common stock or securities convertible into or exchangeable or exercisable for any common stock without the prior written consent of Cowen and Company, LLC and RBC Capital Markets, LLC, for a period of 180 days after the date of the pricing of the offering.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition. The exceptions permit us, among other things and subject to restrictions, to: (a) issue common stock or options pursuant to employee benefit plans or (b) issue common stock upon exercise of outstanding options or warrants. The exceptions permit parties to the ‘‘lock-up’’ agreements, among other things and subject to restrictions, to: (a) participate in tenders involving the acquisition of a majority of our stock, (b) participate in transfers or exchanges involving common stock or securities convertible into common stock or (c) make certain gifts. In addition, the lock-up provision will not restrict broker-dealers from engaging in market making and similar activities conducted in the ordinary course of their business.

Electronic Offer, Sale and Distribution of Shares. A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representatives may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

Other Relationships. Certain of the underwriters and their affiliates have provided, and may in the future provide, various investment banking, commercial banking and other financial services for us and our affiliates for which they are received, and may in the future receive, customary fees.

Directed Share Program

At our request, the underwriters have reserved up to 5.0% of the shares of common stock offered by this prospectus for sale, at the initial public offering price, to our directors, officers, employees, investors and their affiliated entities, and other individuals associated with us and members of their respective families. The sales will be made by RBC Wealth Management, a selected dealer affiliated with RBC Capital Markets, LLC, an underwriter of this offering, through a directed share program. We do not know if these persons will choose to purchase all or any portion of these reserved shares, but any purchases they do make will reduce the number of shares available to the general public. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares of common stock. Any shares of common stock sold to our director or executive officers pursuant to the directed share program will be subject to the 180-day lock-up restrictions described above.

Selling Restrictions

No action has been taken in any jurisdiction except the United States that would permit a public offering of our common stock, or the possession, circulation or distribution of this prospectus or any other material relating to us or our common stock in any jurisdiction where action for that purpose is required. Accordingly, the shares may not be offered or sold, directly or indirectly, and neither this prospectus nor any other offering material or advertisements in connection with the shares may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable rules and regulations of any such country or jurisdiction.

United Kingdom

Each of the underwriters has, separately and not jointly, represented and agreed that:

- it has not made or will not make an offer of the securities to the public in the United Kingdom within the meaning of Section 102B of the Financial Services and Markets Act 2000 (as amended), or the FSMA, except to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities or otherwise in circumstances which do not require the publication by us of a prospectus pursuant to the Prospectus Rules of the Financial Services Authority, or FSA;
- it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of FSMA) to persons who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 or in circumstances in which Section 21 of FSMA does not apply to us; and
- it has complied with and will comply with all applicable provisions of FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the United Kingdom.

European Economic Area

In relation to each Member State of the European Economic Area (Iceland, Norway and Lichtenstein in addition to the member states of the European Union) that has implemented the Prospectus Directive (each, a Relevant Member State), each underwriter has, separately and not jointly, represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, or the Relevant Implementation Date, it has not made and will not make an offer of the securities to the public in that Relevant Member State prior to the publication of a prospectus in relation to the securities that has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that it may, with effect from and including the Relevant Implementation Date, make an offer of the securities to the public in that Relevant Member State at any time:

- to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts; and
- in any other circumstances which do not require the publication by the issuer of a prospectus pursuant to Article 3 of the Prospectus Directive.

Each person in a Relevant Member State who receives any communication in respect of, or who acquires any securities under, the offer contemplated in this prospectus will be deemed to have represented, warranted and agreed to and with us and the underwriters that:

- it is a qualified investor within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive; and
- in the case of any securities acquired by it as a financial intermediary, as that term is used in Article 3(2) of the Prospectus Directive, (1) the securities acquired by it in the offer have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant Member State other than qualified investors, as that term is defined in the Prospectus Directive, or in circumstances in which the prior consent of the underwriters has been given to the offer or resale; or (2) where securities have been acquired by it on behalf of persons in any Relevant Member State other than qualified investors, the offer of those securities to it is not treated under the Prospectus Directive as having been made to such persons.

For the purposes of the provisions in the two immediately preceding paragraphs, the expression an “offer of the securities to the public” in relation to the securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State, and the expression “Prospectus Directive” means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

Israel

In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase securities under the Israeli Securities Law, 5728 – 1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728–1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions (the “Addressed Investors”); or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728 – 1968, subject to certain conditions (the “Qualified Investors”). The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. The company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728 – 1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our securities to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728 – 1968. In particular, we may request, as a condition to be offered securities, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728 – 1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728 – 1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728 – 1968 and the regulations promulgated thereunder in connection with the offer to be issued securities; (iv) that the securities that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728 – 1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728 – 1968; and (v) that it is willing to provide further evidence of its Qualified Investor

status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

Other Relationships

Cowen KP Investment LLC, an affiliate of Cowen and Company, LLC, purchased 3,200,000 shares of Series D-1 redeemable convertible preferred stock on February 19, 2015, which shares are deemed to be underwriting compensation by FINRA. The shares of Series D-1 redeemable convertible preferred stock will automatically convert into common stock upon closing of this offering at a conversion price of 87.5% of the initial public offering price of the Common Stock. At the initial public offering price of $11.00 per share of common stock, Cowen KP Investment LLC will receive 415,584 shares of common stock. Pursuant to the requirements of FINRA Rule 5110(g)(1), none of the shares of Series D-1 redeemable convertible preferred stock, or the shares of common stock into which the Series D-1 redeemable convertible preferred stock is convertible, may be sold, transferred, assigned, pledged or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the common stock, for a period of 180 days following the date the registration statement, of which this prospectus forms a part, is declared effective by the SEC, except as permitted by Rule 5110(g)(2).

LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Cooley LLP, Broomfield, Colorado. A partner of Cooley LLP is our secretary. Certain legal matters related to this offering will be passed upon for the underwriters by Morgan, Lewis & Bockius LLP, New York, New York.

EXPERTS

The financial statements of KemPharm, Inc. at December 31, 2013 and 2014, and for the years then ended appearing in this prospectus and registration statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to our company and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the internet at the SEC's website at *www.sec.gov*. You may also read and copy any document we file with the SEC at its public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

Upon completion of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We also maintain a website at *www.kempharm.com*, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of KemPharm, Inc.:

We have audited the accompanying balance sheets of KemPharm, Inc. as of December 31, 2013 and 2014, and the related statements of operations, changes in redeemable convertible preferred stock and stockholders' deficit and cash flows for each of the two years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, 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, 2013 and 2014, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has recurring losses from operations and has a stockholders' deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Minneapolis, Minnesota
March 11, 2015, except for the effect of the reverse stock split discussed in the fifth paragraph of Note 16 to the financial statements, as to which the date is April 3, 2015

KEMPHARM, INC.

BALANCE SHEETS

	As of December 31,		Pro forma December 31,
	2013	2014	2014
			(unaudited)
Assets			
Current assets:			
Cash and cash equivalents	$ 1,968,632	$ 10,255,021	$ 10,255,021
Prepaid expenses and other current assets	70,970	22,593	22,593
Total current assets	2,039,602	10,277,614	10,277,614
Debt issuance costs, net	–	1,467,959	1,467,959
Property and equipment, net	380,203	352,194	352,194
Other long-term assets	9,179	1,616,013	1,616,013
Total assets	$ 2,428,984	$ 13,713,780	$ 13,713,780
Liabilities, redeemable convertible preferred stock, and stockholders' deficit			
Current liabilities:			
Accounts payable and accrued expenses	$ 1,365,574	$ 3,903,055	$ 3,903,055
Current portion of capital lease obligation	31,303	31,507	31,507
Convertible notes	3,846,000	–	–
Total current liabilities	5,242,877	3,934,562	3,934,562
Convertible notes, net of discount	–	7,235,441	7,235,441
Term notes, net of discount	–	10,853,162	10,853,162
Line of credit	34,845	–	–
Derivative and warrant liability	2,813,260	15,965,891	15,965,891
Capital lease obligation, net of current portion	57,919	26,412	26,412
Total liabilities	8,148,901	38,015,468	38,015,468
Commitments and contingencies (Note 7)			
Redeemable convertible preferred stock:			
Series A redeemable convertible preferred stock, $0.0001 par value; 10,000,000 and 9,705,000 shares authorized, 9,704,215 shares issued and outstanding as of December 31, 2013 and 2014; no shares issued and outstanding pro forma; liquidation preference of $3,881,686 as of December 31, 2014	3,342,849	3,342,849	–
Series B redeemable convertible preferred stock, $0.0001 par value; 7,000,000 and 6,220,000 shares authorized, 6,220,000 shares issued and outstanding as of December 31, 2013 and 2014; no shares issued and outstanding pro forma; liquidation preference of $3,856,400 as of December 31, 2014	3,312,465	3,312,465	–
Series C redeemable convertible preferred stock, $0.0001 par value; 33,000,000 and 18,558,000 shares authorized, 18,557,408 shares issued and outstanding as of December 31, 2013 and 2014; no shares issued and outstanding pro forma; liquidation preference of $14,474,778 as of December 31, 2014	11,892,066	11,892,066	–
Series D redeemable convertible preferred stock, $0.0001 par value; 0 and 75,000,000 shares authorized, 0 and 7,255,425 shares issued and outstanding as of December 31, 2013 and 2014, respectively; no shares issued and outstanding pro forma; liquidation preference of $5,659,232 as of December 31, 2014	–	5,659,232	–
Total redeemable convertible preferred stock	18,547,380	24,206,612	–
Stockholders' deficit:			
Common stock, no par value, 85,000,000 shares authorized, 2,381,041 shares issued and outstanding as of December 31, 2013; $0.0001 par value, 140,000,000 shares authorized, 2,381,041 shares issued and outstanding as of December 31, 2014; 7,945,593 shares issued and outstanding pro forma	1,438,302	238	795
Additional paid-in capital	–	1,651,822	25,857,877
Accumulated deficit	(25,705,599)	(50,160,360)	(50,160,360)
Total stockholders' deficit	(24,267,297)	(48,508,300)	(24,301,688)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	$ 2,428,984	$ 13,713,780	$ 13,713,780

See accompanying notes to financial statements.

KEMPHARM, INC.

STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2013	2014
Revenue	$ –	$ –
Operating expenses:		
Research and development	3,366,932	11,917,217
General and administrative	1,350,971	4,526,093
Total operating expenses	4,717,903	16,443,310
Loss from operations	(4,717,903)	(16,443,310)
Other (expense) income:		
Gain on extinguishment of debt	–	1,900,000
Interest expense	(1,716,869)	(2,715,350)
Fair value adjustment	1,137,348	(7,222,631)
Interest and other income	51,435	4,283
Total other expense	(528,086)	(8,033,698)
Loss before income taxes	(5,245,989)	(24,477,008)
Income tax benefit	19,544	22,247
Net loss	$ (5,226,445)	$ (24,454,761)
Net loss per share:		
Basic and diluted	$ (2.20)	$ (10.27)
Basic and diluted, pro forma (unaudited)		$ (3.13)
Weighted average common shares outstanding:		
Basic and diluted	2,381,041	2,381,041
Basic and diluted, pro forma (unaudited)		7,823,352

See accompanying notes to financial statements.

KEMPHARM, INC.

STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

	Redeemable Convertible Preferred Stock					Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Series								
	A	B	C	D	Total				
Balance as of January 1, 2013	$ 3,342,849	$ 3,312,465	$ 11,892,066	$ –	$ 18,547,380	$ 1,304,557	$ –	$ (20,479,154)	$ (19,174,597)
Net loss	–	–	–	–	–	–	–	(5,226,445)	(5,226,445)
Stock-based compensation expense	–	–	–	–	–	133,745	–	–	133,745
Balance as of December 31, 2013	3,342,849	3,312,465	11,892,066	–	18,547,380	1,438,302	–	(25,705,599)	(24,267,297)
Net loss	–	–	–	–	–	–	–	(24,454,761)	(24,454,761)
Adjustment for change in par value	–	–	–	–	–	(1,438,064)	1,438,064	–	–
Stock-based compensation expense	–	–	–	–	–	–	213,758	–	213,758
Conversion of 2013 Convertible Notes into Series D Preferred	–	–	–	4,159,232	4,159,232	–	–	–	–
Issuance of Series D Preferred as financing fee	–	–	–	1,500,000	1,500,000	–	–	–	–
Balance as of December 31, 2014	$ 3,342,849	$ 3,312,465	$ 11,892,066	$5,659,232	$ 24,206,612	$ 238	$1,651,822	$ (50,160,360)	$ (48,508,300)

See accompanying notes to financial statements.

KEMPHARM, INC.

STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2013	2014
Cash flows from operating activities:		
Net loss	$(5,226,445)	$(24,454,761)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss (gain) on sale or disposal of assets	11,876	(3,031)
Stock-based compensation expense	133,745	213,758
Non-cash interest expense	151,989	1,601,639
Amortization of debt issuance costs and debt discount	1,560,000	1,113,711
Depreciation and amortization expense	67,724	74,763
Gain on extinguishment of debt	–	(1,900,000)
Fair value adjustment	(1,137,348)	7,222,631
Change in assets and liabilities:		
Prepaid expenses and other current assets	(3,898)	523,077
Accounts payable and accrued expenses	126,300	934,127
Net cash used in operating activities	(4,316,057)	(14,674,086)
Cash flows from investing activities:		
Proceeds from sale of assets	5,000	5,000
Purchases of property and equipment	(50,968)	(48,723)
Net cash used in investing activities	(45,968)	(43,723)
Cash flows from financing activities:		
Proceeds from issuance of debt	3,846,000	25,000,000
Repayment of line of credit	(4,516)	(34,845)
Payment of deferred offering costs	–	(1,766,587)
Payment of debt issuance costs	–	(163,067)
Repayment of obligations under capital lease	(52,514)	(31,303)
Net cash provided by financing activities	3,788,970	23,004,198
Increase (decrease) in cash and cash equivalents	(573,055)	8,286,389
Cash and cash equivalents, beginning of year	2,541,687	1,968,632
Cash and cash equivalents, end of year	$ 1,968,632	$ 10,255,021
Supplemental cash flow information:		
Cash paid for interest	$ 4,880	$ 2,577
Non-cash financing and investing activities:		
Conversion Feature on 2013 Convertible Notes and Put Option	$ 1,150,000	$ –
Issuance of 2013 Warrants and Deerfield Warrant	$ 410,000	$ 7,610,000
Fixed assets financed by capital lease	$ 94,388	$ –
Embedded Deerfield Put Option on Deerfield Warrant	$ –	$ 220,000
Issuance of Series D Preferred as transaction fee	$ –	$ 1,500,000
Conversion of 2013 Convertible Notes and interest into Series D Preferred	$ –	$ 4,159,232
Deferred offering costs included in accounts payable and accrued expenses	$ –	$ 314,947

See accompanying notes to financial statements.

KEMPHARM, INC.

NOTES TO FINANCIAL STATEMENTS

1. 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 new molecular entity (NME) prodrugs. The Company was formed on October 30, 2006 and incorporated in Iowa. 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 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, 2014. 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.

The Company has financed its operations primarily through issuances of redeemable convertible preferred stock and convertible notes. Although the Company believes that it will be able to successfully fund its operations, there can be no assurances that the Company would be successful in obtaining additional financing.

Domicile Change

During 2014, the Company's board of directors unanimously approved and authorized the Company to change its domicile from Iowa to Delaware. The domicile change became effective on May 30, 2014.

Concurrent with the domicile change, the Company amended its Certificate of Incorporation to increase the number of its authorized shares of capital stock and create a par value for the shares. Following the amendment, the Company was authorized to issue 140,000,000 shares of common stock, par value $0.0001 per share, and 109,483,000 shares of preferred stock, par value $0.0001 per share. As a result of the change to par value common stock, the Company recorded an adjustment of $1,438,064 to reduce common stock and record additional paid-in capital.

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. See Note 16.

2. Summary of Significant Accounting Policies

Unaudited Pro Forma Presentation

The unaudited pro forma net loss per share for the year ended December 31, 2014 assumes (i) the conversion of the 2013 Convertible Notes as of January 1, 2014 or at the time the interest is accrued, and (ii) the conversion of all outstanding shares of redeemable convertible preferred stock as of January 1, 2014 or the time of issuance, if later, into an aggregate of 5,564,552 shares of common stock upon the completion of an initial public offering (IPO) (Note 14).

KEMPHARM, INC.

NOTES TO FINANCIAL STATEMENTS (continued)

The Company believes that the unaudited pro forma information is material to investors because certain convertible notes converted into redeemable convertible preferred stock during the year ended December 31, 2014 and the conversion of the redeemable convertible preferred stock into common stock will occur upon the closing of an IPO. Therefore, the disclosure provides a measure of total liabilities, stockholders' deficit and net loss per share that is comparable to what the Company will report as a public company.

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

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.

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 five 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.

Deferred Offering Costs

Upon the consummation of the Company's planned IPO, deferred offering costs will be offset against the gross proceeds of the offering and included in stockholders' deficit. If the offering is aborted, the deferred offering costs will be expensed immediately. Deferred offering costs of $0 and $1.5 million, consisting primarily of incremental legal and accounting fees incurred directly relating to the IPO, are included in other long-term assets on the balance sheets as of December 31, 2013 and 2014, respectively.

KEMPHARM, INC.

NOTES TO FINANCIAL STATEMENTS (continued)

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 8).

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 had occurred as of December 31, 2013 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.

KEMPHARM, INC.

NOTES TO FINANCIAL STATEMENTS (continued)

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 statement 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 as of December 31, 2013 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 2010 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 valuation 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, 2013 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 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 did not have a material impact on its financial statements as no uncertain tax positions existed as of December 31, 2013 and 2014.

In June 2014, the FASB issued ASU No. 2014-10, *Development Stage Entities* (Topic 915): *Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation* (ASU 2014-10). This ASU removes all incremental financial reporting requirements for development stage entities, including the removal of Topic 915 from the FASB Accounting Standards Codification (ASC). The amendments in this ASU eliminate certain disclosure requirements to (1) present inception-to-date information in the statements of income, cash flows and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the

entity is engaged and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. The ASU clarifies that disclosures about risks and uncertainties required by Topic 275 also apply to entities that have not commenced planned principal operations.

The Company elected to early adopt ASU 2014-10 in 2013. The amendments primarily relate to disclosure matters and, therefore, have no impact on the Company's financial statements, other than the elimination of previously required disclosures including inception-to-date financial information.

Application of New or Revised Accounting Standards—Not Yet Adopted

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 is currently evaluating the impact of the adoption of ASU 2014-12 on its financial statements and disclosures.

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 May 2014, the FASB issued guidance codified in ASC 606, *Revenue Recognition—Revenue from Contracts with Customers*, which amends the guidance in former ASC 605, *Revenue Recognition*, and becomes effective beginning January 1, 2017. The Company is currently evaluating the impact of the provisions of ASC 606 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*, 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. This ASU 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.

3. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	December 31,	
	2013	2014
Income tax receivable	$ 20,427	$22,415
Leased equipment deposit	41,760	—
Other current assets	8,783	178
Total	$70,970	$22,593

4. Property and Equipment

Property and equipment consists of the following:

	December 31,	
	2013	2014
Laboratory equipment	$ 537,058	$ 530,495
Computers and hardware	56,156	72,691
Furniture and office equipment	105,048	137,235
Leasehold improvements	6,226	6,226
Total property and equipment	704,488	746,647
Less: accumulated depreciation and amortization	(324,285)	(394,453)
Property and equipment, net	$ 380,203	$ 352,194

The Company leases various equipment under capital lease agreements. The assets under capital leases are included in property and equipment as follows:

	December 31,	
	2013	2014
Furniture and office equipment	$ 94,388	$ 94,388
Less: accumulated depreciation and amortization	(3,146)	(12,585)
	$91,242	$ 81,803

The estimated useful lives of property and equipment are as follows:

Asset Category	Useful Life (in years)
Laboratory equipment	10
Computers and hardware	5-7
Furniture and office equipment	5-10
Leasehold improvements	10-15

Depreciation and amortization expense, including amounts pertaining to assets held under capital leases, was $67,724 and $74,763 for the years ended December 31, 2013 and 2014, respectively.

5. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	December 31,	
	2013	2014
Accounts payable	$ 386,071	$1,670,486
Accrued interest	151,989	1,437,846
Accrued banking fees	700,000	700,000
Accrued payroll	127,514	94,723
Total	$1,365,574	$3,903,055

6. Debt Obligations

Convertible Notes

From June 2013 through October 2013, the Company issued 10.0% unsecured convertible promissory notes (the 2013 Convertible Notes) for gross proceeds of $3,846,000. The 2013 Convertible Notes accrue interest from the date of issuance through the date of maturity, with such interest payable in cash upon maturity. The 2013 Convertible Notes do not have a stated maturity date and mature instead 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 (the Put Option). The principal amount and accrued interest of the 2013 Convertible Notes automatically convert (the Conversion Feature) into subsequently issued equity securities if the Company issues equity securities in a transaction or series of related transactions that result in aggregate gross proceeds to the Company of at least $7,500,000 (a Qualified Financing). Upon a Qualified Financing, the principal amounts of the 2013 Convertible Notes and all accrued interest automatically convert into the equity securities issued pursuant to the Qualified Financing at a conversion price equal to the per share price paid by the purchasers of such equity securities in the Qualified Financing.

In connection with the issuance of the 2013 Convertible Notes, the Company also issued warrants (the 2013 Warrants) to purchase 1,079,453 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. Upon the closing of an IPO, the 2013 Warrants will be exercisable only into shares of the Company's common stock. The fair value of the 2013 Warrants at issuance was recorded as a debt discount. The Company determined that the 2013 Warrants should be recorded as a liability and stated at fair value at each reporting period (Notes 9 and 12).

The Company accounted for the embedded Conversion Feature and Put Option in the 2013 Convertible Notes under the derivative accounting guidance. Under this guidance, a company may be required to bifurcate an embedded feature from its host instrument and account for the embedded derivative as a free-standing derivative financial instrument that is measured at fair value at issuance and adjusted to its current fair value at each period. The Company determined that the embedded Conversion Feature and Put Option should be bifurcated from the 2013 Convertible Notes and recorded at fair value. The fair value of the Conversion Feature and Put Option was $1,150,000 at

issuance and $1,360,000 at December 31, 2013 (Note 12). The fair value of the Conversion Feature and Put Option was $0 at December 31, 2014 since the 2013 Convertible Notes were converted in June 2014. Changes in fair value of the Conversion Feature and Put Option are recorded as a fair value adjustment within other (expense) income in the statements of operations.

Deerfield Facility Agreement

On June 2, 2014, the Company entered into a $60,000,000 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 bear interest at 9.75% per annum. The Company also issued to Deerfield a warrant to purchase 14,423,076 shares of Series D redeemable convertible preferred stock (Series D Preferred) at an exercise price of $0.78 per share, which is exercisable until June 2, 2024 (the Deerfield Warrant). 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 Embedded Deerfield 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) after an IPO, the shares of common stock cease to be listed on any eligible market; and (vi) after an IPO, the shares of common stock cease to be registered under Section 12 of the Exchange Act.

In addition, the Company issued to Deerfield 1,923,077 shares of Series D Preferred as consideration for the loans provided to the Company under the Deerfield facility. The Company recorded the fair value of the shares of Series D Preferred of $1,500,000 to debt issuance costs on the date of issuance. The Company recorded the fair value of the Deerfield Warrant of $7,610,000 and the fair value of the Embedded Deerfield Put Option of $220,000 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, provided that all such interest will be due on July 1, 2016.

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.

KEMPHARM, INC.

NOTES TO FINANCIAL STATEMENTS (continued)

As of December 31, 2014, borrowings available to the Company under the Deerfield Facility Agreement were $35,000,000. Under the terms of the Deerfield Facility Agreement, future tranches to the Company are as follows:

- The second tranche consists of a $10,000,000 term loan that bears interest at 9.75% and a warrant to purchase 9,615,385 shares of Series D Preferred at an exercise price of $0.78.
- The third and fourth tranches each consist of a $12,500,000 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 to such weighted average sales price.

Deerfield may convert all or any portion of the outstanding principal and any accrued but unpaid interest on the Deerfield Convertible Notes into shares of Series D Preferred at an initial conversion price of $0.78 per share. At its option, the Company may convert the outstanding principal and accrued interest under the Deerfield Convertible Notes into shares of Series D Preferred at an initial conversion price of $0.78 per share if either of the following occurs prior to June 30, 2016: (i) the FDA has approved, without requiring the performance of an efficacy study, the NDA for KP201/APAP for the treatment of acute pain; or (ii) the FDA has accepted the NDA for KP201/APAP for review and a qualified IPO, as defined in the Deerfield Facility Agreement, has occurred.

Upon the closing of an IPO, the Deerfield Convertible Notes will be convertible only into shares of the Company's common stock upon the election of the note holder. Similarly, the Deerfield Warrant will be exercisable only for shares of the Company's common stock upon the closing of an IPO.

Conversion of 2013 Convertible Notes into Series D Preferred

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 $3,846,000 and all accrued interest of $313,232 converted into 5,332,348 shares of Series D Preferred at $0.78 per share. Upon the conversion of the 2013 Convertible Notes, the embedded Conversion Feature and Put Option was marked to fair value and the balance of $1,900,000 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, 2013 and 2014, the Company had $15,155 and $50,000 available under the Line of Credit Agreement, respectively. The Line of Credit Agreement is collateralized by all of the Company's business assets as well as the personal guarantees of the Company's officers. 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% for the years ended December 31, 2013 and 2014.

KEMPHARM, INC.

NOTES TO FINANCIAL STATEMENTS (continued)

7. 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 and current warrant holder 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 judgment finding that such purported right was invalid and unenforceable. A trial date for this matter has been scheduled for August 2015 and the Company is unable to predict the timing or outcome of this litigation as of the date of this report. However, if it is determined that such purported right of first refusal and right to receive a cash fee related to any such specified strategic transactions are valid, then the Company could be required to pay the counterparty a portion of the consideration or proceeds received in any such specified strategic transaction, including the Company's IPO and future capital raising transactions.

Lease Agreements

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. The Company leases office space in Florida under a long-term non-cancelable operating lease, which expires in October 2017.

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, 2014, the interest rate for assets under remaining capital leases was 0.65%.

Rent expense for non-cancelable operating leases was $144,896 and $193,372 for the years ended December 31, 2013 and 2014, respectively.

Future minimum lease payments under capital leases and non-cancelable operating leases as of December 31, 2014 were as follows:

Year Ending December 31,	Capital Leases	Operating Leases
2015	$ 31,789	$ 168,101
2016	26,492	146,923
2017	—	65,494
Total minimum lease payments	58,281	$ 380,518
Less: amounts representing interest	(362)	
Total	$ 57,919	

KEMPHARM, INC.

NOTES TO FINANCIAL STATEMENTS (continued)

8. Supply Arrangement

As of December 31, 2014, 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 with Johnson Matthey Inc. (JMI) whereby JMI has agreed to supply the Company with all of the KP201, the Company's NME prodrug of hydrocodone, 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. KP201/APAP is designed to provide abuse-deterrent properties, which will be useful to address issues such as opioid abuse. The Company intends to submit 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, 2013 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 Federal Drug Administration approved drug incorporating KP201. No reliable estimate of the future payments can be made at this time.

9. Redeemable Convertible Preferred Stock and Warrants

Authorized, Issued, and Outstanding Redeemable Convertible Preferred Stock

Effective May 30, 2014, the Company amended its Certificate of Incorporation to increase the number of its authorized shares of preferred stock to 109,483,000 shares with a par value of $0.0001 per share.

The following table summarizes authorized, issued and outstanding Series A redeemable convertible preferred stock (Series A Preferred), Series B redeemable convertible preferred stock (Series B Preferred), Series C redeemable convertible preferred stock (Series C Preferred) and Series D Preferred as of December 31, 2014:

	Authorized	Outstanding	Issue Price	Conversion Price	Liquidation Preference
Series A Preferred	9,705,000	9,704,215	$ 0.40	$ 3.00	$ 3,881,686
Series B Preferred	6,220,000	6,220,000	$ 0.62	$ 4.65	3,856,400
Series C Preferred	18,558,000	18,557,408	$ 0.78	$ 5.85	14,474,778
Series D Preferred	75,000,000	7,255,425	$ 0.78	$ 5.85	5,659,232
Total	109,483,000	41,737,048			$27,872,096

KEMPHARM, INC.

NOTES TO FINANCIAL STATEMENTS (continued)

Preferred Stock Activity

The following table summarizes redeemable convertible preferred stock activity for the years ended December 31, 2013 and 2014:

	Shares of				
	Series A Preferred	Series B Preferred	Series C Preferred	Series D Preferred	Total
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

Series A Redeemable Convertible Preferred Stock (Series A Preferred)

On June 18, 2008, the Company adopted a resolution to amend its Articles of Incorporation to increase the number of authorized shares to 75,000,000, consisting of 50,000,000 shares of common stock, no par value, and 25,000,000 shares of preferred stock, no par value, of which 10,000,000 shares are designated as Series A Preferred.

On June 23, 2008, the Company entered into a private placement offering to secure additional equity capital. The private placement offering resulted in the issuance of 7,500,000 shares of Series A Preferred at $0.40 per share and the later issuance of warrants to purchase 99,929 shares of common stock at $3.90 per share. The gross proceeds of the private placement offering totaled $3,000,000 and direct offering costs were $403,757 resulting in net proceeds to the Company of $2,596,243. The warrants were separately issued to the placement agent for the private offering (Note 10).

During 2009, certain convertible debentures were exchanged for Series A Preferred. As a result, the Company issued 2,204,215 Series A Preferred shares for full redemption of the debentures.

Series B Redeemable Convertible Preferred Stock (Series B Preferred)

On April 22, 2009, the Company adopted a resolution to amend its Articles of Incorporation to authorize 7,000,000 shares of Series B Preferred, no par value.

On April 22, 2009, the Company entered into a private placement offering to secure additional equity capital. The private placement offering resulted in the issuance of 6,220,000 shares of Series B Preferred at $0.62 per share and the issuance of warrants to purchase 82,895 shares of common stock at $4.65 per share. The gross proceeds of the private placement offering totaled $3,856,400 and direct offering costs were $357,335, resulting in net proceeds to the Company of $3,499,065. The warrants were separately issued to the placement agent for the private offering (Note 10).

KEMPHARM, INC.

NOTES TO FINANCIAL STATEMENTS (continued)

Series C Redeemable Convertible Preferred Stock (Series C Preferred)

On July 15, 2010, the Company adopted a resolution to amend its Articles of Incorporation to authorize 18,000,000 shares of Series C Preferred, no par value.

During 2010, the Company entered into a private placement offering to secure additional equity capital. In 2010, a total of 5,617,835 shares of Series C Preferred were sold at $0.78 per share. In conjunction with the private placement offering, the Company also issued a warrant to purchase 112,289 shares of common stock at $5.85 per share. The gross proceeds of the private placement offering totaled $4,381,916 and direct offering costs were $405,074, resulting in net proceeds to the Company of $3,976,842. The warrant was separately issued to the placement agent for the private offering (Note 10).

On July 15, 2011, the Company adopted a resolution to amend its Articles of Incorporation to increase the number of authorized shares of common stock, no par value, from 70,000,000 to 85,000,000 and Class C Preferred, no par value, from 18,000,000 to 33,000,000.

During 2011, the Company entered into a private placement offering to secure additional equity capital. The Company sold a total of 12,158,638 shares of Series C Preferred at $0.78 per share. In conjunction with the private placement offering, the Company also issued warrants to purchase 242,911 shares of common stock at $5.85 per share. The gross proceeds of the private placement offering totaled $9,483,738 and direct offering costs were $892,070, resulting in net proceeds to the Company of $8,591,668. The warrants were separately issued to the placement agent for the private offering.

During 2012, the Company sold a total of 864,268 shares of Series C Preferred at $0.78 per share. In conjunction with the private placement offering, the Company also issued warrants to purchase 16,430 shares of common stock at $5.85 per share. The gross proceeds of the private placement offering totaled $674,129 and direct offering costs were $148,636, resulting in net proceeds to the Company of $525,493. The warrants were separately issued to the placement agent for the private offering. In addition, 83,333 shares of Series C Preferred were repurchased from a former employee of the Company at $0.78 per share.

Series D Redeemable Convertible Preferred Stock

During 2014, the Company issued 7,255,425 shares of Series D Preferred at $0.78 per share in connection with the Qualified Financing (Note 6). On June 2, 2014, the Company issued 5,332,348 shares of Series D Preferred upon conversion of the 2013 Convertible Notes and 1,923,077 shares of Series D Preferred to Deerfield as a financing fee.

Significant terms of the redeemable convertible preferred stock (together the Preferred Stock) are as follows:

Conversion Rights

Each share of Series A Preferred, Series B Preferred, Series C Preferred and Series D Preferred is convertible, at the option of the holder, at any time after the date of issuance into the number of shares of common stock determined by dividing the original issue price by the conversion price upon a qualifying liquidation or capital event.

KEMPHARM, INC.

NOTES TO FINANCIAL STATEMENTS (continued)

The initial conversion price of each share will be adjusted for stock splits, combinations, recapitalizations, reclassifications and similar events. The conversion price is subject to adjustment if the Company issues additional shares of common stock at a price less than the Series A Preferred, Series B Preferred, Series C Preferred and/or Series D Preferred conversion prices in effect at the time of such issuance.

All outstanding shares of Preferred Stock automatically convert into shares of common stock upon the closing of a Qualified Public Offering; an underwritten public offering of common stock that is not a Qualified Public Offering but that is approved by Deerfield and the board of directors; or the date specified by written consent or agreement of the holders of a majority of the then-outstanding shares of Preferred Stock, voting together as a separate class on an as-converted to common stock basis. A Qualified Public Offering is defined as the closing of the sale of shares of common stock to the public at a price of at least $9.375 per share in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, with at least $25,000,000 of gross proceeds to the Company and a listing of the common stock on the NASDAQ Stock Market or the New York Stock Exchange.

Dividend Rights

With respect to the Company's payment of dividends or distributions, if any, the Series D Preferred ranks senior in priority to the Series C Preferred, which ranks senior in priority to the Series B Preferred, which ranks senior in priority to the Series A Preferred, which ranks senior in priority to all shares of common stock. Such dividends are payable only when, and if, declared by the board of directors and are noncumulative.

Voting Rights

The Company's Series A Preferred, Series B Preferred and Series C Preferred are non-voting except to the extent voting rights are required by General Corporation Law of the State of Delaware. Each holder of Series D Preferred is entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of Series D Preferred held by such holder are convertible. Holders of Series D Preferred vote together with the holders of common stock as a single class.

Liquidation

Upon an Event of Liquidation, subject to the prior payment of any and all amounts required under the Deerfield Convertible Notes, the Deerfield Warrant and the Term Note, the assets and funds of the Company legally available for distribution, if any, shall be distributed among the holders of common stock and Preferred Stock as follows:

- Before any distribution or payment is made to any holder of common stock, Series A Preferred, Series B Preferred or Series C Preferred, the holders of shares of Series D Preferred are entitled to be paid an amount equal to the liquidation preference amount with respect to each share of Series D Preferred. If the holders of Series D Preferred have been paid in full the liquidation preference amounts to which they are entitled, then, before any distribution or payment is made to any holder of common stock, Series A Preferred or Series B Preferred, the holders of shares of Series C Preferred are entitled to be paid an amount equal to the liquidation preference amount with respect to each share of Series C Preferred. If the holders of Series D Preferred and the Series C Preferred have been paid in full the liquidation preference amounts to which they are entitled, then, before any distribution or payment is

made to any holder of common stock or Series A Preferred, the holders of shares of Series B Preferred are entitled to be paid an amount equal to the liquidation preference amount with respect to each share of Series B Preferred. If the holders of Series D Preferred, the Series C Preferred, and the Series B Preferred have been paid in full the liquidation preference amounts to which they are entitled, then, before any distribution or payment is made to any holder of common stock, the holders of shares of Series A Preferred are entitled to be paid an amount equal to the liquidation preference amount with respect to each share of Series A Preferred.

- If, upon an Event of Liquidation, holders of the Preferred Stock have been paid in full the liquidation preference amounts to which they are entitled, the remaining assets and funds of the Company legally available for distribution, if any, will be distributed among the holders of the common stock and the Preferred Stock in proportion to the shares of common stock then held by them and the shares of common stock that they have the right to acquire upon conversion of the shares of Preferred Stock.

An Event of Liquidation means (i) any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, or (ii) any Deemed Liquidation Event. A Deemed Liquidation Event means (i) any merger, consolidation or share exchange transaction in which the Company is a party and the Company issues shares of its capital stock pursuant to such merger or consolidation (except any such merger, consolidation or share exchange involving the Company in which the shares of capital stock of the Company outstanding immediately prior to such merger, consolidation or share exchange continue to represent, or are converted into or exchanged for, shares of capital stock that represent, immediately following such merger or consolidation, at least a majority, by voting power, of the capital stock of the surviving or resulting corporation) or (ii) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Company of all or substantially all the assets or capital stock of the Company.

As a result of the existence of the deemed liquidation feature, the Company determined that all series of Preferred Stock are redeemable upon the occurrence of a deemed liquidation event. They are carried at initial fair value at each reporting period and excluded from stockholders' deficit in the accompanying balance sheets. If the occurrence of a deemed liquidation event becomes probable, all series of the Preferred Stock will be adjusted to liquidation value during that period.

Series D Preferred Protective Provisions

The Company cannot take any of the following actions without the written consent or affirmative vote of the holders of at least a majority of the issued and outstanding shares of Series D Preferred, which majority must include Deerfield:

- liquidate, dissolve or wind up the business of the Company, or effect any merger or consolidation or any other Deemed Liquidation Event;
- amend, alter or repeal any provision of the Certificate of Incorporation or Bylaws in a manner that adversely affects the holders of Series D Preferred;
- create or issue shares of any additional class of capital stock unless the same ranks junior to the Series D Preferred with respect to distributions upon an Event of Liquidation, the payment of dividends and rights of redemption;
- increase the authorized number of shares of Series D Preferred or increase the authorized number of shares of any other class of capital stock unless the same ranks junior to the Series D Preferred with respect to distributions upon an Event of Liquidation, the payment of dividends and rights of redemption;

KEMPHARM, INC.

NOTES TO FINANCIAL STATEMENTS (continued)

- issue any shares of Series D Preferred other than as contemplated by the Deerfield Facility Agreement, the Deerfield Convertible Notes or the Deerfield Warrant;
- reclassify, alter or amend any existing security of the Company (i) that is pari passu with the Series D Preferred with respect to distributions payable upon an Event of Liquidation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to the Series D Preferred with respect to any such right, preference or privilege or (ii) that is junior to the Series D Preferred with respect to distributions payable upon an Event of Liquidation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to or pari passu with the Series D Preferred with respect to any such right, preference or privilege;
- declare, pay, or make any dividends or other distributions to any holders of common stock, Series A Preferred, Series B Preferred, Series C Preferred, or any other capital stock that is junior to the Series D Preferred with respect to the payment of dividends or distributions, or to any holders of shares of a class of capital stock issued following the Series D Preferred original issue date that is pari passu to the Series D Preferred with respect to the payment of dividends;
- purchase, redeem or otherwise acquire any shares of common stock, Series A Preferred, Series B Preferred, Series C Preferred, or any other capital stock that is junior to the Series D Preferred, or to any holders of shares of a class of capital stock issued following the Series D Preferred original issue date that is pari passu to the Series D Preferred; *provided*, *however*, that the approval by the Series D Preferred and Deerfield is not required for: (1) shares repurchased from former employees, consultants or directors of the Company in accordance with restricted stock purchase agreements with such employees, consultants or directors entered into with approval of the board of directors, (2) the repurchase of up to $100,000 of additional shares, in the aggregate, of such junior or pari passu classes or series of capital stock, and (3) redemptions of the Series D Preferred as expressly authorized in the Certificate of Incorporation; or
- increase or decrease the authorized number of directors constituting the board of directors.

Warrants

As of December 31, 2014, outstanding warrants to purchase the Company's Series D Preferred were as follows:

Issuance Date	Number of Underlying Shares	Exercise Price
2013	1,079,453	$ 0.78
2014	14,423,076	$ 0.78
	15,502,529	

During 2013, the Company issued $3,846,000 of 2013 Convertible Notes and the 2013 Warrants to purchase 1,079,453 shares of equity securities in a future financing meeting specified criteria (a Qualified Financing) (Note 6). 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. The 2013 Warrants, if unexercised, expire on the earlier of June 2, 2019 or upon a liquidation event.

KEMPHARM, INC.

NOTES TO FINANCIAL STATEMENTS (continued)

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. 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. 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. Changes to the fair value of the warrant liability are recorded through the statements of operations as a fair value adjustment (Note 12).

10. Common Stock and Warrants on Common Stock

Authorized, Issued, and Outstanding Common Shares

Effective May 30, 2014, the Company amended its Certificate of Incorporation to increase the number of its authorized shares of common stock to 140,000,000 shares and change the common stock from no par value to $0.0001 per share. Of the authorized shares, 2,381,041 shares were issued and outstanding at December 31, 2013 and 2014.

At December 31, 2014, the Company had reserved authorized shares of common stock for future issuance as follows:

	Shares of Common Stock
Conversion of Series A Preferred	1,293,838
Conversion of Series B Preferred	829,234
Conversion of Series C Preferred	2,474,121
Conversion of Series D Preferred	967,359
Conversion of Deerfield Convertible Notes	1,808,353
Outstanding Series D Preferred Warrants	2,066,970
Outstanding awards under Incentive Stock Plan	395,185
Outstanding common stock warrants	595,920
Possible future issuances under Incentive Stock Plan	365,706
Total common shares reserved for future issuance	10,796,686

Common Stock Activity

There was no common stock activity during the years ended December 31, 2013 and 2014.

Liquidation Rights

In the event of any liquidation or dissolution of the Company, the holders of the common stock are entitled to share ratably with holders of the series of outstanding Preferred Stock, on an as-if-converted to common stock basis, in the remaining assets of the Company legally available for distribution after the payment of the full liquidation preference for all series of the outstanding Preferred Stock.

Dividends and Voting Rights

The holders of the common stock are entitled to receive dividends, when and if declared by the board of directors of the Company after all dividends on the Preferred Stock have been paid or funds have been set aside to pay such Preferred Stock dividends.

The holders of the common stock have the right to one vote per share of common stock.

Warrants on Common Stock

In connection with the issuances of Series A Preferred, Series B Preferred and Series C Preferred (Note 9), the Company issued warrants to purchase common stock to the underwriters as consideration for facilitating the private placements (Underwriter Warrants). The Underwriter Warrants were fully vested upon issuance and, if unexercised, expire on the earlier of the seventh anniversary of the issue date or upon the second anniversary of the first sale of securities to the public in an offering pursuant to an effective registration statement under the Securities Act. No Underwriter Warrants have been exercised since issuance and, as of December 31, 2014, the Company's outstanding Underwriter Warrants and related exercise price by issuance were as follows:

Issuance Date	Number of Underlying Shares	Exercise Price
2008/2009	99,929	$ 3.90
2009	82,895	$ 4.65
2010	112,289	$ 5.85
2011	242,911	$ 5.85
2012	16,430	$ 5.85
	554,454	

The Underwriter Warrants include down-round protection in that the exercise price is adjusted if the Company issues any additional shares of common stock, including securities convertible into or warrants exercisable for common stock, without consideration or for consideration per share (or conversion price or exercise price per share) less than the exercise price then in effect for the Underwriter Warrants. The Underwriter Warrants also allow for net share settlement under the terms of the contract.

The Company determined that the Underwriter Warrants do not meet the criteria for equity classification and, consequently, the Underwriter Warrants were recorded as liabilities within the derivative and warrant liability on the balance sheets. These liabilities are adjusted to fair value at each reporting period (Note 12) with the change in fair value recorded within fair value adjustment within other (expense) income in the statements of operations.

At December 31, 2013 and 2014, the fair value of the Underwriter Warrants was $1,053,260 and $2,745,891, respectively.

11. Stock-Based Compensation

The Company has a share-based compensation plan (the Incentive Stock Plan or the Plan) that is designed to allow the Company to attract and retain highly qualified employees and directors. No stock options were exercised during the years ended December 31, 2013 and 2014.

Under the Plan, the Company may grant awards of incentive stock, non-qualified stock options, and incentive stock options to employees, directors, and consultants. In July 2014, the Company's Incentive Stock Plan was revised to increase the maximum number of shares issuable under the Plan from 666,666 to 800,000. Of this amount, 365,706 shares were available for awards as of

December 31, 2014. Options may take the form of either incentive stock options or non-qualified stock options. Options granted under the Plan generally vest over one year to three years and expire in seven to 10 years from the date of grant. Stock-based compensation expense recorded under the Plan is included in the following line items in the accompanying statements of operations:

	Year Ended December 31,	
	2013	2014
Research and development	$ 29,296	$ 61,467
General and administrative	104,449	152,291
	$133,745	$213,758

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 current price of the underlying stock, 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 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, 2013 and 2014 was $3.00 and $4.50 per share, respectively. The assumptions used to estimate fair value are as follows:

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

KEMPHARM, INC.

NOTES TO FINANCIAL STATEMENTS (continued)

The activity under the Plan for the year ended December 31, 2014 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, 2014	296,256	$ 5.24	7.24	$ –
Granted	112,262	$ 5.85		
Exercised	–	–		
Cancelled	(13,333)	$ 5.85		
Outstanding balance at December 31, 2014	395,185	$ 5.40	7.24	$1,275,980
Exercisable at December 31, 2014	170,167	$ 4.80	5.71	$ 651,543
Vested and expected to vest at December 31, 2014	297,899	$ 5.25	6.47	$1,006,008

Information regarding currently outstanding and exercisable options as of December 31, 2014 is as follows:

	Options Outstanding		Options Exercisable	
Exercise Price	Number of Shares	Weighted-Average Remaining Contractual Term (in years)	Number of Shares	Weighted-Average Remaining Contractual Term (in years)
$0.75	12,000	2.50	12,000	2.50
$3.00	20,667	3.54	20,667	3.54
$4.65	49,327	3.61	49,327	3.61
$5.85	313,191	8.24	88,173	7.82
	395,185	7.24	170,167	5.71

The total fair value of stock options vested during the years ended December 31, 2013 and 2014 was $173,579 and $175,697, respectively.

Unvested stock options as of December 31, 2013 and 2014 were as follows:

	Number of Unvested Shares As of December 31	
Exercise Price	2013	2014
$5.85	161,511	225,018
	161,511	225,018

As of December 31, 2014, there was $495,093 of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under the Plan. That compensation cost is expected to be recognized over a weighted-average period of 1.56 years.

During 2012, certain executives were granted 80,000 performance-based stock options. These performance-based awards will vest if the Company achieves certain strategic initiatives, such as the achievement of certain clinical milestones or the occurrence of a liquidity event for stockholders. Compensation expense is recognized for the Company's performance-based grants when the milestone is met or when it is probable that the milestone will be achieved, as determined on a case by case basis depending upon the milestone. The strategic initiatives set forth in these grants were not achieved or probable of achievement and, as such, the Company did not record any compensation expense for these awards for the years ended December 31, 2013 and 2014.

Additionally, during 2013, the Company promised an executive the right to receive 40,000 shares of common stock and 160,000 stock options if the Company achieves certain strategic initiatives, such as the closing of certain financing transactions or the occurrence of a change of control transaction. During the year ended December 31, 2014, the Company recognized $62,806 of stock-based compensation expense in connection with the grant of 13,333 fully vested stock options as a result of the Company entering into the Deerfield Facility Agreement.

12. 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 carrying amount of the line of credit approximates fair value due to the variable interest rate in that instrument.

The fair value of the Company's 2013 Convertible Notes was $3,650,000 at December 31, 2013. The 2013 Convertible 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. The 2013 Convertible Notes were converted into Series D Preferred on June 2, 2014.

The fair value of the Deerfield Convertible Notes and the Term Notes was $17,350,000 and $9,032,000 at December 31, 2014, respectively. 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, 2013 and 2014:

	Balance at December 31, 2013	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Underwriter Warrant liability	$1,053,260	$ –	$ –	$1,053,260
Preferred stock warrant liability	400,000	–	–	400,000
Conversion Feature and Put Option	1,360,000	–	–	1,360,000
	$2,813,260	$ –	$ –	$2,813,260

KEMPHARM, INC.

NOTES TO FINANCIAL STATEMENTS (continued)

	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	$ 2,745,891	$ –	$ –	$ 2,745,891
Preferred stock warrant liability	13,080,000	–	–	13,080,000
Embedded Deerfield Put Option	140,000	–	–	140,000
	$15,965,891	$ –	$ –	$15,965,891

The Company's Underwriter Warrant liability, preferred stock warrant liability, the Conversion Feature and Put Option on the 2013 Convertible Notes and the Embedded Deerfield Put Option on the Deerfield Warrant are measured at fair value on a recurring basis. As of December 31, 2013, the Underwriter Warrant liability, the preferred stock warrant liability and the Conversion Feature and Put Option are reported on the balance sheet in derivative and warrant liability. As of December 31, 2014, the Underwriter Warrant liability, the preferred stock warrant liability and the Embedded Deerfield Put Option are reported on the balance sheet in derivative and warrant liability. The Company used a Monte Carlo simulation to value the Underwriter Warrant liability and the preferred stock warrant liability at December 31, 2013 and 2014. The Company used a Monte Carlo simulation to value the Conversion Feature and Put Option at issuance and December 31, 2013 and the Embedded Deerfield Put Option at December 31, 2014. Significant unobservable inputs used in measuring the fair value of financial instruments included the Company's estimated enterprise value, an estimate of the timing of a liquidity event, a present value discount rate, a risk-free rate of interest 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 preferred stock warrant liability and the Conversion Feature and Put Option are reflected in the statements of operations as a fair value adjustment. A 10% increase in the enterprise value would result in a $158,891 increase in the estimated fair value of the Underwriter Warrant liability and a $60,000 increase in the estimated fair value of the preferred stock warrant liability, while an increase of 100 basis points in the discount rate would result in a $610,000 increase in the estimated fair value of the Conversion Feature and Put Option at December 31, 2013. A 10% increase in the enterprise value would result in a $423,477 increase in the estimated fair value of the Underwriter Warrant liability, a $1,694,484 increase in the estimated fair value of the preferred stock warrant liability and no change in the estimated fair value of the Embedded Deerfield Put Option at December 31, 2014.

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:

	2013	2014
Balance at January 1	$ 2,390,608	$ 2,813,260
Issuance of 2013 Warrants	410,000	–
Issuance of 2013 Convertible Notes	1,150,000	–
Issuance of Deerfield Convertible Notes and Term Notes	–	7,610,000
Embedded Deerfield Put Option	–	220,000
Conversion of 2013 Convertible Notes	–	(1,900,000)
Adjustment to fair value	(1,137,348)	7,222,631
Balance at December 31	$ 2,813,260	$ 15,965,891

KEMPHARM, INC.

NOTES TO FINANCIAL STATEMENTS (continued)

13. Income Taxes

The Company's financial statements include a total state tax benefit of $19,544 and $22,247 on a loss before income taxes of $5,245,989 and $24,477,008 for the years ended December 31, 2013 and 2014, 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:

	Year Ended December 31,			
	2013		2014	
Federal statutory rate	$ (1,783,637)	34.0%	$ (8,322,268)	34.0%
Effect of:				
Change in valuation allowance	2,013,636	(38.4)	8,047,512	(32.9)
State income taxes	(394,912)	7.5	(1,459,773)	6.0
Underwriter warrant liability	(454,698)	8.7	575,495	(2.4)
State research and development credit	(19,544)	0.4	(22,497)	0.1
Federal research and development credit	(132,681)	2.5	(804,916)	3.3
Preferred stock warrant liability	136,000	(2.6)	1,723,800	(7.0)
Conversion Feature and Put Option on 2013 Convertible Notes	462,400	(8.8)	307,864	(1.3)
Interest expense	51,676	(1.0)	(51,676)	0.2
Other	102,216	(1.9)	(16,038)	0.1
Federal income tax provision effective rate	$ (19,544)	0.4%	$ (22,497)	0.1%

The components of deferred tax assets and liabilities are as follows:

	December 31,	
	2013	2014
Deferred tax assets relating to:		
Net operating loss carryforwards	$ 9,606,253	$ 16,389,697
Research and development tax carryforward	898,813	1,792,778
Compensation	75,872	83,377
Total gross deferred tax assets	10,580,938	18,265,852
Deferred tax liabilities relating to:		
Property and equipment	175,891	169,469
Total gross deferred tax liabilities	175,891	169,469
Deferred tax assets less liabilities	10,405,047	18,096,383
Valuation allowance	(10,405,047)	(18,096,383)
Net deferred tax asset (liability)	$ –	$ –

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.

KEMPHARM, INC.

NOTES TO FINANCIAL STATEMENTS (continued)

The Company had the following federal net operating loss carryforward and research activities credits as of December 31, 2014:

Year Incurred	Net Operating Loss	Research Activities Credit	Expiration
2007	$ 454,280	$ 29,977	2027
2008	1,178,096	64,677	2028
2009	3,060,387	175,635	2029
2010	3,423,056	149,246	2030
2011	9,928,651	176,585	2031
2012	–	170,012	2032
2013	4,521,783	132,681	2033
2014	15,801,891	893,965	2034
	$38,368,144	$1,792,778	

The Company also has certain state net operating loss carryforwards, primarily from Iowa, where $38,289,880 of net operating loss carryforwards exist that expire between 2027 and 2034. 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.

14. 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 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. Due to the existence of net losses for the years ended December 31, 2013 and 2014, basic and diluted loss per share were the same, as the effect of potentially dilutive securities would have been anti-dilutive.

KEMPHARM, INC.

NOTES TO FINANCIAL STATEMENTS (continued)

The following table summarizes the computation of basic and diluted net loss and net loss per share of the Company:

	Year Ended December 31,	
	2013	2014
Net loss—basic and diluted	$ (5,226,445)	$ (24,454,761)
Weighted-average number of common shares—basic and diluted	2,381,041	2,381,041
Net loss per share—basic and diluted	$ (2.20)	$ (10.27)

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:

	Year Ended December 31,	
	2013	2014
Redeemable convertible preferred stock:		
Series A	1,293,838	1,293,838
Series B	829,234	829,234
Series C	2,474,121	2,474,121
Series D	–	967,359
Warrants to purchase common stock	595,920	595,920
Warrants to purchase Series D Preferred	143,893	2,066,970
Awards under Incentive Stock Plan	296,255	395,185
2013 Convertible Notes	683,417	–
Deerfield Convertible Notes	–	1,808,353

Pro Forma Net Loss Per Share (unaudited)

The denominator used in computing pro forma net loss per share for the year ended December 31, 2014 has been adjusted to assume the conversion of the principal amount and accrued interest of the 2013 Convertible Notes at the beginning of the period or at the time the interest is accrued and the conversion of all outstanding shares of Preferred Stock into common stock as of the beginning of the year or at the time of issuance, if later. The calculation of pro forma net loss per share is as follows:

	December 31, 2014
Numerator:	
Historical net loss	$(24,454,761)(a)
Pro forma numerator for basic and diluted loss per share	$(24,454,761)
Denominator:	
Historical denominator for basic and diluted net loss per share—weighted average shares	2,381,041(b)
Plus: conversion of redeemable convertible preferred stock to common stock	5,162,081(c)
Plus: conversion of 2013 Convertible Notes	280,230(d)
Pro forma denominator for basic and diluted net loss per share	7,823,352
Pro forma basic and diluted loss per share	$ (3.13)

(a) Represents actual net loss.
(b) Represents actual weighted average common shares outstanding—basic.
(c) Represents the number of shares of common stock that would have been outstanding had all outstanding shares of the Preferred Stock converted into shares of common stock as of January 1, 2014 or the issuance dates of the Preferred Stock, if later, computed on a weighted average basis.
(d) Represents the number of shares of common stock that would have been outstanding had the principal amount and accrued interest of the 2013 Convertible Notes converted into shares of common stock at the beginning of the period or at the time the interest is accrued, computed on a weighted average basis.

15. 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 $49,901 and $68,513 for the years ended December 31, 2013 and 2014, 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 2013 or 2014.

16. Subsequent Events

The Company evaluated subsequent events through March 11, 2015, the date on which the December 31, 2014 financial statements were available to be issued. There are no significant events that require disclosure in these financial statements, except as follows:

Issuance of Series D-1 Convertible Preferred Stock

On February 19, 2015, the Company issued and sold 3,200,000 shares of Series D-1 Convertible Preferred Stock at $1.25 per share for an aggregate of $4,000,000.

Grant of Stock Options

On March 2, 2015, the Company granted options to purchase 145,999 shares of common stock at an exercise price of $8.63 per share.

The Company updated its evaluation of subsequent events through April 3, 2015, the date on which the December 31, 2014 financial statements were reissued. There are no additional significant events that require disclosure in these financial statements, except as follows:

Reverse Stock Split

On April 2, 2015, the Company amended its amended and restated certificate of incorporation effecting a 1-for-7.5 reverse stock split of its common stock. The reverse stock split did not cause an adjustment to the par value or the authorized shares of the common stock or preferred stock. As a result of the reverse stock split, the Company also adjusted the share and per-share amounts under its Incentive Stock Plan and common stock warrant agreements with third parties. No fractional shares were issued in connection with the reverse stock split. All disclosure of common shares and per-common share data in the accompanying financial statements and related notes have been adjusted retroactively to reflect the reverse stock split for all periods presented.

5,090,909 Shares

Common Stock

PROSPECTUS

Cowen and Company **RBC Capital Markets**

Canaccord Genuity **Oppenheimer & Co.**

April 15, 2015

Until May 10, 2015, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.