UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2016

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

Commission File No. 001-36913

KEMPHARM, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**20-5894398**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
2500 Crosspark Road, Suite E126, Coralville, IA 52241	**(319) 665-2575**
(Address of principal executive offices and zip code)	**(Registrant's telephone number, including area code)**

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $0.0001 par value	**The NASDAQ Stock Market LLC (NASDAQ Global Market)**

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2016, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $46,412,563, based upon the closing sales price for the registrant's common stock, as reported on the NASDAQ Global Market. The calculation of the aggregate market value of voting and non-voting common equity excludes 2,985,534 shares of common stock the registrant held by executive officers, directors and stockholders that the registrant concluded were affiliates of the registrant on that date. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of management or policies of the registrant or that such person is controlled by or under common control with the registrant.

As of March 7, 2017, the registrant had 14,646,982 shares of common stock outstanding.

Documents Incorporated by Reference

Portions of the registrant's definitive proxy statement for its 2017 annual meeting of stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2016. Except with respect to information specifically incorporated by reference in this Annual Report on Form 10-K, the definitive proxy statement is not deemed to be filed as part of this Annual Report on Form 10-K.

KEMPHARM, INC.
FORM 10-K

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

NOTE REGARDING COMPANY REFERENCE

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

NOTE REGARDING MARKET AND INDUSTRY DATA

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

Any information in this Annual Report on Form 10-K provided by Symphony Health Solutions, or SHS, is an estimate derived from the use of information under license from the following SHS service: SHS Pharmaceutical Audit Suite (PHAST), in each case, for the period January 2012 to December 2016. SHS expressly reserves all rights, including rights of copying, distribution and republication.

PART I

ITEM 1. BUSINESS.

Overview

We are a clinical-stage specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs that we believe will be improved versions of widely prescribed, approved drugs. We employ our Ligand Activated Therapy, or LAT, platform technology to create our prodrugs. We are building a pipeline of prodrug product candidates that target large market opportunities in pain, attention deficit hyperactivity disorder, or ADHD, and central nervous system, or CNS, disorders. Our two lead product candidates are KP415, our extended release, or ER, d-threo-methylphenidate product candidate for the treatment of ADHD, and KP201/IR, our acetaminophen, or APAP, free, single-entity, benzhydrocodone hydrochloride immediate-release, or IR, abuse-deterrent product candidate designed for the treatment of acute pain. We own worldwide commercial rights for all of our product candidates, except that Shire Pharmaceuticals, LLC, or Shire, has a right of first refusal to acquire, license or commercialize KP415.

We previously submitted a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, for our product candidate Apadaz, which consists of KP201, our prodrug of hydrocodone, and acetaminophen. In June 2016, the FDA issued a complete response letter, or CRL, for our Apadaz NDA. Generally, the FDA issues CRLs to indicate that the FDA considers the review cycle for an application complete and that the application is not ready for approval in its present form. In its CRL, the FDA advised us that it did not believe our proposed labeling included in the application accurately conveyed the outcome of our abuse deterrence studies of Apadaz. In August 2016, we completed our end-of-review meeting with the FDA. At the end-of-review meeting, we discussed with the FDA the issues identified by the FDA in the Apadaz NDA and what we believe is the potential to achieve a path forward for an Apadaz product label that could include abuse deterrence claims. The meeting also involved discussions pertaining to abuse deterrence in relation to the broader IR prescription opioid market, hydrocodone-acetaminophen combination products, and published industry guidance from the FDA concerning the evaluation and labeling of abuse deterrent opioids. In November 2016, we elected to continue the regulatory review process for Apadaz with the submission of a Formal Dispute Resolution Request, or FDRR, to the FDA. We anticipate up to twelve months may be required to complete all parts of the FDRR process.

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 marketing approval. New River Pharmaceuticals was acquired by Shire plc in 2007 and Vyvanse generated over $2.0 billion in sales in 2016.

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

We intend to advance our pipeline of product candidates for the treatment of ADHD, pain and various CNS indications, and we anticipate reporting human proof-of-concept, or POC, data for KP201/IR in 2018, additional pharmacokinetic, or PK, data for KP415 in 2017 and pivotal efficacy trial data for KP415 in 2018. We filed an Investigational New Drug application, or IND, for KP511/ER, our extended release formulation of KP511, our prodrug of hydromorphone, for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate, which took effect in March 2016 and received "Fast Track" designation by the FDA in May 2016. We also filed an IND for KP415, which took effect in October 2016, and an IND for KP201/IR, which took effect in November 2016 and received "Fast Track" designation for KP201/IR in December 2016. In addition, we anticipate submitting an NDA for each of KP415 and KP201/IR (APAP-free) in 2018, potentially followed by an NDA for each of KP511/IR and KP511/ER in 2019. 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 may be eligible for composition-of-matter patent protection and we intend to use the 505(b)(2) NDA pathway when available, which we believe may reduce drug development time, risk and expense.

As of December 31, 2016, our patent portfolio consisted of 69 granted patents and 70 pending patent applications worldwide. Within that patent portfolio, we have received granted U.S. composition-of-matter patents covering KP201, KP201-related compositions-of-matter, and prodrugs underlying two of our other product candidates.

Our Strategy

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

- ***Leverage our LAT platform technology to improve the attributes of approved drugs in large markets***. We plan to employ our LAT platform technology to develop additional prodrugs that have improved properties over approved drugs and address unmet medical needs in large, established markets. We intend to develop prodrugs of FDA-approved drugs in multiple therapeutic areas.

- ***Advance the development of our pipeline product candidates***. We plan to advance the development of our lead product candidates, KP415, for the treatment of ADHD and KP201/IR (APAP-free), for the short-term management of acute pain. We plan to initiate PK and human abuse liability studies related to KP415 and KP201/IR, respectively, in 2017. We also anticipate beginning a pivotal efficacy trial for KP415 in 2017. We are also developing KP511/ER, for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate, KP511/IR, for the short duration management of acute pain, KP303, our prodrug of quetiapine, for the treatment of schizophrenia and other CNS disorders, KP606/IR, our IR formulation of our prodrug of oxycodone, for the management of moderate to severe pain where the use of an opioid analgesic is appropriate, and KP746, our prodrug of oxymorphone, for the management of moderate to severe pain where the use of an opioid analgesic is appropriate.

- ***Continue to build a global intellectual property portfolio***. We intend to vigorously pursue composition-of-matter patent protection for our prodrugs in markets covering a majority of the global commercial opportunity.

Our LAT Prodrug Platform Technology

We use our LAT platform technology to create prodrugs by chemically attaching one or more molecules, referred to as ligands, to an FDA-approved parent drug. We typically use ligands that have been demonstrated to be safe in toxicological studies or have been granted Generally Recognized as Safe, or GRAS, status for food use by the FDA. Our prodrugs are chemical successors of the parent drugs, but may be considered to be NMEs and thus may be eligible for potential 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 gastrointestinal, or GI, tract, separate the ligand from the prodrug and release the parent drug, which can then exert its therapeutic effect. We select ligands that, when combined with the parent drug, create prodrugs believed to have improved drug attributes while maintaining efficacy potentially equivalent to the parent drug.

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

- ***Improved drug properties***. We seek to develop prodrugs with improved attributes over FDA-approved drugs, such as reduced susceptibility to abuse, enhanced bioavailability and increased safety.

- ***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, provided that all other applicable legal and regulatory requirements are met. We seek patent protection not only for our prodrug product candidates, but also for related compounds with the intention of creating potential heightened barriers to market entry.

- ***Eligibility for 505(b)(2) NDA pathway***. Our LAT platform technology allows us to develop prodrugs that may be eligible to use the 505(b)(2) NDA pathway. Under that regulatory pathway, if we are able to demonstrate the bioequivalence of our product candidates to appropriate approved drugs, we will then be able to reference the FDA's previous findings of safety and effectiveness for the approved drugs in our 505(b)(2) NDA submissions. This may allow us to avoid the significant time and expense of conducting large clinical trials and eliminate the need for some preclinical activities.

The Unmet Need for Addressing Early Morning Behavioral Deficits and Maintaining Consistent, Sustained Efficacy in Daily ADHD Treatment

The ADHD market is relatively well served by a number of methylphenidate and amphetamine stimulate products. While many of the currently marketed stimulant products provide good symptom control for up to 12 hours post-dose, there is increasing attention to addressing early morning behavioral deficits.

Such early-morning deficits can include difficulties getting out of bed, difficulty getting ready for school, arguing and excessive struggling, and extreme irritability. A recent study, authored by Floyd R. Sallee and published in the *Journal of Child & Adolescent Psychopharmacology*, entitled "Early Morning Functioning in Stimulant-Treated Children and Adolescents with Attention-Deficit/Hyperactivity Disorder, and its Impact on Caregivers," characterized the frequency and severity of ADHD symptoms throughout the day in children and adolescents treated with stable doses of stimulant medications.

Results of that particular study indicated that the most severe symptoms occurred during the early morning routine, followed by evening homework time and bedtime. The time from awakening to arriving at school can comprise up to 20% of waking hours per day (2-3 hours), and therefore such symptoms can cause significant distress for both children and caregivers. Therefore, we believe there is a need to develop a methylphenidate product that provides early-morning control of symptoms while also providing sustained, consistent efficacy through the day and into the early evening hours.

The Epidemic of Prescription Drug Abuse in the United States

The United States is facing an epidemic of prescription drug abuse. 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 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 nine abuse-deterrent opioids, OxyContin, Targiniq ER, Embeda, Hysingla, MorphaBond, Xtampza, Troxyca, Arymo and Vantrela. These actions reinforce the FDA's public statement that the development of abuse-deterrent opioid analgesics is a public health priority.

- ***FDA Public Meetings***. 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. On October 31 and November 1, 2016, the FDA convened a public meeting for Abuse-Deterrent Generic Products and Standardization of *In Vitro* Testing. The public meeting was held to review and evaluate FDA draft guidance to establish a pathway for generic abuse-deterrent formulation approvals and to standardize testing requirements for *In Vitro* testing regimes. The FDA has not indicated a timeline for finalizing this draft guidance.

Our Prodrug Product Candidates

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

Selected KemPharm Prodrug Product Candidates

Indication / Parent Drug	Product Candidate	Development Status	Key Milestone
ADHD			
Methylphenidate (controlled release)	KP415	Clinical	NDA Submission - 2018 Pivotal Efficacy Trial Data - 2018
Pain			
Hydrocodone (IR)	KP201/IR (APAP-free)	"Fast Track" Designation December 2016	NDA Submission - 2018 Human POC Data - 2017
Hydromorphone (ER)	KP511/ER	"Fast Track" Designation May 2016	NDA Submission - 2019 Human POC Data - 2018
Hydromorphone (IR)	KP511/IR	Clinical	NDA Submission - 2019 Human POC Data - 2018
Oxycodone (IR)	KP606/IR	Preclinical	
Oxymorphone	KP746	Preclinical	
CNS			
Quetiapine	KP303	Preclinical	

KP415

Overview

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

We plan to seek approval of KP415 under the 505(b)(1) NDA pathway, which will not allow us to rely on the FDA's previous findings of safety and effectiveness for one or more approved products that may be available for a 505(b)(2) NDA. We anticipate reporting additional PK data for KP415 in 2017 and pivotal efficacy trial data for KP415 in 2018 and submitting a 505(b)(1) NDA for KP415 in 2018. KP415 has received "Fast Track" designation by the FDA.

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 an agreement with MonoSol Rx, LLC, or MonoSol, pursuant to which 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.

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 new treatment option in this large market segment. While methylphenidate is available as a generic product, the branded formulations, Concerta, Focalin XR, Quillivant XR and Daytrana, accounted for sales of $800 million in 2016.

Key Product Features of KP415

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

- ***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 intravenous, or 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 and, based on our preclinical and clinical studies, we believe it will have abuse-deterrent characteristics.

- ***Faster early-morning symptom control and sustained effectiveness***. In December 2016, we announced the results of our Phase I POC clinical trial of KP415. This trial was designed to assess the relative PK of 32 mg of KP415 compared with 36 mg of Concerta after oral administration under fasted conditions. In this trial, we observed that KP415 had PK properties that produced earlier d-methylphenidate exposure followed by a slower extended release of d-methylphenidate relative to the comparator, Concerta. We believe that this PK profile may provide quicker onset of action than existing alternatives, thereby providing faster control of symptoms following administration early in the morning, as well as sustained, consistent effectiveness through the day and into the early evening hours.

- ***Once-daily dosing***. PK 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 CR attribute of KP415 may allow for convenient, once-daily dosing.

- ***Amenable to patient-friendly formulations***. Although we believe our prodrug, KP415, possesses abuse-deterrent properties, our preclinical and clinical data shows that KP415 could ultimately be used in a variety of patient-friendly dosage forms such as oral thin film, orally dissolving tablets, chewable tablets and liquids as a means of increasing patient convenience and compliance.

- ***Composition-of-matter patent protection***. KP415 is generally protected by a U.S. composition-of-matter patent that will expire, after utilizing all appropriate patent term adjustments but excluding possible term extensions, in 2032. Our patent strategy is focused primarily on key geographic market opportunities, and, as of December 31, 2016, a composition-of-matter patent on KP415 was granted in New Zealand and South Africa, and additional KP415 patent filings were pending in the United States and an additional 23 foreign jurisdictions. In addition, subject to further discussions with the FDA, we believe KP415 may be eligible for new chemical entity, or NCE, exclusivity status, which could allow for five years of U.S. market exclusivity following the FDA's approval of an NDA for KP415.

- ***No generic equivalent product***. KP415 is a prodrug that we believe will be given a new chemical name, which could mean that there would be no generic equivalent product for KP415 in most states, making drug-equivalent substitution potentially difficult at the pharmacy.

KP201/IR (APAP-free)

Overview

KP201/IR (APAP-free), is an IR formulation of KP201 without any APAP. We are developing KP201/IR (APAP-free) for the short-term management of acute pain. KP201/IR (APAP-free) is designed to be an abuse-deterrent opioid product that offers comparable efficacy to the existing standard-of-care, IR hydrocodone/APAP combination products, such as Vicodin, Norco and Lortab, but with the potential safety advantage of having no added APAP.

We anticipate intitiating human clinical trials in 2017, including an intranasal human abuse liability study. Based on our current development timelines, we anticipate submitting an NDA utilizing the 505(b)(1) pathway for KP201/IR (APAP-free) in 2018. We believe that KP201/IR (APAP-free), like other abuse-deterrent opioids, would receive priority review. KP201/IR (APAP-free) has received "Fast Track" designation by the FDA.

Market Opportunity

Currently, there are no IR hydrocodone products approved in the United States that are formulated without APAP, with or without an abuse-deterrent label. We believe KP201/IR (APAP-free), if approved, would provide physicians with an abuse-deterrent hydrocodone product alternative not currently available to help them with the short-term management of acute pain in patients.

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

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

- ***Abuse-deterrent technology***. KP201/IR (APAP-free) uses our KP201 prodrug, which incorporates our LAT platform technology, to create its abuse-deterrent properties and thus may provide a higher barrier against attempted abuse than many existing formulation-based approaches.

- ***No added APAP***. KP201/IR (APAP-free) contains no acetaminophen. According to the FDA, overdoses of APAP are the most common cause of drug-related liver injury. In 2011, the FDA limited the amount of APAP in prescription combination products and required warnings be added to all APAP prescription products.

- ***Composition-of-matter patent protection***. KP201/IR (APAP-free) is protected by a U.S. composition-of-matter patent on KP201 that will expire, after utilizing all appropriate patent term adjustments but excluding possible patent term extensions, no earlier than 2030.

- ***No generic equivalent product***. We believe the difference in chemical name, prescription strength and lack of APAP in the formulation may potentially mean that there will be no generic equivalent product for KP201/IR (APAP-free) in most states, making drug equivalent substitution potentially difficult at the pharmacy.

- ***Convenient dosing***. We believe that KP201/IR (APAP-free) will be as convenient as existing IR hydrocodone/APAP combination products.

KP511

Overview

KP511 is our prodrug of hydromorphone, which we are developing for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. We are currently working on an ER and IR formulation of KP511. KP511 is designed to be an abuse-deterrent opioid product that offers equivalent efficacy to approved hydromorphone products. KP511 combines hydromorphone with one or more ligands. We believe KP511 does not 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 and KP511/IR 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 POC data for KP511/ER and KP511/IR in 2018 and submitting a 505(b)(2) NDA for KP511/ER and KP511/IR in 2019.

In June 2016, we announced results from a Phase 1 POC trial of KP511. In the trial, we observed comparable hydromorphone exposure between 4 mg Dilaudid Oral Liquid and an equimolar 8 mg dose of KP511. Additionally, in January 2017, we announced the results of our exploratory Phase 1, double-blind, single-dose, 2-treatment, 2-period, randomized, crossover study, intended to assess the PK, safety and intranasal abuse potential of KP511, compared to equivalent doses of hydromorphone hydrochloride, or HM. In this trial, KP511 produced statistically significant reduction in peak and overall hydromorphone exposure with KP511 versus HM. The improved PK of KP511 resulted in meaningful, statistically lower scores in the exploratory pharmacodynamic measures of "Drug Liking," "Feeling High," "Overall Drug Liking" and "Take Drug Again" when compared to HM.

Market Opportunity

Oral hydromorphone products are typically used for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. SHS estimates that in 2016 there were nearly 3 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 clinical and preclinical data, we believe KP511/ER and KP511/IR, 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:

- ***Abuse-deterrent technology***. In order to evaluate the abuse-deterrent qualities of KP511, we conducted clinical and preclinical studies of KP511. As described above, our Phase 1 POC trial of KP511 produced meaningful, statistically lower scores in the exploratory pharmacodynamic measures of "Drug Liking," "Feeling High," "Overall Drug Liking" and "Take Drug Again" when compared to HM. We also 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 incorporates our LAT platform technology to create its abuse-deterrent properties and, based on our preclinical and clinical studies, we believe it may have abuse-deterrent characteristics.

- ***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. Thus, as to 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 may reduce the risk of oral overdosing.

- ***Composition-of-matter patent protection***. KP511/ER and KP511/IR are protected by a U.S. composition-of-matter patent on KP511 that will expire, after utilizing all appropriate patent term adjustments but excluding possible patent term extensions, in 2032. Our patent strategy is focused primarily on key geographic market opportunities, and, as of December 31, 2016, a composition-of-matter patent on KP511 was granted in Australia, Japan, Philippines, New Zealand, South Africa, and Singapore, and applications covering KP511 were pending in the United States and an additional 20 foreign jurisdictions.

- ***No generic equivalent product***. KP511 is a prodrug that we believe will be given a new chemical name, which would mean that there may be no generic equivalent product for KP511/ER or KP511/IR in most states, making drug equivalent substitution difficult at the pharmacy.

Other Product Candidates

We are using our LAT platform technology to develop other product candidates in pain. One example is KP606/IR, an IR formulation of KP606, our prodrug of oxycodone, which we are developing for the management of moderate to severe pain where the use of an opioid analgesic is appropriate. KP606/IR is designed to be an IR abuse-deterrent opioid product that may potentially offer equivalent efficacy to OxyContin. KP606 combines oxycodone with one or more ligands. Another example is KP746, our prodrug of oxymorphone, which is currently in preclinical development. We are developing KP746 for the management of moderate to severe pain where the use of an opioid analgesic is appropriate.

In addition to our product candidates in pain, we are using our LAT platform technology to develop product candidates for the treatment of CNS disorders. KP303, our prodrug of quetiapine, is currently in preclinical development. We are developing KP303 for the treatment of CNS disorders.

Our Intellectual Property

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

To date, we have internally developed all of our intellectual property, related to our LAT platform technology. As of December 31, 2016, we have been granted 14 issued patents within the United States, and an additional 55 foreign patents covering our prodrugs or product candidates. The terms of the 14 issued U.S. patents extend to various dates ranging, for example, between 2030 and 2032. The term of our overall domestic and foreign patent portfolio related to our prodrugs and product candidates, including patent term adjustments but excluding possible patent term extensions, extend to various dates ranging, for example, between 2030 and 2032, if pending patent applications in each of our patent families issue as patents. As of December 31, 2016, we filed 11 pending patent applications under active prosecution in the United States, and an additional 59 pending foreign patent applications potentially covering our prodrugs and product candidates. Our issued and granted patents provide protection in jurisdictions that include the United States, Australia, Canada, China, Colombia, Israel, Japan, Kazakhstan, Malaysia, Mexico, New Zealand, Philippines, Russia, Ukraine, Singapore, Indonesia and South Africa.

In 2013, the United States Patent and Trademark Office, or the USPTO, issued a composition-of-matter patent covering KP201, which will expire, after utilizing all appropriate patent term adjustments but excluding possible patent term extensions, no earlier than 2030. Further, there are granted or recently allowed compositions-of-matter patents covering KP201 in Australia, Canada, China, Colombia, Israel, Japan, Kazakhstan, Malaysia, Mexico, New Zealand, Russia, Ukraine, Indonesia and South Africa. In addition, one U.S. patent application covering KP201-related compositions-of-matter was pending as of December 31, 2016, and patent applications covering KP201 were pending as of December 31, 2016, in the United Arab Emirates, Brazil, Belarus, Chile, Costa Rica, Cuba, Egypt, Europe, Hong Kong, India, South Korea, Oman, Philippines, Singapore, Thailand and Vietnam.

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

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. To help protect our LAT platform technology, as well as any proprietary know-how and show-how beyond that which is 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, inventions and improvements important to our business.

Commercialization

We have not yet begun commercialization activities for any our product candidates in active development. 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 or other marketing organization. Alternatively, we may conclude that building our own focused sales and marketing organization will be most appropriate, perhaps as part of a co-promotional arrangement, or some other form of collaboration. As we get closer to potential approval of our product candidates, we will work to identify and implement the commercialization strategies that we conclude are the most desirable with regard to the specific product candidates.

Research and Development

Historically, we have devoted a significant amount of resources to develop our product candidates. For the years ended December 31, 2016, 2015 and 2014, we recorded $20.5 million, $13.9 million and $11.9 million, respectively, in research and development expenses. We plan to increase our research and development expense for the foreseeable future as we continue our efforts to commercialize, if approved, and further advance the development of our product candidates, subject to the availability of additional funding.

Competition

Our industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We will face competition and potential competition from a number of sources, including pharmaceutical and biotechnology companies, specialty pharmaceutical companies, generic drug companies, drug delivery companies and academic and research institutions. We believe the key competitive factors that will affect the development and commercial success of our product candidates include their potential degree of abuse deterrence, onset of action, bioavailability, therapeutic efficacy, convenience of dosing, safety, tolerability and cost. Many of our potential competitors have substantially greater financial, technical and human resources than we do, as well as more experience in the development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Consequently, our competitors may develop abuse-deterrent or other products for the treatment of ADHD, the short-term management of acute pain, or for other indications we are pursuing or may pursue in the future, and such competitors' products may be more effective, better tolerated and less costly than our product candidates. Our competitors may also be more successful in manufacturing and marketing their products than we are. We will also face competition in recruiting and retaining qualified personnel and establishing clinical trial sites and patient enrollment in clinical trials.

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

If approved, our abuse-deterrent opioid product candidates will face competition from commercially available branded and generic opioid drugs, including hydrocodone, hydromorphone, oxycodone, fentanyl, morphine, oxymorphone and methadone, as well as other marketed non-opioid products for the treatment of pain, and potential competition from opioid and non-opioid products for the treatment of pain that are currently in clinical development. In addition, our product candidates will face competition from approved and abuse-deterrent labeled opioid drugs and potential competition from abuse-deterrent opioid drugs that are currently in clinical development. We may compete with multiple companies that have developed and are developing abuse-deterrent technologies that may be applied to a variety of drugs, including those being developed for the short-term management of acute pain as well as for other indications that we are pursuing or may pursue in the future. If approved, our abuse-deterrent opioid product candidates may face competition from opioid products or abuse-deterrent technologies from companies including Allergan plc, Acura Pharmaceuticals, Inc., Cara Therapeutics, Inc., Collegium Pharmaceutical, Inc., Depomed, Inc., DURECT Corporation, Egalet Corporation, Elite Pharmaceuticals, Inc., Endo International plc, Grünenthal Group, Inspirion Delivery Technologies, LLC, 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/IR (APAP-free) will compete against currently marketed, branded and generic IR hydrocodone/APAP combination products indicated for the short-term management of acute pain. Some of these currently marketed products include AbbVie's Vicodin, Allergan's Norco, Shionogi's Xodol and UCB Pharma's Lortab, in addition to multiple other branded and generic hydrocodone/APAP combination products marketed by companies including Allergan plc, Endo International plc and Mallinckrodt plc. In addition, if approved, KP201/IR (APAP-free) will face potential competition from any abuse-deterrent IR or hydrocodone/APAP combination or other APAP-free products for the short-term management of acute pain that are currently in or may enter into clinical development.

If approved, KP511 will compete against currently marketed, branded and generic, IR and ER hydromorphone products approved for use in opioid-tolerant patients for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Some of these currently marketed products include Purdue Pharma L.P.'s Dilaudid and Mallinckrodt plc's Exalgo, in addition to multiple other branded and generic IR and ER hydromorphone products marketed by companies including Allergan plc, Mallinckrodt plc, Rhodes Pharmaceuticals L.P. and Roxanne Laboratories, Inc. In addition, if approved, KP511/ER and KP511/IR 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.

Manufacturing

Our manufacturing strategy is to rely on contract manufacturers to produce our prodrug product candidates for clinical trials and, if approved, drug product for commercial sale. We currently have no manufacturing facilities and limited personnel with manufacturing experience. We rely on Johnson Matthey Inc., or JMI, a third-party manufacturer, to produce the bulk quantities of KP201 required for the manufacture of the KP201/IR used in our clinical trials under a supply agreement. JMI is also currently contracted to manufacture of KP511 to be used in our non-clinical, clinical and formulation development programs needed to support an NDA filing. We have contracted with another third-party manufacturer to supply KP415 to be used in our non-clinical, clinical and formulation development programs necessary to support an NDA filing. We plan to continue to rely on these manufacturers to manufacture commercial quantities of KP201 used in production of KP201/IR, KP511 and KP415, respectively, for sale in the United States, if and when we receive approval by the FDA. We expect to contract with third-party manufacturers for the manufacture of all API supply needs outside the United States if and when we receive approval 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, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreements to resolve allegations of non-compliance with these laws, 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 individual imprisonments.

Supply Agreement with Johnson Matthey

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

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

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

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 any product that utilizes KP201 as the API, 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 the commercial launch of any product that utilizes KP201 as the API, 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 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, and private managed care organizations and health insurers. Decisions regarding the extent of coverage and amount of reimbursement to be provided for each of our product candidates will be made on a plan-by-plan basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Each third-party payor determines whether or not it will provide coverage for a drug, what amount it will pay providers for the drug, and on what tier of its formulary the drug will be placed. These decisions are influenced by the existence of multiple drug products within a therapeutic class and the net cost to the plan, including the amount of the prescription price, if any, rebated by the drug's manufacturer. Typically, generic versions of drugs are placed in a preferred tier. The position of a drug on the formulary generally determines the co-payment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Additionally, a third-party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Also, third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. As a result, coverage, reimbursement and placement determinations are complex and are often the subject of extensive negotiations between the payor and the owner of the drug.

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

Within the Medicare program, as self-administered drugs, KP201/IR (APAP-free), KP303, KP415, KP511/ER, KP511/IR, KP606/IR and KP746 would be reimbursed under the expanded prescription drug benefit known as Medicare Part D. This program is a voluntary Medicare benefit administered by private plans that operate under contracts with the federal government. These plans develop formularies that determine which products are covered and what co-pay will apply to covered drugs. The plans have considerable discretion in establishing formularies and tiered co-pay structures, negotiating rebates with manufacturers and placing prior authorization and other restrictions on the utilization of specific products, subject to review by the Centers for Medicare and Medicaid Services, or CMS, for discriminatory practices. These Part D plans negotiate discounts with drug manufacturers, which are passed on, in whole or in part, to each of the plan's enrollees through reduced premiums. Historically, Part D beneficiaries have been exposed to significant out-of-pocket costs after they surpass an annual coverage limit and until they reach a catastrophic coverage threshold. However, changes made by the Patient Protection and Affordable Care Act as amended by the Health Care Education and Reconciliation Act, or the ACA, will reduce this patient coverage gap, known as the "donut hole", by transitioning patient responsibility in that coverage range from 100% in 2010 to only 25% in 2020. To help achieve this reduction, pharmaceutical manufacturers are required to provide quarterly discounts of 50% off the negotiated price of branded drugs dispensed to Medicare Part D patients in the donut hole.

If a drug product is available for reimbursement by Medicare or Medicaid, its manufacturer must comply with various health regulatory requirements and price reporting metrics, which may include, as applicable, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, or the OBRA, and the Veterans Health Care Act of 1992, or the VHCA, each as amended. Among other things, the OBRA requires drug manufacturers with certain drugs covered by Medicaid to pay rebates on prescription drugs to state Medicaid programs. States may also negotiate "supplemental" Medicaid rebates on drug products dispensed under Medicaid. Manufacturers participating in Medicaid are also generally required to participate in the Public Health Service 340B Drug Discount Program, which imposes a mandatory discount on purchases by certain customers. Manufacturers of innovator drugs, including 505(b)(2) drugs, that participate in the Medicaid program are also required to offer the drugs on the Federal Supply Schedule purchasing program of the General Services Administration for purchase by the Department of Veterans Affairs, the Department of Defense and other authorized users at a mandatory discount. Additional laws and requirements apply to these contracts. Participation in such federal programs may result in prices for our future products that will likely be lower than the prices we might otherwise obtain.

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

Government Regulation

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

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

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

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

The testing and approval process requires substantial time, effort and financial resources. Preclinical studies include laboratory evaluation of drug substance chemistry, pharmacology, toxicity and drug product formulation, as well as animal studies to assess potential safety and efficacy. Prior to commencing the first clinical trial with a product candidate, we must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical studies may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the conduct of the clinical trial by imposing a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development, as well as amendments to previously submitted clinical trials. Further, an independent IRB for each study site proposing to conduct the clinical trial must review and approve the plan for any clinical trial, its informed consent form and other communications to study subjects before the clinical trial commences at that site. The IRB must continue to oversee the clinical trial while it is being conducted, including any changes to the study plans. Regulatory authorities, an IRB or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk, the clinical trial is not being conducted in accordance with the FDA's or the IRB's requirements, if the drug has been associated with unexpected serious harm to subjects, or based on evolving business objectives or competitive climate. Some studies also include a data safety monitoring board, which receives special access to unblinded data during the clinical trial and may advise us to halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

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

- *Phase 1*—Studies are initially conducted to test the product candidate for safety, dosage tolerance, structure-activity relationships, mechanism of action, absorption, metabolism, distribution and excretion in healthy volunteers or subjects with the target disease or condition. If possible, Phase 1 trials may also be used to gain an initial indication of product effectiveness.

- *Phase 2*—Controlled studies are conducted with groups of subjects with a specified disease or condition to provide enough data to evaluate the preliminary efficacy, optimal dosages and dosing schedule and expanded evidence of safety. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- *Phase 3*—These clinical trials are undertaken in larger subject populations to provide statistically significant evidence of clinical efficacy and to further test for safety in an expanded subject population at multiple clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. These trials may be done globally to support global registrations so long as the global sites are also representative of the U.S. population and the conduct of the study at global sites comports with FDA regulations and guidance, such as compliance with GCPs.

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

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

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

The manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the 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 have and expect to be able to continue to rely on information from studies previously conducted by the companies that obtained approval for drugs containing such APIs.

Orange Book Listing

Section 505 of the 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 the Orange Book. These products may be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

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

If the competitor has provided a Paragraph IV certification to the FDA, the competitor must also send notice of the Paragraph IV certification to the holder of the NDA for the reference listed drug and the patent owner once the application has been accepted for filing by the FDA. The NDA holder or patent owner may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification prevents the FDA from approving the application until the earlier of 30 months from the date of the lawsuit, expiration of the patent, settlement of the lawsuit, a decision in the infringement case that is favorable to the applicant or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a Paragraph IV certification, the NDA holder or patent owner regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation. The applicant may also elect to submit a statement certifying that its proposed label does not contain, or carves out, any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

Exclusivity

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

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

NDA Submission and Review by the FDA

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

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA for a new active ingredient, indication, dosage form, dosage regimen or route of administration must contain data that are adequate to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers from the pediatric data requirements.

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

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

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

FDA approval of any NDA submitted by us will be at a time the FDA chooses. Also, if regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed or may include contraindications, warnings or precautions in the product labeling, including a black box warning. If the FDA requires a boxed 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. The Drug Supply Chain Security Act also imposes obligations on manufacturers of pharmaceutical products related to product tracking and tracing.

Failure to comply with any of the FDA's requirements could result in significant adverse enforcement actions. These include a variety of administrative or judicial sanctions, such as refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, cyber letters, modification of promotional materials or labeling, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, debarment, injunctions, fines, consent decrees, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, 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 individual imprisonment. Any of these sanctions could result in adverse publicity, among other adverse consequences.

Risk Evaluation and Mitigation Strategy (REMS)

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

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

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

DEA Regulation

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

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

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

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

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

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

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

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

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

Other Healthcare Regulations

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

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for, 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.

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

Additionally, the federal Open Payments program, created under Section 6002 of the ACA and its implementing regulations, require some manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with specified exceptions) to report annually 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."

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers. Several states have also enacted legislation requiring pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, or register their sales representatives, as well as prohibiting pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and prohibiting certain other sales and marketing practices.

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, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, exclusion of products from reimbursement under government programs, refusal to allow us to enter into supply contracts, including government contracts, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our business.

Healthcare Reform Measures

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

For example, in March 2010, the ACA was passed. The ACA has substantially changed health care financing by both governmental and private insurers, and significantly affected the U.S. pharmaceutical industry. The ACA, among other things, subjected manufacturers to new annual fees and taxes for specified branded prescription drugs, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, expanded health care fraud and abuse laws, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, imposed an inflation penalty on new formulations of drugs, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, expanded the 340B program which caps the price at which manufacturers can sell covered outpatient pharmaceuticals to specified hospitals, clinics and community health centers, and provided incentives to programs that increase the federal government's comparative effectiveness research. There have been judicial and congressional challenges to certain aspects of the ACA. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law; however, it is widely viewed as the first step toward the passage of repeal legislation. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the ACA that are repealed. We continue to evaluate the effect that the ACA has on our business. Final regulations, guidance, amendments and judicial orders are anticipated in the future and we will continue to assess the ACA's impact on us as final regulations, guidance, amendments and judicial orders are issued.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2025 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. Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs.

The Foreign Corrupt Practices Act

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

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products to the extent we choose to develop or sell any products outside of the United States. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Employees

As of December 31, 2016, we employed 32 full-time employees. We have never had a work stoppage, and none of our employees is represented by a labor organization or under any collective bargaining arrangements. We consider our employee relations to be good.

Segments and Geographic Information

We view our operations and manage our business as one operating segment. See our financial statements for a discussion of revenues, operating loss, net loss and total assets. All of our assets were held in the United States for the years ended December 31, 2016, 2015 and 2014.

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 2500 Crosspark Road, Suite E126, 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 Annual Report on Form 10-K.

ITEM 1A. RISK FACTORS.

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

Risks Related to Our Financial Position and Capital Needs

In light of our receipt of the CRL from the FDA regarding our NDA for Apadaz, the U.S. regulatory pathway for Apadaz is uncertain, and we may never obtain regulatory approval in the United States.

In December 2015, we submitted an NDA to the FDA for the marketing and sale of Apadaz. The NDA was accepted for filing by the FDA in February 2016. In June 2016, the FDA issued the CRL regarding the NDA, indicating that their review was complete and the NDA was not ready for approval in its present form. In its CRL, the FDA advised us that it did not believe our proposed labeling included in the application accurately conveyed the outcome of our abuse deterrence studies of Apadaz.

In August 2016, we completed our end-of-review meeting with the FDA. At the end-of-review meeting, we discussed with the FDA the issues identified by the FDA in the Apadaz NDA and what we believe is the potential to achieve a path forward for an Apadaz product label that could include abuse deterrence claims. Despite this end-of-review meeting with the FDA, we cannot guarantee when, or if, we will be successful in receiving approval for an Apadaz label that includes abuse deterrent claims.

In November 2016, we elected to continue the regulatory review process for Apadaz with the submission of a FDRR to the FDA. We anticipate up to twelve months may be required to complete all parts of the FDRR process. We cannot guarantee that the FDRR or any other action will be resolved in our favor. As a result, the approval of our NDA for Apadaz has been substantially delayed and may never occur.

We cannot predict whether the FDA will have concerns regarding the abuse deterrent or other features of our product candidates for any future NDA we may submit. If the FDA were to raise similar concerns regarding the abuse deterrent or other features of our product candidates in the future, the FDA may not approve any such product candidates or we may not have sufficient capital resources to fully fund any new trials that the FDA may require as a condition to approval of our product candidates.

The U.S. regulatory pathway for Apadaz, and potentially our other product candidates, is highly uncertain at this time, and we may never obtain regulatory approval of any of our product candidates in the United States. If that were to occur, it would have a material adverse effect on our operations and financial condition.

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

We have incurred operating losses since our inception and, as of December 31, 2016, had an accumulated deficit of $121.3 million. Our loss from operations for the years ended December 31, 2016, 2015 and 2014, were $37.5 million, $22.8 million and $16.4 million, respectively. We have financed our operations to date with $25.3 million raised in private placements of redeemable convertible preferred stock, $115.9 million in convertible promissory notes and term debt and $59.9 million in aggregate net proceeds from our initial public offering.

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

- continue our ongoing preclinical studies, clinical trials and our product development activities for our pipeline of product candidates;
- seek regulatory approvals for 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; and
- incur additional legal, accounting and other expenses in operating as a public company.

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

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

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

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

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through the second quarter of 2019. However, we will need to obtain substantial additional funding in connection with our continuing operations. Our future capital requirements will depend on many factors, including:

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

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval for our product candidates or claims necessary to make such candidates profitable, and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of prodrug products that we do not expect to be commercially available for the foreseeable future, 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 debt securities, the terms of these securities or this debt may restrict our ability to operate. Our credit facility agreement with Deerfield Private Design Fund III, L.P., or Deerfield, dated June 2, 2014, or the Deerfield facility includes, and any future debt financing and equity financing, if available, may involve agreements that include, covenants limiting and restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, entering into profit-sharing or other arrangements or declaring dividends. Additionally, in February 2016, we issued $86.25 million aggregate principal amount of our 5.50% senior convertible notes due 2021, or the 2021 Notes. We are required to make periodic interest payments to the holders of the 2021 Notes and to make payments of principal upon maturity. In this regard, if holders of the 2021 Notes do not convert their 2021 Notes prior to the maturity date, we will be required to repay the principal amount of all then outstanding 2021 Notes plus any accrued and unpaid interest. We may also be required to repurchase the 2021 Notes for cash upon the occurrence of a change of control or certain other fundamental changes involving us. If our capital resources are insufficient to satisfy our debt service obligations, we will be required to seek to sell additional equity or debt securities or to obtain debt financing. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

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

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

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

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

Risks Related to the Development of Our Product Candidates

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

A key element of our strategy is to use our LAT platform technology to build a pipeline of prodrugs and progress product candidates based on these prodrugs through clinical development for the treatment of a variety of diseases and conditions. The scientific discoveries that form the basis for our efforts to discover and develop prodrugs are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. Although our research and development efforts to date have resulted in a pipeline of prodrug product candidates, we may not be able to develop prodrugs that are bioequivalent, safe and effective and that have commercially significant improvements over already approved drugs. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects, a lack of efficacy, or other characteristics that indicate that they are unlikely to be prodrugs that will receive marketing approval and achieve market acceptance. For instance, in June 2016, we received the CRL from the FDA for our Apadaz NDA indicating that the FDA considers the review cycle for the Apadaz NDA complete and that the application is not ready for approval in its present form. In November 2016, we elected to continue the regulatory review process for Apadaz with the submission of a FDRR to the FDA. Despite this, we cannot guarantee when, or if, we will be successful in receiving approval for an Apadaz label that includes abuse deterrent claims. If we do not successfully develop and commercialize product candidates based upon our LAT platform technology, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

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

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

Even if regulatory approval is obtained, subsequent safety, efficacy, quality or other issues can result in a product approval being suspended or withdrawn. Other than the submission of our NDA for Apadaz to the FDA, as to which the FDA issued the June 2016 CRL, we have not yet submitted comparable applications to other regulatory authorities. If our development efforts for our product candidates, including regulatory approval, are not successful for their planned indications or are delayed, or if adequate demand for our product candidates that are approved for marketing, if any, is not generated, our business will be harmed.

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

- the FDA or comparable foreign regulatory authorities, IRBs or ethics committees may disagree with the design or conduct of our clinical trials;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or other regulatory agencies for marketing approval or for us to receive approval for claims that are necessary for commercialization, for instance in June 2016, the FDA issued the CRL for our Apadaz NDA;
- the dosing in a particular clinical trial may not be at an optimal level;
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our product candidates;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA or other submission to regulatory authorities or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies or may later suspend or withdraw such approval;
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and
- even if we obtain marketing approval in one or more countries, future safety or other issues could result in the suspension or withdrawal of regulatory approval in such countries.

We have only limited experience in filing the applications necessary to gain regulatory approvals and have relied, and expect to continue to rely, on consultants and third-party contract research organizations, or CROs, with expertise in this area to assist us in this process. Securing FDA approval requires the submission of extensive nonclinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA for each therapeutic indication to establish a product candidate's safety and efficacy for each indication and manufacturing quality. Additionally, we cannot guarantee that regulators will agree with our assessment of the results of the clinical trials we have conducted or that any future trials will be successful. For example, in May 2016, the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the FDA voted 16 to four for the approval of Apadaz, but voted 18 to two against inclusion of abuse deterrent labeling for Apadaz. Additionally, in June 2016, we received the CRL from the FDA for our Apadaz NDA indicating that the FDA considers the review cycle for the Apadaz NDA complete and that the application is not ready for approval in its present form. In November 2016, we elected to continue the regulatory review process for Apadaz with the submission of a FDRR to the FDA. Despite this, we cannot guarantee when, or if, we will be successful in receiving approval for an Apadaz label that includes abuse deterrent claims.

Any product candidate we develop may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications.

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

We are very early in our development efforts and only a limited number of our product candidates have entered clinical development. All of our other active product candidates are still in preclinical development. If we are unable to commercialize our product candidates, or experience significant delays in doing so, our business will be harmed.

We are very early in our development efforts and only a limited number of our product candidates have entered clinical development. All of our other active product candidates are still in preclinical development. We have not completed the development of any product candidates, we generate no revenue from the sale of any prodrugs and we may never be able to develop a marketable prodrug product. We have invested substantially all of our efforts and financial resources in the development of our LAT platform technology, the identification of potential product candidates and the development of our product candidates. Our ability to generate revenue from our product candidates 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, if applicable, 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;
- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for our product candidates and otherwise protecting our rights in our intellectual property portfolio;
- maintaining compliance with regulatory requirements, including cGMPs;
- launching commercial sales of product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our prodrug product candidates, if approved, by patients, the medical community and third-party payors;
- competing effectively with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement; and
- maintaining a continued acceptable safety and efficacy profile of the prodrug products following approval.

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

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

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

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

The commercial success of most of our 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.

There can be no assurance that any of our product candidates will receive FDA-approved labeling that describes the abuse-deterrent features of such products. The FDA may find that our trials do not support abuse-deterrent labeling or that our product candidates do not provide substantial abuse deterrence because, for example, their deterrence mechanisms do not address the way they are most likely to be abused. For instance, in May 2016, the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the FDA voted 18 to two against inclusion of abuse-deterrent labeling for Apadaz. Subsequently, in June 2016, the FDA issued the CRL for our Apadaz NDA indicating that the FDA considers the review cycle for the Apadaz NDA complete and that the application is not ready for approval in its present form. In its CRL, the FDA advised us that it did not believe our proposed labeling included in the application accurately conveyed the outcome of our abuse deterrence studies of Apadaz. In November 2016, we elected to continue the regulatory review process for Apadaz with the submission of a FDRR to the FDA. Despite this, we cannot guarantee when, or if, we will be successful in receiving approval for an Apadaz label that includes abuse deterrent claims.

As with all claims, we will be required to provide adequate substantiation. For example, we will need to demonstrate that our product candidates have abuse-deterrent properties sufficient to achieve abuse-deterrent labeling.

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

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

If we attempt to rely on the 505(b)(2) pathway and 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 our product candidates through the 505(b)(2) NDA pathway where possible. The 505(b)(2) pathway 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. For instance, we currently plan on relying on the 505(b)(1) pathway for any NDA we submit for KP415 and KP201/IR. Additionally, we do not anticipate that the 505(b)(2) pathway will be available for every product candidate. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates, and complications and risks associated with our product candidates, would likely substantially increase.

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

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

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

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

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

- the NDA is incomplete because it does not on its face contain the information required under the FFDCA or the FDA's regulations;
- the NDA does not contain a statement that each nonclinical laboratory study was conducted in compliance with the GLP requirements, or for each study not so conducted, a brief statement of the reason for the noncompliance;
- the NDA does not contain a statement that each clinical trial was conducted in compliance with the IRB regulations or was not subject to those regulations, and the agency's informed consent regulations or a brief statement of the reason for noncompliance; or
- the drug is a duplicate of a listed drug approved before receipt of the NDA and is eligible for approval under an ANDA for generic drugs.

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

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

Additionally, the FDA will refuse to file an NDA if an approved drug with the same active moiety is entitled to five years of exclusivity, unless the exclusivity period has elapsed or unless four years of the five-year period have elapsed and the NDA contains a certification of patent invalidity or non-infringement. An active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a

salt with hydrogen or coordination bond) or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the therapeutic activity of the drug substance.

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

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

The risk of failure for our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Interpretation of results from early, usually smaller, studies that suggest positive trends in some subjects, requires caution. Results from later stages of clinical trials enrolling more subjects may fail to show the desired safety and efficacy results or otherwise fail to be consistent with the results of earlier trials of the same product candidates. Later clinical trial results may not replicate earlier clinical trials for a variety of reasons, including differences in trial design, different trial endpoints, or lack of trial endpoints in exploratory studies, subject population, number of subjects, subject selection criteria, trial duration, drug dosage and formulation and lack of statistical power in the earlier studies. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. For instance, in June 2016, the FDA issued the CRL for our Apadaz NDA indicating that the FDA considers the review cycle for the Apadaz NDA complete and that the application is not ready for approval in its present form. In its CRL, the FDA advised us that it did not believe our proposed labeling included in the application accurately conveyed the outcome of our abuse deterrence studies of Apadaz. In November 2016, we elected to continue the regulatory review process for Apadaz with the submission of a FDRR to the FDA. Despite this, we cannot guarantee when, or if, we will be successful in receiving approval for an Apadaz label that includes abuse deterrent claims.

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 IRBs may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site or amend clinical trial protocols as needed;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and CROs;
- clinical trials of our product candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance in cases where that is required, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon prodrug development programs;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or trial protocols, or meet their contractual obligations to us in a timely manner, or at all;
- regulators or IRBs 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 IRBs to suspend or terminate the trials.

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

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

- have the product removed from the market after obtaining marketing approval.

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

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

As product candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, various aspects of the development program, such as manufacturing methods and formulation, may be altered along the way in an effort to optimize processes and results. Such changes may not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence product sales and generate revenue.

Our decision to seek approval of our product candidates under 505(b)(2), if available, 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 may submit 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 our 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, which the FDA continually updates. The REMS introduces new safety measures designed to reduce risks and improve the safe use of ER and long-acting opioids, while ensuring access to needed medications for patients in pain. The ER and long-acting opioid REMS affects more than 25 companies that manufacture these opioid analgesics. Under the new REMS, companies are required to make education programs available to prescribers. It is expected that companies will meet this obligation by taking specific steps to ensure that health care providers are aware of the availability of the training and by providing educational grants to continuing education providers, who will develop and deliver the training. The REMS also requires companies to make available FDA-approved patient education materials on the safe use of these drugs. The companies must perform periodic assessments of the implementation of the REMS and the success of the program in meeting its goals. The FDA will review these assessments and may require additional elements to achieve the goals of the program. Independent audits must also be conducted of the educational efforts.

We anticipate that most of our product candidates, 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/IR (APAP-free), KP303, KP415, KP511/ER, KP511/IR, KP606/IR and KP746, if approved, will be regulated as "controlled substances" as defined in the CSA and the implementing regulations of the DEA, which establish registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA. These requirements are applicable to us, to our contract manufacturers and to distributors, prescribers and dispensers of our product candidates. The DEA regulates the handling of controlled substances through a closed chain of distribution. This control extends to the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce. A number of states and foreign countries also independently regulate these drugs as controlled substances.

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

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

We expect that most of our product candidates may be listed by the DEA as Schedule II controlled substances under the CSA. Consequently, the manufacturing, shipping, storing, selling and using of the products will be subject to a high degree of regulation. In addition to maintaining an importer and/or exporter registration, importers and exporters of controlled substances must obtain a permit for every import of a Schedule I or II substance and a narcotic substance in Schedule III, IV and V, as well as every export of a Schedule I or II substance and a narcotic substance in Schedule III and IV. For all other drugs in Schedule III, IV and V, importers and exporters must submit an import or export declaration. Schedule II drugs are subject to the strictest requirements for registration, security, recordkeeping and reporting. Also, distribution and dispensing of these drugs are highly regulated. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription. Electronic prescriptions may also be permissible depending on the state, so long as the prescription complies with the DEA's requirements for electronic prescriptions.

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

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

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

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

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

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

- the size and nature of the subject population specified in the trial protocol;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the fact that the product candidate is a controlled substance;
- severe or unexpected drug-related adverse events experienced by subjects in a clinical trial;
- the availability of drugs approved to treat the diseases or conditions under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the severity of the disease or condition under investigation;
- the ability to obtain and maintain subject informed consent;
- the ability to retain subjects in the clinical trial and their return for follow-up;
- the clinical trial design, including required tests, procedures and follow-up;
- the ability to monitor subjects adequately during and after treatment;
- delays in adding new investigators and clinical sites;
- withdrawal of clinical trial sites from clinical trials; and
- the proximity and availability of clinical trial sites for prospective subjects.

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

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

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

If our product candidates are associated with side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The FDA or an IRB 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.

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

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, investigators and trial sites. We also are required to register specified ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. In addition, we must conduct our clinical trials with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process. Failure to comply with the applicable requirements related to clinical investigations by us, our CROs or clinical trial sites can also result in clinical holds and termination of clinical trials, debarment, FDA refusal to approve applications based on the clinical data, warning letters, withdrawal of marketing approval if the product has already been approved, fines and other monetary penalties, delays, adverse publicity and civil and criminal sanctions, among other consequences.

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

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

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

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

We contract with third parties for the manufacture of our product candidates that utilize KP201, KP511 and KP415 as the API used in our clinical trials and with a sole source supplier for the manufacture of bulk quantities of KP201, KP511 and KP415 used in product candidates that utilize these moieties as the API 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, KP511 or KP415, 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 the bulk drug substances for KP201, KP511 and KP415 from sole-source, third-party manufacturers and the product candidates that utilize these moieties as the API used in our clinical trials from other third parties. 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, KP511, KP415, other bulk drug substances or our product candidates, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our ability to timely conduct our clinical trials or our other development or commercialization efforts.

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

- reliance on the third party for FDA and DEA regulatory compliance and quality assurance;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- disruption and costs associated with changing suppliers, including additional regulatory filings;
- the possible breach, termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our product candidates in a timely fashion, in sufficient quantities or under acceptable terms; and
- carrier disruptions or increased costs that are beyond our control.

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

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

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

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

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

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

There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for KP201, KP511 or KP415 bulk drug substance. If our current contract manufacturer for KP201, KP511 or KP415 bulk drug substance cannot perform as agreed, we may be required to replace such manufacturer and we may incur added costs and delays in identifying and qualifying any such replacement.

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

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

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

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

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

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

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

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

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

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

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

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

Provisions in our facility agreement with Deerfield 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. Deerfield's interests may not always coincide with our corporate interests or the interests of our other stockholders, and Deerfield may act in a manner with which you may not agree or that may not be in the best interests of our other stockholders. If Deerfield does not approve our entry into specified transactions, it could significantly delay or inhibit the commercialization of our product candidates.

Risks Related to Our Intellectual Property

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

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

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents, licensed to third parties by us.

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

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States or visa-versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and utility, or equivalent, patent applications in the United States and other jurisdictions are typically not published until 18 months after the filing date of such patent applications, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and drugs. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

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

- we may fail to seek patent protection for inventions that are important to our success;
- our pending patent applications may not result in issued patents;
- we cannot be certain that we are the first to invent the inventions covered by pending patent applications or that we are the first to file such applications and, if we are not, we may be subject to priority disputes or lose rights;
- we may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications;
- we may file patent applications but have claims restricted or we may not be able to supply sufficient data to support our claims and, as a result, may not obtain the original claims desired or we may receive restricted claims; alternatively, it is possible that we may not receive any patent protection from an application;
- even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, and may not be of sufficient scope or strength to provide us with any commercial advantage;
- our competitors may be able to design around our owned or licensed patents by developing similar or alternative technologies or drugs without infringing on our intellectual property rights;
- we could inadvertently abandon a patent or patent application, resulting in the loss of protection of intellectual property rights in a particular country, and we, our collaborators or our patent counsel may take action resulting in a patent or patent application becoming abandoned which may not be able to be reinstated or if reinstated, may suffer patent term adjustments;
- the claims of our issued patents or patent applications when issued may not cover our product candidates;
- no assurance can be given that our patents would be declared by a court to be valid or enforceable or that a competitor's technology or product would be found by a court to infringe our patents and our patents or patent applications may be challenged by third parties in patent litigation or in proceedings before the USPTO or its foreign counterparts, and may ultimately be declared invalid or unenforceable or narrowed in scope;
- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim and there may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim;
- third parties may develop products that have the same or similar effect as our products without infringing our patents;
- third parties may intentionally circumvent our patents by means of alternate designs or processes or file applications or be granted patents that would block or hurt our efforts;
- there may be dominating patents relevant to our product candidates of which we are not aware;
- obtaining regulatory approval for pharmaceutical products is a lengthy and complex process, and as a result, any patents covering our product candidates may expire before or shortly after such product candidates are approved and commercialized;
- the patent and patent enforcement laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions; and
- we may not develop additional proprietary technologies that are patentable.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If we or our third-party licensors fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

We are currently party to a license agreement for technologies that we anticipate using in our product development activities. In the future, we may become party to licenses that are important for product development and commercialization. If we or our third-party licensors fail to comply with the obligations under current or future license and funding agreements, our counterparties may have the right to terminate these agreements, we may be forced to terminate these agreement or we may no longer effectively rely on any licenses to us under these agreements, in which event we might not be able to develop, manufacture or market any product or utilize any technology that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could materially and adversely affect the value of a product candidate being developed under any such agreement or could restrict our drug discovery activities. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

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

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

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

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

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

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and could be a distraction to management. In addition, any litigation or threat thereof may adversely affect our ability to hire employees or contract with independent service providers. Moreover, a loss of key personnel or their work product could hamper or prevent our ability to commercialize our products.

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

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet solicited trademarks for our current product candidates and have not yet begun the process of applying to register trademarks for our current 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 any of our 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 adequate reimbursement levels;
- the inability of sales personnel to obtain access to physicians or achieve adequate numbers of physicians to prescribe any future prodrug products;
- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- liability for personnel, including sales personnel, failing to comply with applicable legal requirements; and
- costs associated with maintaining compliance with the FDA's marketing and promotional requirements, including ongoing training and monitoring, as well as unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

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

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

- the efficacy and potential advantages compared to alternative treatments, including less expensive generic treatments;
- the ability to obtain abuse-deterrent claims in the labels for most of our product candidates;
- our ability to offer our prodrug products for sale at competitive prices;
- the clinical indications for which our product candidates are approved;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the cost of treatment in relation to alternative treatments;
- the steps that prescribers and dispensers must take, since most of our product candidates are controlled substances, as well as the perceived risks based upon their controlled substance status;
- the ability to manufacture our product in sufficient quantities and yields;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement or willingness of patients to pay out of pocket in the absence of third-party coverage;
- the prevalence and severity of any side effects;
- any potential unfavorable publicity;
- any restrictions on the use, sale or distribution of our product candidates, including through REMS; and
- any restrictions on the use of our prodrug products together with other medications.

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

Our industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We will face competition and potential competition from a number of sources, including pharmaceutical and biotechnology companies, specialty pharmaceutical companies, generic drug companies, drug delivery companies and academic and research institutions. Our competitors may develop or market drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products. See "Item 1 - Business - Competition" for more information about our potential competitors.

Many of our potential competitors have substantially greater financial, technical and human resources than we do, as well as more experience in the development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Consequently, our competitors may develop abuse-deterrent or other products for the short-term management of acute pain, or for other indications we are pursuing or may pursue in the future, and such competitors' products may be more effective, better tolerated and less costly than our product candidates. Our competitors may also be more successful in manufacturing and marketing their products than we are. We will also face competition in recruiting and retaining qualified personnel and establishing clinical trial sites and patient enrollment in clinical trials.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The FDA closely regulates promotional materials and other promotional activities. Even if the FDA initially approves product labeling that includes a description of the abuse-deterrent claims, the FDA may object to our marketing claims and product advertising campaigns. Failure to comply with the FDA's

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

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

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

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

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- termination of clinical trial sites or entire trial programs;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- significant costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards paid to trial participants or patients;
- product recalls, withdrawals or labeling revisions and marketing or promotional restrictions;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any prodrug products that we may develop.

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

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

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

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

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

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

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

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

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

- differing regulatory requirements in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market with low or lower prices rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA 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. For instance, we expect that at least some of our product candidates would likely be required to carry black box warnings, including warnings regarding tampering, lethality if our oral tablets are prepared for injection and hepatotoxicity.

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

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

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

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

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or arranging for the purchase, lease or order of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid;

- federal civil and criminal false claims laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making or using a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government, including erroneous pricing information on which mandatory rebates, discounts and reimbursement amounts are based, or in the case of the civil False Claims Act, for violations of the Anti-Kickback Statute in connection with a claim for payment or for conduct constituting reckless disregard for the truth;

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

- HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by HITECH and their respective implementing regulations, which impose obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, created under Section 6002 of the ACA, and its implementing regulations, which imposes 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, including, other state legislation, which requires pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, or register their sales representatives, and that prohibits pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and prohibiting certain other sales and marketing practices.

These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us.

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, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, 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.

There have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments in the future. In January 2017, Congress voted to approve the Budget Resolution that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law; however, it is widely viewed as the first step toward the passage of repeal legislation. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the ACA that are repealed. We cannot predict how the ACA, its possible repeal, or any legislation that may be proposed to replace the ACA will impact our business.

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 2025 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. Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. 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 expect that the healthcare reform measures that have been adopted and may be adopted in the future, may, among other things, result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our prodrug product candidates.

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

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

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

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

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

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

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

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

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from malicious human acts, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Moreover, despite network security and back-up measures, some of our and our vendors' servers are potentially vulnerable to physical or electronic break-ins, including cyber-attacks, computer viruses and similar disruptive problems. These events could lead to the unauthorized access, disclosure and use of non-public information. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. If our computer systems are compromised, we could be subject to fines, damages, litigation and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business and could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

Risks Related to Employee Matters and Managing Our Growth

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

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

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

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

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

Prior to our initial public offering, there had been no public market for our common stock. An active trading market for our shares may not be sustained. If an active market for our common stock is not sustained, it may be difficult for you to sell our shares at an attractive price or at all.

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

Our stock price has been, and is likely to continue to be, volatile. Since shares of our common stock were sold in our initial public offering in April 2015 at a price of $11.00 per share, our stock price has ranged from $2.90 to $26.15 through March 7, 2017. In addition, the stock market in general and the market for pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- actual or anticipated variations in our operating results;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the pharmaceutical industry;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- adverse regulatory announcements or determinations regarding our product candidates;
- 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.

Many of the factors described above are not within our control. For instance, in May 2016, we announced that the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the FDA voted 16 to four for the approval of Apadaz, but voted 18 to two against inclusion of abuse deterrent labeling for Apadaz. The announcement was followed by a substantial decrease in the trading price of our common stock on The NASDAQ Global Market. Additionally, when we announced in June 2016 that the FDA had issued the CRL for our Apadaz NDA, the trading price of our common stock on The NASDAQ Global Market was subject to another substantial decrease. We cannot guarantee that future announcements will not have similar effects on the trading price of our common stock.

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. For instance, in December 2016, we received notice of a class action suit filed against us by a stockholder in the Iowa District Court in Johnson county alleging that we, certain of our senior executives and directors who signed the registration statement in connection with our initial public offering, and each of the investment banks that acted as underwriters for the offering negligently issued untrue statements of material facts and omitted to state material facts required to be stated in the registration statement and incorporated offering materials that we filed with the SEC in support of the offering. The plaintiff does not quantify any alleged damages in his complaint but, in addition to attorneys' fees and costs, the plaintiff seeks to recover damages and obtain other relief on behalf of himself and all other persons who purchased our common stock pursuant or traceable to the offering and the registration statement and who were allegedly damaged thereby. In January 2017, the suit was removed to the U.S. District Court for the Southern District of Iowa. The plaintiff has since filed a motion to remand the case to the Iowa District Court, and that motion is still pending. The suit is still in a preliminary stage and has not yet been set for trial. As such, we are unable to predict the timing or outcome of this litigation as of the date of this report. Such litigation could cause us to incur substantial costs and divert management's attention and resources from our business. Further, companies listed on The NASDAQ Global Market, and biotechnology and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

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

The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our shares or change their opinion of our shares, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

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

In December 2016, we received notice of a class action suit filed against us by a stockholder in the Iowa District Court in Johnson county alleging that we, certain of our senior executives and directors who signed the registration statement in connection with our initial public offering, and each of the investment banks that acted as underwriters for the offering negligently issued untrue statements of material facts and omitted to state material facts required to be stated in the registration statement and incorporated offering materials that we filed with the SEC in support of the offering. The plaintiff does not quantify any alleged damages in his complaint but, in addition to attorneys' fees and costs, the plaintiff seeks to recover damages and obtain other relief on behalf of himself and all other persons who purchased our common stock pursuant or traceable to the offering and the registration statement and who were allegedly damaged thereby. In January 2017, the suit was removed to the U.S. District Court for the Southern District of Iowa. The plaintiff has since filed a motion to remand the case to the Iowa District Court, and that motion is still pending. The suit is still in a preliminary stage and has not yet been set for trial. 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.

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

As of December 31, 2016, we had outstanding immediately exercisable warrants to purchase 59,714 shares of our common stock at a weighted average exercise price of $5.85 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 (i) a warrant to purchase 14,423,076 shares of Series D redeemable convertible preferred stock at an exercise price of $0.78 per share, which is exercisable until June 2, 2024, or the Deerfield Warrant, and (ii) a secured convertible note, or the Deerfield Note, in the principal amount of $10.0 million, which bears interest at 9.75% per annum. Upon completion of our initial public offering, the Deerfield Warrant automatically converted into a warrant to purchase 1,923,077 shares of our common stock at an exercise price of $5.85 per share and the outstanding principal and accrued interest under the Deerfield Note became convertible into shares of our common stock at a conversion price of $5.85 per share. The Deerfield Warrant and Deerfield Note each include an exercise or conversion, as applicable, price protection provision, pursuant to which the exercise or conversion, as applicable, price of the warrant or note 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 Deerfield Warrant's exercise price or the Deerfield Note's conversion price, as applicable, or the closing sale price of our common stock as reported on The NASDAQ Global Market on the last trading date immediately prior to such issuance or, in the case of a firm commitment underwritten offering, on the date of execution of the underwriting agreement between us and the underwriters for such offering. Additionally, pursuant to the terms of our fourth amendment to the Deerfield Warrant and Deerfield Note, if we effect an "at the market offering" as defined in Rule 415 of the Securities Act, of our common stock, the exercise price of the Deerfield Warrant and conversion price of the Deerfield Note will be adjusted downward pursuant to this anti-dilution adjustment only if such sales are made at a price less than $5.85 per share.

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.

Additionally, we previously 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 on the Deerfield Note into shares of our common stock at a conversion price of $5.85 per share.

According to the terms of the Deerfield Note, in no event may Deerfield convert the Deerfield Note to the extent such conversion would result in Deerfield beneficially owning more than 9.985% of the then issued and outstanding shares of our common stock. This conversion limitation may not be waived and any purported conversion that is inconsistent with this conversion limitation will be null and void. This conversion limitation will not apply to any conversion made immediately prior to a change of control transaction. If Deerfield is only able to convert the Deerfield Note into a limited number of shares due to this conversion limitation, the Deerfield Note could subsequently become convertible into the remainder of the shares as a result of a variety of events. This could occur, for example, if we issue more shares or Deerfield sells some of its existing shares. Without regard to this conversion limitation, the Deerfield Note is convertible into 1,751,296 shares of our common stock, assuming a conversion date of December 31, 2016. The conversion price of the Deerfield Note will be adjusted downward if we issue or sell any shares of common stock, convertible securities, warrants or options at a sale or exercise price per share less than the greater of the Deerfield Note's conversion price or the closing sale price of our common stock as reported on The NASDAQ Global Market on the last trading date immediately prior to such issuance, or, in the case of a firm commitment underwritten offering, on the date of execution of the underwriting agreement between us and the underwriters for such offering. Although, if we effect an "at the market offering" as defined in Rule 415 of the Securities Act, of our common stock, the exercise price of the Deerfield Warrant and conversion price of the Deerfield Note will be adjusted downward pursuant to this anti-dilution adjustment only if such sales are made at a price less than $5.85 per share.

Additionally, in February 2016, we issued the 2021 Notes. The 2021 Notes are convertible at an initial conversion rate of 58.4454 shares of our common stock per $1,000 principal amount of the 2021 Notes, subject to adjustment under the indenture governing the 2021 Notes, which is equal to an initial conversion price of approximately $17.11 per share of our common stock. Upon conversion, the 2021 Notes will be settled in shares of our common stock, together with a cash payment in lieu of delivering any fractional shares. The conversion rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date, we will increase the conversion rate for a holder who elects to convert its 2021 Notes in connection with such a corporate event in certain circumstances. Holders who convert on or after the date that is one year after the last date of original issuance of the 2021 Notes may also be entitled to receive, under certain circumstances, an interest make-whole payment payable in shares of common stock. Without regard to this conversion, the 2021 Notes are convertible into 5,040,914 shares of our common stock, assuming a conversion date of December 31, 2016.

If Deerfield or the holders of the 2021 Notes elect to convert the Deerfield Note or the 2021 Notes, your ownership interest will be diluted and the market price of our common stock may be materially and adversely effected.

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

Additionally, in October 2016, we entered into a Common Stock Sales Agreement, or the ATM Agreement, with Cowen and Company, LLC, or Cowen, under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $50,000,000 through Cowen as our sales agent. Cowen may sell common stock under the ATM Agreement by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act, including without limitation sales made by means of ordinary brokers' transactions on The NASDAQ Global Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise directed by us. Cowen will use commercially reasonable efforts to sell the common stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). To the extent that we direct Cowen to make any sales of our common stock under the ATM Agreement, our stockholders may experience additional dilution, which could cause our stock price to fall.

Our substantial indebtedness may limit cash flow available to invest in the ongoing needs of our business.

As of December 31, 2016, we had $96.25 million of convertible notes outstanding, consisting of the $10 million Deerfield Note and $86.25 million of 2021 Notes.

The Deerfield Note bears interest at 9.75% per annum. Interest accrued on outstanding debt under the Deerfield Note 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 Note, provided that all such interest were due on July 1, 2016. We elected this option on all eight of the scheduled interest payments through June 30, 2016 and paid such interest on July 1, 2016. We must repay one-third of the outstanding principal amount of all debt issued under the Deerfield Note on the fourth and fifth anniversaries of the Deerfield Note. We are then obligated to repay the balance of the outstanding principal amount on February 14, 2020. If we are required to pay additional outstanding amounts due under the Deerfield Note prior to maturity or otherwise incur unanticipated monetary obligations under the Deerfield Note, our cash flow available to invest in the ongoing needs of our business may be limited.

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

also lead to a default under agreements governing future indebtedness. Our inability to generate sufficient cash flow to satisfy our debt service obligations, or to refinance or restructure our obligations on commercially reasonable terms or at all, would likely have a material adverse effect on our business, financial condition and results of operations.

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

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

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

The 2021 Notes contain an embedded derivative, which requires mark-to-market accounting treatment and could result in a gain or loss on a quarterly basis with regards to the mark-to-market value of that feature. Such accounting treatment could have a material impact on, and could potentially result in significant volatility in, our quarterly results of operations. Additionally, certain features of the 2021 Notes may result in the yield on the 2021 Notes not being deductible by us for tax purposes.

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

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

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

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

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

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

In addition, the provisions of our termination agreement with MonoSol and our agreements with Deerfield and the holders of our 2021 Notes may discourage, delay or prevent a change in control of our company. For example, if we enter into a merger, an asset sale or any other change of control transaction, then MonoSol will be entitled to a percentage in the low teens of the price being paid to us and our stockholders in such transaction which is attributable to the value of KP415. Pursuant to the Deerfield Note, 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 the Deerfield Note immediately prior to consummation of such event. Further, under the Deerfield Warrant, Deerfield has the right to demand that we redeem the Deerfield Warrant for a cash amount equal to the Black-Scholes value of a portion of the warrant upon the occurrence of specified events, including a merger, an asset sale or any other change of control transaction. Furthermore, the indenture governing the 2021 Notes requires us to repurchase the 2021 Notes for cash if we undergo certain fundamental changes. A takeover of us may trigger the requirement that we repurchase the 2021 Notes, which could make it more costly for a potential acquirer to engage in a business combination transaction with us.

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

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

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

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

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

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

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

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

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

As of December 31, 2016, we had federal net operating loss carryforwards of approximately $103.4 million, due to prior period losses, which if not utilized will begin to expire in 2027. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities, which could adversely affect our profitability. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ''ownership change,'' which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have not determined if we have experienced Section 382 ownership changes in the past and if a portion of our net operating loss carryforwards are subject to an annual limitation under Section 382. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, including as a result of our initial public offering, the conversion of our outstanding convertible debt or as a result of future changes in our stock ownership. If we determine that an ownership change has occurred and our ability to use our historical net operating loss carryforwards is materially limited, it would harm our future operating results by increasing our future tax obligations.

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

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Commencing with our fiscal year ending December 31, 2016, we performed 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 this Annual Report on Form 10-K, as required by Section 404 of the Sarbanes-Oxley Act. We will be required to perform this 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 on an annual basis. This will require that we incur substantial additional professional fees and internal costs and that we expend significant management efforts on an annual basis. We have and will be required to test our internal controls within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements.

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, 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 SEC, or other regulatory authorities.

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

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We occupy 1,000 square feet of headquarters office and laboratory space in Coralville, Iowa, under a non-cancelable lease agreement that expires in September 2017, and we have the right to extend the term of the lease for successive one year terms upon expiration. We also occupy approximately 17,000 square feet of office space in Celebration, Florida, comprised of two contiguous office suites, under a non-cancelable lease agreement that expires in August 2025 and February 2026, respectively. We have the right to extend the term of the lease for two successive five-year terms upon expiration. In addition, we occupy leased spaces in Durham, North Carolina and Blacksburg, Virginia. We believe that our facilities are adequate for our current needs.

ITEM 3. LEGAL PROCEEDINGS

In December 2016, we received a class action suit filed against us by a stockholder in the Iowa District Court in Johnson county alleging that we, certain of our senior executives and directors who signed the registration statement in connection with our initial public offering, and each of the investment banks that acted as underwriters for the offering negligently issued untrue statements of material facts and omitted to state material facts required to be stated in the registration statement and incorporated offering materials that we filed with the SEC in support of the offering. The plaintiff does not quantify any alleged damages in his complaint but, in addition to attorneys' fees and costs, the plaintiff seeks to recover damages and obtain other relief on behalf of himself and all other persons who purchased our common stock pursuant or traceable to the offering and the registration statement and who were allegedly damaged thereby.

In January 2017, the suit was removed to the U.S. District Court for the Southern District of Iowa. The plaintiff has since filed a motion to remand the case to the Iowa District Court, and that motion is still pending. The suit is still in a preliminary stage and has not yet been set for trial. As such, we are unable to predict the timing or outcome of this litigation as of the date of this report.

From time to time, we may be involved in routine legal proceedings, as well as demands, claims and threatened litigation, which arise in the normal course of our business. As of the date of this report we are unable to predict whether the pending litigation described above could have a material adverse effect on our results of operations or financial condition.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES

Price Range of Common Stock

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

	Low	High
Year ended December 31, 2015		
Second Quarter (beginning April 16, 2015)	$ 10.90	$ 20.08
Third Quarter	$ 14.60	$ 26.15
Fourth Quarter	$ 12.79	$ 21.30
Year Ended December 31, 2016		
First Quarter	$ 10.16	$ 19.72
Second Quarter	$ 3.52	$ 19.75
Third Quarter	$ 3.69	$ 5.50
Fourth Quarter	$ 2.90	$ 5.09

Holders of our Common Stock

As of March 7, 2017, we had 172 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

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

Securities Authorized for Issuance under Equity Compensation Plans

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

Recent Sales of Unregistered Securities

Not applicable.

Issuer Purchases of Equity Securities

Not applicable.

Use of Proceeds

On April 21, 2015, we closed our initial public offering, in which we issued and sold 5,090,909 shares of common stock at a public offering price of $11.00 per share. Subsequently, on May 12, 2015, we sold an additional 763,636 shares of our common stock pursuant to the underwriters’ option to purchase additional shares. In the aggregate, the gross proceeds of our initial public offering, including gross proceeds from the underwriters’ exercise of their option to purchase additional shares, were $64.4 million. All of the shares issued and sold in our initial public offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-202660), which was declared effective by the SEC on April 15, 2015. Cowen and Company, LLC, RBC Capital Markets, LLC, Canaccord Genuity Inc. and Oppenheimer & Co. Inc. acted as the underwriters. The offering commenced on April 15, 2015, and did not terminate before all of the securities registered in the registration statement were sold.

The net offering proceeds to us were $59.9 million, after deducting underwriting discounts and commissions totaling $4.5 million. In addition, offering expenses totaled $2.8 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. There has been no material change in the planned use of proceeds from our initial public offering as described in our prospectus dated April 15, 2015, and filed with the SEC on April 16, 2015, pursuant to Rule 424(b) of the Securities Act. Through December 31, 2016, $35.6 million of the net proceeds had been used to fund the development of Apadaz and our other product candidates and for working capital and other general corporate purposes.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

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

Overview

We are a clinical-stage specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs that we believe will be improved versions of widely prescribed, approved drugs. We employ our LAT platform technology to create our prodrugs. We are building a pipeline of prodrug product candidates that target large market opportunities in pain, ADHD and CNS disorders. Our two lead product candidates are KP415, our ER d-threo-methylphenidate product candidate for the treatment of ADHD, and KP201/IR, our APAP-free, single-entity, benzhydrocodone hydrochloride IR abuse-deterrent product candidate designed for the treatment of acute pain. We own worldwide commercial rights for all of our product candidates, except that Shire has a right of first refusal to acquire, license or commercialize KP415.

We previously submitted an NDA to the FDA for our product candidate Apadaz, which consists of KP201, our prodrug of hydrocodone, and acetaminophen. In June 2016, the FDA issued the CRL for our Apadaz NDA. Generally, the FDA issues CRLs to indicate that the FDA considers the review cycle for an application complete and that the application is not ready for approval in its present form. In its CRL, the FDA advised us that it did not believe our proposed labeling included in the application accurately conveyed the outcome of our abuse deterrence studies of Apadaz. In August 2016, we completed our end-of-review meeting with the FDA. At the end-of-review meeting, we discussed with the FDA the issues identified by the FDA in the Apadaz NDA and what we believe is the potential to achieve a path forward for an Apadaz product label that could include abuse deterrence claims. The meeting also involved discussions pertaining to abuse deterrence in relation to the broader IR prescription opioid market, hydrocodone-acetaminophen combination products, and published industry guidance from the FDA concerning the evaluation and labeling of abuse deterrent opioids. In November 2016, we elected to continue the regulatory review process for Apadaz with the submission of a FDRR to the FDA. We anticipate up to twelve months may be required to complete all parts of the FDRR process.

We are a development stage company and have not generated any revenue. We have incurred operating losses since our inception and, as of December 31, 2016, had an accumulated deficit of $121.3 million. Our losses from operations for the years ended December 31, 2016, 2015 and 2014 were $37.5 million, $22.8 million and $16.4 million, respectively.

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

- continue our ongoing preclinical studies, clinical trials and our product development activities for our pipeline of product candidates;
- seek regulatory approvals for any 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; and
- incur additional legal, accounting and other expenses in operating as a public company.

Our commercial revenue, if any, will be derived from sales of prodrug products and we do not currently know when, if ever, any of our product candidates will be commercially available. 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 debt securities, the terms of these securities 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 the Supply Agreement with JMI, pursuant to which JMI has agreed to supply us with all of the KP201 necessary for clinical trials and commercial sale for a price equal to JMI's manufacturing cost and to provide process optimization and development services for KP201. In exchange, we issued shares of our common stock to JMI, provided that the commercial supply arrangement for KP201 would be exclusive to JMI in the United States and agreed to pay JMI royalties on the net sales of any products that utilize KP201 as the API. 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 any products that utilize KP201 as the API, JMI will manufacture batches of KP201 at a price to be negotiated. Failure to agree upon this pricing would result in JMI supplying these batches to us free of charge and we would pay JMI an additional royalty payment on such batches. The percentage royalty rate ranges from the low teens at low volumes to the low single digits at higher volumes and is additive to any minimum royalty we may owe JMI on such batch. JMI will manufacture and supply KP201 at a price equal to JMI's fully allocated manufacturing cost after commercial launch should we obtain approval for marketing from the FDA.

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 any product that utilizes KP201 as the API, 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 the commercial launch of any product that utilizes KP201 as the API, whichever date is later. Upon the expiration of such term, the agreement will automatically renew for a period of two years unless either party provides 12 months' prior notice of its intent not to renew.

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

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

Components of our Results of Operations

Revenue

To date, we have not generated any revenue. We do not currently know when, if ever, we will generate revenue. 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 three categories: research and development expenses, general and administrative expenses and severance expense. 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 research and development expenses and general and administrative expenses 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.

The following table summarizes our research and development expenses for the years ended December 31, 2016, 2015 and 2014 (in thousands):

	Year Ended December 31, 2016	Year Ended December 31, 2015	Year Ended December 31, 2014
Outsourced development costs directly identified to programs:			
Apadaz	$ 7,019	$ 7,342	$ 9,049
KP201/IR (APAP-free)	18	—	—
KP415	2,889	111	—
KP511	2,511	1,564	—
KP606/IR	24	—	—
Total costs directly identified to programs	12,461	9,017	9,049
Costs not directly allocated to programs:			
Employee expenses including cash compensation, benefits and share-based compensation	5,198	3,655	1,861
Facilities	394	197	160
Other	2,419	1,062	847
Total costs not directly allocated to programs	8,011	4,914	2,868
Total research and development expenses	$ 20,472	$ 13,931	$ 11,917

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

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

General and Administrative Expense

General and administrative expense consists primarily of salaries and personnel-related costs, including employee benefits and any stock-based compensation, for employees performing functions other than research and development. This includes personnel in executive, finance, human resources and administrative support functions. Other general and administrative expenses include facility-related costs not otherwise allocated to research and development expense, professional fees for auditing, tax and legal services, expenses associated with obtaining and maintaining patents, consulting costs and costs of our information systems.

We expect that our general and administrative expense will increase as we continue to operate as a public reporting company and continue to develop our product candidates. We believe that these increases will likely include increased 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.

Severance Expense

Severance expense consists primarily of salaries and personnel-related costs, including employee benefits and any stock-based compensation, for employees terminated in the third quarter of 2016 due to the deferral of commercial operations and realignment of financial resources and operational priorities during the period. At this time, we do not expect to incur significant additional severance expense in future periods.

Other Income (Expense)

Other income (expense) 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 income (expense) also includes interest expense incurred on our outstanding borrowings, as well as, interest and other income consisting primarily of interest earned on investments. Additionally, we recognized a loss on extinguishment of debt, for the year ended December 31, 2016, related to the payment of our term note previously issued to Deerfield and for 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 income (expense) in our statements of operations.

Income Tax Benefit (Expense)

Income tax benefit (expense) 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, 2016 and 2015 (in thousands):

	Year Ended December 31, 2016	Year Ended December 31, 2015	Period-to-Period Change
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	20,472	13,931	6,541
General and administrative	14,000	8,883	5,117
Severance expense	3,010	—	3,010
Total operating expenses	37,482	22,814	14,668
Loss from operations	(37,482)	(22,814)	(14,668)
Other income (expense):			
Loss on extinguishment of debt	(4,740)	—	(4,740)
Interest expense related to amortization of debt issuance costs and discount	(1,616)	(1,909)	293
Interest expense on principal	(5,511)	(2,671)	(2,840)
Fair value adjustment	32,465	(27,276)	59,741
Interest and other income	353	32	321
Total other income (expense)	20,951	(31,824)	52,775
Loss before income taxes	(16,531)	(54,638)	38,107
Income tax benefit (expense)	15	(26)	41
Net loss	$ (16,516)	$ (54,664)	$ 38,148

Net Loss

Net loss for the year ended December 31, 2016 was $16.5 million, which was a decrease of $38.2 million compared to net loss for the year ended December 31, 2015 of $54.7 million. The decrease was primarily attributable to an increase in the non-cash income recognized from fair value adjustments of $59.7 million, partially offset by an increase in loss from operations of $14.7 million due to increased activity on the development programs for our product candidates, increased personnel-costs related to an increase in headcount and severance expense, as well as recognition of non-cash loss on extinguishment of debt of $4.7 million, and an increase in net interest expense and other items of $2.1 million.

Research and Development

Research and development expenses increased by $6.6 million, from $13.9 million for the year ended December 31, 2015, to $20.5 million for the year ended December 31, 2016. This increase was primarily attributable to a $3.5 million payment to a third-party to license an abuse deterrent technology, as well as a $1.2 million increase in personnel-related costs due to increased headcount, a $1.0 million increase in professional fees and other expenses related to preparation for, and attendance at, the FDA advisory committee meeting held during the second quarter of 2016, a $0.5 million increase in various research and development costs related to overhead, and a $0.4 million increase in stock-based compensation expense related to the vesting of stock awards during the year ended December 31, 2016.

General and Administrative

General and administrative expenses increased by $5.1 million, from $8.9 million for the year ended December 31, 2015, to $14.0 million for the year ended December 31, 2016. This increase was primarily attributable to a $1.9 million increase in stock-based compensation expense related to the vesting of stock awards, a $1.2 million increase in salaries and personnel-related costs due to increased headcount, a $1.1 million increase in professional fees and other expenses related to Apadaz pre-commercialization efforts, and a $0.9 million increase in various general and administrative costs related to overhead and corporate governance.

Severance Expense

Severance expense of $3.0 million was recognized during the year ended December 31, 2016 due to the deferral of commercial operations and realignment of financial resources and operational priorities during the third quarter of 2016. Severance expense includes $1.1 million of personnel and other related charges and $1.9 million of stock-based compensation expense related to the acceleration of vesting on certain stock options upon termination. We had no severance expense in the year ended December 31, 2015, and we do not expect for severance expense to recur on an annual basis going forward.

Other Income (Expense)

Other income (expense) increased by $52.8 million, from an expense of $31.8 million for the year ended December 31, 2015, to income of $21.0 million for the year ended December 31, 2016. This was primarily attributable to the $59.7 million increase in the fair value adjustment related to our derivative and warrant liability, an increase in interest and other income of $0.3 million and a $0.3 million decrease in the amortization of the debt issuance costs and debt discount during the year ended December 31, 2016. These changes were partially offset by a $4.7 million increase in the loss on extinguishment of debt recognized in the first quarter of 2016 related to the payment of the term note previously issued to Deerfield and a $2.8 million increase in interest expense primarily related to the 2021 Notes during the year ended December 31, 2016.

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

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

Net Loss

Net loss for the year ended December 31, 2015 was $54.7 million, which was an increase of $30.2 million compared to net loss for the year ended December 31, 2014 of $24.5 million. The increase was primarily attributable to an increase in non-cash expense recognized from fair value adjustments of $20.1 million, an increase in loss from operations of $6.4 million, the absence of the non-cash gain on extinguishment of debt of $1.9 million, and an increase in non-cash net interest expense of $1.8 million.

Research and Development

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

General and Administrative

General and administrative expenses increased by $4.4 million, from $4.5 million for the year ended December 31, 2014, to $8.9 million for the year ended December 31, 2015. This increase was primarily attributable to a $1.9 million increase in personnel-related costs due to increased headcount, a $1.6 million increase in stock-based compensation expense related to the vesting of stock awards, a $0.4 million increase in marketing expenses, and a $0.5 million increase in various general and administrative costs related to overhead, accounting expenses and professional fees.

Other Expenses

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

Liquidity and Capital Resources

Sources of Liquidity

Through December 31, 2016, we have funded our research and development and operating activities primarily through the issuance of $115.9 million of debt, $25.3 million of private placements of redeemable convertible preferred stock and the sale of common stock in our initial public offering. As of December 31, 2016, we had cash and cash equivalents of $16.8 million, restricted cash of $1.1 million, marketable securities of $51.0 million, trade date receivables of $5.0 million and long-term investments of $8.2 million. We completed the initial closing of our initial public offering in April 2015, with a subsequent closing in May 2015, pursuant to which we received net proceeds, including net proceeds from the underwriters' exercise of their option to purchase additional shares, of $59.9 million, after deducting underwriting discounts and commissions of $4.5 million. In addition, we incurred offering expenses totaling $2.8 million.

We filed a registration statement on Form S-3 covering the sale from time to time of up to $150.0 million of our common stock, preferred stock, debt securities and/or warrants, which was declared effective by the SEC on October 17, 2016. We have not issued any of our securities under this registration statement.

On October 3, 2016, we entered into the ATM Agreement with Cowen under which we may offer and sell, from time to time, in our sole discretion, shares of common stock having an aggregate offering price of up to $50,000,000 through Cowen as our sales agent. The registration statement on Form S-3 included a prospectus covering the offering up to $20,000,000 of shares of common stock in accordance with the ATM Agreement. We have not sold any shares of our common stock pursuant to the terms of the ATM Agreement.

We have incurred operating losses since our inception and, as of December 31, 2016, had an accumulated deficit of $121.3 million. We anticipate that we will continue to incur operating 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.

Convertible Debt

As of December 31, 2016, we had $96.25 million of convertible notes outstanding comprised of the $10 million Deerfield Note and $86.25 million of 2021 Notes.

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 the $10.0 million Deerfield Note. We used approximately $18.6 million of the net proceeds from the offering of our 2021 Notes to repay in full the $15.0 million original principal amount on the term note issued under Deerfield facility plus all accrued but unpaid interest on the term note, a make whole interest payment on the term note and a prepayment premium on the term note. Deerfield is no longer obligated to provide us any additional disbursements under the Deerfield facility.

All loans issued under the Deerfield facility, including the Deerfield Note, 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 was due on July 1, 2016. We elected this option on all eight of the scheduled interest payments through June 30, 2016 and paid all such interest 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. However, in connection with our offering of the 2021 Notes, on February 3, 2016, we entered into an amendment to the Deerfield facility in which Deerfield consented to the prepayment of the term note and the issuance of the 2021 Notes.

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

We also issued the Deerfield Warrant to purchase 14,423,076 shares of our Series D redeemable convertible preferred stock at an initial exercise price of $0.78 per share. Upon closing of our initial public offering, this warrant converted into a warrant exercisable for 1,923,077 shares of our common stock at an exercise price of $5.85 per share.

Pursuant to the Deerfield facility, we may not enter into specified transactions, including a debt financing in the aggregate value of $750,000 or more, a merger, an asset sale or any other change of control transaction or any joint venture, partnership or other profit sharing arrangement, without the prior approval of Deerfield. Additionally, if we were to enter into a major transaction, including a merger, consolidation, sale of substantially all of our assets or other change of control transaction, Deerfield would have the ability to demand that prior to consummation of such transaction we repay all outstanding principal and accrued interest of the Deerfield Note. Deerfield has the right to demand that we redeem the Deerfield 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 that go into effect in June 2019. After this time, if at any interest payment date our outstanding indebtedness under the Deerfield facility would qualify as an "applicable high yield discount obligation" under the Internal Revenue Code, as amended, or the Code, then we are obligated to prepay in cash on each such date the amount necessary to avoid such classification.

2021 Notes

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

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

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

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

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

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

Cash Flows (in thousands):

Comparison of the Years Ended December 31, 2016 and 2015 (in thousands)

	Year Ended December 31, 2016	Year Ended December 31, 2015	Period-to-Period Change
Net cash used in operating activities	$ (29,772)	$ (20,268)	$ (9,504)
Net cash used in investing activities	(46,947)	(19,137)	(27,810)
Net cash provided by financing activities	61,163	61,468	(305)
Net (decrease) increase in cash and cash equivalents	$ (15,556)	$ 22,063	$ (37,619)

Operating Activities

For the year ended December 31, 2016, net cash used in operating activities of $29.8 million consisted of a net loss of $16.5 million primarily attributable to changes in fair value of our derivative and warrant liabilities and our spending on research and development programs for KP415, KP201/IR and KP511 and $16.6 million in adjustments for non-cash items, partially offset by $3.3 million in changes in working capital. The adjustments for non-cash items primarily consisted of changes in fair value of our derivative and warrant liabilities of $32.5 million and were partially offset by stock-based compensation expense of $6.6 million, a loss on extinguishment of debt of $4.7 million related to the repayment of the term note issued under the Deerfield facility, non-cash interest expense of $2.2 million, amortization of debt issuance costs and debt discount of $1.6 million, and $0.7 million related to the write-off of deferred offering costs, depreciation and amortization and loss on disposal of fixed assets. The changes in working capital were comprised of $1.1 million related to accounts payable and accrued expenses, $2.0 million related to prepaid expenses and other assets, which includes the impact of the refund of the $2.4 million user fee for the Apadaz NDA, and $0.2 million related to other long-term liabilities.

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

Investing Activities

For the year ended December 31, 2016, net cash used in investing activities was $46.9 million, which was primarily attributable to purchases of marketable securities and long-term investments of $89.8 million, cash restricted for collateral of $1.1 million and purchases of property and equipment of $0.6 million, partially offset by maturities of marketable securities of $44.6 million.

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

Financing Activities

For the year ended December 31, 2016, net cash provided by financing activities was $61.2 million. Net cash consisted of (i) $82.8 million in proceeds, net of discounts and commissions, from the issuance of the 2021 Notes, of which we used approximately $18.6 million to repay in full the $15.0 million principal amount, accrued but unpaid interest, a make whole interest payment and a prepayment premium all related to the term note issued under the Deerfield facility and (ii) $0.1 million in proceeds from the exercise of common stock options and warrants; partially offset by payment of $1.9 million of principal on the Deerfield Note, related to capitalized interest that was added to principal, payment of debt issuance costs of $1.0 million and payment of $0.2 million of deferred offering costs and obligations under a capital lease.

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

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

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

Operating Activities

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

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

Investing Activities

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

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

Financing Activities

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

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

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 one of our product candidates. In addition, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, product candidates. We also expect to incur additional costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Based upon our current operating plan, we believe that our existing cash and cash equivalents, restricted cash, marketable securities and long-term investments will enable us to fund our operating expenses and capital expenditure requirements through the second quarter of 2019. 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. To meet any additional cash requirements, we may seek to sell additional equity or convertible securities that may result in dilution to our stockholders. 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 any of our product candidates.

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

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

Our commercial revenue, if any, will be derived from sales of prodrug products and we do not currently know when, if ever, any of our product candidates will be commercially available. 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 debt securities, 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.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Significant Judgments and Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, as well as the reported revenues and expenses during the reported periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

Accrued Expenses

We enter into contractual agreements with third-party vendors who provide research and development, manufacturing, and other services in the ordinary course of business. Some of these contracts are subject to milestone-based invoicing and services are completed over an extended period of time. We record liabilities under these contractual commitments when an obligation has been incurred. This accrual process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed and estimating the level of service performed and the associated cost when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date based on the facts and circumstances known to us. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued expenses include:

- fees paid to CROs in connection with preclinical and toxicology studies and clinical trials;
- fees paid to investigative sites in connection with clinical trials;
- fees paid to contract manufacturers in connection with the production of our raw materials, drug substance and product candidates; and
- professional fees.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of these costs, our actual expenses could differ from our estimates.

Stock-Based Compensation

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

	Year Ended December 31, 2016	Year Ended December 31, 2015	Year Ended December 31, 2014
Research and development	$ 1,051	$ 610	$ 62
General and administrative	3,639	1,759	152
Severance expense	1,910	—	—
	$ 6,600	$ 2,369	$ 214

Determination of the Fair Value of Stock-Based Compensation Grants

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

- we do not have sufficient history to estimate the volatility of our common stock. We calculate expected volatility based on reported data for selected similar publicly traded companies for which the historical information is available. For the purpose of identifying peer companies, we consider characteristics such as industry, length of trading history, similar vesting terms and in-the-money option status. We plan to continue to use the guideline peer group volatility information until the historical volatility of our common stock is sufficient to measure expected volatility for future option grants;

- the assumed dividend yield is based on our expectation of not paying dividends for the foreseeable future;

- we determine the average expected life of "plain vanilla" stock options based on the simplified method in accordance with SEC Staff Accounting Bulletin Nos. 107 and 110, as our common stock to date has been publicly traded for a limited amount of time. We expect to use the simplified method until we have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term. For options that are not considered "plain vanilla," such as those with exercise prices in excess of the fair market value of the underlying stock, we use an expected life equal to the contractual term of the option;

- we determine the risk-free interest rate by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant; and

- we estimate forfeitures based on our historical analysis of actual stock option forfeitures.

We account for stock-based compensation arrangements with directors and consultants that 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 consultant and other non-employee options subject to vesting, the compensation costs of these arrangements are subject to re-measurement over the vesting period.

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

	Year Ended December 31, 2016	Year Ended December 31, 2015	Year Ended December 31, 2014
Risk-free interest rate	1.29% - 1.50%	1.40% - 1.99%	0.91% - 2.70%
Expected term (in years)	5.50 - 6.25	4.33 - 6.25	7.00 - 10.00
Expected volatility	77.38% - 94.78%	68.79% - 86.84%	86.00% - 95.00%
Expected dividend yield	0%	0%	0%

Based upon the stock price of $2.95 per share, which is the last sale price of our common stock reported on The NASDAQ Global Market as of December 31, 2016, the aggregate intrinsic value of outstanding options to purchase shares of our common stock as of December 31, 2016 and 2015, was $26,000 and $9.2 million, respectively, of which $26,000 as of December 31, 2016, and $5.1 million as of December 31, 2015, related to vested options and $0 as of December 31, 2016, and $4.1 million as of December 31, 2015, related to unvested options.

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

The following table summarizes by grant date the number of shares of common stock subject to stock options granted between January 1, 2014 and March 2, 2015, as well as the associated per-share exercise price and the estimated fair value per share of our common stock on the grant date:

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

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

In 2014, we undertook third-party valuations of the fair value of our common stock as of 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 June 2, 2014 stock option grants, were used to measure the stock-based compensation expense for options granted during these periods.

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

Common Stock Valuation Methodology—Third-Party Valuations

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

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

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

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

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

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

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

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

Fair Value of Financial Instruments

We have common stock warrants, put options embedded within those warrants and fundamental change and make-whole interest provisions embedded within our convertible notes that meet the definition of derivative financial instruments and are accounted for as derivatives. The fair value of these derivatives are based on Monte Carlo simulation models at each reporting period.

The derivative liability for the common stock warrants was $4.2 million at December 31, 2016, and $37.6 million at December 31, 2015. The derivative liability for the put options embedded within the common stock warrants was $0.4 million at December 31, 2016, and $0.2 million at December 31, 2015. The derivative liability for the fundamental change and make-whole interest provisions embedded within our convertible notes was $6,000 at December 31, 2016, and had no value at December 31, 2015, as the convertible notes were issued during 2016. A 10% increase in the enterprise value would result in an increase of $0.5 million in the estimated fair value of the common stock warrants, an increase of $19,000 in the estimated fair value of the put options embedded within the common stock warrants, and an increase of $1,000 in the estimated fair value of the fundamental change and make-whole interest provisions embedded within our convertible notes at December 31, 2016.

Upon exercise of the warrants, we will adjust the associated derivative liability to fair value with any changes recorded in other income (expense). At such time, such 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, 2016, we had federal net operating loss, or NOL, carryforwards of approximately $103.4 million with expiration dates from 2027 to 2036. We also had research and development credit carryforwards of $3.2 million with expiration dates ranging from 2027 to 2036.

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

Emerging Growth Company Status

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

Recent Accounting Pronouncements

On April 5, 2012, President Obama signed the 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, we 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. We have 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 June 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or 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,* or 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. 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. We prospectively adopted ASU 2014-12 effective January 1, 2016. The adoption of ASU 2014-12 did not have a material impact on our financial statements as we do not have any performance-based awards whereby performance could be achieved after the requisite service period.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, or 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 adoption of ASU 2014-15 did not have a material impact on our financial statements as we determined there was no substantial doubt about its ability to continue as a going concern as of December 31, 2016.

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, or ASU 2015-01*, which eliminates from GAAP the concept of extraordinary items, stating that the concept causes uncertainty because (1) it is unclear when an item should be considered both unusual and infrequent and (2) users do not find the classification and presentation necessary to identify those events and transactions. ASU 2015-01 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. We adopted ASU 2015-01 effective January 1, 2016. The adoption of ASU 2015-01 did not have a material impact on our financial statements as we had no extraordinary and/or unusual items recorded in prior periods.

In April 2015, the FASB issued ASU 2015-03, *Interest – Imputation of Interest (Subtopic 835-30),* or ASU 2015-03, which requires the debt issuance costs related to a recognized debt liability be presented in the balance sheet as direct deduction from the carrying amount of that debt liability, consistent with the presentation of debt discounts. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. The adoption of ASU 2015-03 reduced our assets and liabilities by the amount of the debt issuance costs, which was $1.1 million at December 31, 2015. This reclassification had no effect on reported net loss or cash flows.

In May 2014, the FASB issued guidance codified in ASC Topic 606, *Revenue Recognition - Revenue from Contracts with Customers*, which amends the guidance in former ASC 605, *Revenue Recognition*, and becomes effective beginning January 1, 2018. We do not currently expect this standard to have a material effect on its financial statements upon adoption since we are not generating revenue at this time.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes: Balance Sheet Classification of Deferred Taxes (Topic 740)*, or ASU 2015-17, which requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. This update applies to all entities that present a classified statement of financial position. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. We do not currently expect this standard to have a material effect on our financial statements and disclosures upon adoption since we currently maintain a full valuation allowance.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments Overall - Recognition and Measurement of Financial Assets and Liabilities (Topic 825-10)*, or ASU 2016-01, which provides several updates related to Topic 825-10. This update applies to all entities that hold financial assets or owe financial liabilities. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company is currently evaluating the impact of the adoption of ASU 2016-01 on its financial statements and disclosures.

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

In March 2016, the FASB issued ASU 2016-06, *Derivatives and Hedging (Topic 815), Contingent Put and Call Options in Debt Instruments*, or ASU 2016-06, which clarifies the requirements for assessing whether contingent call and put options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts. ASU 2016-06 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted. We do not currently expect this standard to have a material effect on our financial statements and disclosures upon adoption.

In March 2016, the FASB issued ASU 2016-09, *Compensation - Stock Compensation (Topic 718), Improvements to Employee Share-Based Payment Accounting*, or ASU 2016-09, which simplifies several aspects of the accounting for stock-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted. We do not currently expect this standard to have a material effect on our financial statements and disclosures upon adoption.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows - Classification of Certain Cash Receipts and Cash Payments (Topic 230)*, or ASU 2016-15, which addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. This update applies to all entities that are required to present a statement of cash flows under Topic 230. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. We are currently evaluating the impact of the adoption of ASU 2016-15 on our financial statements and disclosures.

In November 2016, the FASB issued ASU 2016-18, *Statements of Cash Flows (Topic 320) - Restricted Cash*, or ASU 2016-18, which addresses the treatment of restricted cash and restricted cash equivalents in the statement of cash flows. This update applies to all entities that have restricted cash or restricted cash equivalents and are required to present a statement of cash flows. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. We are currently evaluating the impact of the adoption of ASU 2016-15 on our financial statements and disclosures.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Our management, with the participation of our chief executive officer and our chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2016. Based on the evaluation of our disclosure controls and procedures as of December 31, 2016, our chief executive officer and our chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our chief executive officer and chief financial officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that: (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(e) under the Exchange Act. Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting. Management has used the framework set forth in the report entitled "*Internal Control – Integrated Framework (2013)"* published by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our internal control over financial reporting. Based on its evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2016, the end of our most recent fiscal year.

Our independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. For as long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

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

Inherent Limitations on Effectiveness of Controls

Our management, including our chief executive officer and our chief financial officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item 10 will be set forth under the headings “Proposal 1 - Election of Directors,” “Executive Officers,” “Information Regarding the Board of Directors and Corporate Governance” and “Section 16(a) Beneficial Ownership Reporting Compliance” in our definitive proxy statement for our 2017 annual meeting of stockholders, or the proxy statement, and, is incorporated herein by reference.

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

ITEM 11. EXECUTIVE COMPENSATION

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

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

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

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

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

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

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

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

(1) *Index list to Financial Statements:*

(2) *Financial Statement Schedules*

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

(3) *Exhibits*

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of KemPharm, Inc.

We have audited the accompanying balance sheets of KemPharm, Inc. as of December 31, 2016 and 2015, and the related statements of operations, changes in redeemable convertible preferred stock and stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2016. 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, 2016 and 2015, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

As discussed in Note A to the financial statements, the Company changed its presentation of debt issuance costs as a result of the adoption of FASB Accounting Standards Update 2015-03, *Interest- Imputation of Interest (Subtopic 835-30)*, effective January 1, 2016.

/s/ Ernst & Young LLP
Certified Public Accountants

Tampa, Florida
March 10, 2017

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

	December 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 16,762	$ 32,318
Restricted cash	1,100	—
Marketable securities	51,003	19,002
Trade date receivables	5,003	—
Prepaid expenses and other current assets	489	2,758
Total current assets	74,357	54,078
Property and equipment, net	1,970	403
Long-term investments	8,200	—
Other long-term assets	360	109
Total assets	$ 84,887	$ 54,590
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 6,444	$ 4,906
Current portion of convertible notes	—	1,369
Current portion of term notes	—	2,041
Current portion of capital lease obligation	157	26
Other current liabilities	41	—
Total current liabilities	6,642	8,342
Convertible notes, net	91,170	7,412
Term notes, net	—	11,118
Derivative and warrant liability	4,618	37,839
Other long-term liabilities	1,153	—
Total liabilities	103,583	64,711
Commitments and contingencies (Note G)		
Stockholders' deficit:		
Common stock, $0.0001 par value, 250,000,000 shares authorized, 14,646,982 shares issued and outstanding as of December 31, 2016; 14,490,954 shares issued and outstanding as of December 31, 2015	1	1
Additional paid-in capital	102,643	94,702
Preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of December 31, 2016 or December 31, 2015	—	—
Accumulated deficit	(121,340)	(104,824)
Total stockholders' deficit	(18,696)	(10,121)
Total liabilities and stockholders' deficit	$ 84,887	$ 54,590

See accompanying notes to financial statements

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

	Year ended December 31,		
	2016	**2015**	**2014**
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	20,472	13,931	11,917
General and administrative	14,000	8,883	4,526
Severance expense	3,010	—	—
Total operating expenses	37,482	22,814	16,443
Loss from operations	(37,482)	(22,814)	(16,443)
Other income (expense):			
(Loss) gain on extinguishment of debt	(4,740)	—	1,900
Interest expense related to amortization of debt issuance costs and discount	(1,616)	(1,909)	(1,114)
Interest expense on principal	(5,511)	(2,671)	(1,605)
Fair value adjustment	32,465	(27,276)	(7,223)
Interest and other income	353	32	8
Total other income (expense)	20,951	(31,824)	(8,034)
Loss before income taxes	(16,531)	(54,638)	(24,477)
Income tax benefit (expense)	15	(26)	22
Net loss	$ (16,516)	$ (54,664)	$ (24,455)
Net loss per share:			
Basic and diluted	$ (1.13)	$ (7.42)	$ (10.27)
Weighted average common shares outstanding:			
Basic and diluted	14,597,053	7,368,681	2,381,041

See accompanying notes to financial statements

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

	Redeemable Convertible Preferred Stock										
	Series						Common	Additional Paid-in	Preferred	Accumulated	Total Stockholders'
	A	B	C	D	D-1	Total	Stock	Capital	Stock	Deficit	Equity
Balance as of January 1, 2014	$ 3,343	$ 3,313	$ 11,892	$ —	$ —	$ 18,548	$ 1,438	$ —	$ —	$ (25,705)	$ (24,267)
Net loss	—	—	—	—	—	—	—	—	—	(24,455)	(24,455)
Stock-based compensation expense	—	—	—	—	—	—	—	214	—	—	214
Change in par value	—	—	—	—	—	—	(1,438)	1,438	—	—	—
Conversion of 2013 convertible notes into Series D preferred stock	—	—	—	4,159	—	4,159	—	—	—	—	—
Issuance of Series D preferred stock as financing fee	—	—	—	1,500	—	1,500	—	—	—	—	—
Balance as of December 31, 2014	$ 3,343	$ 3,313	$ 11,892	$ 5,659	$ —	$ 24,207	$ —	$ 1,652	$ —	$ (50,160)	$ (48,508)
Net loss	—	—	—	—	—	—	—	—	—	(54,664)	(54,664)
Stock-based compensation expense	—	—	—	—	—	—	—	2,369	—	—	2,369
Exercise of stock options and warrants	—	—	—	—	—	—	—	4,749	—	—	4,749
Issuance of Series D-1 preferred stock	—	—	—	—	4,000	4,000	—	—	—	—	—
Issuance of common stock in connection with IPO, net of discounts and commissions	—	—	—	—	—	—	1	59,891	—	—	59,892
Conversion of 2013 warrants to equity classification	—	—	—	—	—	—	—	1,110	—	—	1,110
Conversion of preferred stock into common stock upon IPO	(3,343)	(3,313)	(11,892)	(5,659)	(4,000)	(28,207)	—	28,207	—	—	28,207
Offering expenses charged to equity	—	—	—	—	—	—	—	(3,276)	—	—	(3,276)
Balance as of December 31, 2015	$ —	$ —	$ —	$ —	$ —	$ —	$ 1	$ 94,702	$ —	$ (104,824)	$ (10,121)
Net loss	—	—	—	—	—	—	—	—	—	(16,516)	(16,516)
Stock-based compensation expense	—	—	—	—	—	—	—	6,600	—	—	6,600
Exercise of stock options	—	—	—	—	—	—	—	896	—	—	896

and warrants											
Write-off of deferred offering costs	—	—	—	—	—	—	—	445	—	—	445
Balance as of December 31, 2016	$ —	$ —	$ —	$ —	$ —	$ —	$ 1	$ 102,643	$ —	$ (121,340)	$ (18,696)

See accompanying notes to financial statements

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

	Year ended December 31,		
	2016	**2015**	**2014**
Cash flows from operating activities:			
Net loss	$ (16,516)	$ (54,664)	$ (24,455)
Adjustments to reconcile net loss to net cash used in operating activities:			
Loss (gain) on extinguishment of debt	4,740	—	(1,900)
Write-off of deferred offering costs	445	—	—
Stock-based compensation expense	6,600	2,369	214
Non-cash interest expense	2,222	2,671	1,602
Amortization of debt issuance costs and debt discount	1,616	1,909	1,114
Depreciation and amortization expense	175	84	75
Fair value adjustment	(32,465)	27,276	7,223
Loss on disposal of fixed assets	91	—	—
Change in assets and liabilities:			
Prepaid expenses and other assets	2,018	(1,228)	523
Accounts payable and accrued expenses	1,118	1,315	933
Other long-term liabilities	184	—	—
Net cash used in operating activities	(29,772)	(20,268)	(14,671)
Cash flows from investing activities:			
Purchases of property and equipment	(643)	(135)	(47)
Restricted cash for collateral	(1,100)	—	—
Purchases of marketable securities and long-term investments	(89,849)	(19,002)	—
Maturities of marketable securities and long-term investments	44,645	—	—
Net cash used in investing activities	(46,947)	(19,137)	(47)
Cash flows from financing activities:			
Proceeds from issuance of debt, net of discounts and commissions	82,800	—	25,000
Repayment of term notes and related accrued interest	(18,621)	—	—
Payment of principal on convertible notes arising from capitalized interest	(1,931)	—	—
Payment of deferred offering costs	(164)	(315)	(1,767)
Payment of debt and stock issuance costs	(983)	(2,533)	(163)
Repayment of obligations under capital lease	(79)	(32)	(31)
Proceeds from exercise of common stock options and warrants	141	413	—
Proceeds from issuance of Series D-1 redeemable convertible preferred stock	—	4,000	—
Proceeds from initial public offering, net of discounts and commissions	—	59,892	—
Proceeds from exercise of Series D preferrred stock warrants	—	43	
Repayment of line of credit	—	—	(35)
Net cash provided by financing activities	61,163	61,468	23,004
Net (decrease) increase in cash and cash equivalents	(15,556)	22,063	8,286
Cash and cash equivalents, beginning of year	32,318	10,255	1,969
Cash and cash equivalents, end of year	$ 16,762	$ 32,318	$ 10,255
Supplemental cash flow information:			
Cash paid for interest	$ 3,289	$ —	$ 3
Transfer of warrants to equity upon exercise	755	4,293	—
Fixed assets included in accounts payable and accrued expenses	281	—	—
Deferred offering costs included in accounts payable and accrued expenses	85	428	315
Fixed assets financed under a capital lease agreement	867	—	—
Trade date receivables	5,003	—	—
Unpaid offering costs charged to equity	—	3,276	—
Conversion of preferred stock into common stock upon initial public offering	—	28,207	—
Reclassification of 2013 warrants to equity	—	1,110	—
Embedded put option on Deerfield warrant	—	—	220
Issuance of Series D preferred stock as transaction fee	—	—	1,500
Conversion of 2013 convertible notes and interest into Series D preferred stock	—	—	4,159
Issuance of 2013 warrants and Deerfield warrant	—	—	7,610

See accompanying notes to financial statements

A. Description of Business and Basis of Presentation

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

The Company has experienced recurring losses from operations and negative operating cash flows due to its ongoing research and development of its potential product candidates. The Company also has an accumulated deficit at December 31, 2016. 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.

Reverse Stock Split

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

Initial Public Offering

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

Entry into ATM Agreement

On October 3, 2016, the Company entered into a Common Stock Sales Agreement (the "ATM Agreement") with Cowen and Company ("Cowen") under which the Company may offer and sell, from time to time, in its sole discretion, shares of common stock having an aggregate offering price of up to $50,000,000 through Cowen as the Company's sales agent. The registration statement on Form S-3 included a prospectus covering the offering up to $20,000,000 of shares of common stock in accordance with the ATM Agreement.

The Company's registration statement on Form S-3 contemplated under the ATM Agreement was declared effective by the SEC on October 17, 2016.

Cowen may sell common stock under the ATM Agreement by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act, including without limitation sales made by means of ordinary brokers' transactions on The NASDAQ Global Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise directed by the Company. Cowen will use commercially reasonable efforts to sell the common stock from time to time, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company will pay Cowen a commission of up to three percent (3.0%) of the gross sales proceeds of any common stock sold through Cowen under the ATM Agreement, and also has provided Cowen with customary indemnification rights.

The Company is not obligated to make any sales of common stock under the ATM Agreement. The offering of shares of common stock pursuant to the ATM Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the ATM Agreement, or (ii) termination of the ATM Agreement in accordance with its terms. As of December 31, 2016, the Company had deferred offering costs recorded within other long-term assets in the amount of $0.2 million.

Reclassifications

During the first quarter of 2016, the Company adopted Accounting Standards Update ("ASU") 2015-03, *Interest – Imputation of Interest (Subtopic 835-30)* ("ASU 2015-03"), which requires the debt issuance costs related to a recognized debt liability be presented in the balance sheet as direct deduction from the carrying amount of that debt liability, consistent with the presentation of debt discounts. The adoption of ASU 2015-03 reduced the Company's assets and liabilities by the amount of the debt issuance costs, which was $1.1 million at December 31, 2015. This reclassification had no effect on reported net loss or cash flows.

B. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("GAAP") 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, 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 equivalents.

Marketable Securities and Long-term Investments

The Company maintains investment securities that are classified as trading securities. These securities are carried at fair value with unrealized gains and losses included in other income (expense) on the statements of operations. The securities primarily consist of certificates of deposit, U.S. Treasury securities and U.S. government-sponsored agency securities. As of December 31, 2016 and 2015, respectively, the Company held marketable securities and long-term investments with an aggregate fair value of $50.4 million and $10.1 million that contained aggregate unrealized losses of $50,000 and $6,000, respectively. These marketable securities and long-term investments have been in a continuous unrealized loss position for less than 12 months and the Company expects these investments to fully recovery prior to their maturity.

Property and Equipment

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

Debt Issuance Costs

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

Supply Arrangements

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

Impairment of Long-Lived Assets

Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets may not be recoverable. When such events occur, the Company compares the carrying amounts of the assets to their undiscounted expected future cash flows. If the undiscounted cash flows are insufficient to recover the carrying values, an impairment loss is recorded for the difference between the carrying values and fair values of the asset. No such impairment occurred for the years ended December 31, 2016, 2015 and 2014.

Fair Value of Financial Instruments

The accounting standard for fair value measurements provides a framework for measuring fair value and requires disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, based on the Company's principal or, in absence of a principal, most advantageous market for the specific asset or liability.

The Company uses a three-tier fair value hierarchy to classify and disclose all assets and liabilities measured at fair value on a recurring basis, as well as assets and liabilities measured at fair value on a non-recurring basis, in periods subsequent to their initial measurement. The hierarchy requires the Company to use observable inputs when available, and to minimize the use of unobservable inputs, when determining fair value. The three tiers are defined as follows:

- Level 1—Observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets;
- Level 2—Observable inputs other than quoted prices in active markets that are observable either directly or indirectly in the marketplace for identical or similar assets and liabilities; and
- Level 3—Unobservable inputs that are supported by little or no market data, which require the Company to develop its own assumptions.

Research and Development

Major components of research and development costs include cash compensation, stock-based compensation, depreciation and amortization expense on research and development property and equipment, costs of preclinical studies, clinical trials and related clinical manufacturing, costs of drug development, costs of materials and supplies, facilities cost, overhead costs, regulatory and compliance costs, and fees paid to consultants and other entities that conduct certain research and development activities on the Company's behalf. Costs incurred in research and development are expensed as incurred.

The Company records nonrefundable advance payments it makes for future research and development activities as prepaid expenses. Prepaid expenses are recognized as expense in the statements of operations as the Company receives the related goods or services.

The Company enters into contractual agreements with third-party vendors who provide research and development, manufacturing, and other services in the ordinary course of business. Some of these contracts are subject to milestone-based invoicing and services are completed over an extended period of time. The Company records liabilities under these contractual commitments when an obligation has been incurred. This accrual process involves reviewing open contracts and purchase orders, communicating with the applicable personnel to identify services that have been performed and estimating the level of service performed and the associated cost when the Company has not yet been invoiced or otherwise notified of actual cost. The majority of the service providers invoice the Company monthly in arrears for services performed. The Company makes estimates of the accrued expenses as of each balance sheet date based on the facts and circumstances known. The Company periodically confirms the accuracy of the estimates with the service providers and make adjustments if necessary.

Patent Costs

Patent costs, including related legal costs, are expensed as incurred and recorded within general and administrative expenses on the statements of operations.

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial reporting and tax basis of assets and liabilities, as well as for operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using the tax rates that are expected to apply to taxable income for the years in which those tax assets and liabilities are expected to be realized or settled. Valuation allowances are recorded to reduce deferred tax assets to the amount the Company believes is more likely than not to be realized.

Uncertain tax positions are recognized only when the Company believes it is more likely than not that the tax position will be upheld on examination by the taxing authorities based on the merits of the position. The Company recognizes interest and penalties, if any, related to unrecognized income tax uncertainties in income tax expense. The Company did not have any accrued interest or penalties associated with uncertain tax positions as of December 31, 2016 and 2015.

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 2012, although carryforward attributes that were generated prior to 2012 may still be adjusted upon examination by the Internal Revenue Service if used in a future period. No income tax returns are currently under examination by taxing authorities.

Stock-Based Compensation

The Company measures and recognizes compensation expense for all stock-based payment awards made to employees, officers and directors based on the estimated fair values of the awards as of the grant date. The Company records the value of the portion of the award that is ultimately expected to vest as expense over the requisite service period. The Company also accounts for equity instruments issued to non-employees using a fair value approach under Accounting Standards Codification ("ASC") subtopic 505-50. The Company values equity instruments and stock options granted using the Black-Scholes option pricing model. The value of non-employee stock-based compensation is subject to periodic adjustments as the underlying equity instruments vest and is recognized as an expense over the term of the related financing or the period over which services are received.

Basic and Diluted Net Loss per Share of Common Stock

The Company uses the two-class method to compute net loss per common share because the Company has issued securities, other than common stock, that contractually entitle the holders to participate in dividends and earnings of the Company. The two-class method requires earnings for the period to be allocated between common stock and participating securities based upon their respective rights to receive distributed and undistributed earnings. Holders of each series of the Company's redeemable convertible preferred stock are entitled to participate in distributions, when and if declared by the board of directors, that are made to common stockholders and, as a result, are considered participating securities.

Segment and Geographic Information

Operating segments are defined as components of an enterprise (business activity from which it earns revenue and incurs expenses) for which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker (CODM) is its Chief Executive Officer. The Company views its operations and manages its business as a single operating and reporting segment. All assets of the Company were held in the United States as of December 31, 2016 and 2015.

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 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. 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. The Company prospectively adopted ASU 2014-12 effective January 1, 2016. The adoption of ASU 2014-12 did not have a material impact on the financial statements as the Company does not have any performance-based awards whereby performance could be achieved after the requisite service period.

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 adoption of ASU 2014-15 did not have a material impact on the Company's financial statements as the Company determined there was no substantial doubt about its ability to continue as a going concern as of December 31, 2016.

In January 2015, the FASB issued ASU No. 2015-01, *Income Statement - Extraordinary and Unusual Items (Subtopic 225-20); Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items ("ASU 2015-01")*, which eliminates from GAAP the concept of extraordinary items, stating that the concept causes uncertainty because (1) it is unclear when an item should be considered both unusual and infrequent and (2) users do not find the classification and presentation necessary to identify those events and transactions. ASU 2015-01 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. The Company adopted ASU 2015-01 effective January 1, 2016. The adoption of ASU 2015-01 did not have a material impact on the Company's financial statements as the Company had no extraordinary and/or unusual items recorded in prior periods.

In April 2015, the FASB issued ASU 2015-03, which requires the debt issuance costs related to a recognized debt liability be presented in the balance sheet as direct deduction from the carrying amount of that debt liability, consistent with the presentation of debt discounts. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. The adoption of ASU 2015-03 reduced the Company's assets and liabilities by the amount of the debt issuance costs, which was $1.1 million at December 31, 2015. This reclassification had no effect on reported net loss or cash flows.

Application of New or Revised Accounting Standards—Not Yet Adopted

In May 2014, the FASB issued guidance codified in ASC Topic 606, *Revenue Recognition—Revenue from Contracts with Customers* ("ASC 606"), which amends the guidance in former ASC 605, *Revenue Recognition*, and becomes effective beginning January 1, 2018. The Company does not currently expect this standard to have a material effect on its financial statements upon adoption since the Company is not generating revenue at this time.

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

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments Overall – Recognition and Measurement of Financial Assets and Liabilities (Topic 825-10)* ("ASU 2016-01"), which provides several updates related to Topic 825-10. This update applies to all entities that hold financial assets or owe financial liabilities. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company is currently evaluating the impact of the adoption of ASU 2016-01 on its financial statements and disclosures.

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

In March 2016, the FASB issued ASU 2016-06, *Derivatives and Hedging (Topic 815), Contingent Put and Call Options in Debt Instruments* ("ASU 2016-06"), which clarifies the requirements for assessing whether contingent call and put options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts. ASU 2016-06 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted. The Company does not currently expect this standard to have a material effect on its financial statements and disclosures upon adoption.

In March 2016, the FASB issued ASU 2016-09, *Compensation–Stock Compensation (Topic 718), Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"), which simplifies several aspects of the accounting for share-based payment transactions, including the income tax

consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted. The Company does not currently expect this standard to have a material effect on its financial statements and disclosures upon adoption.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows – Classification of Certain Cash Receipts and Cash Payments (Topic 230)* ("ASU 2016-15"), which addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. This update applies to all entities that are required to present a statement of cash flows under Topic 230. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company is currently evaluating the impact of the adoption of ASU 2016-15 on its financial statements and disclosures.

In November 2016, the FASB issued ASU 2016-18, *Statements of Cash Flows (Topic 320) – Restricted Cash* ("ASU 2016-15"), which addresses the treatment of restricted cash and restricted cash equivalents in the statement of cash flows. This update applies to all entities that have restricted cash or restricted cash equivalents and are required to present a statement of cash flows. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company is currently evaluating the impact of the adoption of ASU 2016-15 on its financial statements and disclosures.

C. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31,	
	2016	2015
Prepaid insurance	$ 333	$ 290
Other receivables	58	2,375
Other prepaid expenses and current assets	98	93
Total	$ 489	$ 2,758

D. Property and Equipment

Property and equipment consists of the following (in thousands):

	December 31,	
	2016	2015
Laboratory equipment	$ 842	$ 530
Furniture and office equipment	733	169
Computers and hardware	231	176
Leasehold improvements	769	6
Total property and equipment	2,575	881
Less: accumulated depreciation and amortization	(605)	(478)
Property and equipment, net	$ 1,970	$ 403

The Company leases various equipment and leasehold improvements under capital lease agreements. The assets under capital leases are included in property and equipment as follows (in thousands):

	December 31,	
	2016	2015
Laboratory equipment	$ 271	$ —
Furniture and office equipment	537	94
Leasehold improvements	59	—
Total property and equipment financed under a capital lease agreement	867	94
Less: accumulated depreciation and amortization	(31)	(22)
Property and equipment financed under a capital lease agreement, net	$ 836	$ 72

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

Asset Category	Useful Life (in years)
Laboratory equipment	10
Furniture and office equipment	5 - 10
Computers and hardware	3 - 7
Leasehold improvements	9

Depreciation and amortization expense, including amounts pertaining to assets held under capital leases, was approximately $175,000, $84,000 and $75,000 for the years ended December 31, 2016, 2015 and 2014, respectively.

E. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following (in thousands):

	December 31, 2016	December 31, 2015
Accrued interest	$ 2,222	$ 698
Accrued banking fees	700	700
Accrued severance	646	—
Accrued payroll	1,024	947
Accounts payable	469	1,252
Other accrued expenses	1,383	1,309
Total	$ 6,444	$ 4,906

F. Debt Obligations

Deerfield Facility Agreement

On June 2, 2014, the Company entered into a $60 million facility agreement (the "Deerfield Facility Agreement") with Deerfield Private Design Fund III, LP ("Deerfield"). The first payment to the Company under the terms of the Deerfield Facility Agreement consisted of a term loan of $15 million (the "Term Notes") and a senior secured loan of $10 million (the "Deerfield Convertible Notes"). Deerfield is no longer obligated to provide the Company any additional disbursements under the Deerfield Facility Agreement. All loans issued under the Deerfield Facility Agreement bear interest at 9.75% per annum. Deerfield may convert any portion of the outstanding principal and any accrued but unpaid interest on the Deerfield Convertible Notes into shares of the Company's common stock at an initial conversion price of $5.85 per share.

The Company also issued to Deerfield a warrant to purchase 14,423,076 shares of Series D redeemable convertible preferred stock ("Series D Preferred") at an exercise price of $0.78 per share, which is exercisable until June 2, 2024 (the "Deerfield Warrant"). Upon completion of the IPO, the Deerfield Warrant automatically converted into a warrant to purchase 1,923,077 shares of the Company's common stock at an exercise price of $5.85 per share. This warrant qualifies as a participating security under ASC Topic 260, *Earnings per Share*, and is treated as such in the earnings per share calculation (Note I). In the event that a Major Transaction occurs, as defined below, Deerfield may require the Company to redeem the Deerfield Warrant for a cash amount equal to the Black-Scholes value of the portion of the Deerfield Warrant to be redeemed (the "Put Option"). A Major Transaction is (i) a consolidation, merger, exchange of shares, recapitalization, reorganization, business combination or other similar event; (ii) the sale or transfer in one transaction or a series of related transactions of all or substantially all of the assets of the Company; (iii) a third-party purchase, tender or exchange offer made to the holders of outstanding shares, such that following such purchase, tender or exchange offer a change of control has occurred; (iv) the liquidation, bankruptcy, insolvency, dissolution or winding-up affecting the Company; (v) the shares of the Company's common stock cease to be listed on any eligible market; and (vi) at any time, the shares of the Company's common stock cease to be registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

In addition, the Company issued to Deerfield 1,923,077 shares of Series D Preferred as consideration for the loans provided to the Company under the Deerfield Facility Agreement. Upon completion of the IPO, these shares automatically reclassified into 256,410 shares of the Company's common stock. The Company recorded the fair value of the shares of Series D Preferred of $1.5 million, to debt issuance costs on the date of issuance. The Company recorded the fair value of the Deerfield Warrant and the embedded Put Option 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.

Pursuant to the Deerfield Facility Agreement, the Company 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 the Company were to enter into a major transaction, including a merger, consolidation, sale of substantially all of its assets or other change of control transaction, Deerfield would have the ability to demand that prior to consummation of such transaction the Company repay all outstanding principal and accrued interest of any notes issued under the Deerfield Facility Agreement. Under the terms of the Deerfield Warrant, 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 Deerfield Warrant upon the occurrence of specified events, including a merger, an asset sale or any other change of control transaction.

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 also obligated to repay the balance of the outstanding principal amount on February 14, 2020. The Company prepaid all outstanding interest and principal on the Term Notes in February 2016.

Interest accrued on outstanding debt under the Deerfield Facility Agreement is due quarterly in arrears. Upon notice to Deerfield, the Company may choose to have one or more of the first eight of such scheduled interest payments added to the outstanding principal amount of the debt issued under the Deerfield Facility Agreement, provided that all such interest was due on July 1, 2016. The Company elected this option on all eight of the scheduled interest payments through June 30, 2016. The accrued interest added to outstanding principal, was paid to Deerfield on July 1, 2016. This accrued interest added to outstanding principal, is reflected as a cash outflow from financing activities in the statement of cash flows.

Second Amendment to Senior Secured Convertible Note and Warrant

On January 6, 2016, the Company entered into a Second Amendment (the "Second Amendment") to the Deerfield Convertible Notes and Deerfield Warrant, by and between the Company and Deerfield. The Second Amendment, among other things, clarified the calculation of an anti-dilution adjustment of the conversion price and exercise price of the Deerfield Convertible Notes and Deerfield Warrant, respectively, in the event that the Company effects a firm commitment underwritten public offering of its securities. Except as modified by the Second Amendment, the Third Amendment (as described below) and the Fourth Amendment (as described below), all terms and conditions of the Deerfield Convertible Notes and Deerfield Warrant remain in full force and effect.

Issuance of 5.50% Senior Convertible Notes and Third Amendment to Senior Secured Convertible Note and Warrant

On February 9, 2016, the Company issued $86.25 million aggregate principal amount of its 5.50% Senior Convertible Notes due 2021 (the "2021 Notes") to Cowen and Company, LLC and RBC Capital Markets, LLC., as representatives of the several initial purchasers (the "Initial Purchasers"), who subsequently resold the 2021 Notes to qualified institutional buyers (the "Note Offering") in reliance on the exemption from registration provided by Rule 144A under the Securities Act of 1933, as amended (the "Securities Act").

The net proceeds from the Note Offering were approximately $82.8 million, after deducting the Initial Purchasers' discount and estimated offering expenses. Concurrent with the Note Offering, the Company used approximately $18.6 million of the net proceeds from the Note Offering to repay in full the Term Notes, plus all accrued but unpaid interest, a make-whole interest payment and a prepayment premium on the Term Notes. This principal, accrued but unpaid interest, make-whole interest payment and prepayment premium on the Term Notes is reflected as a cash outflow from financing activities in the statement of cash flows.

The 2021 Notes were issued pursuant to an Indenture, dated as of February 9, 2016 (the "Indenture"), between the Company and U.S. Bank National Association, as trustee. Interest on the 2021 Notes is payable semi-annually in cash in arrears on February 1 and August 1 of each year, beginning on August 1, 2016, at a rate of 5.50% per year. The 2021 Notes mature on February 1, 2021 unless earlier converted or repurchased. The 2021 Notes are not redeemable prior to the maturity date, and no sinking fund is provided for the 2021 Notes.

The 2021 Notes are convertible at an initial conversion rate of 58.4454 shares of the Company's common stock per $1,000 principal amount of the 2021 Notes, subject to adjustment under the Indenture, which is equal to an initial conversion price of approximately $17.11 per share of common stock. Upon conversion, the 2021 Notes will be settled in shares of the Company's common stock, together with a cash payment in lieu of delivering any fractional share. The conversion rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date, the Company will increase the conversion rate for a holder who elects to convert its 2021 Notes in connection with such a corporate event in certain circumstances.

If the Company undergoes a "fundamental change" (as defined in the Indenture), holders may require that the Company repurchase for cash all or any portion of their 2021 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2021 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. In addition, holders who convert their 2021 Notes on or after the date that is one year after the last date of original issuance of the 2021 Notes may also be entitled to receive, under certain circumstances, an interest make-whole payment payable in shares of the Company's common stock. The Company is bifurcating the fundamental change and make-whole interest payment provisions as embedded derivatives and marking them to fair value each reporting period (Note L).

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

In connection with the Note Offering, on February 3, 2016, the Company entered into a Third Amendment (the "Third Amendment") to the Deerfield Facility Agreement, Deerfield Convertible Notes and Deerfield Warrant with Deerfield. The Third Amendment, among other things, eliminated the Company's ability to require Deerfield to convert the Deerfield Convertible Notes into Company common stock. In addition, pursuant to the Third Amendment, Deerfield consented to the prepayment of the Term Notes and the issuance of the 2021 Notes. Except as modified by the Third Amendment and the Fourth Amendment (as described below), all terms and conditions of the Deerfield Facility Agreement remain in full force and effect.

Fourth Amendment to Deerfield Convertible Notes and Deerfield Warrant

In connection with entering into the ATM Agreement, on October 3, 2016, the Company entered into a Fourth Amendment (the "Fourth Amendment") to the Deerfield Convertible Note and the Deerfield Warrant, by and between the Company and Deerfield. The Fourth Amendment, among other things, clarifies the calculation of an anti-dilution adjustment of the conversion price and exercise price of the Deerfield Convertible Note and Deerfield Warrant, respectively, in the event that the Company effects an "at the market offering" as defined in Rule 415 of the Securities Act of its common stock.

Line of Credit

During the second quarter of 2016, the Company opened a line of credit with a total borrowing capacity of $1.1 million with City National Bank of Florida (the "Line of Credit Agreement") to support several irrevocable letters of credit issued by the bank on behalf of the Company. As of December 31, 2016 the Company had unused letters of credit in the amount of $0.4 million. The line of credit has a maturity date of January 31, 2018. As of December 31, 2016, the Company had no outstanding balance under the line of credit. The Line of Credit Agreement is collateralized by a restricted money market account, equal to the total amount of the borrowing capacity under the line of credit, held by the same bank institution. The money market account is reported as restricted cash on the balance sheet. The line of credit contains no financial covenants. Borrowings under the Line of Credit Agreement carry interest at a rate equal to the 1-month London Interbank Offered Rate plus 2.00% per annum. The interest rate under the Line of Credit Agreement was 2.77%, as of December 31, 2016.

G. Commitments and Contingencies

Legal Matters

From time to time, the Company is involved in various legal proceedings arising in the normal course of business. For some matters, a liability is not probable or the amount cannot be reasonably estimated and, therefore, an accrual has not been made. However, for such matters when it is probable that the Company has incurred a liability and can reasonably estimate the amount, the Company accrues and discloses such estimates. As of December 31, 2016, no accruals have been made related to commitments and contingencies. As of December 31, 2015, the Company had accrued $20,000 related to commitments and contingencies.

In 2014, a former financial advisor of the Company filed a request with the Iowa District Court to declare valid a purported right of first refusal to serve as the Company's exclusive financial advisor for specified strategic transactions and to receive fees for the specified strategic transactions irrespective of whether any such specified transaction occurred during or after the term of the financial advisor's service agreement. This filing by the former financial advisor was made in response to an action initiated by the Company in 2013 seeking a declaratory judgement finding that such purported right was invalid and unenforceable. Two former members of the Company's board of directors (the "Board") joined the lawsuit as intervenors based on the former financial advisor's purported assignment of its rights, or a portion thereof, under the agreement to the intervenors. In September 2015, the court granted summary judgement in favor of the Company with respect to the Company's declaratory judgement action and the former financial advisor's counterclaims and the Company separately entered into settlement agreements with each of the intervenors. The settlements reached with the intervenors did not differ from the accrual previously recorded by the Company by a material amount. The former financial advisor subsequently filed a notice of appeal of the court's ruling with the Supreme Court of Iowa. On January 6, 2016, the Company entered into a Settlement Agreement and Mutual Release (the "Settlement Agreement") with the former financial advisor and Donald DeWaay, Jr. pursuant to which, among other things, the former financial advisor agreed, in exchange for the consideration described therein, to dismiss with prejudice its pending appeal. DeWaay Financial Network's appeal was subsequently dismissed by the Supreme Court of Iowa on January 7, 2016. The settlement amount was commensurate with the contingency recorded in the books and records of the Company. The consideration in the settlement agreement did not differ from the accrual previously recorded by the Company by a material amount.

In December 2016, the Company received notice of a class action suit filed against it by a stockholder in the Iowa District Court in Johnson county alleging that the Company, certain of is senior executives and directors who signed the registration statement in connection with its initial public offering, and each of the investment banks that acted as underwriters for the offering negligently issued untrue statements of material facts and omitted to state material facts required to be stated in the registration statement and incorporated offering materials that the Company filed with the U.S Securities and Exchange Commission in support of the offering. The plaintiff does not quantify any alleged damages in his complaint but, in addition to attorneys' fees and costs, the plaintiff seeks to recover damages and obtain other relief on behalf of himself and all other persons who purchased the Company's common stock pursuant or traceable to the offering and the registration statement and who were allegedly damaged thereby.

In January 2017, the suit was removed to the U.S. District Court for the Southern District of Iowa. The plaintiff has since filed a motion to remand the case to the Iowa District Court, and that motion is still pending. The suit is still in a preliminary stage and has not yet been set for trial. As such, the Company unable to predict the timing or outcome of this litigation as of the date of this report.

Lease Agreements

Iowa

The Company leases office and laboratory facilities in Iowa under a non-cancelable operating lease. The Company's lease for its Iowa facilities expires in September 2017 and includes a renewal option that could extend the lease for successive one year terms upon expiration.

Florida

The Company leases office space in Florida, comprised of two contiguous office suites, under a non-cancelable operating lease, which expires in August 2025 and February 2026, as to each space respectively, and includes the right to extend the term of the lease for two successive five year terms upon expiration.

Virginia

The Company leases office and laboratory facilities in Virginia under a non-cancelable operating lease. In February 2017, the Company modified the lease to expand the amount of office space in the current facility. The Company's lease for its Virginia facilities expires in August 2017.

North Carolina

The Company leases office space in North Carolina under a non-cancelable operating lease. The expiration date of the Company's lease is May 2020, and includes renewal options that could extend the lease for an additional three years.

Capital Lease

The Company leases various laboratory equipment, furniture and office equipment and leasehold improvements 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, 2016, the interest rates for assets under remaining capital leases were 7.19% and 8.05%.

Rent expense for non-cancelable operating and capital leases was $0.6 million, $0.3 million and $0.2 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Future minimum lease payments under capital leases and non-cancelable operating leases as of December 31, 2016, were as follows (in thousands):

Year Ending December 31,	**Capital Leases**	**Operating Leases**
2017	$ 214	$ 555
2018	208	585
2019	208	569
2020	208	499
2021	127	449
Thereafter	—	1,836
Total minimum lease payments	965	$ 4,493
Less: amounts representing interest	(152)	
Total	$ 813	

H. Supply Arrangement

As of December 31, 2016, the Company has one manufacturing arrangement that involves potential future expenditures related to research and development.

In November 2009, the Company entered into a supply agreement (the "Supply Agreement") with Johnson Matthey Inc. ("JMI") whereby JMI has agreed to supply the Company with all of the KP201 necessary for clinical trials and commercial sale for a price equal to JMI's manufacturing cost and to provide process optimization and development services for KP201. The Company's product candidate, KP201/IR, contains KP201 and is under development to treat acute pain. No expense was recorded under this agreement for the years ended December 31, 2016, 2015 and 2014. The Company must purchase all of its U.S. KP201 needs from JMI and JMI cannot supply KP201 to other companies. The term of the Supply Agreement extends as long as the Company holds a valid and enforceable patent for KP201 or until the tenth anniversary of KP201's commercial launch, whichever date is later. Upon the expiration of such term, the agreement will automatically renew for a period of two years unless either party provides 12 months prior notice of its intent not to renew. Under the agreement, JMI will receive a tiered-based royalty share on the net sales on the commercial sale of a FDA approved drug incorporating KP201. No reliable estimate of the future payments can be made at this time.

I. Preferred Stock and Warrants

Authorized, Issued, and Outstanding Preferred Stock

In April 2015, the Company amended and restated its Certificate of Incorporation to decrease the number of its authorized shares of preferred stock to 10,000,000 shares with a par value of $0.0001 per share. As described in Note A, in April 2015, the Company completed an IPO of its common stock. Upon completion of the IPO, all outstanding shares of the Company's redeemable convertible preferred stock were automatically converted or reclassified into an aggregate of 5,980,564 shares of the Company's common stock. As of December 31, 2016, the Company had 10,000,000 shares of authorized and undesignated preferred stock, and did not have any preferred stock outstanding.

Preferred Stock Activity

The following table summarizes redeemable convertible preferred stock activity for the years ended December 31, 2016, 2015 and 2014:

	Shares of					
	Series A Preferred	Series B Preferred	Series C Preferred	Series D Preferred	Series D-1 Preferred	Total
Balance, January 1, 2014	9,704,215	6,220,000	18,557,408	—	—	34,481,623
Shares issued upon conversion of 2013 Convertible Notes	—	—	—	5,332,348	—	5,332,348
Shares issued for financing fee to Deerfield	—	—	—	1,923,077	—	1,923,077
Balance, December 31, 2014	9,704,215	6,220,000	18,557,408	7,255,425	—	41,737,048
Issuance of Series D-1 preferred stock	—	—	—	—	3,200,000	3,200,000
Exercise of Series D preferred warrants	—	—	—	3,205	—	3,205
Effect of reverse stock split	(8,410,377)	(5,390,766)	(16,083,286)	(6,290,844)	(2,784,416)	(38,959,689)
Less: Conversion of preferred stock into common stock upon IPO	(1,293,838)	(829,234)	(2,474,122)	(967,786)	(415,584)	(5,980,564)
Balance, December 31, 2015	—	—	—	—	—	—
Balance, December 31, 2016	—	—	—	—	—	—

Series D-1 Redeemable Convertible Preferred Stock

In February 2015, the Company entered into a stock purchase agreement with Cowen KP Investment LLC in which Cowen KP Investment LLC agreed to purchase and the Company agreed to sell 3,200,000 shares of the Company's Series D-1 redeemable convertible preferred stock for $1.25 per share, or an aggregate of $4.0 million. Upon completion of the IPO, these shares automatically converted into 415,584 shares of the Company's common stock.

Warrants

As described in Note A, in April 2015, the Company completed an IPO of its common stock. Upon completion of the IPO, warrants to purchase 15,499,324 shares of Series D preferred stock were reclassified into warrants to purchase 2,066,543 shares of the Company's common stock.

During 2013, the Company issued $3.8 million of convertible notes and the warrants (the "2013 Warrants") to purchase 1,079,453 shares of equity securities in a future financing meeting specified criteria (a "Qualified Financing"). The 2013 Warrants allow the holders to purchase shares of the same class and series of equity securities issued in the Qualified Financing for an exercise price equal to the per share price paid by the purchasers of such equity securities in the Qualified Financing. When the Company entered into the Deerfield Facility Agreement, the 2013 Warrants became warrants to purchase 1,079,453 shares of Series D preferred stock. Upon completion of the IPO, the 2013 Warrants automatically converted into warrants to purchase 143,466 shares of the Company's common stock at an exercise price of $5.85 per share. The 2013 Warrants, if unexercised, expire on the earlier of June 2, 2019, or upon a liquidation event.

On June 2, 2014, pursuant to the terms of the Deerfield Facility Agreement, the Company issued the Deerfield Warrant to purchase 14,423,076 shares of Series D preferred stock (Note F). The Company recorded the fair value of the Deerfield Warrant as a debt discount and a warrant liability. The Deerfield Warrant, if unexercised, expires on the earlier of June 2, 2024, or upon a liquidation event. Upon completion of the IPO, the Deerfield Warrant automatically

converted into a warrant to purchase 1,923,077 shares of the Company's common stock at an exercise price of $5.85 per share. The Company is amortizing the debt discount to interest expense over the term of the Deerfield Convertible Notes.

The Company determined that the 2013 Warrants and Deerfield Warrant should be recorded as a liability and stated at fair value at each reporting period upon inception. As stated above, upon completion of the IPO, the 2013 Warrants and the Deerfield Warrant automatically converted into warrants to purchase the Company's common stock. The Company marked the 2013 Warrants to fair value and reclassified them to equity upon closing of the IPO. The Deerfield Warrant remains classified as a liability and is recorded at fair value at each reporting period since it can be settled in cash. Changes to the fair value of the warrant liability are recorded through the statements of operations as a fair value adjustment (Note L).

J. Common Stock and Warrants

Authorized, Issued, and Outstanding Common Shares

In April 2015, the Company amended its Certificate of Incorporation to increase the number of its authorized shares of common stock to 250,000,000 shares. Of the authorized shares, 14,646,982 and 14,490,954 shares of common stock were issued and outstanding at December 31, 2016 and 2015, respectively.

At December 31, 2016 and 2015, the Company had reserved authorized shares of common stock for future issuance as follows:

	December 31,	
	2016	**2015**
Conversion of Deerfield Convertible Notes	1,751,296	1,991,219
Conversion of 2021 Notes	5,040,914	—
Outstanding awards under equity incentive plans	1,990,260	1,397,511
Outstanding common stock warrants	2,087,477	2,325,383
Possible future issuances under equity incentive plans	1,244,671	1,410,848
Total common shares reserved for future issuance	12,114,618	7,124,961

Common Stock Activity

The following table summarizes common stock activity for the year ended December 31, 2016, 2015 and 2014:

	Shares of Common Stock
Balance at January 1, 2014	2,381,041
Balance at December 31, 2014	2,381,041
Issuance of common stock in connection with the IPO	5,854,545
Conversion of preferred stock to common stock in connection with the IPO	5,980,564
Common stock warrants exercised	270,038
Common stock options exercised	4,766
Balance at December 31, 2015	14,490,954
Common stock warrants exercised	141,095
Common stock options exercised	14,933
Balance at December 31, 2016	14,646,982

The Company calculates the fair value of common stock warrants using a Monte Carlo simulation. There were warrants exercised for an aggregate of 141,095 and 270,038 shares of common stock during the years ended December 31, 2016 and 2015, respectively. No warrants were exercised during the year ended December 31, 2014. From 2008 through 2012, the Company issued warrants to purchase 595,920 shares of common stock in its private placement offerings of Series A redeemable convertible preferred stock, Series B redeemable convertible preferred stock and Series C redeemable convertible preferred stock (the "Underwriter Warrants") and for leasing laboratory space. The Company accounted for the Underwriter Warrants as a derivative liability, which is adjusted to fair value at each reporting period, with the change in fair value recorded within other expenses in the statements of operations.

K. Stock-Based Compensation

The Company maintains a stock-based compensation plan (the "Incentive Stock Plan") that governs stock awards made to employees and directors prior to completion of the IPO.

In November 2014, the Board, and in April 2015, the Company's stockholders, approved the Company's 2014 Equity Incentive Plan (the "2014 Plan") which became effective in April 2015. The 2014 Plan provides for the grant of stock options, other forms of equity compensation, and performance cash awards. The maximum number of shares of common stock that may be issued under the 2014 Plan is 2,846,304, as of December 31, 2016. In addition, the number of shares of common stock reserved for issuance under the 2014 Plan will automatically increase on January 1 of each year, beginning on January 1, 2016, and ending on and including January 1, 2024, by 4% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Board. Pursuant to the terms of the 2014 Plan, on January 1, 2017, the common stock reserved for issuance under the 2014 Plan automatically increased by 585,879 shares.

During the year ended December 31, 2016, stock options to acquire 14,933 shares of common stock were exercised for approximately $71,000 with an intrinsic value of $169,000. During the year ended December 31, 2015, stock options to acquire 4,766 shares of common stock were exercised for approximately $28,000 with an intrinsic value of $54,000. No stock options were exercised during the year ended December 31, 2014.

Stock-based compensation expense recorded under the Incentive Stock Plan and the 2014 Plan is included in the following line items in the accompanying statements of operations (in thousands):

	Year ended December 31,		
	2016	**2015**	**2014**
Research and development	$ 1,051	$ 610	$ 62
General and administrative	3,639	1,759	152
Severance expense	1,910	—	—
	$ 6,600	$ 2,369	$ 214

Stock Option Awards

The Company estimates the fair value of stock options using the Black-Scholes option-pricing model, which requires the use of subjective assumptions, including the expected term of the option, the expected stock price volatility, expected dividend yield and the risk-free interest rate for the expected term of the option. The expected term represents the period of time the stock options are expected to be outstanding. Due to the lack of sufficient historical exercise data to provide a reasonable basis upon which to otherwise estimate the expected term of the stock options, the Company uses the simplified method to estimate the expected term for its "plain vanilla" stock options. Under the simplified method, the expected term of an option is presumed to be the mid-point between the vesting date and the end of the contractual term. Some options, for example those that have exercise prices in excess of the fair value of the underlying stock, are not considered "plain vanilla" stock options. For these options, the Company uses an expected term equal to the contractual term of the option. Expected volatility is based on historical volatilities for publicly traded stock of comparable 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, 2016, 2015 and 2014, fair value was $9.25, $10.63 and $4.50 per share, respectively. The assumptions used to estimate fair value are as follows:

	December 31, 2016	December 31, 2015	December 31, 2014
Risk-free interest rate	1.29% - 1.50%	1.40% - 1.99%	0.91% - 2.70%
Expected term (in years)	5.50 - 6.26	4.33 - 6.25	7.00 - 10.00
Expected volatility	77.38% - 94.78%	68.79% - 86.84%	86.00% - 95.00%
Expected dividend yield	0%	0%	0%

The activity under the Incentive Stock Plan and the 2014 Plan for the year ended December 31, 2016, 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, 2016	1,397,511	$ 13.28	8.58	$ 9,204,403
Granted	959,375	$ 13.31		
Exercised	(14,933)	$ 4.78		
Canceled, forfeited or expired	(351,693)	$ 11.65		
Outstanding balance at December 31, 2016	1,990,260	$ 13.64	8.27	$ 26,400
Exercisable at December 31, 2016	637,492	$ 10.77	6.78	$ 26,400
Vested and expected to vest at December 31, 2016	1,978,260	$ 13.62	8.27	$ 26,400

Information regarding currently outstanding and exercisable options as of December 31, 2016, 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	0.50	12,000	0.50
$ 3.00	20,666	1.54	20,666	1.54
$ 3.80	99,000	9.81	—	—
$ 4.65	35,994	2.06	35,994	2.06
$ 5.85	298,661	6.26	261,661	6.07
$ 6.05	50,000	9.40	—	—
$ 8.63	21,306	8.12	10,826	8.15
$ 11.00	21,333	8.25	5,333	8.25
$ 11.41	88,000	8.41	88,000	8.41
$ 12.62	340,000	9.11	—	—
$ 13.96	22,500	9.13	—	—
$ 16.06	12,000	9.26	—	—
$ 16.25	98,750	9.17	—	—
$ 16.31	13,500	9.17	—	—
$ 16.61	11,250	8.93	2,812	8.93
$ 17.93	4,500	9.27	—	—
$ 18.10	140,000	9.29	—	—
$ 18.29	205,000	8.48	51,250	8.48
$ 18.38	54,000	9.28	—	—
$ 18.61	32,000	8.65	8,000	8.65
$ 19.02	62,000	8.65	54,000	8.65
$ 20.45	335,000	8.68	83,750	8.68
$ 21.37	6,400	8.69	1,600	8.69
$ 22.12	6,400	8.70	1,600	8.70
	1,990,260	8.27	637,492	6.78

The total fair value of stock options vested during the years ended December 31, 2016, 2015 and 2014, was $5.4 million, $1.1 million and $0.2 million, respectively.

Unvested stock options as of December 31, 2016 and 2015, were as follows:

	Number of Unvested Shares	
Exercise Price	December 31, 2016	December 31, 2015
$ 3.80	99,000	—
$ 5.85	37,000	97,633
$ 6.05	50,000	—
$ 8.63	10,480	147,973
$ 11.00	16,000	21,333
$ 11.41	—	82,035
$ 12.62	340,000	—
$ 13.96	22,500	—
$ 16.06	12,000	—
$ 16.25	98,750	—
$ 16.31	13,500	—
$ 16.61	8,438	11,250
$ 17.93	4,500	—
$ 18.10	140,000	—
$ 18.29	153,750	205,000
$ 18.38	54,000	—
$ 18.61	24,000	38,400
$ 19.02	8,000	62,000
$ 20.45	251,250	335,000
$ 21.37	4,800	6,400
$ 22.12	4,800	6,400
	1,352,768	1,013,424

As of December 31, 2016, there was $10.6 million of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under the Incentive Stock Plan and 2014 Plan. That compensation cost is expected to be recognized over a weighted-average period of 2.86 years.

During the year ended December 31, 2016, the Company recognized $44,000 of stock-based compensation expense related to performance-based awards included in research and development expenses. These awards were in connection with the strategic initiatives set for the award that were achieved in 2016 exercisable for an aggregate of 13,333 shares of common stock during the year ended December 31, 2016. During the year ended December 31, 2015, the Company recognized $0.7 million of stock-based compensation expense related to performance-based awards included in general and administrative expenses and $0.2 million of stock-based compensation expense related to performance-based awards included in research and development expenses. These awards were in connection with the grant of fully vested stock options exercisable for an aggregate of 163,998 shares of common stock during the year ended

December 31, 2015. The Company did not recognize any stock-based compensation expense related to performance-based incentive awards during the year ended December 31, 2014, since the strategic initiatives set for the awards were not achieved or probable of achievement.

L. Fair Value of Financial Instruments

The carrying amounts of certain financial instruments, including cash and cash equivalents, restricted cash and accounts payable, approximate their respective fair values due to the short-term nature of such instruments.

The fair value of the Deerfield Convertible Notes was $10.2 million and $42.0 million, respectively, at December 31, 2016 and 2015. The fair value of the 2021 Notes, which were issued during the first quarter of 2016, was $46.3 million at December 31, 2016. Both the Deerfield Convertible Notes and 2021 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 Company used a Tsiveriotis-Fernandes model to value the Deerfield Convertible Notes at December 31, 2016 and 2015 and the 2021 Notes at December 31, 2016.

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, 2016 and 2015 (in thousands):

	Balance at December 31, 2016	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Underwriter Warrant liability	$ 16	$ —	$ —	$ 16
Deerfield Warrant liability	4,231	—	—	4,231
Embedded Put Option	365	—	—	365
Fundamental change and make-whole interest provisions embedded in 2021 Notes	6	—	—	6
Total liabilities	$ 4,618	$ —	$ —	$ 4,618
Trading securities:				
Certificates of deposit	7,788	7,788	—	—
U.S. Treasury securities	37,066	37,066	—	—
U.S. government-sponsored agency securities	14,349	—	14,349	—
Total assets	$ 59,203	$ 44,854	$ 14,349	$ —

	Balance at December 31, 2015	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Underwriter Warrant liability	$ 3,877	$ —	$ —	$ 3,877
Deerfield Warrant liability	33,750	—	—	33,750
Embedded Put Option	212	—	—	212
Total liabilities	$ 37,839	$ —	$ —	$ 37,839
Trading securities:				
Certificates of deposit	8,951	8,951	—	—
U.S. Treasury securities	4,996	4,996	—	—
U.S. government-sponsored agency securities	5,055	5,055	—	—
Total assets	$ 19,002	$ 19,002	$ —	$ —

The Company's Underwriter Warrant liability, Deerfield Warrant liability, embedded Put Option and the fundamental change and the make-whole interest provisions embedded in the 2021 Notes, as well as the trading securities are measured at fair value on a recurring basis. As of December 31, 2016 and 2015, the Underwriter Warrant liability, Deerfield Warrant liability and embedded Put Option are reported on the balance sheet in derivative and warrant liability, while the trading securities are reported on the balance sheet in marketable securities and long-term investments. The 2021 Notes were issued during the first quarter of 2016 and the fundamental change and make-whole interest provisions embedded in the 2021 Notes are reported on the balance sheet in derivative and warrant liability. The Company used a Monte Carlo simulation to value the Underwriter Warrant liability, Deerfield Warrant liability and the embedded Put Option at December 31, 2016 and 2015. A Monte Carlo simulation was also used to value the fundamental change and make-whole interest provisions embedded in the 2021 Notes as of the issuance date and December 31, 2016. Significant unobservable inputs used in measuring the fair value of these financial instruments included the Company's estimated enterprise value, an estimate of the timing of a liquidity or fundamental change event, a present value discount rate and an estimate of the Company's stock volatility using the volatilities of guideline peer companies. Changes in the fair value of the Underwriter Warrant liability, the Deerfield Warrant liability, the embedded Put Option and the fundamental change and make-whole interest provisions embedded in the 2021 Notes are reflected in the statements of operations as a fair value adjustment.

A reconciliation of the beginning and ending balances for the derivative and warrant liability measured at fair value on a recurring basis using significant unobservable inputs (Level 3) is as follows (in thousands):

	2016	2015
Balance at beginning of period	$ 37,839	$ 15,966
Reclassification of 2013 warrants to equity	—	(1,110)

Exercise of warrants	(756)	(4,293)
Adjustment to fair value	(32,465)	27,276
Balance at end of period	$ 4,618	$ 37,839

M. Income Taxes

The Company's financial statements include a total state tax benefit of $15,000, $15,000 and $22,000 on a loss before income taxes of $16.5 million, $54.6 million and $24.5 million for the years ended December 31, 2016, 2015 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 (in thousands):

	Year ended December 31,		
	2016	2015	2014
Federal statutory rate	34.00%	34.00%	34.00%
Effect of:			
Change in valuation allowance	(69.31)	(19.25)	(32.88)
Return to provision and deferred true-up	(23.83)	—	0.36
Change in rate	(14.63)	—	—
State tax benefit (net of federal)	15.64	4.06	5.96
Warrant liability	68.44	(15.28)	(9.39)
State research and development credit	0.09	0.03	0.09
Federal research and development credit	5.65	0.84	3.29
Amortization	(3.15)	—	—
Conversion feature and put option on 2013 convertible notes	—	(1.68)	(1.26)
Interest expense	—	—	0.21
Stock-based compensation	(12.71)	(1.28)	—
Other	(0.10)	(1.42)	(0.29)
Federal income tax provision effective rate	0.09%	0.02%	0.09%

The components of deferred tax assets and liabilities are as follows (in thousands):

	December 31, 2016	December 31, 2015	December 31, 2014
Deferred tax assets relating to:			
Net operating loss carryforwards	$ 44,984	$ 26,617	$ 16,390
Research and development tax carryforward	3,166	2,254	1,793
Compensation	715	232	83
Total gross deferred tax assets	48,865	29,103	18,266
Deferred tax liabilities relating to:			
Property and equipment	89	80	170
Total gross deferred tax liabilities	89	80	170
Deferred tax assets less liabilities	48,776	29,023	18,096
Valuation allowance	(48,776)	(29,023)	(18,096)
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.

The Company had the following federal net operating loss carryforward and research activities credits as of December 31, 2016 (in thousands):

Year Incurred	Net Operating Loss Carryforwards	Research Activities Credit	Expiration
2007	$ 454	$ 30	2027
2008	1,178	65	2028
2009	3,060	176	2029
2010	3,423	149	2030
2011	9,929	176	2031
2012	—	170	2032
2013	4,353	133	2033
2014	15,819	894	2034
2015	24,189	461	2035
2016	40,959	912	2036
	$ 103,364	$ 3,166	

The Company also has certain state net operating loss carryforwards totaling $108.6 million that expire between 2027 and 2036. Due to potential ownership changes that may have occurred or would occur in the future, IRC Section 382 may place additional limitations on the Company's ability to utilize the net operating loss carryforward.

Financial Interpretation No. 48 ("FIN 48"), *Accounting for Uncertainty in Income Taxes*, uses the term "more likely than not" to evaluate whether or not a tax position will be sustained upon examination. The Company has not identified any tax positions that do not meet the more likely than not threshold.

N. Net Loss Per Share

Under the two-class method, for periods with net income, basic net income per common share is computed by dividing the net income attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Net income attributable to common stockholders is computed by subtracting from net income the portion of current year earnings that participating securities would have been entitled to receive pursuant to their dividend rights had all of the year's earnings been distributed. No such adjustment to earnings is made during periods with a net loss as the holders of the participating securities have no obligation to fund losses. Diluted net loss per common share is computed under the two-class method by using the weighted average number of shares of common stock outstanding plus, for periods with net income attributable to common stockholders, the potential dilutive effects of stock options and warrants. In addition, the Company analyzes the potential dilutive effect of the outstanding participating securities under the if-converted method when calculating diluted earnings per share in which it is assumed that the outstanding participating securities convert into common stock at the beginning of the period. The Company reports the more dilutive of the approaches (two-class or if-converted) as its diluted net income per share during the period.

The following table summarizes the computation of basic and diluted net loss and net loss per share of the Company (in thousands, except share and per share amounts):

	Year ended December 31,		
	2016	2015	2014
Net loss - basic and diluted	$ (16,516)	$ (54,664)	$ (24,455)
Weighted-average number of common shares - basic and diluted	14,597,053	7,368,681	2,381,041
Net loss per share - basic and diluted	$ (1.13)	$ (7.42)	$ (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:

	December 31, 2016	December 31, 2015	December 31, 2014
Redeemable convertible preferred stock:			
Series A	—	—	1,293,838
Series B	—	—	829,234
Series C	—	—	2,474,122
Series D	—	—	967,359
Total redeemable convertible preferred stock	—	—	5,564,553
Warrants to purchase common stock	2,087,477	2,325,383	595,920
Warrants to purchase Series D preferred stock	—	—	2,066,970
Awards under equity incentive plans	1,990,260	1,397,511	395,185
Deerfield Convertible Notes	1,751,296	1,991,219	1,808,353
2021 Notes	5,040,914	—	—
Total	10,869,947	5,714,113	10,430,981

O. Severance Expense

On September 15, 2016, the Company announced its intention to defer its commercial operations and realign its financial resources and operational priorities towards its product development pipeline. The activities related to the deferral and realignment were completed during the year ended December 31, 2016. As part of these activities, the Company reduced its workforce by three employees. Personnel and other related charges of approximately $1.1 million and stock compensation expense of approximately $1.9 million related to the acceleration of vesting on certain stock options, related to the workforce reduction, are presented as severance expense in the statements of operations. As of December 31, 2016, the Company had accrued severance expense recorded within accounts payable and accrued expenses in the amount of $0.6 million.

P. Employee Benefit Plan

The Company has a 401(k) retirement plan (the "401(k) Plan") that covers substantially 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 $213,000, $113,000 and $69,000 for the years ended December 31, 2016, 2015 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 2016, 2015 or 2014.

Q. Quarterly Results of Operations (unaudited)

The following tables set forth unaudited quarterly statements of operations data for each of the quarters indicated. The financial statements for each of these quarters have been prepared on the same basis as the audited financial statements included herein and, in the opinion of management, include all adjustments, consisting only of normal recurring adjustments, necessary for the fair statement of the results of operations for these periods. You should read this information together with our financial statements and related notes included herein. These quarterly operating results are not necessarily indicative of the results for any future period.

	Three-Months Ended							
	Dec 31, 2016	Sep 30, 2016	Jun 30, 2016	Mar 31, 2016	Dec 31, 2015	Sep 30, 2015	Jun 30, 2015	Mar 31, 2015
Revenue	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —
Operating expenses:								
Research and development	7,963	4,287	4,988	3,234	4,716	4,328	2,768	2,119
General and administrative	2,873	3,104	4,287	3,736	2,566	2,152	3,188	977
Restructuring charges	—	3,010	—	—	—	—	—	—
Total operating expenses	10,836	10,401	9,275	6,970	7,282	6,480	5,956	3,096
Loss from operations	(10,836)	(10,401)	(9,275)	(6,970)	(7,282)	(6,480)	(5,956)	(3,096)
Other (expense) income:								
Loss on extinguishment of debt	—	—	—	(4,740)	—	—	—	—
Interest expense related to amortization of debt issuance costs and discount	(391)	(390)	(393)	(442)	(475)	(479)	(477)	(477)
Interest expense on principal	(1,445)	(1,441)	(1,475)	(1,150)	(698)	(687)	(654)	(632)
Fair value adjustment	2,723	(1,299)	20,763	10,278	(764)	(2,089)	(22,661)	(1,762)
Interest and other income	9	98	144	102	15	11	5	—
Total other income (expense)	896	(3,032)	19,039	4,048	(1,922)	(3,244)	(23,787)	(2,871)
(Loss) income before income taxes	(9,940)	(13,433)	9,764	(2,922)	(9,204)	(9,724)	(29,743)	(5,967)
Income tax benefit (expense)	4	19	4	(12)	1	(20)	—	(7)
Net (loss) income	$ (9,936)	$ (13,414)	$ 9,768	$ (2,934)	$ (9,203)	$ (9,744)	$ (29,743)	$ (5,974)
Net (loss) income per share:								
Basic	$ (0.68)	$ (0.92)	$ 0.59	$ (0.20)	$ (0.64)	$ (0.68)	$ (2.45)	$ (2.50)
Diluted	$ (0.68)	$ (0.92)	$ (0.58)	$ (0.20)	$ (0.64)	$ (0.68)	$ (2.45)	$ (2.50)

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

KEMPHARM, INC.

Dated: March 10, 2017

By: /s/ Travis C. Mickle
Travis C. Mickle, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Dated: March 10, 2017

By: /s/ R. LaDuane Clifton
R. LaDuane Clifton, CPA
Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer)

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitute and appoint Travis C. Mickle and R. LaDuane Clifton, and each of them (with full power to each of them to act alone), as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution in each of them for him and in his name, place and stead, and in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Travis C. Mickle Travis C. Mickle, Ph.D.	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 10, 2017
/s/ R. LaDuane Clifton R. LaDuane Clifton, CPA	Chief Financial Officer, Secretary and Treasurer (Principal Financial Officer)	March 10, 2017
/s/ Timothy J. Sangiovanni Timothy J. Sangiovanni, CPA	Vice President, Corporate Controller (Principal Accounting Officer)	March 10, 2017
/s/ Danny L. Thompson Danny L. Thompson	Director	March 10, 2017
/s/ Matthew R. Plooster Matthew R. Plooster	Director	March 10, 2017
/s/ Richard W. Pascoe Richard W. Pascoe	Director	March 10, 2017
/s/ Joseph B. Saluri Joseph B. Saluri	Director	March 10, 2017
/s/ David S. Tierney David S. Tierney	Director	March 10, 2017

EXHIBIT INDEX

Exhibit No.	Description
2.1+	Asset Purchase Agreement, by and between Shire LLC and Travis C. Mickle, Ph.D. and the Registrant, dated as of March 21, 2012 (incorporated herein by reference to the Registrant's Amendment No. 1 to Registration Statement on Form S-1/A (File No. 333-202660) as filed with the SEC on April 3, 2015).
3.1	Amended and Restated Certificate of Incorporation of KemPharm, Inc. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on April 21, 2015).
3.2	Amended and Restated Bylaws, as currently in effect, of KemPharm, Inc. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on April 21, 2015).
4.1	Reference is made to Exhibits 3.1 and 3.2 hereof.
4.2	Specimen stock certificate evidencing shares of Common Stock (incorporated herein by reference to the Registrant's Amendment No. 2 to Registration Statement on Form S-1/A (File No. 333-202660) as filed with the SEC on April 9, 2015).
4.3	Indenture, by and between the Registrant and U.S. Bank National Association, dated as of February 9, 2016 (incorporated herein by reference to the Registrant's Current Report on Form 8-K filed with the SEC on February 9, 2016).
4.4	Form of Note representing the Company's 5.50% Senior Convertible Notes due 2021 (included as Exhibit A to the Indenture filed hereto as Exhibit 4.3) (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on February 9, 2016).
10.1+	Material Supply Agreement, by and between the Registrant and Johnson Matthey, Inc., dated as of November 2, 2009 (incorporated by reference Registrant's Amendment No. 1 to Registration Statement on Form S-1/A (File No. 333-202660) as filed with the SEC on April 3, 2015).
10.2	Facility Agreement, by and between the Registrant and Deerfield Private Design Fund III, L.P., dated as of June 2, 2014 (incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.2.1	First Amendment to Facility Agreement, Senior Secured Convertible Note and Warrant, by and between Registrant and Deerfield Private Design Fund III, L.P., dated March 6, 2015 (incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.2.2	Second Amendment to Facility Agreement by and between Registrant and Deerfield Private Design Fund III, L.P., dated December 17, 2015 (incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-208633) as filed with the SEC on December 18, 2015).
10.2.3	Third Amendment to Facility Agreement, Senior Secured Convertible Note and Warrant, by and between Registrant and Deerfield Private Design Fund III, L.P., dated February 3, 2016 (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on February 9, 2016).
10.3	Senior Secured Convertible Note issued to Deerfield Private Design Fund III, L.P., dated as of June 2, 2014 (incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.3.1	Second Amendment to Senior Secured Convertible Note and Warrant, by and between Registrant and Deerfield Private Design Fund III, L.P., dated January 6, 2016 (incorporated by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on January 11, 2016).
10.3.2	Fourth Amendment to Senior Secured Convertible Note and Warrant, effective as of October 3, 2016, by and between KemPharm, Inc. and Deerfield Private Design Fund III, L.P. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on October 3, 2016).
10.4	Amended and Restated Investors' Rights Agreement, dated as of February 19, 2015, by and among the Registrant and certain of its stockholders (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.5	Warrant to Purchase Shares of Series D Preferred Stock issued to Deerfield Private Design Fund III, L.P., dated as of June 2, 2014 (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.6	Form of Stock Purchase Warrant to purchase shares of Series D Convertible Preferred Stock issued in bridge financing, along with a schedule of warrantholders (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.7.1	Form of Common Stock Purchase Warrants issued by KemPharm, Inc., an Iowa corporation, along with a schedule of warrantholders (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.7.1	Form of Common Stock Purchase Warrants issued by KemPharm, Inc., a Delaware corporation, along with a schedule of warrantholders (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015)
10.8+	Agreement to Terminate CLA, by and between MonoSol Rx, LLC and the Registrant, dated as of March 20, 2012 (incorporated herein by reference to the Registrant's Amendment No. 1 to Registration Statement on Form S-1/A (File No. 333-202660) as filed with the SEC on April 3, 2015).
10.9#	Incentive Stock Plan, as amended to date (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.10#	Form of Incentive Stock Option Agreement under Incentive Stock Plan (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.11#	Form of Nonqualified Stock Option Agreement under Incentive Stock Plan (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.12#	Form of 2014 Equity Incentive Plan (incorporated herein by reference to Registrant's Amendment No. 1 to Registration Statement on Form S-1/A (File No. 333-202660) as filed with the SEC on April 3, 2015).
10.13#	Form of Stock Option Grant Notice and Stock Option Agreement under 2014 Equity Incentive Plan (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 File No. 333-202660) as filed with the SEC on March 11, 2015).
10.14#	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under 2014 Equity Incentive Plan (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 File No. 333-202660) as filed with the SEC on March 11, 2015).
10.15#	Non-Employee Director Compensation Policy (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 15, 2016).
10.16#	Form of Indemnification Agreement with the Registrant's directors and executive officers (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.17#	Amended and Restated Employment Agreement by and between the Registrant and R. LaDuane Clifton, dated as of June 25, 2015 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 14, 2015).

EXHIBIT INDEX

Exhibit No.	Description
10.17.1#	Amendment to Amended and Restated Employment Agreement by and between the Registrant and R. LaDuane Clifton, dated as of October 13, 2015 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on November 13, 2015).
10.18#	Employment Agreement by and between the Registrant and Christal M.M. Mickle, dated as of May 30, 2014 (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.18.1#	Amendment to Employment Agreement by and between the Registrant and Christal M.M. Mickle, dated as of October 13, 2015 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2015).
10.19#	Amended and Restated Employment Agreement by and between the Registrant and Gordon K. Johnson, dated as of June 25, 2015 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 14, 2015).
10.19.1#	Amendment to Amended and Restated Employment Agreement by and between the Registrant and Gordon K. Johnson, dated as of October 13, 2015 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on November 13, 2015).
10.20#	Employment Agreement by and between the Registrant and Travis C. Mickle, Ph.D., dated as of May 30, 2014 (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.20.1#	Amendment to Employment Agreement by and between the Registrant and Travis C. Mickle, Ph.D., dated as of October 13, 2015 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2015).
10.21#	Employment Agreement by and between the Registrant and Tracy Woody, dated as of March 30, 2015 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on May 29, 2015).
10.21.1#	Amendment to Employment Agreement by and between the Registrant and Tracy M. Woody, dated as of September 4, 2015 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on November 13, 2015).
10.22#	Board of Directors Services Agreement by and between Registrant and Richard W. Pascoe, dated as of January 1, 2014 (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.23#	Board of Directors Services Agreement by and between Registrant and Joseph B. Saluri, dated as of January 1, 2014 (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.24#	Employment Agreement by and between the Registrant and Daniel L. Cohen, dated as of April 13, 2016 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on May 13, 2016).
10.25#	Amended and Restated Employment Agreement by and between the Registrant and Sven Guenther, dated as of April 13, 2016 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on May 13, 2016).
10.26	Common Stock Sales Agreement, dated October 3, 2016, by and between KemPharm, Inc. and Cowen and Company, LLC (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on October 3, 2016).
10.27	Lease Agreement, by and between KemPharm, Inc. and the Board of Regents, State of Iowa for the Use and Benefit of the University of Iowa, dated as of September 15, 2016. (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on November 10, 2016).
10.28*	Lease Agreement, by and between KemPharm, Inc. and BRE/COH FL LLC, dated as of November 3, 2014.
10.29*	First Amendment to the Lease Agreement, by and between KemPharm, Inc. and BRE/COH FL LLC, dated as of April 21, 2015.
10.30*	Second Amendment to the Lease Agreement, by and between KemPharm, Inc. and BRE/COH FL LLC, dated as of December 22, 2015.
10.31*	Third Amendment to the Lease Agreement, by and between KemPharm, Inc. and BRE/COH FL LLC, dated as of July 15, 2016.
23.1*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (included on signature page).
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (1)
32.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (1)
101.INS**	XBRL Instance Document.
101.SCH**	XBRL Taxonomy Extension Schema Document.
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document.

*	Filed herewith
**	Attached as Exhibit 101 to this Annual Report on Form 10-K for the year ended December 31, 2016, formatted in XBRL (Extensible Business Reporting Language): (i) Balance Sheets, (ii) Statements of Operations, (iii) Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Deficit, (iv) Statements of Cash Flows, and (v) Notes to Financial Statements, tagged as blocks of text and including detailed tags.
#	Indicates management contract or compensatory plan.
+	Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a grant for confidential treatment and have been separately filed with the Securities and Exchange Commission.
(1)	This certification accompanies the Annual Report on Form 10-K to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Registrant under the Securities Act or the Exchange Act (whether made before or after the date of the Annual Report on Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 10.28

Office Lease

CELEBRATION OFFICE CENTER II

1170 CELEBRATION BOULEVARD
CELEBRATION, FLORIDA

Between

BRE/COH FL LLC, a Delaware limited liability company

as Landlord,

and

KEMPHARM, INC., a Delaware corporation

as Tenant

OFFICE LEASE

This Office Lease (this "**Lease**"), dated as of the date set forth in Section 1.1, is made by and between **BRE/COH FL LLC, a Delaware limited liability company** ("**Landlord**"), and **KEMPHARM, INC., a Delaware corporation** ("**Tenant**"). The following exhibits are incorporated herein and made a part hereof: **Exhibit A** (Outline of Premises); **Exhibit B** (Work Letter); **Exhibit C** (Form of Confirmation Letter); **Exhibit D** (Rules and Regulations); **Exhibit E** (Additional Provisions); and **Exhibit F** (Potential Offering Space).

1 BASIC LEASE INFORMATION

1.1Date:	November 3, 2014
1.2Premises.	
1.2.1"**Building**":	1170 Celebration Boulevard, Celebration, Florida, commonly known as Celebration Office Center II.
1.2.2"**Premises**":	Subject to Section 2.1.1, 3,221 rentable square feet of space located on the first floor of the Building and commonly known as Suite 103, the outline and location of which is set forth in **Exhibit A**. If the Premises include any floor in its entirety, all corridors and restroom facilities located on such floor shall be considered part of the Premises.
1.2.3"**Property**":	The Building, the parcel(s) of land upon which it is located, and, at Landlord's discretion, any parking facilities and other improvements serving the Building and the parcel(s) of land upon which such parking facilities and other improvements are located.
1.2.4"**Project**":	The Property or, at Landlord's discretion, any project containing the Property and any other land, buildings or other improvements.
1.3Term	
1.3.1Term:	The term of this Lease (the "**Term**") shall commence on the Commencement Date and end on the Expiration Date (or any earlier date on which this Lease is terminated as provided herein).
1.3.2"**Commencement Date**":	The earlier of (i) the first date on which Tenant conducts business in the Premises, or (ii) the date referenced in Section 1.1 above; provided, however, that if Landlord fails to deliver the Premises to Tenant pursuant to this Lease on or before the date described in the preceding clause (ii) as a result of any holdover or unlawful possession by another party, the Commencement Date shall be the date on which Landlord delivers possession of the Premises to Tenant pursuant to this Lease free from occupancy by any party.
1.3.3"**Expiration Date**":	The last day of the 36th full calendar month commencing on or after the Commencement Date.

1.4"**Base Rent**":

Period During Term	Annual Base Rent Per Rentable Square Foot	Monthly Base Rent Per Rentable Square Foot (rounded to the nearest 100th of a dollar)	Monthly Installment of Base Rent
Commencement Date through last day of 12th full calendar month of Term	$23.00	$1.92	$6,173.58
13th through 24th full calendar months of Term	$23.69	$1.97	$6,358.79
25th full calendar month of Term through Expiration Date	$24.40	$2.03	$6,549.37

1.5"**Base Year**" for Expenses:

Calendar year 2014.

"**Base Year**" for Taxes:

Calendar year 2014.

1.6"**Tenant's Share**": 4.0043% (based upon a total of 80,439 rentable square feet in the Building), subject to Section 2.1.1.

1.7"**Permitted Use**": General office use consistent with a first-class office building.

1.8."**Security Deposit**": $24,694.32, as more particularly described in Section 21.

Prepaid Base Rent: $6,173.58, as more particularly described in Section 3.

1.9Parking:

16 unreserved parking spaces, at the rate of $0 per space per month, as such rate may be adjusted from time to time to reflect Landlord's then current rates.

1.10Address of Tenant: Before the Commencement Date:

2656 Crosspark Road
Suite 100
Coralville, IA 52241
From and after the Commencement Date: the Premises.

1.11Address of Landlord:	BRE/COH FL LLC c/o Equity Office 2311 Cedar Springs, Suite 300 Dallas, Texas 75201 Attn: Rob Shults with copies to: BRE/COH FL LLC c/o Equity Office 2655 Campus Drive, Suite 100 San Mateo, California 94403 Attn: Managing Counsel and BRE/COH FL LLC c/o Equity Office Two North Riverside Plaza Suite 2100 Chicago, Illinois 60606 Attn: Lease Administration
1.12Broker(s):	Century 21- Metro Lifestyles ("**Tenant's Broker**"), representing Tenant, and Jones Lang LaSalle ("**Landlord's Broker**"), representing Landlord.
1.13Building HVAC Hours and Holidays:	"**Building HVAC Hours**" means 8:00 a.m. to 6:00 p.m., Monday through Friday and 8:00 a.m. to 1:00 p.m. on Saturday, excluding the day of observation of New Year's Day, Presidents Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, Christmas Day, and, at Landlord's discretion, any other locally or nationally recognized holiday that is observed by other buildings comparable to and in the vicinity of the Building (collectively, "**Holidays**").
1.14"**Transfer Radius**":	None.
1.15"**Tenant Improvements**":	Defined in **Exhibit B**, if any.
1.16"**Guarantor**":	None.

2 PREMISES AND COMMON AREAS.

2.1 The Premises.

2.1.1 Subject to the terms hereof, Landlord hereby leases the Premises to Tenant and Tenant hereby leases the Premises from Landlord. Landlord and Tenant acknowledge that the rentable square footage of the Premises is as set forth in Section 1.2.2 and the rentable square footage of the Building is as set forth in Section 1.6; provided, however, that Landlord may from time to time re-measure the Premises and/or the Building in accordance with any generally accepted measurement standards selected by Landlord and adjust Tenant's Share based on such re-measurement; provided further, however, that any such re-measurement shall not affect the amount of Base Rent payable for, or the amount of any tenant allowance applicable to, the initial Term. At any time Landlord may deliver to Tenant a notice substantially in the form of **Exhibit C**, as a confirmation of the information set forth therein. Tenant shall execute and return (or, by notice to Landlord, reasonably object to) such notice within five (5) days after receiving it, and if Tenant fails to do so, Tenant shall be deemed to have executed and returned it without exception.

2.1.2 Except as expressly provided herein, the Premises are accepted by Tenant in their configuration and condition existing on the date hereof (or in such other configuration and condition as any existing tenant of the Premises may cause to exist in accordance with its lease), without any obligation of Landlord to perform or pay for any alterations to the Premises, and without any representation or warranty regarding the configuration or condition of the Premises, the Building or the Project or their suitability for Tenant's business.

2.2 Common Areas. Tenant may use, in common with Landlord and other parties and subject to the Rules and Regulations (defined in **Exhibit D**), any portions of the Property that are designated from time to time by Landlord for such use (the "**Common Areas**").

3 RENT. Tenant shall pay all Base Rent and Additional Rent (defined below) (collectively, "**Rent**") to Landlord or Landlord's agent, without prior notice or demand or any setoff or deduction, at the place Landlord may designate from time to time, in money of the United States of America that, at the time of payment, is legal tender for the payment of all obligations. As used herein, "**Additional Rent**" means all amounts, other than Base Rent, that Tenant is required to pay Landlord hereunder. Monthly payments of Base Rent and monthly payments of Additional Rent for Expenses (defined in Section 4.2.2), Taxes (defined in Section 4.2.3) and parking (collectively, "**Monthly Rent**") shall be paid in advance on or before the first day of each calendar month during the Term; provided, however, that the installment of Base Rent for the first full calendar month for which Base Rent is payable hereunder shall be paid upon Tenant's execution and delivery hereof. Except as otherwise provided herein, all other items of Additional Rent shall be paid within 30 days after Landlord's request for payment. Rent for any partial calendar month shall be prorated based on the actual number of days in such month. Without limiting Landlord's other rights or remedies, (a) if any installment of Rent is not received by Landlord or its designee within five (5) business days after its due date, Tenant shall pay Landlord a late charge equal to 5% of the overdue amount; and (b) any Rent that is not paid within 10 days after its due date shall bear interest, from its due date until paid, at the lesser of 18% per annum or the highest rate permitted by Law (defined in Section 5). Tenant's covenant to pay Rent is independent of every other covenant herein.

4 EXPENSES AND TAXES.

4.1 General Terms. In addition to Base Rent, Tenant shall pay, in accordance with Section 4.4, for each Expense Year (defined in Section 4.2.1), an amount equal to the sum of (a) Tenant's Share of any amount (the "**Expense Excess**") by which Expenses for such Expense Year exceed Expenses for the Base Year, plus (b) Tenant's Share of any amount (the "**Tax Excess**") by which Taxes for such Expense Year exceed Taxes for the Base Year. No decrease in Expenses or Taxes for any Expense Year below the corresponding amount for the Base Year shall entitle Tenant to any decrease in Base Rent or any credit against amounts due hereunder. Tenant's Share of the Expense Excess and Tenant's Share of the Tax Excess for any partial Expense Year shall be prorated based on the number of days in such Expense Year.

4.2 Definitions. As used herein, the following terms have the following meanings:

4.2.1 "**Expense Year**" means each calendar year (other than the Base Year and any preceding calendar year) in which any portion of the Term occurs.

4.2.2 "**Expenses**" means all expenses, costs and amounts that Landlord pays or accrues during the Base Year or any Expense Year because of or in connection with the ownership, management, maintenance, security, repair, replacement, restoration or operation of the Property. Landlord shall act in a reasonable manner in incurring Expenses. Expenses shall include (i) the cost of supplying all utilities, the cost of operating, repairing, maintaining and renovating the utility, telephone, mechanical, sanitary, storm-drainage, and elevator systems, and the cost of maintenance and service contracts in connection therewith; (ii) the cost of licenses, certificates, permits and inspections, the cost of contesting any Laws that may affect Expenses, and the costs of complying with any governmentally-mandated transportation-management or similar program; (iii) the cost of all insurance premiums and deductibles; (iv) the cost of landscaping and relamping; (v) the cost of parking-area operation, repair, restoration, and maintenance; (vi) a management fee in the amount (which is hereby acknowledged to be reasonable) of 3% of gross annual receipts from the Building (excluding the management fee), together with other fees and costs, including consulting fees, legal fees and accounting fees, of all contractors and consultants in connection with the management, operation, maintenance and repair of the Property; (vii) payments under any equipment-rental agreements and the fair rental value of any management office space; (viii) wages, salaries and other compensation, expenses and benefits, including taxes levied thereon, of all persons engaged in the operation, maintenance and security of the Property, and costs of training, uniforms, and employee enrichment for such persons; (ix) the costs of operation, repair, maintenance and replacement of all systems and equipment (and components thereof) of the Property; (x) the cost of janitorial, alarm, security and other services, replacement of wall and floor coverings, ceiling tiles and fixtures in Common Areas, maintenance and replacement of curbs and walkways, repair to roofs and re-roofing; (xi) rental or acquisition costs of supplies, tools, equipment, materials and personal property used in the maintenance, operation and repair of the Property; (xii) the cost of capital improvements or any other items that are (A) intended to effect economies in the operation or maintenance of the Property, reduce current or future Expenses, enhance the safety or security of the Property or its occupants, or enhance the environmental sustainability of the Property's operations, (B) replacements or modifications of the nonstructural portions of the Base Building (defined in Section 7) or Common Areas that are required to keep the Base Building or Common Areas in good condition, or (C) required under any Law; (xiii) the cost of tenant-relation programs reasonably established by Landlord; and (xiv) payments under any existing or future reciprocal easement agreement, transportation management agreement, cost-sharing agreement or other covenant, condition, restriction or similar instrument affecting the Property.

Notwithstanding the foregoing, Expenses shall not include: (a) capital expenditures not described in clauses (xi) or (xii) above (in addition, any capital expenditure shall be included in Expenses only if paid or accrued after the Base Year and shall be amortized (including actual or imputed interest on the amortized cost) over such period of time as Landlord shall reasonably determine); (b) depreciation; (c) principal payments of mortgage or other non-operating debts of Landlord; (d) costs of repairs to the extent Landlord is reimbursed by insurance or condemnation proceeds; (e) except as provided in clause (xiii) above, costs of leasing space in the Building, including brokerage commissions, lease concessions, rental abatements and construction allowances granted to specific tenants; (f) costs of selling, financing or refinancing the Building; (g) fines, penalties or interest resulting from late payment of Taxes or Expenses; (h) organizational expenses of creating or operating the entity that constitutes Landlord; or (i) damages paid to Tenant hereunder or to other tenants of the Building under their respective leases.

If, during any portion of the Base Year or any Expense Year, the Building is not 95% occupied (or a service provided by Landlord to tenants of the Building generally is not provided by Landlord to a tenant that provides such service itself, or any tenant of the Building is entitled to free rent, rent abatement or the like), Expenses for such year shall be determined as if the Building had been 95% occupied (and all services provided by Landlord to tenants of the Building generally had been provided by Landlord to all tenants, and no tenant of the Building had been entitled to free rent, rent abatement or the like) during such portion of such year. If insurance, security or utility costs for any Expense Year are less than insurance, security or utility costs, respectively, for the Base Year, then, for purposes of determining Expenses for such Expense Year, such costs for such Expense Year shall be deemed to be increased so as to be equal to such corresponding costs for the Base Year. Notwithstanding any contrary provision hereof, Expenses for the Base Year shall exclude (a) any market-wide cost increases resulting from extraordinary circumstances, including Force Majeure (defined in Section 25.2), boycotts, strikes, conservation surcharges, embargoes or shortages, and (b) at Landlord's option, the cost of any repair or replacement that Landlord reasonably expects will not recur on an annual or more frequent basis.

4.2.3 "**Taxes**" means all federal, state, county or local governmental or municipal taxes, fees, charges, assessments, levies, licenses or other impositions, whether general, special, ordinary or extraordinary, that are paid or accrued during the Base Year or any Expense Year (without regard to any different fiscal year used by such governmental or municipal authority) because of or in connection with the ownership, leasing or operation of the Property. Taxes shall include (a) real estate taxes; (b) general and special assessments; (c) transit taxes; (d) leasehold taxes; (e) personal property taxes imposed upon the fixtures, machinery, equipment, apparatus, systems, appurtenances, furniture and other personal property used in connection with the Property; (f) any tax on the rent, right to rent or other income from any portion of the Property or as against the business of leasing any portion of the Property; and (g) any assessment, tax, fee, levy or charge imposed by any governmental agency, or by any non-governmental entity pursuant to any private cost-sharing agreement, in order to fund the provision or enhancement of any fire-protection, street-, sidewalk- or road-maintenance, refuse-removal or other service that is normally provided by governmental agencies to property owners or occupants without charge (other than through real property taxes). Any costs and expenses (including reasonable attorneys' and consultants' fees) incurred in attempting to protest, reduce or minimize Taxes shall be included in Taxes for the year in which they are incurred. Notwithstanding any contrary provision hereof, Taxes shall be determined without regard to any "green building" credit and shall exclude (i) all excess profits taxes, franchise taxes, gift taxes, capital stock taxes, inheritance and succession taxes, estate taxes, federal and state income taxes, and other taxes to the extent (x) applicable to Landlord's general or net income (as opposed to rents, receipts or income attributable to operations at the Property), or (y) measured solely by the square footage, rent, fees, services, tenant allowances or similar amounts, rights or obligations described or provided in or under any particular lease, license or similar agreement or transaction at the Building; (ii) any Expenses, and (iii) any items required to be paid or reimbursed by Tenant under Section 4.5.

4.3 Allocation. Landlord, in its reasonable discretion, may equitably allocate Expenses among office, retail or other portions or occupants of the Property. If Landlord incurs Expenses or Taxes for the Property together with another property, Landlord, in its reasonable discretion, shall equitably allocate such shared amounts between the Property and such other property.

4.4 Calculation and Payment of Expense Excess and Tax Excess.

4.4.1 Statement of Actual Expenses and Taxes; Payment by Tenant. Landlord shall endeavor to give to Tenant, after the end of each Expense Year, a statement (the "**Statement**") setting forth the actual Expenses, Taxes, Expense Excess and Tax Excess for such Expense Year. If the amount paid by Tenant for such Expense Year pursuant to Section 4.4.2 is less or more than the sum of Tenant's Share of the actual Expense Excess plus Tenant's Share of the actual Tax Excess (as such amounts are set forth in such Statement), Tenant shall pay Landlord the amount of such underpayment, or receive a credit in the amount of such overpayment, with or against the Rent then or next due hereunder; provided, however, that if this Lease has expired or terminated and Tenant has vacated the Premises, Tenant shall pay Landlord the amount of such underpayment, or Landlord shall pay Tenant the amount of such overpayment (less any Rent due), within 30 days after delivery of such Statement. Any failure of Landlord to timely deliver the Statement for any Expense Year shall not diminish either party's rights under this Section 4.

4.4.2 Statement of Estimated Expenses and Taxes. Landlord shall endeavor to give to Tenant, for each Expense Year, a statement (the "**Estimate Statement**") setting forth Landlord's reasonable estimates of the Expenses, Taxes, Expense Excess (the "**Estimated Expense Excess**") and Tax Excess (the "**Estimated Tax Excess**") for such Expense Year. Upon receiving an Estimate Statement, Tenant shall pay, with its next installment of Base Rent, an amount equal to the excess of (a) the amount obtained by multiplying (i) the sum of Tenant's Share of the Estimated Expense Excess plus Tenant's Share of the Estimated Tax Excess (as such amounts are set forth in such Estimate Statement), by (ii) a fraction, the numerator of which is the number of months that have elapsed in the applicable Expense Year (including the month of such payment) and the denominator of which is 12, over (b) any amount previously paid by Tenant for such Expense Year pursuant to this Section 4.4.2. Until Landlord delivers a new Estimate Statement (which Landlord may do at any time), Tenant shall pay monthly, with the monthly Base Rent installments, an amount equal to one-twelfth (1/12) of the sum of Tenant's Share of the Estimated Expense Excess plus Tenant's Share of the Estimated Tax Excess, as such amounts are set forth in the previous Estimate Statement. Any failure of Landlord to timely deliver any Estimate Statement shall not diminish Landlord's rights to receive payments and revise any previous Estimate Statement under this Section 4.

4.4.3 Retroactive Adjustment of Taxes. Notwithstanding any contrary provision hereof, if, after Landlord's delivery of any Statement, an increase or decrease in Taxes occurs for the applicable Expense Year or for the Base Year (whether by reason of reassessment, error, or otherwise), Taxes for such Expense Year or the Base Year, as the case may be, and the Tax Excess for such Expense Year shall be retroactively adjusted. If, as a result of such adjustment, it is determined that Tenant has under- or overpaid Tenant's Share of such Tax Excess, Tenant shall pay Landlord the amount of such underpayment, or receive a credit in the amount of such overpayment, with or against the Rent then or next due hereunder; provided, however, that if this Lease has expired or terminated and Tenant has vacated the Premises, Tenant shall pay Landlord the amount of such underpayment, or Landlord shall pay Tenant the amount of such overpayment (less any Rent due), within 30 days after such adjustment is made.

4.5 Charges for Which Tenant Is Directly Responsible. Tenant shall pay, 10 days before delinquency, any taxes levied against Tenant's equipment, furniture, fixtures and other personal property located in or about the Premises. If any such taxes are levied against Landlord or its property (or if the assessed value of Landlord's property is increased by the inclusion therein of a value placed upon such equipment, furniture, fixtures or other personal property of Tenant), Landlord may pay such taxes (or such increased assessment) regardless of their (or its) validity, in which event Tenant, upon demand, shall repay to Landlord the amount so paid. If the Leasehold Improvements (defined in Section 7.1) are assessed for real property tax purposes at a valuation higher than the valuation at which tenant improvements conforming to Landlord's "building standard" in other space in the Building are assessed, the Taxes levied against Landlord or the Property by reason of such excess assessed valuation shall be deemed taxes levied against Tenant's personal property for purposes of this Section 4.5. Notwithstanding any contrary provision hereof, Tenant shall pay 10 days before delinquency (or reimburse to Landlord upon demand, if the same is required by Law to be paid by Landlord): (i) any rent tax, sales tax, service tax, transfer tax, value added tax, use tax, business tax, gross income tax, gross receipts tax, or other tax, assessment, fee, levy or charge measured solely by the square footage, Rent, services, tenant allowances or similar amounts, rights or obligations described or provided in or under this Lease; and (ii) any taxes assessed upon the possession, leasing, operation, management, maintenance, alteration, repair, use or occupancy by Tenant of any portion of the Property.

4.6 Books and Records. Within 60 days after receiving any Statement (the "**Review Notice Period**"), Tenant may give Landlord notice ("**Review Notice**") stating that Tenant elects to review Landlord's calculation of the Expense Excess and/or Tax Excess for the Expense Year to which such Statement applies and identifying with reasonable specificity the records of Landlord reasonably relating to such matters that Tenant desires to review. Within a reasonable time after receiving a timely Review Notice (and, at Landlord's option, an executed confidentiality agreement as described below), Landlord shall deliver to Tenant, or make available for inspection at a location reasonably designated by Landlord, copies of such records. Within 60 days after such records are made available to Tenant (the "**Objection Period**"), Tenant may deliver to Landlord notice (an "**Objection Notice**") stating with reasonable specificity any objections to the Statement, in which event Landlord and Tenant shall work together in good faith to resolve Tenant's objections. Tenant may not deliver more than one Review Notice or more than one Objection Notice with respect to any Expense Year. If Tenant fails to give Landlord a Review Notice before the expiration of the Review Notice Period or fails to give Landlord an Objection Notice before the expiration of the Objection Period, Tenant shall be deemed to have approved the Statement. Notwithstanding any contrary provision hereof, Landlord shall not be required to deliver or make available to Tenant records relating to the Base Year, and Tenant may not object to Expenses or Taxes for the Base Year, other than in connection with the first review for an Expense Year performed by Tenant pursuant to this Section 4.6. If Tenant retains an agent to review Landlord's records, the agent must be with a CPA firm licensed to do business in the State of Florida and its fees shall not be contingent, in whole or in part, upon the outcome of the review. Tenant shall be responsible for all costs of such review. The records and any related information obtained from Landlord shall be treated as confidential, and as applicable only to the Premises, by Tenant, its auditors, consultants, and any other parties reviewing the same on behalf of Tenant (collectively, "**Tenant's Auditors**"). Before making any records available for review, Landlord may require Tenant and Tenant's Auditors to execute a reasonable confidentiality agreement, in which event Tenant shall cause the same to be executed and delivered to Landlord within 30 days after receiving it from Landlord, and if Tenant fails to do so, the Objection Period shall be reduced by one day for each day by which such execution and delivery follows the expiration of such 30-day period. Notwithstanding any contrary provision hereof, Tenant may not examine Landlord's records or dispute any Statement if any Rent remains unpaid past its due date. If, for any Expense Year, Landlord and Tenant determine that the sum of Tenant's Share of the actual Expense Excess plus Tenant's Share of the actual Tax Excess is less or more than the amount reported, Tenant shall receive a credit in the amount of its overpayment against Rent then or next due hereunder, or pay Landlord the amount of its underpayment with the Rent next due hereunder; provided, however, that if this Lease has expired or terminated and Tenant has vacated the Premises, Landlord shall pay Tenant the amount of its overpayment (less any Rent due), or Tenant shall pay Landlord the amount of its underpayment, within 30 days after such determination.

5 USE; COMPLIANCE WITH LAWS. Tenant shall not (a) use the Premises for any purpose other than the Permitted Use, or (b) do anything in or about the Premises that violates any of the Rules and Regulations, damages the reputation of the Project, interferes with, injures or annoys other occupants of the Building, or constitutes a nuisance. Tenant, at its expense, shall comply with all Laws relating to (i) the operation of its business at the Project, (ii) the use, condition, configuration or occupancy of the Premises, or (iii) the Building systems located in or exclusively serving the Premises. If, in order to comply with any such Law, Tenant must obtain or deliver any permit, certificate or other document evidencing such compliance, Tenant shall provide a copy of such document to Landlord promptly after obtaining or delivering it. If a change to any Common Area, the Building structure, or any Building system located outside of and not exclusively serving the Premises becomes required under Law (or if any such requirement is enforced) as a result of any Tenant-Insured Improvement (defined in Section 10.2.2), the installation of any trade fixture, or any particular use of the Premises (as distinguished from general office use), then Tenant, upon demand, shall (x) at Landlord's option, either make such change at Tenant's cost or pay Landlord the cost of making such change, and (y) pay Landlord a coordination fee equal to 10% of the cost of such change. As used herein, "**Law**" means any existing or future law, ordinance, regulation or requirement of any governmental authority having jurisdiction over the Project or the parties.

6 SERVICES.

6.1 Standard Services. Landlord shall provide the following services on all days (unless otherwise stated below): (a) subject to limitations imposed by Law, customary heating, ventilation and air conditioning ("**HVAC**") in season during Building HVAC Hours; (b) electricity supplied by the applicable public utility, stubbed to the Premises; (c) water supplied by the applicable public utility (i) for use in lavatories and any drinking facilities located in Common Areas within the Building, and (ii) stubbed to the Building core for use in any plumbing fixtures located in the Premises; (d) janitorial services to the Premises, except on weekends and Holidays; and (e) elevator service (subject to scheduling by Landlord, and payment of Landlord's standard usage fee, for any freight service).

6.2 Above-Standard Use. Landlord shall provide HVAC service outside Building HVAC Hours if Tenant gives Landlord such prior notice and pays Landlord such hourly cost per zone as Landlord may require; provided that Landlord shall not charge for service on Saturdays between 9:00 a.m. and 1:00 p.m. so long as Tenant provides the prior notice required by Landlord from time to time. Tenant shall not, without Landlord's prior consent, use equipment that may affect the temperature maintained by the air conditioning system or consume above-Building-standard amounts of any water furnished for the Premises by Landlord pursuant to Section 6.1. If Tenant's consumption of electricity or water exceeds the rate Landlord reasonably deems to be standard for the Building, Tenant shall pay Landlord, upon billing, the cost of such excess consumption, including any costs of installing, operating and maintaining any equipment that is installed in order to supply or measure such excess electricity or water. For purposes of the preceding sentence, any consumption of electricity in a computer server room shall be deemed to exceed the standard rate for the Building. The connected electrical load of Tenant's incidental-use equipment shall not exceed the Building-standard electrical design load, and Tenant's electrical usage shall not exceed the capacity of the feeders to the Project or the risers or wiring installation.

6.3 Interruption. Subject to Section 11, any failure to furnish, delay in furnishing, or diminution in the quality or quantity of any service resulting from any application of Law, failure of equipment, performance of maintenance, repairs, improvements or alterations, utility interruption, or event of Force Majeure (each, a "**Service Interruption**") shall not render Landlord liable to Tenant, constitute a constructive eviction, or excuse Tenant from any obligation hereunder. Notwithstanding the foregoing, if all or a material portion of the Premises is made untenantable or inaccessible for more than five (5) consecutive business days after notice from Tenant to Landlord by a Service Interruption that does not result from a Casualty (defined in Section 11) and that Landlord can correct through reasonable efforts, then, as Tenant's sole remedy, Monthly Rent shall abate for the period beginning on the day immediately following such 5-business-day period and ending on the day such Service Interruption ends, but only in proportion to the percentage of the rentable square footage of the Premises made untenantable or inaccessible.

7 REPAIRS AND ALTERATIONS.

7.1 Repairs. Subject to Section 11, Tenant, at its expense, shall perform all maintenance and repairs (including replacements) to the Premises, and keep the Premises in as good condition and repair as existed when Tenant took possession and as thereafter improved by Landlord and/or Tenant, except for reasonable wear and tear and repairs that are Landlord's express responsibility hereunder. Tenant's maintenance and repair obligations shall include (a) all leasehold improvements in the Premises, whenever and by whomever installed or paid for, including any Tenant Improvements, any Alterations (defined in Section 7.2), and any leasehold improvements installed pursuant to any prior lease, but excluding the Base Building (the "**Leasehold Improvements**"); (b) all supplemental heating, ventilation and air conditioning units, kitchens (including hot water heaters, dishwashers, garbage disposals, insta-hot dispensers, and plumbing) and similar facilities exclusively serving Tenant, whether located inside or outside of the Premises, and whenever and by whomever installed or paid for; and (c) all Lines (defined in Section 23) and trade fixtures. Notwithstanding the foregoing, Landlord may, at its option, perform such maintenance and repairs on Tenant's behalf, in which case Tenant shall pay Landlord, upon demand, the cost of such work plus a coordination fee equal to 10% of such cost. Landlord shall perform all maintenance and repairs to (i) the roof and exterior walls and windows of the Building, (ii) the Base Building, and (iii) the Common Areas. As used herein, "**Base Building**" means the structural portions of the Building, together with all mechanical (including HVAC), electrical, plumbing and fire/life-safety systems serving the Building in general, whether located inside or outside of the Premises.

7.2 Alterations. Tenant may not make any improvement, alteration, addition or change to the Premises or to any mechanical, plumbing or HVAC facility or other system serving the Premises (an "**Alteration**") without Landlord's prior consent, which consent shall be requested by Tenant not less than 30 days before commencement of work and shall not be unreasonably withheld by Landlord. Notwithstanding the foregoing, Landlord's prior consent shall not be required for any Alteration that is decorative only (*e.g.,* carpet installation or painting) and not visible from outside the Premises, provided that Landlord receives 30 business days' prior notice. For any Alteration, (a) Tenant, before commencing work, shall deliver to Landlord, and obtain Landlord's approval of, plans and specifications; (b) Landlord, in its discretion, may require Tenant to obtain security for performance satisfactory to Landlord; (c) Tenant shall deliver to Landlord "as built" drawings (in CAD format, if requested by Landlord), completion affidavits, full and final lien waivers, and all governmental approvals; and (d) Tenant shall pay Landlord upon demand (i) Landlord's reasonable out-of-pocket expenses incurred in reviewing the work, and (ii) a coordination fee equal to 10% of the cost of the work; provided, however, that this clause (d) shall not apply to any Tenant Improvements.

7.3 Tenant Work. Before commencing any repair or Alteration ("**Tenant Work**"), Tenant shall deliver to Landlord, and obtain Landlord's approval of, (a) names of contractors, subcontractors, mechanics, laborers and materialmen; (b) evidence of contractors' and subcontractors' insurance; and (c) any required governmental permits. Tenant shall perform all Tenant Work (i) in a good and workmanlike manner using materials of a quality reasonably approved by Landlord; (ii) in compliance with any approved plans and specifications, all Laws, the National Electric Code, and Landlord's construction rules and regulations; and (iii) in a manner that does not impair the Base Building. If, as a result of any Tenant Work, Landlord becomes required under Law to perform any inspection, give any notice, or cause such Tenant Work to be performed in any particular manner, Tenant shall comply with such requirement and promptly provide Landlord with reasonable documentation of such compliance. Landlord's approval of Tenant's plans and specifications shall not relieve Tenant from any obligation under this Section 7.3. In performing any Tenant Work, Tenant shall not use contractors, services, labor, materials or equipment that, in Landlord's reasonable judgment, would disturb labor harmony with any workforce or trades engaged in performing other work or services at the Project.

8 LANDLORD'S PROPERTY. All Leasehold Improvements shall become Landlord's property upon installation and without compensation to Tenant. Notwithstanding the foregoing, if any Tenant-Insured Improvements are not, in Landlord's reasonable judgment, Building-standard, then before the expiration or earlier termination hereof, Tenant shall, at Landlord's election, either (a) at Tenant's expense, and except as otherwise notified by Landlord, remove such Tenant-Insured Improvements, repair any resulting damage to the Premises or Building, and restore the affected portion of the Premises to its configuration and condition existing before the installation of such Tenant-Insured Improvements (or, at Landlord's election, to a Building-standard tenant-improved configuration and condition as determined by Landlord), or (b) pay Landlord an amount equal to the estimated cost of such work, as reasonably determined by Landlord. If Tenant fails to timely perform any work required under clause (a) of the preceding sentence, Landlord may perform such work at Tenant's expense.

9 LIENS. Tenant shall keep the Project free from any lien arising out of any work performed, material furnished or obligation incurred by or on behalf of Tenant. Tenant shall remove any such lien within 10 business days after notice from Landlord, and if Tenant fails to do so, Landlord, without limiting its remedies, may pay the amount necessary to cause such removal, whether or not such lien is valid. The amount so paid, together with reasonable attorneys' fees and expenses, shall be reimbursed by Tenant upon demand. Tenant will notify Landlord in writing at least 30 days prior to commencing any Alterations in order to provide Landlord the opportunity to record and post notices of non-responsibility or such other protective notices available to Landlord under applicable Law.

NOTHING IN THIS LEASE SHALL BE DEEMED TO BE, OR CONSTRUED IN ANY WAY AS CONSTITUTING, THE CONSENT TO OR REQUEST OF LANDLORD, EXPRESS OR IMPLIED, BY INFERENCE OR OTHERWISE, ANY PERSON, FIRM, CORPORATION, OR OTHER ENTITY FOR THE PERFORMANCE OF ANY LABOR OR THE FURNISHING OF ANY MATERIALS FOR ANY CONSTRUCTION, REBUILDING, ALTERATION, OR REPAIR OF OR TO THE PREMISES, THE BUILDING, THE PROPERTY, THE PROJECT, OR ANY PART THEREOF, OR AS GIVING TENANT ANY RIGHT, POWER, OR AUTHORITY TO CONTRACT FOR OR PERMIT THE RENDERING OF ANY SERVICES OR THE FURNISHING OF ANY MATERIALS THAT IN ANY WAY GIVE RISE TO THE RIGHT TO FILE ANY LIEN AGAINST THE PREMISES, THE BUILDING, THE PROPERTY, THE PROJECT, OR LANDLORD'S INTEREST THEREIN. TENANT SHALL NOTIFY ANY CONTRACTOR PERFORMING ANY CONSTRUCTION WORK IN THE PREMISES OR AT THE PROPERTY ON BEHALF OF TENANT THAT THIS LEASE SPECIFICALLY PROVIDES THAT THE INTERESTS OF LANDLORD IN THE PREMISES, THE BUILDING, THE PROPERTY, AND THE PROJECT SHALL NOT BE SUBJECT TO LIENS FOR IMPROVEMENTS MADE BY TENANT, AND NO MECHANIC'S LIEN OR OTHER LIEN FOR ANY SUCH LABOR, SERVICES, MATERIALS, SUPPLIES, MACHINERY, FIXTURES, OR EQUIPMENT SHALL ATTACH TO OR AFFECT THE ESTATE OR INTEREST OF LANDLORD IN AND TO THE PREMISES, THE BUILDING, THE PROPERTY, THE PROJECT, OR ANY PORTION THEREOF. IN ADDITION, LANDLORD SHALL HAVE THE RIGHT TO POST AND KEEP POSTED AT ALL TIMES ON OR AT THE PREMISES OR PROPERTY ANY NOTICES THAT MAY BE REQUIRED OR ADVISABLE FOR THE PROTECTION OF LANDLORD AND THE PREMISES, THE PROPERTY, THE PROJECT, OR THE BUILDING, FROM ANY SUCH LIEN. TENANT AGREES TO PROMPTLY EXECUTE ANY SUCH INSTRUMENTS IN RECORDABLE FORM AND IN ACCORDANCE WITH THE TERMS AND PROVISIONS OF FLORIDA STATUTES, SECTION 713.10.

10 INDEMNIFICATION; INSURANCE.

10.1 Waiver and Indemnification. Tenant waives all claims against Landlord, its Security Holders (defined in Section 17), Landlord's managing agent(s), their (direct or indirect) owners, and the beneficiaries, trustees, officers, directors, employees and agents of each of the foregoing (including Landlord, the "**Landlord Parties**") for (i) any damage to person or property (or resulting from the loss of use thereof), except to the extent such damage is caused by any gross negligence, willful misconduct or breach of this Lease of or by any Landlord Party, or (ii) any failure to prevent or control any criminal or otherwise wrongful conduct by any third party or to apprehend any third party who has engaged in such conduct. Tenant shall indemnify, defend, protect, and hold the Landlord Parties harmless from any obligation, loss, claim, action, liability, penalty, damage, cost or expense (including reasonable attorneys' and consultants' fees and expenses) (each, a "**Claim**") that is imposed or asserted by any third party and arises from (a) any cause in, on or about the Premises, or (b) occupancy of the Premises by, or any negligence, willful misconduct or breach of this Lease of or by, Tenant, any party claiming by, through or under Tenant, their (direct or indirect) owners, or any of their respective beneficiaries, trustees, officers, directors, employees, agents, contractors, licensees or invitees, except to the extent such Claim arises from any gross negligence, willful misconduct or breach of this Lease of or by any Landlord Party.

10.2 Tenant's Insurance. Tenant shall maintain the following coverages in the following amounts:

10.2.1 Commercial General Liability Insurance covering claims of bodily injury, personal injury and property damage arising out of Tenant's operations and contractual liabilities, including coverage formerly known as broad form, on an occurrence basis, with combined primary and excess/umbrella limits of $3,000,000 each occurrence and $4,000,000 annual aggregate.

10.2.2 Property Insurance covering (i) all office furniture, trade fixtures, office equipment, free-standing cabinet work, movable partitions, merchandise and all other items of Tenant's property in the Premises installed by, for, or at the expense of Tenant, and (ii) any Leasehold Improvements installed by or for the benefit of Tenant, whether pursuant to this Lease or pursuant to any prior lease or other agreement to which Tenant was a party ("**Tenant-Insured Improvements**"). Such insurance shall be written on a special cause of loss form for physical loss or damage, for the full replacement cost value (subject to reasonable deductible amounts) new without deduction for depreciation of the covered items and in amounts that meet any co-insurance clauses of the policies of insurance, and shall include coverage for damage or other loss caused by fire or other peril, including vandalism and malicious mischief, theft, water damage of any type, including sprinkler leakage, bursting or stoppage of pipes, and explosion.

10.2.3 Workers' Compensation statutory limits and Employers' Liability limits of $1,000,000.

10.3 Form of Policies. The minimum limits of insurance required to be carried by Tenant shall not limit Tenant's liability. Such insurance shall be issued by an insurance company that has an A.M. Best rating of not less than A-VIII and shall be in form and content reasonably acceptable to Landlord. Tenant's Commercial General Liability Insurance shall (a) name the Landlord Parties and any other party designated by Landlord ("**Additional Insured Parties**") as additional insureds; and (b) be primary insurance as to all claims thereunder and provide that any insurance carried by Landlord is excess and non-contributing with Tenant's insurance. Landlord shall be designated as a loss payee with respect to Tenant's Property Insurance on any Tenant-Insured Improvements. Tenant shall deliver to Landlord, on or before the Commencement Date and at least 15 days before the expiration dates thereof, certificates from Tenant's insurance company on the forms currently designated "ACORD 25" (Certificate of Liability Insurance) and "ACORD 28" (Evidence of Commercial Property Insurance) or the equivalent. Attached to the ACORD 25 (or equivalent) there shall be an endorsement naming the Additional Insured Parties as additional insureds, and attached to the ACORD 28 (or equivalent) there shall be an endorsement designating Landlord as a loss payee with respect to Tenant's Property Insurance on any Tenant-Insured Improvements, and each such endorsement shall be binding on Tenant's insurance company. Upon Landlord's request, Tenant shall deliver to Landlord, in lieu of such certificates, copies of the policies of insurance required to be carried under Section 10.2 showing that the Additional Insured Parties are named as additional insureds and that Landlord is designated as a loss payee with respect to Tenant's Property Insurance on any Tenant-Insured Improvements.

10.4 Subrogation. Each party waives, and shall cause its insurance carrier to waive, any right of recovery against the other party, any of its (direct or indirect) owners, or any of their respective beneficiaries, trustees, officers, directors, employees or agents for any loss of or damage to property which loss or damage is (or, if the insurance required hereunder had been carried, would have been) covered by the waiving party's property insurance. For purposes of this Section 10.4 only, (a) any deductible with respect to a party's insurance shall be deemed covered by, and recoverable by such party under, valid and collectable policies of insurance, and (b) any contractor retained by Landlord to install, maintain or monitor a fire or security alarm for the Building shall be deemed an agent of Landlord.

10.5 Additional Insurance Obligations. Tenant shall maintain such increased amounts of the insurance required to be carried by Tenant under this Section 10, and such other types and amounts of insurance covering the Premises and Tenant's operations therein, as may be reasonably requested by Landlord, but not in excess of the amounts and types of insurance then being required by landlords of buildings comparable to and in the vicinity of the Building.

11 CASUALTY DAMAGE. With reasonable promptness after discovering any damage to the Premises (other than trade fixtures), or to any Common Area or Building system necessary for access to or tenantability of the Premises, resulting from any fire or other casualty (a "**Casualty**"), Landlord shall notify Tenant of Landlord's reasonable estimate of the time required to substantially complete repair of such damage (the "**Landlord Repairs**"). If, according to such estimate, the Landlord Repairs cannot be substantially completed within 270 days after the date of Casualty, either party may terminate this Lease upon 60 days' notice to the other party delivered within 10 days after Landlord's delivery of such estimate. Within 90 days after discovering any damage to the Project resulting from any Casualty, Landlord may, whether or not the Premises are affected, terminate this Lease by notifying Tenant if (i) any Security Holder terminates any ground lease or requires that any insurance proceeds be used to pay any mortgage debt; (ii) any damage to Landlord's property is not fully covered by Landlord's insurance policies; (iii) Landlord decides to rebuild the Building or Common Areas so that it or they will be substantially different structurally or architecturally; (iv) the damage occurs during the last 12 months of the Term; or (v) any owner, other than Landlord, of any damaged portion of the Project does not intend to repair such damage. If this Lease is not terminated pursuant to this Section 11, Landlord shall promptly and diligently perform the Landlord Repairs, subject to reasonable delays for insurance adjustment and other events of Force Majeure. The Landlord Repairs shall restore the Premises (other than trade fixtures) and any Common Area or Building system necessary for access to or tenantability of the Premises to substantially the same condition that existed when the Casualty occurred, except for (a) any modifications required by Law or any Security Holder, and (b) any modifications to the Common Areas that are deemed desirable by Landlord, are consistent with the character of the Project, and do not materially impair access to or tenantability of the Premises. Notwithstanding Section 10.4, Tenant shall assign to Landlord (or its designee) all insurance proceeds payable to Tenant under Tenant's insurance required under Section 10.2 with respect to any Tenant-Insured Improvements, and if the estimated or actual cost of restoring any Tenant-Insured Improvements exceeds the insurance proceeds received by Landlord from Tenant's insurance carrier, Tenant shall pay such excess to Landlord within 15 days after Landlord's demand. No Casualty and no restoration performed as required hereunder shall render Landlord liable to Tenant, constitute a constructive eviction, or excuse Tenant from any obligation hereunder; provided, however, that if the Premises (other than trade fixtures) or any Common Area or Building system necessary for access to or tenantability of the Premises is damaged by a Casualty, then, during any time that, as a result of such damage, any portion of the Premises is inaccessible or untenantable and is not occupied by Tenant, Monthly Rent shall be abated in proportion to the rentable square footage of such portion of the Premises.

12 NONWAIVER. No provision hereof shall be deemed waived by either party unless it is waived by such party expressly and in writing, and no waiver of any breach of any provision hereof shall be deemed a waiver of any subsequent breach of such provision or any other provision hereof. Landlord's acceptance of Rent shall not be deemed a waiver of any preceding breach of any provision hereof, other than Tenant's failure to pay the particular Rent so accepted, regardless of Landlord's knowledge of such preceding breach at the time of such acceptance. No acceptance of payment of an amount less than the Rent due hereunder shall be deemed a waiver of Landlord's right to receive the full amount of Rent due, whether or not any endorsement or statement accompanying such payment purports to effect an accord and satisfaction. No receipt of monies by Landlord from Tenant after the giving of any notice, the commencement of any suit, the issuance of any final judgment, or the termination hereof shall affect such notice, suit or judgment, or reinstate or extend the Term or Tenant's right of possession hereunder.

13 CONDEMNATION. If any part of the Premises, Building or Project is taken for any public or quasi-public use by power of eminent domain or by private purchase in lieu thereof (a "**Taking**") for more than 180 consecutive days, Landlord may terminate this Lease. If more than 25% of the rentable square footage of the Premises is Taken, or access to the Premises is substantially impaired as a result of a Taking, for more than 180 consecutive days, Tenant may terminate this Lease. Any such termination shall be effective as of the date possession must be surrendered to the authority, and the terminating party shall provide termination notice to the other party within 45 days after receiving written notice of such surrender date. Except as provided above in this Section 13, neither party may terminate this Lease as a result of a Taking. Tenant shall not assert any claim for compensation because of any Taking; provided, however, that Tenant may file a separate claim for any Taking of Tenant's personal property or any fixtures that Tenant is entitled to remove upon the expiration hereof, and for moving expenses, so long as such claim does not diminish the award available to Landlord or any Security Holder and is payable separately to Tenant. Under no circumstances may Tenant seek any award or compensation for loss or taking of Tenant's leasehold interest, and Tenant hereby expressly, unconditionally, and irrevocably waives any such claims. If this Lease is terminated pursuant to this Section 13, all Rent shall be apportioned as of the date of such termination. If a Taking occurs and this Lease is not so terminated, Monthly Rent shall be abated for the period of such Taking in proportion to the percentage of the rentable square footage of the Premises, if any, that is subject to, or rendered inaccessible by, such Taking.

14 ASSIGNMENT AND SUBLETTING.

14.1 Transfers. Tenant shall not, without Landlord's prior consent, assign, mortgage, pledge, hypothecate, encumber, permit any lien to attach to, or otherwise transfer this Lease or any interest hereunder, permit any assignment or other transfer hereof or any interest hereunder by operation of law, enter into any sublease or license agreement, otherwise permit the occupancy or use of any part of the Premises by any persons other than Tenant and its employees and contractors, or permit a Change of Control (defined in Section 14.6) to occur (each, a "**Transfer**"). If Tenant desires Landlord's consent to any Transfer, Tenant shall provide Landlord with (i) notice of the terms of the proposed Transfer, including its proposed effective date (the "**Contemplated Effective Date**"), a description of the portion of the Premises to be transferred (the "**Contemplated Transfer Space**"), a calculation of the Transfer Premium (defined in Section 14.3), and a copy of all existing executed and/or proposed documentation pertaining to the proposed Transfer, and (ii) current financial statements of the proposed transferee (or, in the case of a Change of Control, of the proposed new controlling party(ies)) certified by an officer or owner thereof and any other information reasonably required by Landlord in order to evaluate the proposed Transfer (collectively, the "**Transfer Notice**"). Within 30 days after receiving the Transfer Notice, Landlord shall notify Tenant of (a) its consent to the proposed Transfer, (b) its refusal to consent to the proposed Transfer, or (c) its exercise of its rights under Section 14.4. Any Transfer made without Landlord's prior consent shall, at Landlord's option, be void and shall, at Landlord's option, constitute a Default (defined in Section 19). Tenant shall pay Landlord a fee of $1,500.00 for Landlord's review of any proposed Transfer, whether or not Landlord consents to it.

14.2 Landlord's Consent. Subject to Section 14.4, Landlord shall not unreasonably withhold its consent to any proposed Transfer. Without limiting other reasonable grounds for withholding consent, it shall be deemed reasonable for Landlord to withhold its consent to a proposed Transfer if:

14.2.1 The proposed transferee is not a party of reasonable financial strength in light of the responsibilities to be undertaken in connection with the Transfer on the date the Transfer Notice is received; or

14.2.2 The proposed transferee has a character or reputation or is engaged in a business that is not consistent with the quality of the Building or the Project; or

14.2.3 The proposed transferee is a governmental entity or a nonprofit organization; or

14.2.4 In the case of a proposed sublease, license or other occupancy agreement, the rent or occupancy fee charged by Tenant to the transferee during the term of such agreement, calculated using a present value analysis, is less than 95% of the rent being quoted by Landlord or its Affiliate (defined in Section 14.8) at the time of such Transfer for comparable space in the Project for a comparable term, calculated using a present value analysis; or

14.2.5 The proposed transferee or any of its Affiliates, on the date the Transfer Notice is received, leases or occupies (or, at any time during the 6-month period ending on the date the Transfer Notice is received, has negotiated with Landlord to lease) space in the Project.

Notwithstanding any contrary provision hereof, (a) if Landlord consents to any Transfer pursuant to this Section 14.2 but Tenant does not enter into such Transfer within six (6) months thereafter, such consent shall no longer apply and such Transfer shall not be permitted unless Tenant again obtains Landlord's consent thereto pursuant and subject to the terms of this Section 14; and (b) if Landlord unreasonably withholds its consent under this Section 14.2, Tenant's sole remedies shall be contract damages (subject to Section 20) or specific performance, and Tenant waives all other remedies, including any right to terminate this Lease.

14.3 Transfer Premium. If Landlord consents to a Transfer, Tenant shall pay Landlord an amount equal to 75% of any Transfer Premium (defined below). As used herein, "**Transfer Premium**" means (a) in the case of an assignment, any consideration (including payment for Leasehold Improvements) paid by the assignee for such assignment; (b) in the case of a sublease, license or other occupancy agreement, for each month of the term of such agreement, the amount by which all rent and other consideration paid by the transferee to Tenant pursuant to such agreement exceeds the Monthly Rent payable by Tenant hereunder with respect to the Contemplated Transfer Space; and (c) in the case of a Change of Control, any consideration (including payment for Leasehold Improvements) paid by the new controlling party(ies) to the prior controlling party(ies) on account of this Lease. Payment of Landlord's share of the Transfer Premium shall be made (x) in the case of an assignment or a Change of Control, within 10 days after Tenant or the prior controlling party(ies), as the case may be, receive(s) the consideration described above, and (y) in the case of a sublease, license or other occupancy agreement, with respect to each month of the term of such agreement, within five (5) business days after Tenant receives the rent and other consideration described above. Notwithstanding any contrary provision of this Section 14.3, Tenant shall not be required to pay Landlord any portion of any Transfer Premium arising from any Change of Control that occurs for a good faith operating business purpose and not in order to evade the requirements of this Section 14.3.

14.4 Landlord's Right to Recapture. Notwithstanding any contrary provision hereof, except in the case of a Permitted Transfer (defined in Section 14.8), Landlord, by notifying Tenant within 30 days after receiving the Transfer Notice, may terminate this Lease with respect to the Contemplated Transfer Space as of the Contemplated Effective Date. If the Contemplated Transfer Space is less than the entire Premises, then Base Rent, Tenant's Share, and the number of parking spaces to which Tenant is entitled under Section 1.9 shall be deemed adjusted on the basis of the percentage of the rentable square footage of the portion of the Premises retained by Tenant. Upon request of either party, the parties shall execute a written agreement prepared by Landlord memorializing such termination.

14.5 Effect of Consent. If Landlord consents to a Transfer, (i) such consent shall not be deemed a consent to any further Transfer, (ii) Tenant shall deliver to Landlord, promptly after execution, an executed copy of all documentation pertaining to the Transfer in form reasonably acceptable to Landlord, and (iii) Tenant shall deliver to Landlord, upon Landlord's request, a complete statement, certified by an independent CPA or Tenant's chief financial officer, setting forth in detail the computation of any Transfer Premium. In the case of an assignment, the assignee shall assume in writing, for Landlord's benefit, all of Tenant's obligations hereunder. No Transfer, with or without Landlord's consent, shall relieve Tenant or any guarantor hereof from any liability hereunder. Notwithstanding any contrary provision hereof, Tenant, with or without Landlord's consent, shall not enter into, or permit any party claiming by, through or under Tenant to enter into, any sublease, license or other occupancy agreement that provides for payment based in whole or in part on the net income or profit of the subtenant, licensee or other occupant thereunder.

14.6 Change of Control. As used herein, "**Change of Control**" means (a) if Tenant is a closely held professional service firm, the withdrawal or change (whether voluntary, involuntary or by operation of law) of more than 50% of its equity owners within a 12-month period; and (b) in all other cases, any transaction(s) resulting in the acquisition of a Controlling Interest (defined below) by one or more parties that did not own a Controlling Interest immediately before such transaction(s). As used herein, "**Controlling Interest**" means any direct or indirect equity or beneficial ownership interest in Tenant that confers upon its holder(s) the direct or indirect power to direct the ordinary management and policies of Tenant, whether through the ownership of voting securities, by contract or otherwise (but not through the ownership of voting securities listed on a recognized securities exchange).

14.7 Effect of Default. If Tenant is in Default, Landlord is irrevocably authorized, as Tenant's agent and attorney-in-fact, to direct any transferee under any sublease, license or other occupancy agreement to make all payments under such agreement directly to Landlord (which Landlord shall apply towards Tenant's obligations hereunder) until such Default is cured. Such transferee shall rely upon any representation by Landlord that Tenant is in Default, whether or not confirmed by Tenant.

14.8 Permitted Transfers. Notwithstanding any contrary provision hereof, if Tenant is not in Default, Tenant may, without Landlord's consent pursuant to Section 14.1, permit a Change of Control to occur or assign this Lease to (a) an Affiliate of Tenant (other than pursuant to a merger or consolidation), (b) a successor to Tenant by merger or consolidation, or (c) a successor to Tenant by purchase of all or substantially all of Tenant's assets (a "**Permitted Transfer**"), provided that (i) at least 10 business days before the Transfer, Tenant notifies Landlord of such Transfer and delivers to Landlord any documents or information reasonably requested by Landlord relating thereto (provided that if advanced notice is prohibited by a confidentiality agreement or applicable law or is otherwise impracticable, then Tenant shall give Landlord written notice and deliver such documents within 10 days after the effective date of the Permitted Transfer), including reasonable documentation that the Transfer satisfies the requirements of this Section 14.8; (ii) in the case of an assignment pursuant to clause (a) or (c) above, the assignee executes and delivers to Landlord, at least 10 business days before the assignment, a commercially reasonable instrument pursuant to which the assignee assumes, for Landlord's benefit, all of Tenant's obligations hereunder; (iii) in the case of an assignment pursuant to clause (b) above, (A) the successor entity has a net worth (as determined in accordance with GAAP, but excluding intellectual property and any other intangible assets ("**Net Worth**")) immediately after the Transfer that is not less than the Net Worth of Tenant immediately before the Transfer, and (B) if Tenant is a closely held professional service firm, at least 50% of its equity owners existing 12 months before the Transfer are also equity owners of the successor entity; (iv) except in the case of a Change of Control, the transferee is qualified to conduct business in the State of California; (v) in the case of a Change of Control, (A) Tenant is not a closely held professional service firm, and (B) Tenant's Net Worth immediately after the Change of Control is not less than its Net Worth immediately before the Change of Control; and (vi) the Transfer is made for a good faith operating business purpose and not in order to evade the requirements of this Section 14. As used herein, "**Affiliate**" means, with respect to any party, a person or entity that controls, is under common control with, or is controlled by such party.

15 SURRENDER. Upon the expiration or earlier termination hereof, and subject to Sections 8 and 11 and this Section 15, Tenant shall surrender possession of the Premises to Landlord in as good condition and repair as existed when Tenant took possession and as thereafter improved by Landlord and/or Tenant, except for reasonable wear and tear and repairs that are Landlord's express responsibility hereunder. Before such expiration or termination, Tenant, without expense to Landlord, shall (a) remove from the Premises all debris and rubbish and all furniture, equipment, trade fixtures, Lines, free-standing cabinet work, movable partitions and other articles of personal property that are owned or placed in the Premises by Tenant or any party claiming by, through or under Tenant (except for any Lines not required to be removed under Section 23), and (b) repair all damage to the Premises and Building resulting from such removal. If Tenant fails to timely perform such removal and repair, Landlord may do so at Tenant's expense (including storage costs). If Tenant fails to remove such property from the Premises, or from storage, within 30 days after notice from Landlord, any part of such property shall be deemed, at Landlord's option, either (x) conveyed to Landlord without compensation, or (y) abandoned.

16 HOLDOVER. If Tenant fails to surrender the Premises upon the expiration or earlier termination hereof, Tenant's tenancy shall be subject to the terms and conditions hereof; provided, however, that such tenancy shall be a tenancy at sufferance only, without claim of right, for the entire Premises, and Tenant shall pay Monthly Rent (on a per-month basis without reduction for any partial month) at a rate equal to twice the Monthly Rent applicable during the last calendar month of the Term. Nothing in this Section 16 shall limit Landlord's rights or remedies or be deemed a consent to any holdover. If Landlord is unable to deliver possession of the Premises to a new tenant or to perform improvements for a new tenant as a result of Tenant's holdover, Tenant shall be liable for all resulting damages, including lost profits, incurred by Landlord.

17 SUBORDINATION; ESTOPPEL CERTIFICATES. This Lease shall be subject and subordinate to all existing and future ground or underlying leases, mortgages, deeds of trust, deeds to secure debt, and other encumbrances against the Building or Project, all renewals, extensions, modifications, consolidations and replacements thereof (each, a "**Security Agreement**"), and all advances made upon the security of such mortgages, deeds of trust or deeds to secure debt, unless in each case the holder of such Security Agreement (each, a "**Security Holder**") requires in writing that this Lease be superior thereto. Upon any termination or foreclosure (or any delivery of a deed in lieu of foreclosure) of any Security Agreement (a "**Succession**"), Tenant, upon request, shall attorn, without deduction or set-off, to the Security Holder or purchaser or any successor thereto and shall recognize such party (the "**Successor**") as the lessor hereunder if the Successor agrees not to disturb Tenant's occupancy so long as Tenant timely pays the Rent and otherwise performs its obligations hereunder; provided, however, that the Successor shall not be liable for or bound by (i) any payment of Rent made to Landlord more than 30 days before its due date, (ii) any act or omission of or default by Landlord hereunder (but the Successor shall be subject to Landlord's continuing obligations hereunder to the extent arising after the Succession and to the extent of the Successor's interest in the Property), (iii) any credits, claims, setoffs or defenses that Tenant may have against Landlord, (iv) any modification or amendment to this Lease for which the Security Holder's consent is required, but has not been obtained, under the Security Agreement, or (v) any obligation hereunder to maintain a fitness facility at the Building. Within 10 days after request by Landlord, Tenant shall execute such further instruments as Landlord may reasonably deem necessary to confirm such attornment and evidence the subordination or superiority of this Lease to any Security Agreement. Tenant waives any right it may have under Law to terminate or otherwise adversely affect this Lease or Tenant's obligations hereunder upon a foreclosure. Within 10 business days after Landlord's request, Tenant shall execute and deliver to Landlord a commercially reasonable estoppel certificate in favor of such parties as Landlord may reasonably designate, including current and prospective Security Holders and prospective purchasers.

18 ENTRY BY LANDLORD. At all reasonable times and upon reasonable notice to Tenant, or in an emergency, Landlord may enter the Premises to (i) inspect the Premises; (ii) show the Premises to prospective purchasers, current or prospective Security Holders or insurers, or, during the last 12 months of the Term (or while an uncured Default exists), prospective tenants; (iii) post notices of non-responsibility; or (iv) perform maintenance, repairs or alterations. At any time and without notice to Tenant, Landlord may enter the Premises to perform required services. If reasonably necessary, Landlord may temporarily close any portion of the Premises to perform maintenance, repairs or alterations. In an emergency, Landlord may use any means it deems proper to open doors to and in the Premises. No entry into or closure of any portion of the Premises pursuant to this Section 18 shall render Landlord liable to Tenant, constitute a constructive eviction, or excuse Tenant from any obligation hereunder.

19 DEFAULTS; REMEDIES.

19.1 Events of Default. The occurrence of any of the following shall constitute a "**Default**":

19.1.1 Any failure by Tenant to pay any Rent when due unless such failure is cured within five (5) business days after notice; or

19.1.2 Except where a specific time period is otherwise set forth for Tenant's cure herein (in which event Tenant's failure to cure within such time period shall be a Default), and except as otherwise provided in this Section 19.1, any breach by Tenant of any other provision hereof where such breach continues for 30 days after notice from Landlord; provided that if such breach cannot reasonably be cured within such 30-day period, Tenant shall not be in Default as a result of such breach if Tenant diligently commences such cure within such period, thereafter diligently pursues such cure, and completes such cure within 60 days after Landlord's notice; or

19.1.3 Abandonment or vacation of all or a substantial portion of the Premises by Tenant; or

19.1.4 Any breach by Tenant of Sections 5, 14, 17 or 18 where such breach continues for more than two (2) business days after notice from Landlord; or

19.1.5 Tenant becomes in breach of Section 25.3.

If Tenant breaches a particular provision hereof (other than a provision requiring payment of Rent) on three (3) separate occasions during any 12-month period, Tenant's subsequent breach of such provision shall be, at Landlord's option, an incurable Default. The notice periods provided herein are in lieu of, and not in addition to, any notice periods provided by Law, and Landlord shall not be required to give any additional notice in order to be entitled to commence an unlawful detainer proceeding.

19.2 Remedies Upon Default. Upon any Default, Landlord shall have, in addition to any other remedies available to Landlord at law or in equity (which shall be cumulative and nonexclusive), the option to pursue any one or more of the following remedies (which shall be cumulative and nonexclusive) without any notice or demand:

19.2.1 Landlord may terminate this Lease, or terminate Tenant's right of possession to the Premises without terminating this Lease, with or without reentering and repossessing the Premises, and in any such event, Tenant shall immediately surrender the Premises to Landlord, and if Tenant fails to do so, Landlord may, without prejudice to any other remedy it may have for possession or arrearages in Rent, enter upon and take possession of the Premises and expel or remove Tenant and any other person who may be occupying the Premises or any part thereof, without being liable for prosecution or any claim or damages therefor; and Landlord may recover from Tenant the following:

(a) The worth at the time of award of the unpaid Rent which has been earned at the time of such termination; plus

(b) Any other amount necessary to compensate Landlord for all the detriment proximately caused by Tenant's failure to perform its obligations hereunder or which in the ordinary course of things would be likely to result therefrom, including brokerage commissions, advertising expenses, expenses of remodeling any portion of the Premises for a new tenant (whether for the same or a different use), and any special concessions made to obtain a new tenant; plus

(c) At Landlord's option, such other amounts in addition to or in lieu of the foregoing as may be permitted from time to time by Law.

As used in Section 19.2.1(a), the "**worth at the time of award**" shall be computed by allowing interest at a rate per annum equal to the lesser of (i) the annual "Bank Prime Loan" rate cited in the Federal Reserve Statistical Release Publication G.13(415), published on the first Tuesday of each calendar month (or such other comparable index as Landlord shall reasonably designate if such rate ceases to be published) plus two (2) percentage points, or (ii) the highest rate permitted by Law. The amounts described in Sections 19.2.1(a), (b), and (c) above are, collectively, "**Damages**."

19.2.2 If Landlord elects to terminate Tenant's right to possession of the Premises without terminating this Lease, Tenant shall continue to be liable for all Rent and all other Damages, and Landlord may (but shall not be obligated to, except to the extent expressly required by Law) relet the Premises, or any part thereof, to a substitute tenant or tenants, for a period of time equal to or lesser or greater than the remainder of the Term on any terms and conditions Landlord, in its sole discretion, deems advisable. Notwithstanding any provision in this Section 19.2.2 to the contrary, Landlord may (a) at any time after reletting the Premises elect to exercise its rights under Section 19.2.3 below for any previous Default; and (b) upon the default of any substitute tenant or upon the expiration of the lease term of such substitute tenant before the expiration of the Term, either relet to another substitute tenant or exercise its rights under Section 19.2.3 below.

19.2.3 Landlord may declare all Rent and charges due under this Lease to be immediately due and payable, in which case all such amounts due to the end of the Term shall be accelerated; provided, however, such accelerated amounts shall be discounted to present value (using the then-current discount rate of the Federal Reserve Bank of Atlanta) from the respective dates that such amounts would have otherwise have been due under this Lease. In the event that any charges due under this Lease cannot be exactly determined as of the date of acceleration, the amount of such charges shall be determined by Landlord in a reasonable manner based on historical increases in such charges.

19.2.4 Landlord shall at all times have the rights and remedies (which shall be cumulative with each other and cumulative and in addition to those rights and remedies available under Sections 19.2.1, 19.2.2, and 19.2.3 or any Law or other provision hereof), without prior demand or notice except as required by Law, to seek any declaratory, injunctive or other equitable relief, and specifically enforce this Lease, or restrain or enjoin a violation or breach of any provision hereof.

19.3 Efforts to Relet. Unless Landlord provides Tenant with express notice to the contrary, no re-entry, repossession, repair, maintenance, change, alteration, addition, reletting, appointment of a receiver or other action or omission by Landlord shall (a) be construed as an election by Landlord to terminate this Lease or Tenant's right to possession, or to accept a surrender of the Premises, or (b) operate to release Tenant from any of its obligations hereunder. Tenant waives, for Tenant and for all those claiming by, through or under Tenant, any existing or future rights to redeem or reinstate, by order or judgment of any court or by any legal process or writ, this Lease or Tenant's right of occupancy of the Premises after any termination hereof.

19.4 Landlord Default. Landlord shall not be in default hereunder unless it fails to begin within 30 days after notice from Tenant, or fails to pursue with reasonable diligence thereafter, the cure of any breach by Landlord of its obligations hereunder. Before exercising any remedies for a default by Landlord, Tenant shall give notice and a reasonable time (not to exceed 180 days) to cure to any Security Holder of which Tenant has been notified.

20 LANDLORD EXCULPATION. Notwithstanding any contrary provision hereof, (a) the liability of the Landlord Parties to Tenant shall be limited to an amount equal to the lesser of (i) Landlord's interest in the Building, or (ii) the equity interest Landlord would have in the Building if the Building were encumbered by third-party debt in an amount equal to 80% of the value of the Building (as such value is determined by Landlord); (b) Tenant shall look solely to Landlord's interest in the Building for the recovery of any judgment or award against any Landlord Party; (c) no Landlord Party shall have any personal liability for any judgment or deficiency, and Tenant waives and releases such personal liability on behalf of itself and all parties claiming by, through or under Tenant; and (d) no Landlord Party shall be liable for any injury or damage to, or interference with, Tenant's business, including loss of profits, loss of rents or other revenues, loss of business opportunity, loss of goodwill or loss of use, or for any form of special or consequential damage.

21 SECURITY DEPOSIT.

21.1 Concurrently with its execution and delivery hereof, Tenant shall deposit with Landlord the Security Deposit, if any, as security for Tenant's performance of its obligations hereunder. If Tenant breaches any provision hereof, Landlord may, at its option, without notice to Tenant, apply all or part of the Security Deposit to pay any past-due Rent, cure any breach by Tenant, or compensate Landlord for any other loss or damage caused by such breach. If Landlord so applies any portion of the Security Deposit, Tenant, within three (3) days after demand therefor, shall restore the Security Deposit to its original amount. The Security Deposit is not an advance payment of Rent or measure of damages. Any unapplied portion of the Security Deposit shall be returned to Tenant within 60 days after the latest to occur of (a) the expiration of the Term, (b) Tenant's surrender of the Premises as required hereunder, or (c) determination of the final Rent due from Tenant. Landlord shall not be required to keep the Security Deposit separate from its other accounts.

21.2. Subject to the remaining terms of this Section 21, and provided that, during the 12 month period immediately preceding the effective date of any reduction of the Security Deposit, Tenant has timely paid all Rent and no default has occurred under this Lease (the "**Security Reduction Conditions**"), Tenant shall have the right to reduce the amount of the Security Deposit so that the new Security Deposit amount will be $18,520.74 effective as of the first day of the 13th month following the Commencement Date. Notwithstanding anything to the contrary contained herein, if Tenant has been in default under this Lease at any time prior to the effective date of any reduction of the Security Deposit and Tenant has failed to cure such default within any applicable cure period, then Tenant shall have no right to reduce the amount of the Security Deposit as described herein. If Tenant is entitled to a reduction in the Security Deposit, Tenant shall provide Landlord with written notice requesting that the Security Deposit be reduced as provided above (the "**Security Reduction Notice**"). If Tenant provides Landlord with a Security Reduction Notice, and Tenant is entitled to reduce the Security Deposit as provided herein, Landlord shall refund the applicable portion of the Security Deposit to Tenant within 60 days after the later to occur of (a) Landlord's receipt of the Security Reduction Notice, or (b) the date upon which Tenant is entitled to a reduction in the Security Deposit as provided above.

22 RELOCATION. Landlord, after giving notice, may move Tenant to other space in the Project comparable in size and utility to the Premises. In such event, all terms hereof shall apply to the new space, except that Base Rent and Tenant's Share shall not increase as a result of such relocation. Landlord, at its expense, shall provide Tenant with tenant improvements in the new space at least equal in quality to those in the Premises. Landlord shall reimburse Tenant for Tenant's reasonable moving, re-cabling and stationery-replacement costs. The parties shall execute a written agreement prepared by Landlord memorializing the relocation.

23 COMMUNICATIONS AND COMPUTER LINES. All Lines installed pursuant to this Lease shall be (a) installed in accordance with Section 7; and (b) clearly marked with adhesive plastic labels (or plastic tags attached to such Lines with wire) to show Tenant's name, suite number, and the purpose of such Lines (i) every six (6) feet outside the Premises (including the electrical room risers and any Common Areas), and (ii) at their termination points. Landlord may designate specific contractors for work relating to vertical Lines. Sufficient spare cables and space for additional cables shall be maintained for other occupants, as reasonably determined by Landlord. Unless otherwise notified by Landlord, Tenant, at its expense and before the expiration or earlier termination hereof, shall remove all Lines and repair any resulting damage. As used herein, "**Lines**" means all communications or computer wires and cables serving the Premises, whenever and by whomever installed or paid for, including any such wires or cables installed pursuant to any prior lease.

24 PARKING. Tenant may park in the Building's parking facilities (the "**Parking Facility**"), in common with other tenants of the Building, upon the following terms and conditions. Tenant shall not use more than the number of unreserved and/or reserved parking spaces set forth in Section 1.9. Tenant shall pay Landlord, in accordance with Section 3, any fees for the parking spaces described in Section 1.9. Tenant shall pay Landlord any fees, taxes or other charges imposed by any governmental or quasi-governmental agency in connection with the Parking Facility, to the extent such amounts are allocated to Tenant by Landlord. Landlord shall not be liable to Tenant, nor shall this Lease be affected, if any parking is impaired by (or any parking charges are imposed as a result of) any Law. Tenant shall comply with all rules and regulations established by Landlord from time to time for the orderly operation and use of the Parking Facility, including any sticker or other identification system and the prohibition of vehicle repair and maintenance activities in the Parking Facility. Landlord may, in its discretion, allocate and assign parking passes among Tenant and the other tenants in the Building. Tenant's use of the Parking Facility shall be at Tenant's sole risk, and Landlord shall have no liability for any personal injury or damage to or theft of any vehicles or other property occurring in the Parking Facility or otherwise in connection with any use of the Parking Facility by Tenant, its employees or invitees. Landlord may alter the size, configuration, design, layout or any other aspect of the Parking Facility, and, in connection therewith, temporarily deny or restrict access to the Parking Facility, in each case without abatement of Rent or liability to Tenant. Landlord may delegate its responsibilities hereunder to a parking operator, in which case (i) such parking operator shall have all the rights of control reserved herein by Landlord, (ii) Tenant shall enter into a parking agreement with such parking operator, (iii) Tenant shall pay such parking operator, rather than Landlord, any charge established hereunder for the parking spaces, and (iv) Landlord shall have no liability for claims arising through acts or omissions of such parking operator except to the extent caused by Landlord's gross negligence or willful misconduct. Tenant's parking rights under this Section 24 are solely for the benefit of Tenant's employees and invitees and such rights may not be transferred without Landlord's prior consent, except pursuant to a Transfer permitted under Section 14.

25 MISCELLANEOUS.

25.1 Notices. No notice, demand, statement, designation, request, consent, approval, election or other communication given hereunder ("**Notice**") shall be binding upon either party unless (a) it is in writing; (b) it is (i) sent by certified or registered mail, postage prepaid, return receipt requested, (ii) delivered by a nationally recognized courier service, or (iii) delivered personally; and (c) it is sent or delivered to the address set forth in Section 1.10 or 1.11, as applicable, or to such other place (other than a P.O. box) as the recipient may from time to time designate in a Notice to the other party. Any Notice shall be deemed received on the earlier of the date of actual delivery or the date on which delivery is refused, or, if Tenant is the recipient and has vacated its notice address without providing a new notice address, three (3) days after the date the Notice is deposited in the U.S. mail or with a courier service as described above.

25.2 Force Majeure. If either party is prevented from performing any obligation hereunder by any strike, act of God, war, terrorist act, shortage of labor or materials, governmental action, civil commotion or other cause beyond such party's reasonable control ("**Force Majeure**"), such obligation shall be excused during (and any time period for the performance of such obligation shall be extended by) the period of such prevention; provided, however, that this Section 25.2 shall not (a) permit Tenant to hold over in the Premises after the expiration or earlier termination hereof, or (b) excuse any of Tenant's obligations under Sections 3, 4, 5, 21 or 25.3 or any of Tenant's obligations whose nonperformance would interfere with another occupant's use, occupancy or enjoyment of its premises or the Project.

25.3 Representations and Covenants. Tenant represents, warrants and covenants that (a) Tenant is, and at all times during the Term will remain, duly organized, validly existing and in good standing under the Laws of the state of its formation and qualified to do business in the state of Florida; (b) neither Tenant's execution of nor its performance under this Lease will cause Tenant to be in violation of any agreement or Law; (c) Tenant (and any guarantor hereof) has not, and at no time during the Term will have, (i) made a general assignment for the benefit of creditors, (ii) filed a voluntary petition in bankruptcy or suffered the filing of an involuntary petition by creditors, (iii) suffered the appointment of a receiver to take possession of all or substantially all of its assets, (iv) suffered the attachment or other judicial seizure of all or substantially all of its assets, (v) admitted in writing its inability to pay its debts as they come due, or (vi) made an offer of settlement, extension or composition to its creditors generally; and (d) no party that (other than through the passive ownership of interests traded on a recognized securities exchange) constitutes, owns, controls, or is owned or controlled by Tenant, any guarantor hereof or any subtenant of Tenant is, or any time during the Term will be, (i) in violation of any Laws relating to terrorism or money laundering, or (ii) among the parties identified on any list compiled pursuant to Executive Order 13224 for the purpose of identifying suspected terrorists or on the most current list published by the U.S. Treasury Department Office of Foreign Assets Control at its official website, http://www.treas.gov/ofac/tllsdn.pdf or any replacement website or other replacement official publication of such list.

25.4 Signs. Landlord shall include Tenant's name in any tenant directory located in the lobby on the first floor of the Building. If any part of the Premises is located on a multi-tenant floor, Landlord, at Tenant's cost, shall provide identifying suite signage for Tenant comparable to that provided by Landlord on similar floors in the Building. Tenant may not install (a) any signs outside the Premises, or (b) without Landlord's prior consent in its sole and absolute discretion, any signs, window coverings, blinds or similar items that are visible from outside the Premises.

25.5 Supplemental HVAC. If any supplemental HVAC unit (a "**Unit**") serves the Premises, then (a) Tenant shall pay the costs of all electricity consumed in the Unit's operation, together with the cost of installing a meter to measure such consumption; (b) Tenant, at its expense, shall (i) operate and maintain the Unit in compliance with all applicable Laws and such reasonable rules and procedures as Landlord may impose; (ii) keep the Unit in as good working order and condition as exists upon its installation (or, if later, on the date Tenant takes possession of the Premises), subject to normal wear and tear and damage resulting from Casualty; (iii) maintain in effect, with a contractor reasonably approved by Landlord, a contract for the maintenance and repair of the Unit, which contract shall require the contractor, at least once every three (3) months, to inspect the Unit and provide to Tenant a report of any defective conditions, together with any recommendations for maintenance, repair or parts-replacement; (iv) follow all reasonable recommendation of such contractor; and (v) promptly provide to Landlord a copy of such contract and each report issued thereunder; (c) the Unit shall become Landlord's property upon installation and without compensation to Tenant; provided, however, that upon Landlord's request at the expiration or earlier termination hereof, Tenant, at its expense, shall remove the Unit and repair any resulting damage; (d) the Unit shall be deemed (i) a Leasehold Improvement (except for purposes of Section 8), and (ii) for purposes of Section 11, part of the Premises; (e) if the Unit exists on the date of mutual execution and delivery hereof, Tenant accepts the Unit in its "as is" condition, without representation or warranty as to quality, condition, fitness for use or any other matter; (f) if the Unit connects to the Building's condenser water loop (if any), then Tenant shall pay to Landlord, as Additional Rent, Landlord's standard one-time fee for such connection and Landlord's standard monthly per-ton usage fee; and (g) if any portion of the Unit is located on the roof, then (i) Tenant's access to the roof shall be subject to such reasonable rules and procedures as Landlord may impose; (ii) Tenant shall maintain the affected portion of the roof in a clean and orderly condition and shall not interfere with use of the roof by Landlord or any other tenants or licensees; and (iii) Landlord may relocate the Unit and/or temporarily interrupt its operation, without liability to Tenant, as reasonably necessary to maintain and repair the roof or otherwise operate the Building.

25.6 Attorneys' Fees. In any action or proceeding between the parties, including any appellate or alternative dispute resolution proceeding, the prevailing party may recover from the other party all of its costs and expenses in connection therewith, including reasonable attorneys' fees and costs. Tenant shall pay all reasonable attorneys' fees and other fees and costs that Landlord incurs in interpreting or enforcing this Lease or otherwise protecting its rights hereunder (a) where Tenant has failed to pay Rent when due, or (b) in any bankruptcy case, assignment for the benefit of creditors, or other insolvency, liquidation or reorganization proceeding involving Tenant or this Lease.

25.7 Brokers. Tenant represents to Landlord that it has dealt only with Tenant's Broker as its broker in connection with this Lease. Tenant shall indemnify, defend, and hold Landlord harmless from all claims of any brokers, other than Tenant's Broker, claiming to have represented Tenant in connection with this Lease. Landlord shall indemnify, defend and hold Tenant harmless from all claims of any brokers, including Landlord's Broker, claiming to have represented Landlord in connection with this Lease. Tenant acknowledges that any Affiliate of Landlord that is involved in the negotiation of this Lease is representing only Landlord, and that any assistance rendered by any agent or employee of such Affiliate in connection with this Lease or any subsequent amendment or other document related hereto has been or will be rendered as an accommodation to Tenant solely in furtherance of consummating the transaction on behalf of Landlord, and not as agent for Tenant.

25.8 Governing Law; WAIVER OF TRIAL BY JURY. This Lease shall be construed and enforced in accordance with the Laws of the State of Florida. THE PARTIES KNOWINGLY AND VOLUNTARILY WAIVE, TO THE FULLEST EXTENT PERMITTED BY LAW, THE RIGHT TO TRIAL BY JURY IN ANY LITIGATION ARISING OUT OF OR RELATING TO THIS LEASE, THE RELATIONSHIP OF LANDLORD AND TENANT, TENANT'S USE OR OCCUPANCY OF THE PREMISES, AND/OR ANY CLAIM FOR INJURY OR DAMAGE OR ANY EMERGENCY OR STATUTORY REMEDY.

25.9 Interpretation. As used herein, the capitalized term "Section" refers to a section hereof unless otherwise specifically provided herein. As used in this Lease, the terms "herein," "hereof," "hereto" and "hereunder" refer to this Lease and the term "include" and its derivatives are not limiting. Any reference herein to "any part" or "any portion" of the Premises, the Property or any other property shall be construed to refer to all or any part of such property. Wherever this Lease requires Tenant to comply with any Law, rule, regulation, procedure or other requirement or prohibits Tenant from engaging in any particular conduct, this Lease shall be deemed also to require Tenant to cause each of its employees, licensees, invitees and subtenants, and any other party claiming by, through or under Tenant, to comply with such requirement or refrain from engaging in such conduct, as the case may be. Wherever this Lease requires Landlord to provide a customary service or to act in a reasonable manner (whether in incurring an expense, establishing a rule or regulation, providing an approval or consent, or performing any other act), this Lease shall be deemed also to provide that whether such service is customary or such conduct is reasonable shall be determined by reference to the practices of owners of buildings that (i) are comparable to the Building in size, age, class, quality and location, and (ii) at Landlord's option, have been, or are being prepared to be, certified under the U.S. Green Building Council's Leadership in Energy and Environmental Design (LEED) rating system or a similar rating system. Tenant waives the benefit of any rule that a written agreement shall be construed against the drafting party.

25.10 Entire Agreement. This Lease sets forth the entire agreement between the parties relating to the subject matter hereof and supersedes any previous agreements (none of which shall be used to interpret this Lease). Tenant acknowledges that in entering into this Lease it has not relied upon any representation, warranty or statement, whether oral or written, not expressly set forth herein. This Lease can be modified only by a written agreement signed by both parties.

25.11 Other. Landlord, at its option, may cure any Default, without waiving any right or remedy or releasing Tenant from any obligation, in which event Tenant shall pay Landlord, upon demand, the cost of such cure. If any provision hereof is void or unenforceable, no other provision shall be affected**.** Submission of this instrument for examination or signature by Tenant does not constitute an option or offer to lease, and this instrument is not binding until it has been executed and delivered by both parties. If Tenant is comprised of two or more parties, their obligations shall be joint and several. Time is of the essence with respect to the performance of every provision hereof in which time of performance is a factor. So long as Tenant performs its obligations hereunder, Tenant shall have peaceful and quiet possession of the Premises against any party claiming by, through or under Landlord, subject to the terms hereof. Landlord may transfer its interest herein, in which event Landlord shall be released from, Tenant shall look solely to the transferee for the performance of, and the transferee shall be deemed to have assumed, all of Landlord's obligations arising hereunder after the date of such transfer (including the return of any Security Deposit) and Tenant shall attorn to the transferee. Landlord reserves all rights not expressly granted to Tenant hereunder, including the right to make alterations to the Project. No rights to any view or to light or air over any property are granted to Tenant hereunder. The expiration or termination hereof shall not relieve either party of any obligation that accrued before, or continues to accrue after, such expiration or termination.

25.12 Radon Gas. The following disclosure is required by Florida Law: "Radon is a naturally occurring radioactive gas that, when it has accumulated in a structure in sufficient quantities, may present health risks to persons who are exposed to it. Levels of radon that exceed federal and state guidelines have been found in buildings in the State of Florida. Additional information regarding radon and radon testing may be obtainable from the county public health unit." Landlord makes no representation to Tenant concerning the presence or absence of radon gas in or at the Premises, the Building, or the Project at any time or in any quantity. By executing this Lease, and notwithstanding any provision herein to the contrary, Tenant expressly releases Landlord and all other Landlord Parties from any loss, claim, liability, or damage now or hereafter arising from or relating to the presence at any time of such substances in or at the Premises, the Building, or the Project.

25.13 Underlying Documents. Tenant agrees that (i) Tenant's rights under this Lease are subject and subordinate to the Underlying Documents (defined below), (ii) Tenant shall not cause Landlord to be in breach of the Underlying Documents and (iii) to the extent applicable to Tenant's use and occupancy of the Premises and/or Tenant's use of the Building and the Common Areas, Tenant shall comply with the terms of the Underlying Documents at its sole cost and expense. As used herein, the term "**Underlying Documents**" means, other than the the Security Agreement (which document is addressed elsewhere in this Lease), any covenants, conditions restrictions and other documents of record applicable to the Project.

[SIGNATURES ARE ON THE FOLLOWING PAGE]

IN WITNESS WHEREOF, Landlord and Tenant have caused this Lease to be executed the day and date first above written.

WITNESSES:

/s/ Heather Bradley
Print Name: Heather Bradley

/s/ Kimberly Summers
Print Name: Kimberly Summers

/s/ Travis Mickle
Print Name: Travis Mickle

/s/ Les Sessoms
Print Name: Les Sessoms

LANDLORD:

BRE/COH FL LLC, a Delaware limited liability company

By:/s/ Rob Shults
Name:Rob Shults
Title:VP, Asset Management

TENANT:

KEMPHARM, INC., a Delaware corporation

By:/s/ Christal Mickle
Name:Christal Mickle
Title:VP, Operations & Product Development

By:
Name:
Title:

Print Name:

Print Name:

EXHIBIT A

CELEBRATION OFFICE CENTER II

1170 CELEBRATION BOULEVARD
CELEBRATION, FLORIDA

OUTLINE OF PREMISES

EXHIBIT B

CELEBRATION OFFICE CENTER II
1170 CELEBRATION BOULEVARD
CELEBRATION, FLORIDA

WORK LETTER

As used in this **Exhibit B** (this "**Work Letter**"), the following terms shall have the following meanings:

(i) "**Tenant Improvements**" means all improvements to be constructed in the Premises pursuant to this Work Letter;

(ii) "**Tenant Improvement Work**" means the construction of the Tenant Improvements, together with any related work (including demolition) that is necessary to construct the Tenant Improvements;

(iii) "**Agreement**" means the lease of which this Work Letter is a part.

1 ALLOWANCE.

1.1 Allowance. Tenant shall be entitled to a one-time tenant improvement allowance (the "**Allowance**") in the amount of $2.50 per rentable square foot of the Premises to be applied toward the Allowance Items (defined in Section 1.2 below). Tenant shall be responsible for all costs associated with the Tenant Improvement Work, including the costs of the Allowance Items, to the extent such costs exceed the lesser of (a) the Allowance, or (b) the aggregate amount that Landlord is required to disburse for such purpose pursuant to this Work Letter. Notwithstanding any contrary provision of this Agreement, if Tenant fails to use the entire Allowance by within one (1) year following the Commencement Date, the unused amount shall revert to Landlord and Tenant shall have no further rights with respect thereto.

1.2 Disbursement. Except as otherwise provided in this Work Letter, the Allowance shall be disbursed by Landlord only for the following items (the "**Allowance Items**"): (a) the fees of the Architect (defined in Section 2.1 below); (b) the cost of preparing the Engineering Drawings (defined in Section 3.2.1 below); (c) plan-check, permit and license fees relating to performance of the Tenant Improvement Work; (d) the cost of performing the Tenant Improvement Work, including after hours charges, testing and inspection costs, freight elevator usage, hoisting and trash removal costs, and contractors' fees and general conditions; (e) the cost of any change to the base, shell or core of the Premises or Building required by the Plans (defined in Section 4 below) (including if such change is due to the fact that such work is prepared on an unoccupied basis), including all direct architectural and/or engineering fees and expenses incurred in connection therewith; (f) the cost of any change to the Plans or the Tenant Improvement Work required by Law; (g) the Landlord Supervision Fee (defined in Section 3.4.1 below); (h) sales and use taxes; and (i) all other costs expended by Landlord in connection with the performance of the Tenant Improvement Work.

2 ARCHITECTURAL PLANS; PRICING.

2.1 Selection of Architect. Landlord shall retain the architect/space planner of Landlord's choice (the "**Architect**") to prepare the Architectural Drawings (defined in Section 2.5 below).

2.2 [Intentionally Omitted.]

2.3 Space Plan. Tenant shall prepare a space plan for the Tenant Improvements, including a layout and designation of all offices, rooms and other partitioning, and equipment to be contained in the Premises, together with their intended use (the "**Space Plan**"), and shall deliver four (4) copies of the Space Plan, signed by Tenant, to Landlord for its approval. The Space Plan shall (a) comply with the drawing format and specifications required by Landlord, (b) be consistent with Landlord's requirements for avoiding aesthetic, engineering or other conflicts with the design and function of the balance of the Building (collectively, the "**Landlord Requirements**"), and (c) otherwise be subject to Landlord's reasonable approval. Landlord shall provide Tenant with notice approving or reasonably disapproving the Space Plan within 10 business days after the later of Landlord's receipt thereof or the mutual execution and delivery of this Agreement. If Landlord disapproves the Space Plan, Landlord's notice of disapproval shall describe with reasonable specificity the basis for such disapproval and Tenant shall revise the Space Plan and resubmit it for Landlord's approval. Such procedure shall be repeated as necessary until Landlord has approved the Space Plan. Such approved Space Plan shall be referred to herein as the "**Approved Space Plan**." Landlord and Tenant acknowledge that, as of the date of mutual execution and delivery of this Agreement, Tenant has previously delivered to Landlord, and Landlord has approved, the Space Plan dated August 8, 2014 prepared by KemPharm, Inc., as required under this Section 2.3.

2.4 Additional Programming Information. After Landlord approves the Space Plan, Tenant shall deliver to Landlord, in writing, all information (including all interior and special finishes) that, when combined with the Approved Space Plan, will be sufficient to complete the Architectural Drawings, together with all information (including all electrical requirements, telephone requirements, special HVAC requirements, and plumbing requirements) that, when combined with the Approved Space Plan, will be sufficient to complete the Engineering Drawings (collectively, the "**Additional Programming Information**"). The Additional Programming Information shall be (a) consistent with the Approved Space Plan and the Landlord Requirements, and (b) otherwise subject to Landlord's reasonable approval. Landlord shall provide Tenant with notice approving or reasonably disapproving the Additional Programming Information within five (5) business days after the later of Landlord's receipt thereof or the mutual execution and delivery of this Agreement. If Landlord disapproves the Additional Programming Information, Landlord's notice of disapproval shall describe with reasonable specificity the basis for such disapproval and Tenant shall modify the Additional Programming Information and resubmit it for Landlord's approval. Such procedure shall be repeated as necessary until Landlord has approved the Additional Programming Information. Such approved Additional Programming Information shall be referred to herein as the "**Approved Additional Programming Information**." If requested by Tenant, Landlord, in its sole and absolute discretion, may assist Tenant, or cause the Architect and/or other contractors or consultants of Landlord to assist Tenant, in preparing all or a portion of the Additional Programming Information; provided, however, that, whether or not the Additional Programming Information is prepared with such assistance, Tenant shall be solely responsible for the timely preparation and delivery of the Additional Programming Information and for all elements thereof and, subject to Section 1 above, all costs relating thereto. Landlord and Tenant acknowledge that, as of the date of mutual execution and delivery of this Agreement, Tenant has previously delivered to Landlord, and Landlord has approved, the Additional Programming Information, as required under this Section 2.4.

2.5 Architectural Drawings. After approving the Additional Programming Information, Landlord shall cause the Architect to prepare and deliver to Tenant the final architectural (and, if applicable, structural) working drawings for the Tenant Improvement Work that are in a form that (a) when combined with any Approved Additional Programming Information that is not expressly incorporated into such working drawings, will be sufficient to enable the Contractor (defined in Section 3.1 below) and its subcontractors to bid on the Tenant Improvement Work, and (b) when combined with any Engineering Drawings that satisfy the Engineering Requirements (defined in Section 3.2.1 below), will be sufficient to obtain the Permits (defined in Section 3.3 below) (the "**Architectural Drawings**"). The Architectural Drawings shall conform to the Approved Space Plan and the Approved Additional Programming Information. The Architect's preparation and delivery of the Architectural Drawings shall occur within 10 business days after the later of Landlord's approval of the Additional Programming Information or the mutual execution and delivery of this Agreement. Tenant shall approve or disapprove the Architectural Drawings by notice to Landlord. If Tenant disapproves the Architectural Drawings, Tenant's notice of disapproval shall specify any revisions Tenant desires in the Architectural Drawings. After receiving such notice of disapproval, Landlord shall cause the Architect to revise the Architectural Drawings and resubmit them to Tenant, taking into account the reasons for Tenant's disapproval; provided, however, that Landlord shall not be required to cause the Architect to make any revision to the Architectural Drawings that conflicts with the Landlord Requirements or is otherwise reasonably disapproved by Landlord. Such revision and resubmission shall occur within five (5) business days after the later of Landlord's receipt of Tenant's notice of disapproval or the mutual execution and delivery of this Agreement if such revision is not material, and within such longer period of time as may be reasonably necessary (but not more than 15 business days after the later of such receipt or such mutual execution and delivery) if such revision is material. Such procedure shall be repeated as necessary until Tenant has approved the Architectural Drawings. Such approved Architectural Drawings shall be referred to herein as the "**Approved Architectural Drawings**."

2.6 Construction Pricing.

2.6.1 Construction Pricing Proposal. Within 10 business days after the Architectural Drawings are approved by Landlord and Tenant, Landlord shall provide Tenant with Landlord's reasonable estimate (the "**Construction Pricing Proposal**") of the cost of all Allowance Items to be incurred by Tenant in connection with the performance of the Tenant Improvement Work pursuant to the Approved Architectural Drawings and the Approved Additional Programming Information. Tenant shall provide Landlord with notice approving or disapproving the Construction Pricing Proposal. If Tenant disapproves the Construction Pricing Proposal, Tenant's notice of disapproval shall be accompanied by proposed revisions to the Approved Architectural Drawings and/or the Approved Additional Programming Information that Tenant requests in order to resolve its objections to the Construction Pricing Proposal, and Landlord shall respond as required under Section 2.7 below. Such procedure shall be repeated as necessary until the Construction Pricing Proposal is approved by Tenant. Upon Tenant's approval of the Construction Pricing Proposal, Landlord may purchase the items set forth in the Construction Pricing Proposal and begin construction relating to such items.

2.6.2 Over-Allowance Amount. If the Construction Pricing Proposal exceeds the Allowance, then Tenant, concurrently with its delivery to Landlord of its approval of the Construction Pricing Proposal, shall deliver to Landlord cash in the amount of such excess (the "**Over-Allowance Amount**"). Any Over-Allowance Amount shall be disbursed by Landlord before the Allowance and pursuant to the same procedure as the Allowance. If, after the Construction Pricing Proposal is approved by Tenant, (a) any revision is made to the Approved Additional Programming Information or the Approved Architectural Drawings, or Tenant disapproves any Engineering Drawings that satisfy the Engineering Requirements, or the Tenant Improvement Work is otherwise changed, in each case in a way that increases the Construction Pricing Proposal, or (b) the Construction Pricing Proposal is otherwise increased to reflect the actual cost of all Allowance Items to be incurred by Tenant in connection with the performance of the Tenant Improvement Work pursuant to the terms hereof, then Tenant shall deliver any resulting Over-Allowance Amount (or any resulting increase in the Over-Allowance Amount) to Landlord immediately upon Landlord's request.

2.7 Revisions to Approved Architectural Drawings, Approved Additional Programming Information, or Approved Space Plan.

2.7.1 Approved Architectural Drawings. If Tenant requests any revision to the Approved Architectural Drawings, Landlord shall provide Tenant with notice approving or reasonably disapproving such revision, and, if Landlord approves such revision, Landlord shall have such revision made and delivered to Tenant, together with notice of any resulting change in the most recent Construction Pricing Proposal, if any, within 10 business days after the later of Landlord's receipt of such request or the mutual execution and delivery of this Agreement if such revision is not material, and within such longer period of time as may be reasonably necessary (but not more than 15 business days after the later of such receipt or such execution and delivery) if such revision is material, whereupon Tenant, within one (1) business day, shall notify Landlord whether it desires to proceed with such revision. If Landlord has begun performing the Tenant Improvement Work, then, in the absence of such authorization, Landlord shall have the option to continue such performance disregarding such revision. Landlord shall not revise the Approved Architectural Drawings without Tenant's consent, which shall not be unreasonably withheld or conditioned. Tenant shall approve, or reasonably disapprove (and state, with reasonable specificity, its reasons for disapproving), any revision to the Approved Architectural Drawings within two (2) business days after receiving Landlord's request for approval thereof. For purposes hereof, any change order affecting the Approved Architectural Drawings shall be deemed a revision to the Approved Architectural Drawings.

2.7.2 Approved Additional Programming Information. If Tenant requests Landlord's approval of any revision to the Approved Additional Programming Information, Landlord shall provide Tenant with notice approving or reasonably disapproving such revision, together with notice of any resulting change in the most recent Construction Pricing Proposal, if any, within five (5) business days after the later of Landlord's receipt of such request or the mutual execution and delivery of this Agreement, whereupon Tenant, within one (1) business day, shall notify Landlord whether it desires to proceed with such revision. If Landlord has begun performing the Tenant Improvement Work, then, in the absence of such authorization, Landlord shall have the option to continue such performance disregarding such revision. Landlord shall not revise the Approved Additional Programming Information without Tenant's consent, which shall not be unreasonably withheld or conditioned. Tenant shall approve, or reasonably disapprove (and state, with reasonable specificity, its reasons for disapproving), any revision to the Approved Additional Programming Information within two (2) business days after receiving Landlord's request for approval thereof.

2.7.3 Approved Space Plan. If Tenant requests Landlord's approval of any revision to the Approved Space Plan, Landlord shall provide Tenant with notice approving or reasonably disapproving such revision within five (5) business days after the later of Landlord's receipt of such request or the mutual execution and delivery of this Agreement. If Landlord has begun performing the Tenant Improvement Work, then, in the absence of such authorization, Landlord shall have the option to continue such performance disregarding such revision. Landlord shall not revise the Approved Space Plan without Tenant's consent, which shall not be unreasonably withheld or conditioned. Tenant shall approve, or reasonably disapprove (and state, with reasonable specificity, its reasons for disapproving), any revision to the Approved Space Plan within two (2) business days after receiving Landlord's request for approval thereof.

2.8 Tenant's Approval Deadline. Tenant shall approve the Construction Pricing Proposal pursuant to Section 2.6.1 above on or before Tenant's Approval Deadline (defined below). As used in this Work Letter, "**Tenant's Approval Deadline**" means the date occurring 30 days after the mutual execution and delivery of this Agreement; provided, however, that Tenant's Approval Deadline shall be extended by one (1) day for each day, if any, by which Tenant's approval of the Construction Pricing Proposal pursuant to Section 2.6.1 above is delayed by any failure of Landlord to perform its obligations under this Section 2.

3 CONSTRUCTION.

3.1 Contractor. Landlord shall retain a contractor of its choice (the "**Contractor**") to perform the Tenant Improvement Work. In addition, Landlord may select and/or approve of any subcontractors, mechanics and materialmen used in connection with the performance of the Tenant Improvement Work.

3.2 Engineering Drawings.

3.2.1 Preparation. Landlord shall cause the engineering working drawings for the mechanical, electrical, plumbing, fire-alarm and fire sprinkler work in the Premises (the "**Engineering Drawings**") to (a) be prepared by one or more of the Architect, the Contractor, and/or engineers or other consultants selected and/or retained by the Architect, the Contractor or Landlord, and (b) conform to the Approved Space Plan, the Approved Additional Programming Information, the first sentence of Section 4 below, and any then-existing Approved Architectural Drawings (collectively, the "**Engineering Requirements**").

3.2.2 Design Build. Except as provided in Section 3.2.3 below:

A. Delivery and Approval. The Engineering Drawings shall be delivered to Tenant within 10 business days after the later of Tenant's approval of the Architectural Drawings pursuant to Section 2.5 above or the mutual execution and delivery of this Agreement. Tenant shall approve, or reasonably disapprove (and state, with reasonable specificity, its reasons for disapproving), the Engineering Drawings within two (2) business days after the latest of (a) Tenant's receipt of the Engineering Drawings, (b) Tenant's approval of the Architectural Drawings, or (c) the mutual execution and delivery of this Agreement. After receiving any such notice of reasonable disapproval, Landlord shall cause the Contractor to revise the Engineering Drawings and resubmit them to Tenant, taking into account the reasons for Tenant's disapproval; provided, however, that Landlord shall not be required to make any revision to the Engineering Drawings that conflicts with the Engineering Requirements or the Landlord Requirements or is otherwise reasonably disapproved by Landlord. Such procedure shall be repeated as necessary until Tenant has reasonably approved the Engineering Drawings. Such approved Engineering Drawings shall be referred to herein as the "**Approved Engineering Drawings**".

B. Revisions. If Tenant requests any revision to the Approved Engineering Drawings, Landlord shall provide Tenant with notice approving or reasonably disapproving such revision, and, if Landlord approves such revision, Landlord shall have such revision made and delivered to Tenant, together with notice of any resulting change in the most recent Construction Pricing Proposal, within five (5) business days after the later of Landlord's receipt of such request or the mutual execution and delivery of this Agreement if such revision is not material, and within such longer period of time as may be reasonably necessary (but not more than 10 business days after the later of such receipt or such execution and delivery) if such revision is material, whereupon Tenant, within one (1) business day, shall notify Landlord whether it desires to proceed with such revision. If Landlord has begun performing the Tenant Improvement Work, then, in the absence of such authorization, Landlord shall have the option to continue such performance disregarding such revision. Landlord shall not revise the Approved Engineering Drawings without Tenant's consent, which shall not be unreasonably withheld or conditioned. Tenant shall approve, or reasonably disapprove (and state, with reasonable specificity, its reasons for disapproving), any revision to the Approved Engineering Drawings within two (2) business days after receiving Landlord's request for approval thereof. Any change order affecting the Approved Engineering Drawings shall be deemed a revision to the Approved Engineering Drawings.

3.2.3 Design Bid Build. If Landlord, at its option, causes the Engineering Drawings to be delivered to Tenant on or before the date on which the Architectural Drawings are first delivered to Tenant pursuant to Section 2.5 above, then (a) Section 3.2.2 above shall not apply; (b) Tenant's review and approval of, and any revisions to, the Engineering Drawings shall be governed by Sections 2.5 and 2.7 above as if the Engineering Drawings were part of the Architectural Drawings; and (c) the Engineering Drawings, as approved by Tenant pursuant to Section 2.5 above, shall be referred to herein as the "**Approved Engineering Drawings**".

3.3 Permits. Landlord shall cause the Contractor to submit the Approved Architectural Drawings and the Approved Engineering Drawings (collectively, the "**Approved Construction Drawings**") to the appropriate municipal authorities and otherwise apply for and obtain from such authorities all permits necessary for the Contractor to complete the Tenant Improvement Work (the "**Permits**").

3.4 Construction.

3.4.1 Performance of Tenant Improvement Work. Landlord shall cause the Contractor to perform the Tenant Improvement Work in accordance with the Approved Construction Drawings. Tenant shall pay a construction supervision and management fee (the "**Landlord Supervision Fee**") to Landlord in an amount equal to 4% of the aggregate amount of all Allowance Items other than the Landlord Supervision Fee.

3.4.2 Contractor's Warranties. Tenant waives all claims against Landlord relating to any defects in the Tenant Improvements; provided, however, that if, within 30 days after substantial completion of the Tenant Improvement Work, Tenant provides notice to Landlord of any non-latent defect in the Tenant Improvements, or if, within 11 months after substantial completion of the Tenant Improvement Work, Tenant provides notice to Landlord of any latent defect in the Tenant Improvements, then Landlord shall promptly cause such defect to be corrected.

4 COMPLIANCE WITH LAW; SUITABILITY FOR TENANT'S USE. Landlord shall cause the Architect and the Contractor to use the Required Level of Care (defined below) to cause the Architectural Drawings and the Engineering Drawings to comply with Law; provided, however, that Landlord shall not be responsible for any violation of Law resulting from (a) any particular use of the Premises (as distinguished from general office use), or (b) any failure of the Approved Space Plan or the Approved Additional Programming Information to comply with Law. As used herein, "**Required Level of Care**" means the level of care that reputable architects and engineers customarily use to cause architectural and engineering plans, drawings and specifications to comply with Law where such plans, drawings and specifications are prepared for spaces in buildings comparable in quality to the Building. Except as provided above in this Section 4, Tenant shall be responsible for ensuring that the Space Plan, the Additional Programming Information, the Architectural Drawings and the Engineering Drawings (collectively, the "**Plans**") are suitable for Tenant's use of the Premises and comply with Law, and neither the preparation of any of the Plans by the Architect or the Contractor nor Landlord's approval of the Plans shall relieve Tenant from such responsibility. To the extent that either party (the "**Responsible Party**") is responsible under this Section 4 for causing the Plans to comply with Law, the Responsible Party may contest any alleged violation of Law in good faith, including by seeking a waiver or deferment of compliance, asserting any defense allowed by Law, and exercising any right of appeal (provided that the other party incurs no liability as a result of such contest and that, after completing such contest, the Responsible Party makes any modification to the Plans or any alteration to the Premises that is necessary to comply with any final order or judgment).

5 COMPLETION. Tenant acknowledges and agrees that the Tenant Improvement Work may be performed during Building HVAC Hours before or after the Commencement Date. Landlord and Tenant shall cooperate with each other in order to enable the Tenant Improvement Work to be performed in a timely manner and with as little inconvenience to the operation of Tenant's business as is reasonably possible. Notwithstanding any contrary provision of this Agreement, any delay in the completion of the Tenant Improvement Work or inconvenience suffered by Tenant during the performance of the Tenant Improvement Work shall not delay the Commencement Date, nor shall it subject Landlord to any liability for any loss or damage resulting therefrom or entitle Tenant to any credit, abatement or adjustment of rent or other sums payable under the Lease.

6 MISCELLANEOUS. Notwithstanding any contrary provision of this Agreement, if Tenant defaults under this Agreement before the Tenant Improvement Work is completed, Landlord's obligations under this Work Letter shall be excused until such default is cured and Tenant shall be responsible for any resulting delay in the completion of the Tenant Improvement Work. This Work Letter shall not apply to any space other than the Premises.

EXHIBIT C

CELEBRATION OFFICE CENTER II
1170 CELEBRATION BOULEVARD
CELEBRATION, FLORIDA

CONFIRMATION LETTER

_____, 20__

To: _____
_____
_____
_____

Re: Office Lease (the "**Lease**") dated _____, 20____, between **BRE/COH FL LLC, a Delaware limited liability company** ("**Landlord**"), and **KEMPHARM, INC., a Delaware corporation** ("**Tenant**"), concerning Suite 103 on the first floor of the building located at 1170 Celebration Boulevard, Celebration, Florida.

Lease ID: _____
Business Unit Number: _____

Dear _____:

In accordance with the Lease, Tenant accepts possession of the Premises and confirms the following:

1. The Commencement Date is _____ and the Expiration Date is _____.

2. The exact number of rentable square feet within the Premises is 3,221 square feet, subject to Section 2.1.1 of the Lease.

3. Tenant's Share, based upon the exact number of rentable square feet within the Premises, is 4.0043%, subject to Section 2.1.1 of the Lease.

Please acknowledge the foregoing by signing all three (3) counterparts of this letter in the space provided below and returning two (2) fully executed counterparts to my attention. Please note that, pursuant to Section 2.1.1 of the Lease, if Tenant fails to execute and return (or, by notice to Landlord, reasonably object to) this letter within five (5) days after receiving it, Tenant shall be deemed to have executed and returned it without exception.

Landlord's Witnesses:

Print Name:

Print Name:

"Landlord":

BRE/COH FL LLC, a Delaware limited liability company

By:
Name:
Title:

Agreed and Accepted as of _, 20__.
"Tenant":

KEMPHARM, INC., a Delaware corporation

By:
Name:
Title:

Tenant's Witnesses:

Print Name:

Print Name:

EXHIBIT D

CELEBRATION OFFICE CENTER II

1170 CELEBRATION BOULEVARD
CELEBRATION, FLORIDA

RULES AND REGULATIONS

Tenant shall comply with the following rules and regulations (as modified or supplemented from time to time, the "**Rules and Regulations**"). Landlord shall not be responsible to Tenant for the nonperformance of any of the Rules and Regulations by any other tenants or occupants of the Project. In the event of any conflict between the Rules and Regulations and the other provisions of this Lease, the latter shall control.

1. Tenant shall not alter any lock or install any new or additional locks or bolts on any doors or windows of the Premises without obtaining Landlord's prior consent. Tenant shall bear the cost of any lock changes or repairs required by Tenant. Two (2) keys will be furnished by Landlord for the Premises, and any additional keys required by Tenant must be obtained from Landlord at a reasonable cost to be established by Landlord. Upon the termination of this Lease, Tenant shall restore to Landlord all keys of stores, offices and toilet rooms furnished to or otherwise procured by Tenant, and if any such keys are lost, Tenant shall pay Landlord the cost of replacing them or of changing the applicable locks if Landlord deems such changes necessary.

2. All doors opening to public corridors shall be kept closed at all times except for normal ingress and egress to the Premises.

3. Landlord may close and keep locked all entrance and exit doors of the Building during such hours as are customary for comparable buildings in the vicinity of the Building. Tenant shall cause its employees, agents, contractors, invitees and licensees who use Building doors during such hours to securely close and lock them after such use. Any person entering or leaving the Building during such hours, or when the Building doors are otherwise locked, may be required to sign the Building register, and access to the Building may be refused unless such person has proper identification or has a previously arranged access pass. Landlord will furnish passes to persons for whom Tenant requests them. Tenant shall be responsible for all persons for whom Tenant requests passes and shall be liable to Landlord for all acts of such persons. Landlord and its agents shall not be liable for damages for any error with regard to the admission or exclusion of any person to or from the Building. In case of invasion, mob, riot, public excitement or other commotion, Landlord may prevent access to the Building or the Project during the continuance thereof by any means it deems appropriate for the safety and protection of life and property.

4. No furniture, freight or equipment shall be brought into the Building without prior notice to Landlord. All moving activity into or out of the Building shall be scheduled with Landlord and done only at such time and in such manner as Landlord designates. Landlord may prescribe the weight, size and position of all safes and other heavy property brought into the Building and also the times and manner of moving the same in and out of the Building. Safes and other heavy objects shall, if considered necessary by Landlord, stand on supports of such thickness as is necessary to properly distribute the weight. Landlord will not be responsible for loss of or damage to any such safe or property. Any damage to the Building, its contents, occupants or invitees resulting from Tenant's moving or maintaining any such safe or other heavy property shall be the sole responsibility and expense of Tenant (notwithstanding Sections 7 and 10.4 of this Lease).

5. No furniture, packages, supplies, equipment or merchandise will be received in the Building or carried up or down in the elevators, except between such hours, in such specific elevator and by such personnel as shall be designated by Landlord.

6. Employees of Landlord shall not perform any work or do anything outside their regular duties unless under special instructions from Landlord.

7. No sign, advertisement, notice or handbill shall be exhibited, distributed, painted or affixed by Tenant on any part of the Premises or the Building without Landlord's prior consent. Tenant shall not disturb, solicit, peddle or canvass any occupant of the Project.

8. The toilet rooms, urinals, wash bowls and other apparatus shall not be used for any purpose other than that for which they were constructed, and no foreign substance shall be thrown therein. Notwithstanding Sections 7 and 10.4 of this Lease, Tenant shall bear the expense of any breakage, stoppage or damage resulting from any violation of this rule by Tenant or any of its employees, agents, contractors, invitees or licensees.

9. Tenant shall not overload the floor of the Premises, or mark, drive nails or screws or drill into the partitions, woodwork or drywall of the Premises, or otherwise deface the Premises, without Landlord's prior consent. Tenant shall not purchase bottled water, ice, towel, linen, maintenance or other like services from any person not approved by Landlord.

10. Except for vending machines intended for the sole use of Tenant's employees and invitees, no vending machine or machines other than fractional horsepower office machines shall be installed, maintained or operated in the Premises without Landlord's prior consent.

11. Tenant shall not, without Landlord's prior consent, use, store, install, disturb, spill, remove, release or dispose of, within or about the Premises or any other portion of the Project, any asbestos-containing materials, any solid, liquid or gaseous material now or subsequently considered toxic or hazardous under the provisions of 42 U.S.C. Section 9601 et seq. or any other applicable environmental Law, or any inflammable, explosive or dangerous fluid or substance; provided, however, that Tenant may use, store and dispose of such substances in such amounts as are typically found in similar premises used for general office purposes provided that such use, storage and disposal does not damage any part of the Premises, Building or Project and is performed in a safe manner and in accordance with all Laws. Tenant shall comply with all Laws pertaining to and governing the use of such materials by Tenant and shall remain solely liable for the costs of abatement and removal. No burning candle or other open flame shall be ignited or kept by Tenant in or about the Premises, Building or Project.

12. Tenant shall not, without Landlord's prior consent, use any method of heating or air conditioning other than that supplied by Landlord.

13. Tenant shall not use or keep any foul or noxious gas or substance in or on the Premises, or occupy or use the Premises in a manner offensive or objectionable to Landlord or other occupants of the Project by reason of noise, odors or vibrations, or interfere with other occupants or those having business therein, whether by the use of any musical instrument, radio, CD player or otherwise. Tenant shall not throw anything out of doors, windows or skylights or down passageways.

14. Tenant shall not bring into or keep within the Project, the Building or the Premises any animals (other than service animals), birds, aquariums, or, except in areas designated by Landlord, bicycles or other vehicles.

15. No cooking shall be done in the Premises, nor shall the Premises be used for lodging, for living quarters or sleeping apartments, or for any improper, objectionable or immoral purposes. Notwithstanding the foregoing, Underwriters' laboratory-approved equipment and microwave ovens may be used in the Premises for heating food and brewing coffee, tea, hot chocolate and similar beverages for employees and invitees, provided that such use complies with all Laws.

16. The Premises shall not be used for manufacturing or for the storage of merchandise except to the extent such storage may be incidental to the Permitted Use. Tenant shall not occupy the Premises as an office for a messenger-type operation or dispatch office, public stenographer or typist, or for the manufacture or sale of liquor, narcotics or tobacco, or as a medical office, a barber or manicure shop, or an employment bureau, without Landlord's prior consent. Tenant shall not engage or pay any employees in the Premises except those actually working for Tenant in the Premises, nor advertise for laborers giving an address at the Premises.

17. Landlord may exclude from the Project any person who, in Landlord's judgment, is intoxicated or under the influence of liquor or drugs, or who violates any of these Rules and Regulations.

18. Tenant shall not loiter in or on the entrances, corridors, sidewalks, lobbies, courts, halls, stairways, elevators, vestibules or any Common Areas for the purpose of smoking tobacco products or for any other purpose, nor in any way obstruct such areas, and shall use them only as a means of ingress and egress for the Premises.

19. Tenant shall not waste electricity, water or air conditioning, shall cooperate with Landlord to ensure the most effective operation of the Building's heating and air conditioning system, and shall not attempt to adjust any controls. Tenant shall install and use in the Premises only ENERGY STAR rated equipment, where available. Tenant shall use recycled paper in the Premises to the extent consistent with its business requirements.

20. Tenant shall store all its trash and garbage inside the Premises. No material shall be placed in the trash or garbage receptacles if, under Law, it may not be disposed of in the ordinary and customary manner of disposing of trash and garbage in the vicinity of the Building. All trash, garbage and refuse disposal shall be made only through entryways and elevators provided for such purposes at such times as Landlord shall designate. Tenant shall comply with Landlord's recycling program, if any.

21. Tenant shall comply with all safety, fire protection and evacuation procedures and regulations established by Landlord or any governmental agency.

22. Any persons employed by Tenant to do janitorial work shall be subject to Landlord's prior consent and, while in the Building and outside of the Premises, shall be subject to the control and direction of the Building manager (but not as an agent or employee of such manager or Landlord), and Tenant shall be responsible for all acts of such persons.

23. No awning or other projection shall be attached to the outside walls of the Building without Landlord's prior consent. Other than Landlord's Building-standard window coverings, no curtains, blinds, shades or screens shall be attached to or hung in, or used in connection with, any window or door of the Premises. All electrical ceiling fixtures hung in the Premises or spaces along the perimeter of the Building must be fluorescent and/or of a quality, type, design and a warm white bulb color approved in advance by Landlord. Neither the interior nor exterior of any windows shall be coated or otherwise sunscreened without Landlord's prior consent. Tenant shall abide by Landlord's regulations concerning the opening and closing of window coverings.

24. Tenant shall not obstruct any sashes, sash doors, skylights, windows or doors that reflect or admit light or air into the halls, passageways or other public places in the Building, nor shall Tenant place any bottles, parcels or other articles on the windowsills.

25. Tenant must comply with requests by Landlord concerning the informing of their employees of items of importance to the Landlord.

26. Smoking of cigarettes, pipes, cigars or any other substance is prohibited at all times within the interior portions of the Building and Project (including, without limitation, the Premises) and in any exterior portions of the Project other than areas, if any, designated by Landlord for smoking. Tenant must comply with the Florida Clean Indoor Air Act (Florida Statutes, Chapter 386, Part II, and any Florida Administrative Code rules promulgated with respect thereto) and with any local "No-Smoking" ordinance that is not superseded by such law.

27. Tenant shall cooperate in any reasonable safety or security program developed by Landlord or required by Law.

28. All office equipment of an electrical or mechanical nature shall be placed by Tenant in the Premises in settings approved by Landlord, to absorb or prevent any vibration, noise or annoyance.

29. Tenant shall not use any hand trucks except those equipped with rubber tires and rubber side guards.

30. No auction, liquidation, fire sale, going-out-of-business or bankruptcy sale shall be conducted in the Premises without Landlord's prior consent.

31. Without Landlord's prior consent, Tenant shall not use the name of the Project or Building or use pictures or illustrations of the Project or Building in advertising or other publicity or for any purpose other than as the address of the business to be conducted by Tenant in the Premises.

Landlord may from time to time modify or supplement these Rules and Regulations in a manner that, in Landlord's reasonable judgment, is appropriate for the management, safety, care and cleanliness of the Premises, the Building, the Common Areas and the Project, for the preservation of good order therein, and for the convenience of other occupants and tenants thereof. Landlord may waive any of these Rules and Regulations for the benefit of any tenant, but no such waiver shall be construed as a waiver of such Rule and Regulation in favor of any other tenant nor prevent Landlord from thereafter enforcing such Rule and Regulation against any tenant.

EXHIBIT E

CELEBRATION OFFICE CENTER II

1170 CELEBRATION BOULEVARD
CELEBRATION, FLORIDA

ADDITIONAL PROVISIONS

1. **Right of First Offer.**

1.1. **Grant of Option; Conditions.**

A. Subject to the terms of this Section 1, Tenant shall have a right of first offer ("**Right of First Offer**") with respect to the following suite (and with respect to each portion of such suite) (such suite or portion thereof, a **"Potential Offering Space**"): the 1,418 rentable square feet known as Suite 101 on the first floor of the Building shown on the demising plan attached to the Lease as **Exhibit F**. Tenant's Right of First Offer shall be exercised as follows: At any time after Landlord has determined that a Potential Offering Space has become Available (defined below), but before leasing such Potential Offering Space to a third party, Landlord, subject to the terms of this Section 1, shall provide Tenant with a written notice (for purposes of this Section 1, an "**Advice**") advising Tenant of the material terms on which Landlord is prepared to lease such Potential Offering Space (sometimes referred to herein as an "**Offering Space**") to Tenant, which terms shall be consistent with Section 1.2 below. For purposes hereof, a Potential Offering Space shall be deemed to become "**Available**" as follows: (i) if such Potential Offering Space is not leased to a third party as of the date of mutual execution and delivery of this Lease, such Potential Offering Space shall be deemed to become Available when Landlord has located a prospective tenant that may be interested in leasing such Potential Offering Space; and (ii) if such Potential Offering Space is leased to a third party as of, the date of mutual execution and delivery of this Lease, such Potential Offering Space shall be deemed to become Available when Landlord has determined that such third-party tenant, and any occupant of such Potential Offering Space claiming under such third-party tenant, will not extend or renew the term of its lease, or enter into a new lease, for such Potential Offering Space. Upon receiving an Advice, Tenant may lease the Offering Space, in its entirety only, under the terms set forth in the Advice, by delivering to Landlord a written notice of exercise (for purposes of this Section 1, a "**Notice of Exercise**") within five (5) days after receiving the Advice.

B. If Tenant receives an Advice but does not deliver a Notice of Exercise within the period of time required under Section 1.1.A above, Landlord may lease the Offering Space to any party on any terms determined by Landlord in its sole and absolute discretion.

C. Notwithstanding any contrary provision hereof, (i) Landlord shall not be required to provide Tenant with an Advice if any of the following conditions exists when Landlord would otherwise deliver the Advice; and (ii) if Tenant receives an Advice from Landlord, Tenant shall not be entitled to lease the Offering Space based on such Advice if any of the following conditions exists:

(1) a Default exists;

(2) all or any portion of the Premises is sublet);

(3) the Lease has been assigned; or

(4) Tenant is not occupying the Premises.

If, by operation of the preceding sentence, Landlord is not required to provide Tenant with an Advice, or Tenant, after receiving an Advice, is not entitled to lease the Offering Space based on such Advice, then Landlord may lease the Offering Space to any party on any terms determined by Landlord in its sole and absolute discretion.

1.2. **Terms for Offering Space.**

A. The term for the Offering Space shall be coterminous with the term for the balance of the Premises.

B. The term for the Offering Space shall commence on the commencement date stated in the Advice and thereupon the Offering Space shall be considered a part of the Premises subject to the provisions of the Lease; provided, however, that the provisions of the Advice shall prevail to the extent they conflict with the provisions of the Lease.

C. Tenant shall pay Monthly Rent for the Offering Space in accordance with the provisions of the Advice. The Advice shall reflect the Prevailing Market (defined in Section 1.5 below) rate for the Offering Space as determined in Landlord's reasonable judgment.

D. Except as may be otherwise provided in the Advice, (i) the Offering Space (including improvements and personalty, if any) shall be accepted by Tenant in its configuration and condition existing on the earlier of the date Tenant takes possession of the Offering Space or the commencement date for the Offering Space; and (ii) if Landlord is delayed in delivering possession of the Offering Space by any holdover or unlawful possession of the Offering Space by any party, Landlord shall use reasonable efforts to obtain possession of the Offering Space and any obligation of Landlord to tender possession of, permit entry to, or perform alterations to the Offering Space shall be deferred until after Landlord has obtained possession of the Offering Space.

1.3. **Termination of Right of First Offer.**

A. Notwithstanding any contrary provision hereof, Landlord shall not be required to provide Tenant with an Advice, and Tenant shall not be entitled to exercise its Right of First Offer, after September 30, 2016.

B. Notwithstanding any contrary provision hereof, Landlord shall not be required to provide Tenant with an Advice, and Tenant shall not be entitled to exercise its Right of First Offer, with respect to any Potential Offering Space after the date, if any, on which Landlord becomes entitled to lease such Potential Offering Space to a third party under Section 1.1.B or 1.1.C above.

1.4. **Offering Amendment.** If Tenant validly exercises its Right of First Offer, Landlord, within a reasonable period of time thereafter, shall prepare and deliver to Tenant an amendment (the "**Offering Amendment**") adding the Offering Space to the Premises on the terms set forth in the Advice and reflecting the changes in the Base Rent, the rentable square footage of the Premises, Tenant's Share, and other appropriate terms in accordance with this Section 1. Tenant shall execute and return the Offering Amendment to Landlord within 15 days after receiving it, but an otherwise valid exercise of the Right of First Offer shall be fully effective whether or not the Offering Amendment is executed.

1.5. **Definition of Prevailing Market.** For purposes of this Section 1, "**Prevailing Market**" means the arms-length, fair-market, annual rental rate per rentable square foot, under renewal and expansion leases and amendments entered into on or about the date on which the Prevailing Market is being determined hereunder, for space comparable to the Offering Space in the Building and office buildings comparable to the Building in the Celebration, Florida area. The determination of Prevailing Market shall take into account (i) any material economic differences between the terms of the Lease and any comparison lease or amendment, such as rent abatements, construction costs and other concessions, and the manner, if any, in which the landlord under any such lease is reimbursed for operating expenses and taxes; and (ii) any material differences in configuration or condition between the Offering Space and any comparison space.

1.6. **Subordination.** Notwithstanding any contrary provision hereof, Tenant's Right of First Offer shall be subject and subordinate to the expansion rights (whether such rights are designated as a right of first offer, right of first refusal, expansion option or otherwise) of any tenant of the Project existing on the date hereof. In addition, if Landlord, as permitted under Section 1.1.B or 1.1.C above, leases any Potential Offering Space to a third party on terms including a right of first offer, right of first refusal, expansion option or other expansion right with respect to any other Potential Offering Space (and if, in the case of any such lease permitted under Section 1.1.B above, such expansion right was disclosed in the Advice received by Tenant), then Tenant's Right of First Offer with respect to such other Potential Offering Space shall be subject and subordinate to such expansion right in favor of such third party.

EXHIBIT F

CELEBRATION OFFICE CENTER II

1170 CELEBRATION BOULEVARD
CELEBRATION, FLORIDA

POTENTIAL OFFERING SPACE

FIRST AMENDMENT

THIS FIRST AMENDMENT (this **"Amendment")** is made and entered into as of April 21, 2015, by and between **BRE/COH FL LLC, a Delaware limited liability company ("Landlord"),** and **KEMPHARM, INC., a Delaware corporation ("Tenant").**

RECITALS

A. Landlord and Tenant are parties to that certain lease dated November 3, 2014 (the **"Lease").** Pursuant to the Lease, Landlord has leased to Tenant space currently containing approximately **3,221** rentable square feet (the **"Existing Premises")** described as Suite I03 on the first floor of the building commonly known as Celebration Office Center II located at 1170 Celebration Boulevard, Celebration , Florida (the **"Building".)**

B. The Lease will expire by its terms on October 31, 2017 (the **"Existing Expiration Date"),** and the parties wish to extend the term of the Lease on the following terms and conditions.

C. The parties wish to expand the Premises (defined in the Lease) to include additional space, containing approximately **1,418** rentable square feet described as Suite I02B on the first floor of the Building and shown on **Exhibit A** attached hereto (the **"Expansion Space"),** on the following terms and conditions.

NOW, THEREFORE, in consideration of the above recitals which by this reference are incorporated herein, the mutual covenants and conditions contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged , Landlord and Tenant agree as follows:

1. Extension. The term of the Lease is hereby extended through the last day of the 36th full calendar month beginning on or after the Expansion Effective Date (defined in Section 2.2 below) (the **"Extended Expiration Date").** The portion of the term of the Lease beginning on the date immediately following the Existing Expiration Date (the **"Extension Date")** and ending on the Extended Expiration Date shall be referred to herein as the **"Extended Term".**

2. Expansion.

2.1. Effect of Expansion. Effective as of the Expansion Effective Date (defined in Section 2.2 below), the Premises shall be increased from 3,221 rentable square feet on the first floor to **4,639** rentable square feet on the first floor by the addition of the Expansion Space, and, from and after the Expansion Effective Date, the Existing Premises and the Expansion Space shall collectively be deemed the Premises. The term of the Lease for the Expansion Space (the **"Expansion Term")** shall commence on the Expansion Effective Date and, unless sooner terminated in accordance with the Lease, end on the Extended Expiration Date. From and after the Expansion Effective Date, the Expansion Space shall be subject to all the terms and conditions of the Lease except as provided herein. Except as may be expressly provided herein, (a) Tenant shall not be entitled to receive, with respect to the Expansion Space, any allowance, free rent or other financial concession granted with respect to the Existing Premises, and (b) no representation or warranty made by Landlord with respect to the Existing Premises shall apply to the Expansion Space.

2.2. Expansion Effective Date. As used herein, **"Expansion Effective Date"** means the earlier to occur of (i) the first date on which Tenant conducts business in the Expansion Space, or (ii) the date on which the Tenant Improvement Work (defined in **Exhibit B** attached hereto) is Substantially Complete (defined in **Exhibit B** attached hereto), which is anticipated to be May I, 2015 (the **"Target Expansion Effective Date").** The adjustment of the Expansion Effective Date and, accordingly, the postponement of Tenant's obligation to pay rent for the Expansion Space shall be Tenant's sole remedy if the Tenant Improvement Work is not Substantially Complete on the Target Expansion Effective Date.

2.3. Confirmation Letter. At any time after the Expansion Effective Date, Landlord may deliver to Tenant a notice substantially in the form of **Exhibit** C attached hereto, as a confirmation of the information set forth therein. Tenant shall execute and return (or, by written notice to Landlord, reasonably object to) such notice within five (5) days after receiving it.

3. Base Rent.

3.1.

Existing Premises During Extended Term. With respect to the Existing Premises during the Extended Term, the schedule of Base Rent shall be as follows:

Period of Extended Term	Annual Rate Per Square Foot (rounded to the nearest 100th of a dollar) h	Monthly Base Rent
11/1/17 - 4/30/18	$24.93	$6,691.63

All such Base Rent shall be payable by Tenant in accordance with the terms of the Lease.

3.2.

Expansion Space During Expansion Term. With respect to the Expansion Space during the Expansion Term, the schedule of Base Rent shall be as follows:

Period During Expansion Term	Annual Rate Per Square Foot (rounded to the nearest 100th of a dollar)	Monthly Base Rent
Expansion Effective Date through last day of t 2'h full calendar month of Expansion Term	$23.50	$2,776.92
13h1 through 24h1 full calendar months of Expansion Term	$24.21	$2,860.82
251 full calendar month h of Expansion Term through last day of Expansion Term	$24.93	$2,945.90

All such Base Rent shall be payable by Tenant in accordance with the terms of the Lease.

4.

Security Deposit. No additional security deposit shall be required in connection with this Amendment.

5. Tenant's Share. With respect to the Expansion Space during the Expansion Term, Tenant's Share shall be 1.7628%.

6. Expenses and Taxes.

6.1. Existing Premises During Extended Term. With respect to the Existing Premises during the Extended Term, Tenant shall pay for Tenant's Share of Expenses and Taxes in accordance with the terms of the Lease; provided, however, that, with respect to the Existing Premises during the Extended Term, the Base Year for Expenses and Taxes shall be 2015.

6.2. Expansion Space During Expansion Term. With respect to the Expansion Space during the Expansion Term, Tenant shall pay for Tenant's Share of Expenses and Taxes in accordance with the terms of the Lease; provided, however, that, with respect to the Expansion Space during the Expansion Term, the Base Year for Expenses and Taxes shall be 2015.

7. Improvements to Existing Premises and Expansion Space.

7.1. Configuration and Condition of Existing Premises and Expansion Space. Tenant acknowledges that it is **in** possession of the Existing Premises and that it has inspected the Expansion Space, and agrees to accept each such space in its existing configuration and condition (or, in the case of the Expansion Space, in such other configuration and condition as any existing tenant of the Expansion Space may cause to exist in accordance with its lease), without any representation by Landlord regarding its configuration or condition and without any obligation on the part of Landlord to perform or pay for any alteration or improvement, except as may be otherwise expressly provided in this Amendment.

7.2. **Responsibility for Improvements to Existing Premises and Expansion Space.** Landlord shall perform improvements to the Expansion Space in accordance with **Exhibit B** attached hereto.

8. **Other Pertinent Provisions.** Landlord and Tenant agree that, effective as of the date of this Amendment (unless different effective date(s) is/are specifically referenced in this Section), the Lease shall be amended in the following additional respects:

8.1. **Parking.** Effective as of the Expansion Effective Date, the first sentence of Section 1.9 of the Lease is hereby amended by replacing the number " I 6" with the number " 23".

9. **Miscellaneous.**

9. I . This Amendment and the attached exhibits, which are hereby incorporated into and made a part of this Amendment, set forth the entire agreement between the parties with respect to the matters set forth herein. There have been no additional oral or written representations or agreements. Tenant shall not be entitled, in connection with entering into this Amendment, to any free rent, allowance, alteration, improvement or similar economic incentive to which Tenant may have been entitled in connection with entering into the Lease, except as may be otherwise expressly provided in this Amendment.

9.2. Except as herein modified or amended, the provisions, conditions and terms of the Lease shall remain unchanged and in full force and effect.

9.3. In the case of any inconsistency between the provisions of the Lease and this Amendment, the provisions of this Amendment shall govern and control.

9.4. Submission of this Amendment by Landlord is not an offer to enter into this Amendment but rather is a solicitation for such an offer by Tenant. Landlord shall not be bound by this Amendment until Landlord has executed and delivered it to Tenant.

9.5. Capitalized terms used but not defined in this Amendment shall have the meanings given in the Lease.

9.6. Tenant shall indemnify and hold Landlord, its trustees, members, principals, beneficiaries, partners, officers, directors, employees, mortgagee(s) and agents, and the respective principals and members of any such agents harmless from all claims of any **brokers** (other than TLC Home Management, LLC, a Florida limited liability company) claiming to have represented Tenant in connection with this Amendment. Landlord shall indemnify and hold Tenant, its trustees, members, principals, beneficiaries, partners, officers, directors, employees, and agents, and the respective principals and members of any such agents harmless from all claims of any brokers claiming to have represented Landlord in connection with this Amendment. Tenant acknowledges that any assistance rendered by any agent or employee of any affiliate of Landlord in connection with this Amendment has been made as an accommodation to Tenant solely in furtherance of consummating the transaction on behalf of Landlord, and not as agent for Tenant.

9.7. If Tenant has any expansion right (whether such right is designated as a right of first offer, right of first refusal, expansion option or otherwise) that was granted to Tenant under the Lease (as determined without giving effect to this Amendment) and that, by virtue of this Amendment, will continue in effect during the Extended Term , then, from and after the Extension Date, such expansion right shall be subject and subordinate to any expansion right (whether such right is designated as a right of first offer, right of first refusal, expansion option or otherwise) of any tenant of the Building or Project existing on the date of mutual execution and delivery hereof.

9.8. If Tenant has any expansion right (whether such right is designated as a right of first offer, right of first refusal, expansion option or otherwise) that was granted to Tenant under the Lease (as determined without giving effect to this Amendment) and that, by virtue of this Amendment, will apply to space different from or in addition to the space to which such expansion right previously applied, then, as applied to such different or additional space, such expansion right shall be subject and subordinate to any expansion right (whether such right is designated as a right of first offer, right of first refusal, expansion option or otherwise) of any tenant of the Building or Project existing on the date of mutual execution and delivery hereof.

{SIGNATURES ARE ON FOLLOWING PAGE}

IN WITNESS WHEREOF, Landlord and Tenant have duly executed this Amendment as of the day and year first above written.

WITNESSES:

/s/ Blanca Colón-Flynn
Print Name: Blanca Colón-Flynn

/s/ Heather Bradley
Print Name: Heather Bradley

LANDLORD:

BRE/COH FL LLC, a Delaware limited liability company

/s/ Rob Shults
Name: Rob Shults
Title: VP – Asset Management

WITNESSES:

/s/ R. LaDuane Clifton
Print Name: R. LaDuane Clifton

/s/ Christina Cruz
Print Name: Christina Cruz

TENANT:

KEMPHARM, INC, a Delaware corporation

/s/ Christal Mickle
Name: Christal Mickle
Title: VP, Operations and Product Development

EXHIBIT A

OUTLINE AND LOCATION OF EXPANSION SPACE

EXHIBIT B
WORK LETTER

As used in this **Exhibit B** (this **"Work Letter"),** the following terms shall have the following meanings:

(i) **"Tenant Improvements"** means all improvements to be constructed in the Premises pursuant to this Work Letter; and

(ii) **"Tenant Improvement Work"** means the construction of the Tenant Improvements, together with any related work (including demolition) that is necessary to construct the Tenant Improvements.

1 ALLOWANCE.

1.1 Allowance. Tenant shall be entitled to a one-time tenant improvement allowance (the **"Allowance")** in the amount **of$9,926.00** (i.e., $7.00 per rentable square foot of the Expansion Space) to be applied toward the Allowance Items (defined in Section 1.2 below). Tenant shall be responsible for all costs associated with the Tenant Improvement Work, including the costs of the Allowance Items, to the extent such costs exceed the lesser of (a) the Allowance, or (b) the aggregate amount that Landlord is required to disburse for such purpose pursuant to this Work Letter. Notwithstanding any contrary provision of this Amendment, if Tenant fails to use the entire Allowance by December 31, 2015, the unused amount shall revert to Landlord and Tenant shall have no further rights with respect thereto.

1.2 Disbursement. Except as otherwise provided in this Work Letter, the Allowance shall be disbursed by Landlord only for the following items (the **"Allowance Items"):** (a) [Intentionally Omitted};
(b) [Intentionally Omitted}; (c) plan-check, permit and license fees relating to performance of the Tenant Improvement Work; (d) the cost of performing the Tenant Improvement Work, including after hours charges, testing and inspection costs, freight elevator usage, hoisting and trash removal costs, and contractors' fees and general conditions; (e) the cost of any change to the base, shell or core of the Expansion Space or Building required by the Work List (defined in Section 2.1 below) (including if such change is due to the fact that such work is prepared on an unoccupied basis) , including all direct architectural and/or engineering fees and expenses incurred in connection therewith; (f) the cost of any change to the Work List or the Tenant Improvement Work required by Law; (g) the Landlord Supervision Fee (defined in Section 3.4.1 below); (h) sales and use taxes; and (i) all other costs expended by Landlord in connection with the performance of the Tenant Improvement Work.

2 WORK LIST AND PRICING.

2.1 Work List. Landlord shall perform Tenant Improvement Work in accordance with the following work list (the **"Work List")** using Building-standard methods, materials and finishes.

WORK LIST

ITEM
A. Demo wall between suites.
B. Install 4 tele/data back boxes.
C. Replace VCT in demo area with carpet.
D. Touch-up paint in demo area.
E. Add door between existing conference room and new suite.

2.2 [Intentionally Omitted]

2.3 [Intentionally Omitted}

2.4 [Intentionally Omitted]

2.5 [Intentionally Omitted]

2.6 Construction Pricing.

2.6.1 Construction Pricing Proposal. Within five (5) business days after the mutual execution and delivery of this Amendment, Landlord shall provide Tenant with Landlord's reasonable estimate (the **"Construction Pricing Proposal")** of the cost of all Allowance Items to be incurred by Tenant in connection with the performance of the Tenant Improvement Work pursuant to the Work List.

Tenant in connection with the performance of the Tenant Improvement Work pursuant to the Work List. Tenant shall provide Landlord with notice approving or disapproving the Construction Pricing Proposal. If Tenant disapproves the Construction Pricing Proposal, Tenant' s notice of disapproval shall be accompanied by proposed revisions to the Work List that Tenant requests in order to resolve its objections to the Construction Pricing Proposal, and Landlord shall respond as required under Section 2.7 below. Such procedure shall be repeated as necessary until the Construction Pricing Proposal is approved by Tenant. Upon Tenant's approval of the Construction Pricing Proposal, Landlord may purchase the items set forth in the Construction Pricing Proposal and begin construction relating to such items.

2.6.2 Over-Allowance Amount. If the Construction Pricing Proposal exceeds the Allowance, then Tenant, concurrently with its delivery to Landlord of its approval of the Construction Pricing Proposal, shall deliver to Landlord cash in the amount of such excess (the **"Over-Allowance Amount").** Any Over-Allowance Amount shall be disbursed by Landlord before the Allowance and pursuant to the same procedure as the Allowance. If, after the Construction Pricing Proposal is approved by Tenant, (a) any revision is made to the Work List or the Tenant Improvement Work is otherwise changed, in each case in a way that increases the Construction Pricing Proposal, or (b) the Con st ruction Pricing Proposal is otherwise increased to reflect the actual cost of all Allowance Items to be incurred by Tenant in connection with the performance of the Tenant Improvement Work pursuant to the terms hereof, then Tenant shall deliver any resulting Over-Allowance Amount (or any resulting increase in the Over-Allowance Amount) to Landlord immediately upon Landlord's request.

2.7

Revisions to Work List. The Work List shall not be revised without Landlord's agreement, which agreement may be withheld or conditioned in Landlord' s sole and absolute discretion. If Tenant requests any revision to the Work List, Landlord shall provide Tenant with notice approving or disapproving such revision, and, if Landlord approves such revision, Landlord shall have such revision made and delivered to Tenant, together with notice of any resulting change in the most recent Construction Pricing Proposal, if any, within three (3) business s days after the later of Landlord's receipt of such request or the mutual execution and delivery of this Amendment if such revision is not material, and within such longer period of time as may be reasonably necessary (but not more than four (4) business days after the later of such receipt or such execution and delivery) if such revision is material, whereupon Tenant, within one (I) business day, shall notify Landlord whether it desires to proceed with such revision . If Landlord has begun performing the Tenant Improvement Work, then, in the absence of such authorization, Landlord shall have the option to continue such performance disregarding such revision. Landlord shall not revise the Work List without Tenant's consent, which shall not be unreasonably withheld, conditioned or delayed.

2.8 Tenant's Approval Deadline. Tenant shall approve the Construction Pricing Proposal pursuant to Section 2.6.1 above on or before Tenant's Approval Deadline (defined below). As used in this Work Letter, **"Tenant's Approval Deadline"** means the date occurring 10 business days after the mutual execution and delivery of this Amendment; provided, however, that Tenant' s Approval Deadline shall be extended by one (I) day for each day, if any, by which Tenant' s approval of the Construction Pricing Proposal pursuant to Section 2.6. I above is delayed by any failure of Landlord to perform its obligations under this Section 2.

3 CONSTRUCTION.

3.1 Contractor. Landlord shall retain a contractor of its choice (the **"Contractor")** to perform the Tenant Improvement Work. In addition, Landlord may select and/or approve of any subcontractors, mechanics and materialmen used in connection with the performance of the Tenant Improvement Work.

3.2 [Intentionally Omitted]

3.3 Permits. Landlord shall cause the Contractor to apply to the appropriate municipal authorities for, and obtain from such authorities, all permits necessary for the Contractor to complete the Tenant Improvement Work (the **"Permits").**

3.4 Construction.

3.4 .1 **Performance of Tenant Improvement Work.** Landlord shall cause the Contractor to perform the Tenant Improvement Work in accordance with the Work List. Tenant shall pay a construction supervision and management fee (the **"Landlord Supervision Fee")** to Landlord in an amount equal to 4% of the aggregate amount of all Allowance Items other than the Landlord Supervision Fee.

3.4.2 **Contractor's Warranties.** Tenant waives all claims against Landlord relating to any defects in the Tenant Improvements; provided, however, that if, within 30 days after substantial completion of the Tenant Improvement Work, Tenant provides notice to Landlord of any non-latent defect in the Tenant Improvements, or if, within 11 months after substantial completion of the Tenant Improvement Work, Tenant provides notice to Landlord of any latent defect in the Tenant Improvements, then Landlord shall promptly cause such defect to be corrected.

4 COMPLIANCE WITH LAW; SUITABILITY FOR TENANT'S USE. Landlord shall cause its consultants to use the Required Level of Care (defined below) to cause the Work List to comply with Law; provided, however, that Landlord shall not be responsible for any violation of Law resulting from any particular use of the Expansion Space (as distinguished from general office use). As used herein, **"Required Level of Care"** means the level of care that reputable consultants customarily use to cause plans and specifications similar to the Work List to comply with Law where such plans and specifications are prepared for spaces in buildings comparable in quality to the Building. Except as provided above in this Section 4, Tenant shall be responsible for ensuring that the Work List is suitable for Tenant's use of the Expansion Space and complies with Law, and neither the preparation nor the approval of the Work List by Landlord or its consultants shall relieve Tenant from such responsibility. To the extent that either party (the **"Responsible Party")** is responsible under this Section 4 for causing the Work List to comply with Law, the Responsible Party may contest any alleged violation of Law in good faith, including by seeking a waiver or deferment of compliance , asserting any defense allowed by Law, and exercising any right of appeal (provided that the other party incurs no liability as a result of such contest and that, after completing such contest, the Responsible Party makes any modification to the Work List or any alteration to the Expansion Space that is necessary to comply with any final order or judgment).

5 COMPLETION.

5.1

Substantial Completion. For purposes of Section 2.2 of this Amendment, and subject to Section 5.2 below, the Tenant Improvement Work shall be deemed to be **"Substantially Complete"** upon the completion of the Tenant Improvement Work pursuant to the Work List (as reasonably determined by Landlord), with the exception of any details of construction, mechanical adjustment or any other similar matter the non-completion of which does not materially interfere with Tenant's use of the Expansion Space.

5.2 Tenant Cooperation; Tenant Delay. Tenant shall use reasonable efforts to cooperate with Landlord, the Contractor, and Landlord's other consultants to provide any necessary approvals relating to the Work List, approve the Construction Pricing Proposal, obtain the Permits, and complete the Tenant Improvement Work as soon as possible, and Tenant shall meet with Landlord, in accordance with a schedule determined by Landlord, to discuss the parties' progress. Without limiting the foregoing, if

(i) the Tenant Improvements include the installation of electrical connections for furniture stations to be installed by Tenant, and (ii) any electrical or other portions of such furniture stations must be installed in order for Landlord to obtain any governmental approval required for occupancy of the Expansion Space, then (x) Tenant, upon five (5) business days' notice from Landlord, shall promptly install such portions of such furniture stations in accordance with Sections 7.2 and 7.3 of this Lease, and (y) during the period of Tenant's entry into the Expansion Space for the purpose of performing such installation, all of Tenant's obligations under this Amendment relating to the Expansion Space shall apply, except for the obligation to pay Monthly Rent. In addition, without limiting the foregoing, if the Substantial Completion of the Tenant Improvement Work is delayed (a **"Tenant Delay")** as a result of (a) any failure of Tenant to approve the Construction Pricing Proposal pursuant to Section 2.6. l above on or before Tenant's Approval Deadline; (b) [Intentionally Omitted]; (c) any failure of Tenant to timely approve any other matter requiring Tenant's approval; (d) any breach by Tenant of this Work Letter or this Amendment; (e) any request by Tenant for any revision to, or for Landlord's approval of any revision to, the Work List (except to the extent that such delay results from a breach by Landlord of its obligation s under Section 2.7 above); (f) [Intentionally Omitted); (g) [Intentionally Omitted]; or (h) any other act or omission of Tenant or any of its agents, employees or representatives, then, notwithstanding any contrary provision of this Amendment, and regardless of when the Tenant Improvement Work is actually Substantially Completed, the Tenant Improvement Work shall be deemed to be Substantially Completed on the date on which the Tenant Improvement Work would have been Substantially Completed if no such Tenant Delay had occurred. Notwithstanding the foregoing, Landlord shall not be required to tender possession of the Expansion Space to Tenant before the Tenant Improvement Work has been Substantially Completed, as determined without giving effect to the preceding sentence.

6 MISCELLANEOUS. Notwithstanding any contrary provision of this Amendment, if Tenant defaults under this Amendment before the Tenant Improvement Work is completed, Landlord's obligations under this Work Letter shall be excused until such default is cured and Tenant shall be

responsible for any resulting delay in the completion of the Tenant Improvement Work. This Work Letter shall not apply to any space other than the Expansion Space.

EXHIBIT C

NOTICE OF LEASE TERM DATES

_____, 20__

To: ___

Re: Amendment (the **"Amendment"),** dated _____, 20___, to a lease agreement dated _____, 20___, between _____, a **("Landlord"),** and _____ a _____ **(Tenant"),** concerning Suite___on the_____floor of the building located at___ California (the **"Expansion Space").**

LeaseID:----------
Business Unit Number:--------

Dear____

In accordance with the Amendment, Tenant accepts possession of the Expansion Space and confirms that (a) the Expansion Effective Date is _____, 20_, and (b) the expiration date of the Lease is _____, 20__._

Please acknowledge the foregoing by signing all three (3) counterparts of this letter in the space provided below and returning two (2) fully executed counterparts to my attention. Please note that, under Section 2.3 of the Amendment, Tenant is required to execute and return (or reasonably object in writing to) this letter within five (5) days after receiving it.

"Landlord":

By:___ Name:___ Title: ___

Agreed and Accepted as of , 20_.

"Tenant":

By:___ Name:___ Title: ___

SECOND AMENDMENT

THIS SECOND AMENDMENT (this **"Amendment")** is made and entered into as of December 22nd 2015, by and between **BRE/COH FL LLC, a Delaware limited liability company ("Landlord"),** and **KEMPHARM, INC., a Delaware corporation ("Tenant").**

RECITALS

A. Landlord and Tenant are parties to that certain lease dated November 3, 2014, and that certain First Amendment dated April 21, 2015 (as amended, the **"Lease").** Pursuant to the Lease, Landlord has leased to Tenant space currently containing approximately **4,639** rentable square feet (the **"Existing Premises")** described as Suites 102 Band 103 on the first floor of the building commonly known as **Celebration Office Center** II located at 1170 Celebration Boulevard, Celebration, Florida.

B. The Lease will expire by its terms on June 30, 2018 (the **"Existing Expiration Date"),** and the parties wish to extend the term of the Lease on the following terms and conditions.

C. The parties wish to relocate the Premises (defined in the Lease) from the Existing Premises to the space containing approximately **10,772** rentable square feet described as Suites No. 103 & 104 on the first (1st) floor of the building commonly known as **Celebration Office Center** I located at 1180 Celebration Boulevard, Celebration, Florida and shown on **Exhibit A** attached hereto (the **"Substitution Space"),** on the following terms and conditions. Prior to the Substitution Effective Date (defined in Section 2.1 A below), all references in the Lease to the **"Building"** shall refer to **Celebration Office Center** II located at 1170 Celebration Boulevard, Celebration, Florida. From and after the Substitution Effective Date, all references in the Lease to the **"Building"** shall refer to **Celebration Office Center** I located at 1180 Celebration Boulevard, Celebration, Florida.

NOW, THEREFORE, in consideration of the above recitals which by this reference are incorporated herein, the mutual covenants and conditions contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant agree as follows:

l. **Extension.** The term of the Lease is hereby extended through the last day of the 108th full calendar month beginning on or after the Substitution Effective Date (the **"Extended Expiration Date").** The portion of the term of the Lease beginning on the date immediately following the Existing Expiration Date (the **"Extension Date")** and ending on the Extended Expiration Date shall be referred to herein as the **"Extended Term".**

2. Substitution.

2.1. Substitution Term. From and after the Substitution Effective Date (defined in Section 2.1.A below), the Premises shall be the Substitution Space, subject to the terms hereof (the **"Substitution").** The term of the Lease for the Substitution Space (the **"Substitution Term")** shall commence on the Substitution Effective Date and, unless sooner terminated in accordance with the Lease, end on the Extended Expiration Date. From and after the Substitution Effective Date, the Substitution Space shall be subject to all the terms and conditions of the Lease except as provided herein. Except as may be expressly provided herein, (a) Tenant shall not be entitled to receive, with respect to the Substitution Space, any allowance, free rent or other financial concession granted with respect to the Existing Premises, and (b) no representation or warranty made by Landlord with respect to the Existing Premises shall apply to the Substitution Space.

A. Substitution Effective Date. As used herein, **"Substitution Effective Date"** means the earlier to occur of (i) the first date on which Tenant conducts business in the Substitution Space, or (ii) the date on which the Tenant Improvement Work (defined in **Exhibit B** attached hereto) is Substantially Complete (defined in **Exhibit B** attached hereto), which is anticipated to be **March 1, 2016** (the **"Target Substitution Effective Date").** The adjustment of the Substitution Effective Date and, accordingly, the postponement of Tenant's obligation to pay rent for the Substitution Space shall be Tenant's sole remedy if the Tenant Improvement Work is not Substantially Complete on the Target Substitution Effective Date. Without limiting the foregoing, during any period that the

Substitution Effective Date is delayed, Tenant shall continue to pay rent for the Existing Premises in accordance with the terms of the Lease. [If the Substitution Effective Date is delayed, the expiration date under the Lease shall not be similarly extended.

B. Confirmation Letter. At any time after the Substitution Effective Date, Landlord may deliver to Tenant a notice substantially in the form of **Exhibit C** attached hereto, as a confirmation of the information set forth therein. Tenant shall execute and return (or, by written notice to Landlord, reasonably object to) such notice within five (5) days after receiving it.

2.2. **Existing Premises.** Subject to the terms hereof, effective as of the Existing Premises Expiration Date (defined below), the term of the Lease shall expire with respect to the Existing Premises with the same force and effect as if such term were, by the provisions of the Lease, fixed to expire with respect to the Existing Premises on the Existing Premises Expiration Date. As used herein, **"Existing Premises Expiration Date"** means the day prior to the Substitution Effective Date. Without limiting the foregoing:

A. Tenant shall surrender the Existing Premises to Landlord in accordance with the terms of the Lease on or before the Existing Premises Expiration Date.

B. Tenant shall remain liable for all Rent and other amounts payable under the Lease with respect to the Existing Premises for the period up to and including the Existing Premises Expiration Date, even though billings for such amounts may occur after the Existing Premises Expiration Date.

C. Tenant's restoration obligations with respect to the Existing Premises shall be as set forth in the Lease.

D. If Tenant fails to surrender any portion of the Existing Premises on or before the Existing Premises Expiration Date, Tenant's tenancy with respect to the Existing Premises shall be subject to Article 16 of the Lease. Notwithstanding the foregoing, Tenant shall have a grace period of up to seven (7) days from the Substitution Effective Date in which to complete the removal of Tenant's furniture, equipment and other personal property from the Existing Premises. Tenant shall not be required to pay Base Rent or Additional Rent for the Existing Premises during such seven (7) day grace period.

E. Any other rights or obligations of Landlord or Tenant under the Lease relating to the Existing Premises that, in the absence of the Substitution, would have survived the expiration date of the Lease shall survive the Existing Premises Expiration Date.

3. Base Rent.

3.1. Substitution Space During Substitution Term. With respect to the Substitution Space during the Substitution Term, the schedule of Base Rent shall be as follows:

Period During Substitution Term	Annual Rate Per Square Foot (rounded to the nearest 100th of a dollar)	Monthly Base Rent
Substitution Effective Date through last day of 12th full calendar month of Substitution Term	$23.75	$21,319.58
13th through 24th full calendar months of Substitution Term	$24.34	$21,849.21
25th through 361h full calendar months of Substitution Term	$24.95	$22,396.78
37th through 48th full calendar months of Substitution Term	$25.58	$22,962.31
49th through 60111 full calendar months of Substitution Term	$26.22	$23,536.82
61st through 72nd full calendar months of Substitution Term	$26.87	$24,120.30
73rd through 84th full calendar months of Substitution Term	$27.54	$24,721.74
85th through 96th full calendar months of Substitution Term	$28.23	$25,341.13
97th full calendar month of Substitution Term through last day of Substitution Term	$28.94	$25,978.47

All such Base Rent shall be payable by Tenant in accordance with the terms of the Lease.

Notwithstanding the foregoing, Base Rent for the Substitution Space shall be abated, in the amount of $21,319.58 per month, for the first six (6) full calendar months of the Substitution Term; provided, however, that if a Default exists when any such abatement would otherwise apply, such abatement shall be deferred until the date, if any, on which such Default is cured.

4. Additional Security Deposit. Upon Tenant's execution hereof, Tenant shall pay Landlord the sum of $57,805.68, which shall be added to and become part of the Security Deposit held by Landlord pursuant to Section 21 of the Lease. Accordingly, simultaneously with the execution hereof, the Security Deposit is hereby increased from $24,694.32 to $82,500. Effective as of the date hereof, Section 21.2 of the Lease is deleted and replaced with the following:

*"Subject to the remaining terms of this Section 21. and provided that, during the 12 month period immediately preceding the effective date of any reduction of the Security Deposit. Tenant has timely paid all Rent and no default has occurred under this Lease beyond any applicable cure period (the "**Security Reduction Conditions**"), Tenant shall have the right to reduce the amount of the Security Deposit so that the new Security Deposit amount will be: (i) $62,994.83 effective as of the first day of the 30'h full calendar month of the Substitution Term; (ii) $43,489.66 effective as of the first day of the 42nd full calendar month of the Substitution Term; and (iii) $23,984.50 effective as of the first day of the 54th full calendar month of the Substitution Term. Notwithstanding anything to the contrary contained herein. if Tenant has been in default under this Lease at any time prior to the effective date of any reduction of the Security Deposit and Tenant has failed to cure such default within any applicable cure period, then Tenant shall have no right to reduce the amount of the Security Deposit as described herein. If Tenant is*

*entitled to a reduction in the Security Deposit, Tenant shall provide Landlord with written notice requesting that the Security Deposit be reduced as provided above (the "**Security Reduction Notice**"). If Tenant provides Landlord with a Security Reduction Notice, and Tenant is entitled to reduce the Security Deposit as provided herein, Landlord shall refund the applicable portion of the Security Deposit to Tenant within 45 days after the later to occur of (a) Landlord's receipt of the Security Reduction Notice, or (b) the date upon which Tenant is entitled to a reduction in the Security Deposit as provided above.* "

5. **Tenant's Share.** With respect to the Substitution Space during the Substitution Term, Tenant's Share shall be **13.2362%** (based upon a total of **81,383** rentable square feet in the Building).

6. **Expenses and Taxes for Substitution Space During Substitution Term.** With respect to the Substitution Space during the Substitution Term, Tenant shall pay for Tenant's Share of Expenses and Taxes in accordance with the terms of the Lease; provided, however, that, with respect to the Substitution Space during the Substitution Term, the Base Year for Expenses and Taxes shall be 2016. Notwithstanding any contrary provision hereof, Controllable Expenses (defined below) shall not increase after the Base Year by more than **5%** per calendar year, as determined on a compounding and cumulative basis. By way of example and not of limitation, if Controllable Expenses for the Base Year are $10.00 per rentable square foot, then Controllable Expenses for the first calendar year after the Base Year shall not exceed $10.50 per rentable square foot; Controllable Expenses for the second calendar year after the Base Year shall not exceed $11.025 per rentable square foot; and so on. As used herein, **"Controllable Expenses"** means all Expenses other than (i) costs of utilities, (ii) insurance premiums and deductibles, (iii) capital expenditures required by changes in Law, and (iv) any market-wide cost increases resulting from extraordinary circumstances, including Force Majeure, boycotts, strikes, conservation surcharges, embargoes and shortages. For purposes of determining Controllable Expenses, any management fee shall be calculated without regard to any free rent, abated rent, or the like.

7. **Improvements to Substitution Space.**

7.1. **Condition and Configuration of Substitution Space.** Tenant acknowledges that it has inspected the Substitution Space and agrees to accept it in its existing condition and configuration, without any representation by Landlord regarding its condition or configuration and without any obligation on the part of Landlord to perform or pay for any alteration or improvement, except as may be otherwise expressly provided in this Amendment.

7.2. **Responsibility for Improvements to Substitution Space.** Landlord shall perform the Tenant Improvement Work in accordance with the terms and conditions set forth in **Exhibit B** attached hereto.

8. **Representations.** Tenant represents and warrants that, as of the date hereof and the Existing Premises Expiration Date: (a) Tenant is the rightful owner of all of the Tenant's interest in the Lease; (b) Tenant has not made any disposition, assignment, sublease, or conveyance of the Lease or Tenant's interest therein; (c) Tenant has no knowledge of any fact or circumstance which would give rise to any claim, demand, obligation, liability, action or cause of action arising out of or in connection with Tenant's occupancy of the Existing Premises; (d) no other person or entity has an interest in the Lease, collateral or otherwise; and (e) there are no outstanding contracts for the supply of labor or material and no work has been done or is being done in, to or about the Existing Premises which has not been fully paid for and for which appropriate waivers of mechanic's liens have not been obtained.

9. **Extension Options.**

9.1. Grant of Option; Conditions. Subject to the terms herein, Tenant shall have the right to extend the Extended Term (the **"First Extension Option")** for one additional period of 5 years commencing on the day following the Extended Expiration Date and ending on the 5th anniversary of the Extended Expiration Date (the **"First Extension Term"),** and, if Tenant properly exercised the First Extension Option and the Extended Term was extended as a result thereof, Tenant shall also have the right to extend the Extended Term (the **"Second Extension Option")** for one additional period of 5 years commencing on the date following the last day of the First Extension Term and ending on the 5th anniversary of the last day of the First Extension Term (the **"Second Extension Term").** Throughout the remainder of this provision, unless specifically provided otherwise, the First Extension Option and Second Extension Option are each referred to

as an **"Extension Option",** and the First Extension Term and the Second Extension Term are each referred to as an **"Extension Term".**

It is agreed that Tenant may exercise an Extension Option only if:

A. Not less than 9 and not more than 12 full calendar months before the applicable expiration date, Tenant delivers written notice to Landlord (the **"Extension Notice")** electing to exercise the Extension Option and stating Tenant's estimate of the Prevailing Market (defined in Section 9.5 below) rate for the Extension Term;

B. Tenant is not in Default under the Lease beyond any applicable cure period when Tenant delivers the Extension Notice;

C. No part of the Premises is sublet (other than to an Affiliate of Tenant) when Tenant delivers the Extension Notice ; and

D. The Lease has not been assigned (other than pursuant to a Permitted Transfer) before Tenant delivers the Extension Notice.

9.2. Tem1s Applicable to Extension Term.

A. During the Extension Term, (a) the initial Base Rent rate per rentable square foot shall be equal to the Prevailing Market rate per rentable square foot as of the commencement of the Extension Term and shall be subject to annual increases in accordance with the determination of Prevailing Market; and (b) Base Rent shall be payable in monthly installments in accordance with the terms and conditions of the Lease. Except as otherwise expressly provided in this Amendment, the terms and conditions set forth in the Lease, as amended from time to time, shall apply during the Extension Tenn.

B. During the Extension Term Tenant shall pay Tenant's Share of Expenses and Taxes for the Premises in accordance with the Lease. During the Extension Term the Base Year for Expenses and Taxes shall be the calendar year in which the Extension Term commences.

C. Any free rent, construction allowance or similar concession may be part of the negotiations pertinent to determining the Prevailing Market with respect to the Extension Term.

9.3. Procedure for Determining Prevailing Market.

A. Initial Procedure. Within 30 days after receiving the Extension Notice, Landlord shall give Tenant either (i) written notice **("Landlord's Binding Notice")** accepting Tenant's estimate of the Prevailing Market rate for the Extension Term stated in the Extension Notice, or (ii) written notice **("Landlord's Rejection Notice")** rejecting such estimate and stating Landlord's estimate of the Prevailing Market rate for the Extension Term. If Landlord gives Tenant a Landlord's Rejection Notice, Tenant, within 15 days thereafter, shall give Landlord either (i) written notice **("Tenant's Binding Notice")** accepting Landlord's estimate of the Prevailing Market rate for the Extension Term stated in such Landlord's Rejection Notice, or (ii) written notice **("Tenant's Rejection Notice")** rejecting such estimate. If Tenant gives Landlord a Tenant's Rejection Notice, Landlord and Tenant shall work together in good faith to agree in writing upon the Prevailing Market rate and terms for the Extension Tenn. If, within 30 days after delivery of a Tenant's Rejection Notice, the parties fail to agree in writing upon the Prevailing Market rate and terms, the provisions of Section 9.3.B below shall apply.

B. Dispute Resolution Procedure.

I. If, within 30 days after delivery of a Tenant's Rejection Notice, the parties fail to agree in writing upon the Prevailing Market rate and terms, Landlord and Tenant, within five (5) days thereafter, shall each simultaneously submit to the other, in a sealed envelope, its good faith

estimate of the Prevailing Market rate and terms for the Extension Term (collectively, the **"Estimates").** If the higher of such Estimates is not more than 105% of the lower of such Estimates, the Prevailing Market rate shall be deemed to be the average of the two Estimates. Otherwise, within seven (7) days after the exchange of Estimates, Landlord and Tenant shall each select an appraiser to determine which of the two Estimates most closely reflects the Prevailing Market rate and terms for the Extension Term. Each appraiser so selected shall be certified as an MAI appraiser or as an ASA appraiser and shall have had at least five (5) years experience within the previous 10 years as a real estate appraiser working in Celebration/Orlando, Florida, with working knowledge of current rental rates and leasing practices relating to buildings similar to the Building. For purposes hereof, an **"MAI"** appraiser means an individual who holds an MAI designation conferred by, and is an independent member of, the American Institute of Real Estate Appraisers (or its successor organization, or in the event there is no successor organization, the organization and designation most similar), and an **"ASA"** appraiser means an individual who holds the Senior Member designation conferred by, and is an independent member of, the American Society of Appraisers (or its successor organization, or, in the event there is no successor organization, the organization and designation most similar).

2. If each party selects an appraiser in accordance with Section 9.3.B.1 above, the parties shall cause their respective appraisers to work together in good faith to agree upon which of the two Estimates most closely reflects the Prevailing Market rate and terms for the Extension Term. The Estimate, if any, so agreed upon by such appraisers shall be final and binding on both parties as the Prevailing Market rate and terms for the Extension Term and may be entered in a court of competent jurisdiction. If the appraisers fail to reach such agreement within 20 days after their selection, then, within 10 days after the expiration of such 20-day period, the parties shall instruct the appraisers to select a third appraiser meeting the above criteria (and if the appraisers fail to agree upon such third appraiser within 10 days after being so instructed, either party may cause a court of competent jurisdiction to select such third appraiser). Promptly upon selection of such third appraiser, the parties shall instruct such appraiser (or, if only one of the parties has selected an appraiser within the 7-day period described above, then promptly after the expiration of such 7-day period the parties shall instruct such appraiser) to determine, as soon as practicable but in any case within 14 days after his selection, which of the two Estimates most closely reflects the Prevailing Market rate and terms. Such determination by such appraiser (the **"Final Appraiser")** shall be final and binding on both parties as the Prevailing Market rate and terms for the Extension Term and may be entered in a court of competent jurisdiction. If the Final Appraiser believes that expert advice would materially assist **him,** he may retain one or more qualified persons to provide such expert advice. The parties shall share equally in the costs of the Final Appraiser and of any experts retained by the Final Appraiser. Any fees of any other appraiser, counsel or expert engaged by Landlord or Tenant shall be borne by the party retaining such appraiser, counsel or expert.

C. If the Prevailing Market rate and terms has not been determined by the commencement date of the Extension Term, Tenant shall pay Base Rent for the Extension Term upon the terms and conditions in effect during the last month ending on or before the Expiration Date until such time as the Prevailing Market rate and terms has been determined. Upon such determination, the Base Rent for the Extension Term shall be retroactively adjusted. If such adjustment results in an under- or overpayment of Base Rent by Tenant, Tenant shall pay Landlord the amount of such underpayment, or receive a credit in the amount of such overpayment, with or against the next Base Rent due under the Lease.

9.4. Extension Amendment. If Tenant is entitled to and properly exercises its Extension

Option, and if the Prevailing Market rate and terms for the Extension Term is determined in accordance with Section 9.3 above, Landlord, within a reasonable time thereafter, shall prepare and deliver to Tenant an amendment (the **"Extension Amendment")** reflecting changes in the Base Rent, the Term, the expiration date, and other appropriate terms, and Tenant shall execute and return the Extension Amendment to Landlord within 15 days after receiving it. Notwithstanding the foregoing, upon determination of the Prevailing Market rate and terms for the Extension Term in accordance with Section 9.3 above, an otherwise valid exercise of the Extension Option shall be fully effective whether or not the Extension Amendment is executed.

9.5. Definition of Prevailing Market. For purposes of this Extension Option, **"Prevailing Market"** shall mean the arms-length, fair-market, initial annual rental rate per rentable square foot and other business terms under extension and renewal leases and amendments entered into on or about the date on which the Prevailing Market is being determined hereunder for space comparable to the Premises in the Building and other comparable buildings in the Celebration Business Center submarket. The determination of Prevailing Market shall take into account any material economic differences between the terms of the Lease and any comparison lease or amendment, such as rent abatements, construction costs and other concessions, and the manner, if any, in which the landlord under any such lease is reimbursed for operating expenses and taxes. The determination of Prevailing Market shall also take into consideration any reasonably anticipated changes in the Prevailing Market rate from the time such Prevailing Market rate is being determined and the time such Prevailing Market rate will become effective under the Lease.

9.6. Subordination. Notwithstanding anything herein to the contrary, Tenant's Extension Option is subject and subordinate to the expansion rights (whether such rights are designated as a right of first offer, right of first refusal, expansion option or otherwise) of any tenant of the Building or the Project existing on the date hereof.

10. Right of Refusal

10.1 Grant of Option: Conditions. Subject to Section 10.5 below, Tenant shall have the one time right of refusal (the **"Right of Refusal")** with respect to Suite 102A containing approximately 6,302 rentable square feet on the first floor of the Building (i.e. Celebration Office Center I) (the **"Refusal Space").** Tenant's Right of Refusal shall be exercised as follows: when Landlord has a prospective tenant, other than the existing tenant in the Refusal Space (the **"Prospect"),** interested in leasing the Refusal Space (as evidenced by a signed letter of intent or an exchange of good faith proposals and a tenant request to prepare lease documents), Landlord shall advise Tenant (the **"Advice")** of the terms under which Landlord is prepared to lease the Refusal Space to such Prospect and Tenant may lease the Refusal Space, under such terms, by providing Landlord with written notice of exercise (the **"Notice of Exercise")** within 5 business days after the date of the Advice. In the event that another Tenant has superior rights to the Refusal Space in accordance with Section 10.5, Landlord shall have the right to either: (i) send Tenant an Advice only after such superior rights have lapsed or been rejected; or (ii) concurrently send an Advise to Tenant and the tenant with superior rights on the condition that Tenant's right to exercise its Right of Refusal will be conditioned and contingent upon the lapse or rejection of all superior rights to lease the Refusal Space. Notwithstanding the foregoing, Tenant shall only have a Right of Refusal if:

A. Tenant is not in Default under the Lease beyond any applicable cure period when Tenant delivers the Notice of Exercise;

B. No part of the Leased Premises is sublet (other than to a Tenant Affiliate in accordance with the terms of the Lease, as amended hereby) when Tenant delivers the Notice of Exercise; and

C. The Lease, as amended, has not been assigned (other than pursuant to a Permitted Transfer) before Tenant delivers the Notice or Exercise.

10.2. Terms for Refusal Space.

A. The term for the Refusal Space shall commence upon the commencement date stated in the Advice and thereupon such Refusal Space shall be considered a part

of the Premises, subject to the terms and conditions of the Lease, provided, however, that all of the terms stated in the Advice, including the termination date set forth in the Advice, shall govern Tenant's leasing of the Refusal Space and only to the extent that they do not conflict with the Advice, the terms and conditions of the Lease shall apply to the Refusal Space. Tenant shall pay Base Rent and Tenant's Pro Rata Share of Operating Expenses for the Refusal Space in accordance with the terms and conditions of the Advice. Tenant's right, if any, to receive an abatement of rent, tenant improvement allowance and/or other concession shall be in accordance with the terms of the Advice.

B. The Refusal Space (including improvements and personalty, if any) shall be accepted by Tenant in its condition and as-built configuration existing on the earlier of the date Tenant takes possession of the Refusal Space or the date the term for such Refusal Space commences, unless the Advice specifies work to be performed by Landlord in the Refusal Space, in which case Landlord shall perform such work in the Refusal Space. If Landlord is delayed delivering possession of the Refusal Space due to the holdover or unlawful possession of such space by any party, Landlord shall use reasonable efforts to obtain possession of the space, and the commencement of the term for the Refusal Space shall be postponed until the date Landlord delivers possession of the Refusal Space to Tenant free from occupancy by any party.

10.3. Termination of Right of Refusal. The rights of Tenant hereunder with respect to the Refusal Space shall terminate on the earlier to occur of (i) the date on which there is less than one (1) year remaining in the term of the Lease and Tenant has no further options to extend the term of the Lease; (ii) Tenant's failure to exercise its Right of Refusal within the *5* business day period provided in Section 10.1 above; and (iii) the date Landlord would have provided Tenant an Advice for the Refusal Space if Tenant had not been in violation of one or more of the conditions set forth in Section 10. l above.

10.4. Refusal Space Amendment. If Tenant is entitled to and properly exercises its Right of Refusal, Landlord, within a reasonable time thereafter, shall prepare and deliver to Tenant an amendment in commercially reasonable form and substance (for purposes of this Amendment, the **"Refusal Amendment")** reflecting changes in the Base Rent, the term of the Lease for the Refusal Space, the expiration date of the Lease for the Refusal Space, and other reasonably appropriate terms related to the Refusal Space; and, within 15 days after receiving it, Tenant shall either execute and return the Refusal Amendment to Landlord or provide to Landlord reasonable comments thereto. Such process shall be repeated until the Refusal Amendment is acceptable to both parties, as evidenced by their mutual execution and delivery thereof. Notwithstanding the foregoing, an otherwise valid exercise of the Right of Refusal shall be fully effective whether or not the Refusal Amendment is executed.

10.5. Subordination. Notwithstanding anything herein to the contrary, Tenant's Right of Refusal is subject and subordinate to (i) the renewal or extension rights of any tenant leasing all or any portion of the Refusal Space, and (ii) the expansion rights (whether such rights are designated as a right of first offer, right of first refusal, expansion option or otherwise) of any tenant of the Building existing on the date hereof.

10.6 Alternative Space Option. If Tenant is not entitled to lease the Refusal Space as a result of another tenant's exercise of superior rights under Section 10.5, Tenant shall have the right to provide written notice to Landlord of its desire to lease additional space in the Building (the "Alternate Space Notice"), which Alternate Space Notice shall specify the approximate additional square footage that Tenant desires to lease. Upon receipt of an Alternate Space Notice, Landlord shall advise Tenant (the "Alternate Space Advice") as to whether any such space is available in the Building that satisfies Tenant's criteria and, if space is available, the Prevailing Market terms under which it would be willing to lease such space to Tenant. If Tenant does not desire to lease such space upon the terms and conditions designated by Landlord, Tenant shall provide Landlord with written notice of rejection (the "Rejection Notice") within fifteen (15) days after the date of Landlord's Alternate Space Advice. If Tenant provides Landlord with a Rejection Notice in a timely manner, Landlord and Tenant shall work together in good faith to agree upon mutually acceptable terms and conditions. Upon agreement between Landlord and Tenant, Landlord and Tenant shall enter into an amendment to add such additional space to the Premises. If Landlord and Tenant are unable to agree upon the terms for such

additional space, neither party shall have any obligation to the other hereunder. Notwithstanding anything herein to the contrary, Landlord's obligation to work with Tenant in good faith shall be subject to space being available in the building that meets Tenant's criteria. The availability of space shall be determined by Landlord in its reasonable discretion taking into consideration the rights of other tenants in the Building and Landlord's plan for the leasing and marketing of the Building.

11. Other Pertinent Provisions. Landlord and Tenant agree that, effective as of the date of this Amendment (unless different effective date(s) is/are specifically referenced in this Section), the Lease shall be amended in the following additional respects:

11.1 Parking. Effective as of the Substitution Effective Date, the first sentence of Section 1.9 of the Lease, as previously amended by the First Amendment, is hereby amended by replacing the number "23" with the number "53".

11.2 Holdover. Section 16 of the Lease is hereby deleted and replaced with the following:

*"**HOLDOVER.** If Tenant fails to surrender the Premises upon the expiration or earlier termination hereof, Tenant's tenancy shall be subject to the terms and conditions hereof provided, however, that such tenancy shall be a tenancy at sufferance only, without claim of right, for the entire Premises, and Tenant shall pay Monthly Rent (on a per- month basis without reduction for any partial month) at a rate equal to 150% of the Monthly Rent applicable during the last calendar month of the Term. Nothing in this Section 16 shall limit Landlord's rights or remedies or be deemed a consent to any holdover. If Landlord is unable to deliver possession of the Premises to a new tenant or to perform improvements for a new tenant as a result of Tenant's holdover and such holdover continues for a period of 30 days after written notice from Landlord to Tenant advising Tenant of Landlord's inability to deliver possession or perform improvements, Tenant shall be liable for all resulting damages, including lost profits, incurred by Landlord. "*

11.3 Relocation. Section 22 of the Lease is hereby deleted in its entirety and rendered null and void and of no further force or effect.

11.4 Signage. Landlord, as part of the Tenant Improvement Work (and subject to the Maximum Amount), shall provide Tenant with Building standard lobby and suite signage with respect to the Substitution Space.

11.5 Right of First Offer. Section 1 of Exhibit E of the Lease is hereby deleted in its entirety and rendered null and void and of no further force or effect.

11.6 Landlord's Waiver and Consent. Concurrently with its execution of this Amendment, Landlord shall execute and deliver to Tenant the form of Landlord's Waiver and Consent attached hereto as Exhibit D.

12. Miscellaneous.

12.1. This Amendment and the attached exhibits, which are hereby incorporated into and made a part of this Amendment, set forth the entire agreement between the parties with respect to the matters set forth herein. There have been no additional oral or written representations or agreements. Tenant shall not be entitled, in connection with entering into this Amendment, to any free rent, allowance, alteration, improvement or similar economic incentive to which Tenant may have been entitled in connection with entering into the Lease, except as may be otherwise expressly provided in this Amendment.

12.2. Except as herein modified or amended, the provisions, conditions and terms of the Lease shall remain unchanged and in full force and effect.

12.3. In the case of any inconsistency between the provisions of the Lease and this Amendment, the provisions of this Amendment shall govern and control.

12.4. Submission of this Amendment by Landlord is not an offer to enter into this Amendment but rather is a solicitation for such an offer by Tenant. Landlord shall not be bound by this Amendment until Landlord has executed and delivered it to Tenant.

12.5. Capitalized terms used but not defined in this Amendment shall have the meanings given in the Lease.

12.6. Tenant shall indemnify and hold Landlord, its trustees, members, principals, beneficiaries, partners, officers, directors, employees, mortgagee(s) and agents, and the respective principals and members of any such agents harmless from all claims of any brokers (other than Cresa Partners Orlando) claiming to have represented Tenant in connection with this Amendment. Landlord shall indemnify and hold Tenant, its trustees, members, principals, beneficiaries, partners, officers, directors, employees, and agents, and the respective principals and members of any such agents harmless from all claims of any brokers claiming to have represented Landlord in connection with this Amendment. Tenant acknowledges that any assistance rendered by any agent or employee of any affiliate of Landlord in connection with this Amendment has been made as an accommodation to Tenant solely in furtherance of consummating the transaction on behalf of Landlord, and not as agent for Tenant.

IN WITNESS WHEREOF, Landlord and Tenant have duly executed this Amendment as of the day and year first above written.

WITNESSES:

/s/ Sarah Grella
Print Name: Sarah Grella

/s/ Nina H. Siegel
Print Name: Nina H. Siegel

LANDLORD:

BRE/COH FL LLC, a Delaware limited liability company

/s/ Mark W. Smith
Name: Mark W. Smith
Title: Managing Director

WITNESSES:

/s/ Susan Smoker
Print Name: Susan Smoker

/s/ Katy Powell
Print Name: Katy Powell

TENANT:

KEMPHARM, INC, a Delaware corporation

/s/ R. LaDuane Clifton
Name: R. LaDuane Clifton
Title: CFO

EXHIBIT A

OUTLINE AND LOCATION OF SUBSTITUTION SPACE SU1TE 103/104 (10,772 RSF)

EXHIBITB

WORK LETTER

As used in this **Exhibit B** (this **"Work Letter"),** the following terms shall have the following meanings: **"Agreement"** means the Lease of which this Work Letter is a part. **"Tenant Improvements"** means all improvements to be constructed in the Substitution Space pursuant to this Work Letter. **"Tenant Improvement Work"** means the construction of the Tenant Improvements, together with any related work (including demolition) that is necessary to construct the Tenant Improvements.

1. ALLOWANCE. Intentionally Omitted.

2. PLANS.

2.1 Approved Space Plan. Landlord and Tenant acknowledge and agree that they have approved the detailed space plan prepared by C4 Architecture (the **"Architect")** and attached hereto as Exhibit B-1 (the **"Approved Space Plan").** Tenant shall be responsible for ensuring that all elements of the design of the Approved Space Plan are suitable for Tenant's use of the Premises, and neither the preparation of the Approved Space Plan by the Architect nor Landlord's approval of the Approved Space Plan or Approved Construction Drawings (hereinafter defined) shall relieve Tenant from such responsibility. Except as noted in the Approved Space Plan to the contrary, the Tenant Improvements shall be performed using building standard materials.

2.2 Construction Drawings. If necessary based on the scope of the work to be performed, Landlord shall cause the Architect to prepare and deliver to Tenant construction drawings that conform to the Approved Space Plan. Tenant shall approve or disapprove the construction drawings by notice to Landlord within two (2) business days after Tenant's receipt of the construction drawings. If Tenant disapproves the construction drawings, Tenant's notice of disapproval shall specify any revisions Tenant desires in the construction drawings. After receiving such notice of disapproval, Landlord shall cause the Architect to revise the construction drawings, taking into account the reasons for Tenant's disapproval (provided, however, that Landlord shall not be required to cause the Architect to make any revision to the construction drawings that is inconsistent with the Approved Space Plan or Landlord's requirements for avoiding aesthetic, engineering or other conflicts with the design and function of the balance of the Building), and resubmit the construction drawings to Tenant for its approval. Such revision and resubmission shall occur within 5 business days after Landlord's receipt of Tenant's notice of disapproval if such revision is not material, and within such longer period of time as may be reasonably necessary if such revision is material. Such procedure shall be repeated as necessary until Tenant has approved the construction drawings. The construction drawings approved by Landlord and Tenant are referred to in this Work Letter as the **"Approved Construction Drawings".**

2.3 Time Deadlines. Tenant shall use its best efforts to cooperate with Landlord and its architect, engineers and other consultants to complete all phases of the plans and obtain the permits for the Tenant Improvement Work as soon as possible after the execution of this Agreement, and Tenant shall meet with Landlord, in accordance with a schedule determined by Landlord, to discuss the parties' progress.

3 CONSTRUCTION.

3.l **Co<u>n</u>tractor.** A contractor designated by Landlord (the **"Contractor")** shall perform the Tenant Improvement Work in accordance with the Approved Space Plan or, if applicable, the Approved Construction Drawings. In addition, Landlord may select and/or approve of any subcontractors, mechanics and materialmen used in connection with the performance of the Tenant Improvement Work.

3.2 Cost of Tenant Improvement Work. Except as provided in <u>Section 3.3</u> below, the Tenant Improvement Work shall be performed at Landlord's expense.

<u>3.3</u> <u>Maximum Amount; Revisions</u>.

3.3.1 Landlord and Tenant acknowledge that it is not possible to determine the exact cost of the Tenant Improvement Work at this time. Accordingly, Landlord and Tenant agree that Landlord's obligation to pay for the cost of Tenant Improvement Work (inclusive of the cost of preparing plans, obtaining permits and other related costs) shall be limited to **$377,020.00** (i.e. $35.00 per rentable square foot of the Premises) (the **"Maximum Amount"),** and that Tenant shall be responsible for the cost of Tenant Improvement Work, plus any applicable state sales or use tax, if any, to the extent that it exceeds the Maximum Amount. Notwithstanding the foregoing, the calculation of the Maximum Amount shall exclude any increase in the cost of the Tenant Improvement that occurs as a direct result of: (i)

Landlord's failure to timely approve any matter requiring Landlord' s approval, (ii) any failure by Landlord to perform its obligations under this Work Letter or the Lease; or (iii) any other willful misconduct or act or omission of Landlord. If Landlord determines that the cost of the Tenant Improvement Work will, or its likely to, exceed the Maximum Amount, Landlord shall provide Tenant with Landlord's reasonable estimate (the **"Construction Pricing Proposal")** of the cost of the Tenant Improvement Work (inclusive of the cost of preparing plans, obtaining permits and other related costs). Tenant shall provide Landlord with notice approving or disapproving the Construction Pricing Proposal. If Tenant disapproves the Construction Pricing Proposal, Tenant's notice of disapproval shall be accompanied by proposed revisions to the Approved Construction Drawings that Tenant requests in order to resolve its objections to the Construction Pricing Proposal, and Landlord shall respond as required under Section 3.3.2 below. Such procedure shall be repeated as necessary until the Construction Pricing Proposal is approved by Tenant. Upon Tenant's approval of the Construction Pricing Proposal, Landlord may purchase the items set forth in the Construction Pricing Proposal and commence construction relating to such items. Tenant, within 10 days after request by Landlord, shall pay Landlord the amount, if any, by which the approved Construction Pricing Proposal exceeds the Maximum Amount.

3.3.2 If Tenant requests any revision to the Approved Space Plan or, if applicable, the Approved Construction Drawings (a **"Revision"),** Landlord shall provide Tenant with notice approving or reasonably disapproving such Revision, and, if Landlord approves such Revision, Landlord shall have such Revision made and delivered to Tenant, together with notice of any resulting change in the total cost associated with the Tenant Improvement Work, within five (5) business days after the later of Landlord' s receipt of such request or the mutual execution and delivery of this Agreement if such Revision is not material, and within such longer period of time as may be reasonably necessary (but not more than ten
(10) business days after the later of such receipt or such execution and delivery) if such Revision is material, whereupon Tenant, within one business day, shall notify Landlord whether it desires to proceed with such Revision. If Landlord has commenced performance of the Tenant Improvement Work, then, in the absence of such authorization, Landlord shall have the option to continue such performance disregarding such Revision. Tenant shall reimburse Landlord, immediately upon demand, for any increase in the total cost associated with the Tenant Improvement Work that results from any Revision (including the cost of preparing the Revision); but only to the extent that the total cost of the Tenant Improvement Work exceeds the Maximum Amount. It shall be deemed reasonable for Landlord to disapprove any proposed revision to the Approved Space Plan or the Approved Construction Drawings that, in Landlord's reasonable judgment, would fail to comply with law or Landlord's requirements for avoiding aesthetic, engineering or other conflicts with the design and function of the balance of the Building.

3.4 Contractor's Warranties . Tenant waives all claims against Landlord relating to any defects in the Tenant Improvements; provided, however, that Landlord shall obtain a commercially reasonable one-year warranty from Contractor with respect to the performance of the Tenant Improvement Work (the "Warranty"). If , within the period covered by the Warranty, Tenant provides notice to Landlord of any defect in the Tenant Improvements, then Landlord shall, at Landlord's expense, use reasonable efforts to enforce such Warranty directly against the Contractor for Tenant's benefit.

4 COMPLETION.

4.1 Substantial Completion. For purposes of this Agreement, and subject to Section 4.2 below, the Tenant Improvement Work shall be deemed to be **"Substantially Complete"** upon the completion of the Tenant Improvement Work pursuant to the Approved Construction Drawings (as reasonably determined by Landlord), with the exception of any details of construction, mechanical adjustment or any other similar matter the non-completion of which does not materially interfere with Tenant's use of the Premises **("Substantial Completion").**

4.2 Tenant Delay. If the Substantial Completion of the Tenant Improvement Work is delayed (a **"Tenant Delay")** as a result of (a) Tenant's failure to timely approve any matter requiring Tenant's approval; (b) any breach by Tenant of this Work Letter or the Lease; (c) any request by Tenant for a revision to the Approved Construction Drawings (except to the extent such delay results from any failure of Landlord to perform its obligations under Section 3.3 above); (d) Tenant's requirement for materials, components, finishes or improvements that are not available in a commercially reasonable time given the anticipated date of Substantial Completion of the Tenant Improvement Work as set forth in this Agreement; or (e) any other act or omission of Tenant or any of its agents, employees or representatives, then, notwithstanding any contrary provision of this Agreement, and regardless of when the Tenant Improvement Work is actually Substantially Completed, the Tenant Improvement Work shall be deemed to be Substantially Completed on the date on which the Tenant Improvement Work would have been Substantially Completed if no such Tenant Delay had occurred. Notwithstanding the foregoing, Landlord shall not be required to tender possession of the Premises to Tenant before the Tenant

Improvement Work has been Substantially Completed, as determined without giving effect to the preceding sentence.

5. MISCELLANEOUS. Notwithstanding any contrary provision of this Agreement, if Tenant defaults under this Agreement before the Tenant Improvement Work is Substantially Completed, Landlord's obligations under this Work Letter shall be excused until such default is cured and Tenant shall be responsible for any resulting delay in the completion of the Tenant Improvement Work. This Work Letter shall not apply to any space other than the Premises.

EXHIBIT B-1 APPROVED SPACE PLAN

EXHIBITC

NOTICE OF LEASE TERM DATES

_,20

To: ___

Re: Amendment (the **"Amendment"),** dated _____, 20____, to a lease agreement dated _____, 20_____, between_____, a _____ **("Landlord"),** and _____, a _____ **("Tenant"),** concerning Suite_____on the___floor of the building located at___,___California (the **"Substitution Space").**

Lease ID:- - - - - - - - - - - - -
Business Unit Number: - - - - - - - -

Dear - - - - - - - -

In accordance with the Amendment, Tenant accepts possession of the Substitution Space and confirms that (a) the Substitution Effective Date is 20_, and (b) the expiration date of the Lease is___. 20

Please acknowledge the foregoing by signing all three (3) counterparts of this letter in the space provided below and returning two (2) fully executed counterparts to my attention. Please note that, under Section 2.1.B of the Amendment, Tenant is required to execute and return (or reasonably object in writing to) this letter within five (5) days after receiving it.

"Landlord":

By:___ Name:___ Title: ___

Agreed and Accepted as of___,
20_.

"Tenant":

By:___ Name:___ Title: ___

EXHIBITB

COPY OF LEASE OF PREMISES

See attached.

EXHIBIT D

January 17th, 2016 **LANDLORD'S WAIVER AND CONSENT**

THIS LANDLORD'S WAIVER AND CONSENT **("Waiver and Consent")** is made and entered into as of **January 19th, 2016,** by and among BRE/COH FL LL(:, a Delaware limited liability company **("Landlord")** and Deerfield Private Design Fund III, L.P. **("Lender").**

A. Landlord is the owner of the real property commonly known as Celebration Office Center II with an address of 1170 Celebration Boulevard, Celebration, Florida (the "Building") and legally (or otherwise) described on Exhibit A attached hereto and in the Lease (as defined below).

B. Landlord has entered into that certain Lease dated November 3, 2014 (as amended, restated, supplemented or otherwise modified from time to time, the **"Lease"),** with KemPharm, Inc. **("Tenant")** pursuant to which Tenant has acquired a leasehold interest in a portion of the Building containing approximately **10,772** rentable square feet described as Suites No. 103 & 104 on the first (151 floor of the Building (the **"Premises").** Notwithstanding the foregoing, Landlord and Lender acknowledge that: (i) as of the date hereof, the Premises under the Lease consists of approximately **4,639** rentable square feet (the **"Existing Premises")** described as Suites 102 B and 103 on the first floor of the building commonly known as **Celebration Office Center** II located at 1170 Celebration Boulevard, Celebration, Florida; and (ii) upon completion of certain improvements to the Premises, Tenant will relocate from the Existing Premises to the Premises.

C. Tenant and certain affiliates of Tenant have previously entered into or, on or about the date hereof, are entering into certain financing transactions with Lender (the **"Financing Agreements"),** and to secure such financing, Tenant and its affiliates have granted to Lender security interests in and liens upon certain tangible property of Tenant and its affiliates, including, without limitation, all of Tenant's and its affiliates' inventory, goods, machinery, equipment, furniture and fixtures, together with all additions, substitutions, replacements and improvements to, and proceeds of, the foregoing (collectively, the **"Collateral").** For the avoidance of doubt, the parties hereto agree that the term "Collateral" shall not include any tenant improvements located on or affixed to the Premises (collectively, the **"Landlord Property"),** which Landlord Property is, in accordance with the Lease, the property of and owned by Landlord; provided that to the extent that Landlord conveys the Landlord Property to Tenant at the end of the lease term or at any other time, from and after the time of such conveyance, such conveyed Landlord Property shall be deemed to be "Collateral" subject to this Waiver and Consent.

NOW, THEREFORE, in consideration of any financial accommodation extended by Lender to Tenant and its affiliates at any time, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Landlord acknowledges that (a) a true and correct copy of the Lease and all amendments thereto as in effect as of the date hereof is attached hereto as Exhibit B, (b) the Lease is in full force and effect, and (c) Landlord is not aware of any existing default or breach under the Lease.

2. Landlord agrees to use reasonable efforts to provide Lender with (a) a copy of any cancellation, amendment, consent or waiver under the Lease, and (b) written notice of any default or breach by Tenant or claimed default or breach under the Lease (a **"Default Notice")** at the same time as it sends such notice to Tenant; provided that Landlord shall not be liable to Lender in any form or manner as a result of Landlord's failure to provide Lender with a Default Notice. No action by Lender pursuant to this Waiver and Consent shall constitute or be deemed to be an assumption by Lender of any

obligation under the Lease, and except as provided in paragraphs 6 and 7 below, Lender shall not have any obligation to Landlord.

3. Tenant has not granted Landlord any lien or security interest in any of the Collateral. Landlord acknowledges the validity of Lenders' lien on the Collateral and, until such time as all obligations of Tenant and its affiliates to all Lenders are indefeasibly paid in full in cash and the commitments of the Lenders to extend credit have terminated, Landlord waives any interest in the Collateral and agrees not to distrain or levy upon any Collateral or to assert any landlord lien, right of distraint or other claim against the Collateral for any reason.

4. Landlord agrees that the Collateral may be stored, utilized and/or installed at the Premises and shall not be deemed a fixture or part of the real estate but shall at all times be considered personal property, whether or not any Collateral becomes so related to the real estate that an interest therein would otherwise arise under applicable law.

5. Prior to termination of the Lease, Lender and its representatives and invitees may enter upon the Premises at any time or times without charge and without any interference by Landlord to, among other things, inspect, remove, realize upon or otherwise deal with any or all of the Collateral. Notwithstanding the forgoing: (i) any such entry shall be subject to Landlord's reasonably rules and regulations for the performance of work in the Building, including, without limitation, evidence of insurance from all parties entering the Building; and (ii) in no event shall the Premises be used for conducting any public or private sale.

6. In addition to the preceding paragraph, notwithstanding any cancellation or termination of the Lease, action to evict Tenant or repossession of the Premises, Landlord grants Lender and its representatives and invitees the right to possess, occupy, remain on and use the Premises for purposes of removing the Collateral from the Premises; provided, that (a) such period of occupation (the **"Disposition Period")** shall not exceed the earlier to occur of: (i) 30 days from the date on which Landlord provides notice in writing to Lender that Landlord has acquired possession of the Premises from Tenant through cancellation or termination of the Lease, eviction or otherwise, or (ii) 30 days from the date that Landlord notifies Lender in writing that Landlord is required to provide possession of the Premises to, or start construction for, a third party tenant in connection with any reletting of the Premises by Landlord, provided if Landlord is required to provide possession of the Premises to, or start construction for, a third party tenant prior to the end of the Disposition Period, Landlord shall have the right to move the Collateral from the Premises to other space in the Building, in which case Lender shall have the right to remove the Collateral from such other space in accordance with the terms hereof, (b) for the actual period of occupancy by Lender, and only to the extent that Landlord is not otherwise receiving rental payments under the Lease, Lender will pay to Landlord the basic rent due under the Lease pro-rated on a per diem basis determined on a 30-day month, and (c) such amounts paid by Lender to Landlord shall exclude any rent adjustments, indemnity payments or similar amounts payable under the Lease for default, holdover status or other similar charges. During any Disposition Period, (i) the Lender shall use commercially reasonable efforts to complete the removal of the Collateral at the earliest possible date, and (ii) the Lender shall make the Premises available for inspection by Landlord and prospective tenants and shall cooperate in Landlord's reasonable efforts to re-lease the Premises.

7. Upon Lender's removal of any Collateral from the Premises, such Collateral shall be free and clear of any and all claims of Landlord thereto, whether in law, contract or equity, and Landlord hereby disclaims and relinquishes all of the foregoing upon any such removal. Lender shall promptly reimburse Landlord for the cost of repairing any physical damage to the Premises actually caused by the

removal of Collateral by or through Lender (ordinary wear and tear excluded). Lender shall not be liable for any diminution in value of the Premises caused by the absence of Collateral actually removed or by any necessity of replacing the Collateral, and Lender shall not have any duty or obligation to remove or dispose of any Collateral or any other property left on the Premises by Tenant.

8. Any transfer of any capital stock or other equity securities of Tenant due to the exercise of remedies by Lender shall not create a default under, or require Landlord's consent under, any applicable provisions of the Lease, if any, and shall be fully effective notwithstanding any provision to the contrary contained in the Lease.

9. Lender may, without any notice to or consent from Landlord and without affecting the validity of this Waiver and Consent, extend, amend or in any way modify the terms of the Financing Agreements to which they are a party. This Waiver and Consent shall continue in force until all of Tenant's obligations and liabilities to Lender under all of the Financing Agreements are paid and satisfied in full, and all obligations of Lender under all of the Financing Agreements have been terminated.

10. All notices and other communications under this Waiver and Consent shall be in writing and shall be deemed to have been given three days after deposit in the mail, first class mail, postage prepaid, or one day after being entrusted to a reputable commercial overnight delivery service, or when sent out by facsimile transmission addressed to the party to which such notice is directed at its address determined as provided in this paragraph 10:

If to Lender at: c/o Deerfield Management Company, L.P.
780 Third Avenue, 37th Floor New York, New York 10017
Attn: David Clark

If to Landlord at: BRE/COH FL LLC c/o Equity Office
2311 Cedar Springs, Suite 300
Dallas, TX 75201 Attn: Rob Shults

11. This Waiver and Consent may be executed in any number of several counterparts, which shall constitute an original and collectively and separately constitute a single instrument or agreement. Delivery of an executed counterpart of a signature page to this Waiver and Consent by facsimile or electronic transmission shall be effective as delivery of a manually executed counterpart thereof. This Waiver and Consent shall be governed and controlled by, and interpreted under, the laws of the State of Florida, and shall inure to the benefit of Lender and its successors and assigns and shall be binding upon Landlord and its successors and assigns (including any transferees of the Premises). Landlord agrees and consents to the filing of this document for recording in the land records of the county in which the Premises is located.

12. The agreements contained herein may not be modified or terminated orally.

[Signature pages follow.]

IN WITNESS WHEREOF, this Landlord's Waiver and Consent is entered into as of the date first set forth above.

LANDLORD: **BRE/COH FL LLC, a Delaware limited liability company**

By: /s/ Mark W. Smith

Name: Mark W. Smith

Title: Managing Director

LENDER: **DEERFIELD PRIVATE DESIGN FUND III, L.P.**

By: Deerfield Mgmt III, L.P., General Partner

By: J.E. Flynn Capital III, LLC, General Partner

By: /s/ David J. Clark

Name: David J. Clark

Title: Authorized Signatory

THIRD AMENDMENT

THIS THIRD AMENDMENT (this "**Third Amendment") is** made and entered into as of July 15th 2016, by and between **BRE/COH FL LLC, a Delaware limited liability company ("Landlord")** and **KEMPHARM, INC.**, **a Delaware corporation ("Tenant").**

RECITALS

A. Landlord and Tenant are parties to that certain lease dated November 3, 2014 (the **"Original Lease"),** as previously amended by that certain Confirmation Letter dated November 10, 2014 (re: the Original Lease), that certain First Amendment dated April 21, 2015 (the **"First Amendment"),** that certain Notice of Lease Term Dates dated June 12, 2015 (re: First Amendment) and that certain Second Amendment dated January 8, 2016 (the **"Second Amendment")** (as amended, the **"Lease").** Pursuant to the Lease, Landlord has leased to Tenant space currently containing approximately **4,639** rentable square feet (the **"Existing Premises")** described as Suite Nos. 102B and 103 on the first (1^{st}) floor of the building commonly known as **Celebration Office Center II** located at 1170 Celebration Boulevard, Celebration, Florida, which premises are scheduled to be relocated to the Substitution Space (defined in the Second Amendment) in the building commonly known as **Celebration Office Center I** located at 1180 Celebration Boulevard, Celebration, Florida.

B. The parties wish to expand the Premises (defined in the Lease) to include additional space, containing approximately **6,302** rentable square feet described as Suite No. 108 on the first (1st) floor of the building commonly known as **Celebration Office Center** I located at 1180 Celebration Boulevard, Celebration, Florida and shown on **Exhibit A** attached hereto (the "**Suite 108 Expansion Space"),** on the following terms and conditions.

NOW, THEREFORE, in consideration of the above recitals which by this reference are incorporated herein, the mutual covenants and conditions contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant agree as follows:

I. **Suite 108 Expansion.**

1.1. Effect of Suite 108 Expansion. Effective as of the Suite 108 Expansion Effective Date (defined in Section 1.2 below), the Premises shall be the Substitution Space (as defined in Recital C of the Second Amendment) and the Suite 108 Expansion Space, and, from and after the Suite 108 Expansion Effective Date, the Substitution Space and the Suite 108 Expansion Space shall collectively be deemed the **"Premises"** (provided, however, that if the Substitution Effective Date (as defined in the Second Amendment) has not occurred on or before the Suite 108 Expansion Effective Date, then during the period commencing on the Suite 108 Expansion Effective Date and ending on the day preceding the Substitution Effective Date, the Existing Premises and the Suite 108 Expansion Space shall collectively be deemed the **"Premises",** and on and after the Substitution Effective Date the Substitution Space and the Suite 108 Expansion Space shall collectively be deemed the **"Premises").** The term of the Lease for the Suite 108 Expansion Space (the **"Suite 108 Expansion Term")** shall commence on the Suite 108 Expansion Effective Date and, unless sooner terminated in accordance with the Lease, end on the last day of the 108th full calendar month beginning on or after the Suite 108 Expansion Effective Date (the **"Suite 108 Expansion Space Expiration Date").** During the Suite 108 Expansion Term, the Suite 108 Expansion Space shall be subject to all the terms and conditions of the Lease except as provided herein. Except as may be expressly provided herein, (a) Tenant shall not be entitled to receive, with respect to the Suite 108 Expansion Space, any allowance, free rent or other financial concession granted with respect to the Existing Premises or the Substitution Space, and (b) no representation or warranty made by Landlord with respect to the Existing Premises or the Substitution Space shall apply to the Suite 108 Expansion Space.

1.2. Suite 108 Expansion Effective Date. As used herein, **"Suite 108 Expansion Effective Date"** means the earlier of (i) the first date on which Tenant conducts business in the Suite 108 Expansion Space pursuant to this Third Amendment, or (ii) the date on which the Tenant Improvement Work (defined in **Exhibit B** attached hereto) is Substantially Complete (defined in **Exhibit B** attached hereto), which is anticipated to be twelve (12) weeks after the full execution and delivery of this Amendment (the **"Target Suite 108**

Expansion Effective Date"). The adjustment of the Suite l08 Expansion Effective Date and, accordingly, the postponement of Tenant's obligation to pay rent for the Suite 108 Expansion Space shall be Tenant' s sole remedy if the Tenant Improvement Work is not Substantially Complete on the Target Suite l08 Expansion Effective Date.

1.3. **Confirmation Letter.** At any time after the Suite l 08 Expansion Effective Date, Landlord may deliver to Tenant a notice substantially in the form of **Exhibit C** attached hereto, as a confirmation of the information set forth therein. Tenant shall execute and return (or, by written notice to Landlord, reasonably object to) such notice within five (5) days after receiving it.

1.4. **Lease Terms Not-Coterminous.** For the avoidance of doubt, it is acknowledged and agreed that (a) the term of the Lease for the Suite 108 Expansion Space is not coterminous with the term of the Lease for the Substitution Space; and (b) upon the expiration of either such term before the other such term, Sections 8 and 16 and all other provisions of the Original Lease that would apply to the entire Premises if the Term were expiring with respect to the entire Premises shall apply to the space for which the term of the Lease is expiring as if the term of the Lease were expiring with respect to the entire Premises.

2. **Base Rent.** With respect to the Suite 108 Expansion Space during the Suite 108 Expansion Term, the schedule of Base Rent shall be as follows:

Period During Suite 108 Expansion Term	Annual Rate Per Square Foot (rounded to the nearest 100th of a dollar)	Monthly Base Rent*
Suite 108 Expansion Effective Date through last day of 12th full calendar month of Suite 108 Expansion Term	$23.75	$12,472.71
13th through 24th full calendar months of Suite 108 Expansion Term	$24.34	$12,782.56
25th through 36th full calendar months of Suite 108 Expansion Term	$24.95	$13,102.91
37th through 48th full calendar months of Suite 108 Expansion Term	$25.58	$13,433.76
49th through 60th full calendar months of Suite 108 Expansion Term	$26.22	$13,769.87
61st through 72nd full calendar months of Suite 108 Expansion Term	$26.87	$14, I I 1.23
73rd through 84th full calendar months of Suite 108 Expansion Term	$27.54	$14,463.09
85th through 96th full calendar months of Suite 108 Expansion Term	$28.23	$14,825.46
97th full calendar month of Suite 108 Expansion Term through last day of Suite 108 Expansion Term	$28.94	$15,198.32

*plus, applicable State of Florida sales tax.

All such Base Rent shall be payable by Tenant in accordance with the terms of the Lease.

Notwithstanding the foregoing, Base Rent for the Suite 108 Expansion Space shall be abated, in the amount of **$12,472.71** per month , for the first six (6) full calendar months of the Suite 108 Expansion Term; provided, however, that if a Default (as defined in Section 19 of the Original Lease) exists when any such abatement would otherwise apply, such abatement shall be deferred until the date, if any, on which such Default is cured .

3. **Additional** Security Deposit**.** Upon Tenant's execution, hereof, Tenant shall pay Landlord the sum of **$48,273.00,** which shall be added to and become part of the Security Deposit held by Landlord pursuant to Section 21.1 of the Original Lease. Accordingly, simultaneously with the execution hereof, the Security Deposit is hereby increased from $82,500.00 to **$130,773.00.** Effective as of the date hereof, the second (italicized) paragraph of Section 4 of the Second Amendment is deleted in its entirety and replaced with the following:

"Subject to the remaining terms of this Section 21.1. and provided that, during the 12-month period immediately preceding the effective date of any reduction of the Security Deposit, Tenant has timely paid all Rent and no default has occurred under this Lease beyond any applicable cure period (the ***"Security Reduction Conditions"),*** *Tenant shall have the right to reduce the amount of the Security Deposit so that the new Security Deposit amount will be: (i) $98,079.75*
effective as of the first day of the 30h' fall calendar month of the Suite 108 Expansion Term; (ii)

$65,386.50 effective as of the first day of the 4n2d fall calendar month of the Suite 108 Expansion Term; and (iii) $32,693.25 effective as of the first day of the 54th fall calendar month of the Suite 108 Expansion Term. Notwithstanding anything to the contrary contained herein, if Tenant has
been in Default under this Lease at any time prior to the effective date of any reduction of the Security Deposit and Tenant has failed to cure such Default within any applicable cure period, then Tenant shall have no right to reduce the amount of the Security Deposit as described herein. If Tenant is entitled to a reduction in the Security Deposit, Tenant shall provide Landlord with

written notice requesting that the Security Deposit be reduced as provided above (the ***"Security Reduction Notice").*** *If Tenant provides Landlord with a Security Reduction Notice, and Tenant*
is entitled to reduce the Security Deposit as provided herein, Landlord shall refund the applicable portion of the Security Deposit to Tenant within 45 days after the later to occur of (a) Landlord's receipt of the Security Reduction Notice, or (b) the date upon which Tenant is entitled to a reduction in the Security Deposit as provided above. "

4. **Tenant's Share.** With respect to the Suite 108 Expansion Space during the Suite 108 Expansion Term, Tenant's Share shall be **7.7436%.**

5. **Expenses and Taxes** for Suite 108 Expansion Space During Suite 108 Expansion Term**.** With respect to the Suite 108 Expansion Space during the Suite 108 Expansion Term, Tenant shall pay for Tenant's Share of Expenses and Taxes in accordance with the terms of the Lease (including the second sentence of Section 6 of the Second Amendment); provided, however, that, with respect to the Suite 108 Expansion Space during the Suite 108 Expansion Term, the Base Year for Expenses and Taxes shall be **2016.**

6. Improvements to Suite 108 Expansion Space.

6.1. **Configuration and Condition of Suite 108 Expansion Space.** Tenant acknowledges that it has inspected the Suite 108 Expansion Space and agrees to accept it in its existing configuration and condition (or in such other configuration and condition as any existing tenant of the Suite 108 Expansion Space may cause to exist in accordance with its lease), without any representation by Landlord regarding its configuration or condition and without any obligation on the part of Landlord to perform or pay for any alteration or improvement, except as may be otherwise expressly provided in this Third Amendment.

6.2. **Responsibility for Improvements to Suite 108 Expansion Space.** Landlord shall perform improvements to the Suite 108 Expansion Space in accordance with **Exhibit B** attached hereto.

7. **Other Pertinent Provisions.** Landlord and Tenant agree that, effective as of the date of this Third Amendment (unless different effective date(s) is/are specifically referenced in this Section), the Lease shall be amended in the following additional respects:

7.1. **Parking.** In addition to the parking rights previously granted to Tenant under the terms of the Lease, with respect to the Suite 108 Expansion Space during the Suite 108 Expansion Term, Tenant shall have the right, but not the obligation, to rent from Landlord on a monthly basis throughout the Suite 108 Expansion Term, **up to 30 additional unreserved parking passes** (the **"Suite 108 Parking Spaces")** located on the surface parking lot servicing the Project and subject to the terms and conditions set forth in Section 24 of the Original Lease, as amended from time to time. During the Suite 108 Expansion Term the Suite 108 Parking Spaces shall be free of charge. During any extension of the Suite 108

Expansion Term, Tenant shall pay Landlord the prevailing monthly charges established from time to time for such Suite I 08 Parking Spaces, payable in advance, with Tenant's payment of monthly Base Rent.

7.2. Notice Addresses. Any notice required under the Lease to be sent to Landlord shall be sent to the following addresses:

BRE/COH FL LLC

c/o Equity Office

2311 Cedar Springs, Suite 300
Dallas, TX 75201 Attn: Rob Shults

with copies to:

BRE/COH FL LLC
c/o Equity Office
222 South Riverside Plaza Suite 2000
Chicago, IL 60606

Attn: Managing Counsel

Equity Office
222 South Riverside Plaza Suite 2000
Chicago, IL 60606

Attn: Lease Administration

7.3. Above-Standard Use. The parties acknowledge that, as of the date first written above, Landlord's charge for HVAC service outside Building HVAC Hours is **$40.00** per hour per zone, subject to change from time to time.

7.4. Extension Options for the Suite 108 Expansion Space.

7.4.1. Grant of Option: Conditions. Subject to the terms herein, Tenant shall have the right to extend the Suite 108 Expansion Term (the **"First Extension Option")** for one additional period of 5 years commencing on the day following the Suite I 08 Expansion Space Expiration Date and ending on the 5th anniversary of the Suite 108 Expansion Space Expiration Date (the **"First Extension Term"),** and, if Tenant properly exercised the First Extension Option and the Suite I 08 Expansion Term was extended as a result thereof, Tenant shall also have the right to extend the Suite I 08 Expansion Term (the **"Second Extension Option")** for one additional period of 5 years commencing on the date following the last day of the First Extension Term and ending on the 5th anniversary of the last day of the First Extension Term (the **"Second Extension Term").** Throughout the remainder of this provision, unless specifically provided otherwise, the First Extension Option and Second Extension Option are each referred to as an **"Extension Option",** and the First Extension Term and the Second Extension Term are each referred to as an **"Extension Term".**

It is agreed that Tenant may exercise an Extension Option only if:

A. Not less than 9 and not more than 12 full calendar months before the applicable expiration date, Tenant delivers written notice to Landlord (the **"Extension Notice")** electing to exercise the Extension Option and stating Tenant's estimate of the Prevailing Market (defined in Section 7.4.5 below) rate for the Extension Term;

B. Tenant is not in Default under the Lease beyond any applicable cure period when Tenant delivers the Extension Notice;

C. No part of the Suite 108 Expansion Space is sublet (other than to an

Affiliate of Tenant) when Tenant delivers the Extension Notice; and

D. The Lease has not been assigned (other than pursuant to a Permitted Transfer) before Tenant delivers the Extension Notice.

7.4.2. Terms Applicable to Extension Term.

A. During the Extension Term, (a) the initial Base Rent rate per rentable square foot shall be equal to the Prevailing Market rate per rentable square foot as of the commencement of the Extension Term and shall be subject to annual increases in accordance with the determination of Prevailing Market; and (b) Base Rent shall be payable in monthly installments in accordance with the terms and conditions of the Lease. Except as otherwise expressly provided in this Amendment, the terms and conditions set forth in the Lease, as amended from time to time, shall apply during the Extension Term.

B. During the Extension Term Tenant shall pay Tenant's Share of Expenses and Taxes for the Suite 108 Expansion Space in accordance with the Lease. During the Extension Term the Base Year for Expenses and Taxes shall be the calendar year in which the Extension Term commences.

C. Any free rent, construction allowance or similar concession may be part of the negotiations pertinent to determining the Prevailing Market with respect to the Extension Term.

7.4.3. Procedure for Determining Prevailing Market.

A. Initial Procedure. Within 30 days after receiving the Extension Notice, Landlord shall give Tenant either (i) written notice **("Landlord's Binding Notice")** accepting Tenant's estimate of the Prevailing Market rate for the Extension Term stated in the Extension Notice, or (ii) written notice **("Landlord's Rejection Notice")** rejecting such estimate and stating Landlord's estimate of the Prevailing Market rate for the Extension Term. If Landlord gives Tenant a Landlord's Rejection Notice, Tenant, within 15 days thereafter, shall give Landlord either (i) written notice **("Tenant's Binding Notice")** accepting Landlord's estimate of the Prevailing Market rate for the Extension Term stated in such Landlord's Rejection Notice, or (ii) written notice **("Tenant's Rejection Notice")** rejecting such estimate. If Tenant gives Landlord a Tenant's Rejection Notice, Landlord and Tenant shall work together in good faith to agree in writing upon the Prevailing Market rate and terms for the Extension Term. If, within 30 days after delivery of a Tenant's Rejection Notice, the parties fail to agree in writing upon the Prevailing Market rate and terms, the provisions of Section 7.4.3.B below shall apply.

B. Dispute Resolution Procedure.

1. If, within 30 days after delivery of a Tenant's Rejection Notice, the parties fail to agree in writing upon the Prevailing Market rate and terms, Landlord and Tenant, within five (5) days thereafter, shall each simultaneously submit to the other, in a sealed envelope, its good faith estimate of the Prevailing Market rate and terms for the Extension Term (collectively, the **"Estimates").** If the higher of such Estimates is not more than 105% of the lower of such Estimates, the Prevailing Market rate shall be deemed to be the average of the two Estimates. Otherwise, within seven (7) days after the exchange of Estimates, Landlord and Tenant shall each select an appraiser to determine which of the two Estimates most closely reflects the Prevailing Market rate and terms for the Extension Term. Each appraiser so selected shall be certified as an MAI appraiser or as

acknowledges that any assistance rendered by any agent or employee of any affiliate of Landlord in connection with this Third Amendment has been made as an accommodation to Tenant solely in furtherance of consummating the transaction on behalf of Landlord, and not as agent for Tenant.

IN WITNESS WHEREOF, Landlord and Tenant have duly executed this Third Amendment as of the day and year first above written.

WITNESSES:

/s/ Michelle Boyle
Print Name: Michelle Boyle

/s/ Briana Kan
Print Name: Briana Kan

LANDLORD:

BRE/COH FL LLC, a Delaware limited liability company

/s/ Mark W. Smith
Name: Mark W. Smith
Title: Managing Director

WITNESSES:

/s/ Susan Smoker
Print Name: Susan Smoker

/s/ Katy Powell
Print Name: KatyPowell

TENANT:

KEMPHARM, INC, a Delaware corporation

/s/ R. LaDuane Clifton
Name: R. LaDuane Clifton
Title: Chief Financial Officer

EXHIBIT A

OUTLINE AND LOCATION OF SUITE 108 EXPANSION SPACE

EXHIBITB

WORK LETTER

As used in this **Exhibit B** (this **"Work Letter"),** the following terms shall have the following meanings: **"Agreement"** means the Amendment of which this Work Letter is a part. **"Premises"** shall mean the Suite 108 Expansion Space. **"Tenant Improvements"** means all improvements to be constructed in the Premises (i.e., the Suite 108 Expansion Space) pursuant to this Work Letter. **"Tenant Improvement Work"** means the construction of the Tenant Improvements, together with any related work (including demolition) that is necessary to construct the Tenant Improvements.

1 ALLOWANCE.

1.1 Allowance. Tenant shall be entitled to a one-time tenant improvement allowance (the **"Allowance")** in the amount of $189,060.00 (i.e., $30.00 per rentable square foot of the Premises) to be applied toward the Allowance Items (defined in Section 1.2 below). Notwithstanding the foregoing, Tenant, by notice to Landlord, may apply all or any portion of the Allowance to amounts due and owing to Landlord pursuant to Section 3.3 of **Exhibit B** to the Second Amendment as a result of the cost of the "Tenant Improvement Work" under **Exhibit B** to the Second Amendment exceeding the "Maximum Amount" thereunder, in which event the Allowance available to Tenant hereunder shall be reduced by the amount so applied. Tenant shall be responsible for all costs associated with the Tenant Improvement Work, including the costs of the Allowance Items, to the extent such costs exceed the lesser of (a) the Allowance, or (b) the aggregate amount that Landlord is required to disburse for such purpose pursuant to this Work Letter. Notwithstanding any contrary provision of this Agreement, if, for any reason other than a breach by Landlord of its obligations under this Agreement, the entire Allowance is not used within twelve (12) months following the Suite 108 Expansion Effective Date, the unused amount shall revert to Landlord and Tenant shall have no further rights with respect thereto.

1.2 Disbursement. Except as otherwise provided in this Work Letter, the Allowance shall be disbursed by Landlord only for the following items (the **"Allowance Items"):** (a) the fees of the Architect (defined in Section 2.1 below); (b) the cost of preparing the Engineering Drawings (defined in Section 3.2.1 below); (c) plan-check, permit and license fees relating to performance of the Tenant Improvement Work; (d) the cost of performing the Tenant Improvement Work, including after hours charges, testing and inspection costs, freight elevator usage, hoisting and trash removal costs, and contractors' fees and general conditions; (e) the cost of any change to the base, shell or core of the Premises or Building required by the Approved Plans (defined in Section 2.7 below) (including if such change is due to the fact that such work is prepared on an unoccupied basis), including all direct architectural and/or engineering fees and expenses incurred in connection therewith; (t) the cost of any change to the Approved Plans or the Tenant Improvement Work required by law; (g) [intentionally omitted]); (h) sales and use taxes; and (i) all other costs expended by Landlord in connection with the performance of the Tenant Improvement Work.

2 ARCHITECTURAL PLANS; PRICING.

2.1 Selection of Architect. Landlord shall retain the architect/space planner of Landlord's choice (the **"Architect")** to prepare the Architectural Drawings (defined in Section 2.5 below).

2.2 [Intentionally Omitted.]

2.3 Approved Space Plan. Landlord and Tenant acknowledge that they have approved the scope of work described in the space plan for the Premises prepared by C4 Architecture and attached hereto as **Exhibit B-1,** excluding any provision thereof that is inconsistent with any provision of this Agreement (the **"Approved Space Plan").**

2.4 Additional Programming Information. Tenant shall deliver to Landlord, in writing, all information (including all interior and special finishes) that, when combined with the Approved Space Plan, will be sufficient to complete the Architectural Drawings, together with all information (including all electrical requirements, telephone requirements, special HVAC requirements, and plumbing requirements) that, when combined with the Approved Space Plan, will be sufficient to complete the Engineering Drawings (collectively, the **"Additional Programming Information").** The Additional Programming Information shall be (a) consistent with the Approved Space Plan, (b) consistent with Landlord's requirements for avoiding aesthetic, engineering or other conflicts with the design and function of the balance of the Building (collectively, the **"Landlord Requirements"),** and (c) otherwise subject to Landlord's reasonable approval. Landlord shall provide Tenant with notice approving or reasonably disapproving the Additional Programming Information within five (5) business days after the

later of Landlord's receipt thereof or the mutual execution and delivery of this Agreement. If Landlord disapproves the Additional Programming Information, Landlord's notice of disapproval shall describe with reasonable specificity the basis for such disapproval and Tenant shall modify the Additional Programming Information and resubmit it for Landlord's approval. Such procedure shall be repeated as necessary until Landlord has approved the Additional Programming Information. Such approved Additional Programming Information shall be referred to herein as the **"Approved Additional Programming Information."** If requested by Tenant, Landlord, in its sole and absolute discretion, may assist Tenant, or cause the Architect and/or other contractors or consultants of Landlord to assist Tenant, in preparing all or a portion of the Additional Programming Information; provided, however, that, whether or not the Additional Programming Information is prepared with such assistance, Tenant shall be solely responsible for the timely preparation and delivery of the Additional Programming Information and for all elements thereof and, subject to Section I above, all costs relating thereto.

2.5 Architectural Drawings. After approving the Additional Programming Information, Landlord shall cause the Architect to prepare and deliver to Tenant the final architectural (and, if applicable, structural) working drawings for the Tenant Improvement Work that are in a form that (a) when combined with any programming information that is contained in the Approved Space Plan or the Approved Additional Programming Information but not expressly incorporated into such working drawings, will be sufficient to enable the Contractor (defined in Section 3.1 below) and its subcontractors to bid on the Tenant Improvement Work, and (b) when combined with any Engineering Drawings that satisfy the Engineering Requirements (defined in Section 3.2.1 below), will be sufficient to obtain the Permits (defined in Section 3.3 below) (the **"Architectural Drawings").** The Architectural Drawings shall conform to the Approved Space Plan and the Approved Additional Programming Information. The Architect's preparation and delivery of the Architectural Drawings shall occur within 15 business days after the later of Landlord's approval of the Additional Programming Information or the mutual execution and delivery of this Agreement. Tenant shall approve or disapprove the Architectural Drawings by notice to Landlord. If Tenant disapproves the Architectural Drawings, Tenant's notice of disapproval shall specify any revisions Tenant desires in the Architectural Drawings. After receiving such notice of disapproval, Landlord shall cause the Architect to revise the Architectural Drawings and resubmit them to Tenant, taking into account the reasons for Tenant's disapproval; provided, however, that Landlord shall not be required to cause the Architect to make any revision to the Architectural Drawings that conflicts with the Landlord Requirements or is otherwise reasonably disapproved by Landlord. Such revision and resubmission shall occur within five (5) business days after the later of Landlord's receipt of Tenant's notice of disapproval or the mutual execution and delivery of this Agreement if such revision is not material, and within such longer period of time as may be reasonably necessary (but not more than 15 business days after the later of such receipt or such mutual execution and delivery) if such revision is material. Such procedure shall be repeated as necessary until Tenant has approved the Architectural Drawings. Such approved Architectural Drawings shall be referred to herein as the **"Approved Architectural Drawings."**

2.6 Construction Pricing.

2.6.1 Construction Pricing Proposal. Within 10 business days after the Architectural Drawings are approved by Landlord and Tenant, Landlord shall provide Tenant with Landlord's reasonable estimate (the **"Construction Pricing Proposal")** of the cost of all Allowance Items to be incurred by Tenant in connection with the performance of the Tenant Improvement Work pursuant to the Approved Architectural Drawings and the Approved Additional Programming Information. Tenant shall provide Landlord with notice approving or disapproving the Construction Pricing Proposal. If Tenant disapproves the Construction Pricing Proposal, Tenant's notice of disapproval shall be accompanied by proposed revisions to the Approved Architectural Drawings and/or the Approved Additional Programming Information that Tenant requests in order to resolve its objections to the Construction Pricing Proposal, and Landlord shall respond as required under Section 2.7 below. Such procedure shall be repeated as necessary until the Construction Pricing Proposal is approved by Tenant. Upon Tenant's approval of the Construction Pricing Proposal, Landlord may purchase the items set forth in the Construction Pricing Proposal and begin construction relating to such items.

2.6.2 Over-Allowance Amount. If the Construction Pricing Proposal exceeds the Allowance, then Tenant, concurrently with its delivery to Landlord of its approval of the Construction Pricing Proposal, shall deliver to Landlord cash in the amount of such excess (the **"Over-Allowance Amount").** Any Over-Allowance Amount shall be disbursed by Landlord before the Allowance and pursuant to the same procedure as the Allowance. If, after the Construction Pricing Proposal is approved by Tenant, (a) any revision is made to the Approved Additional Programming Information or the Approved Architectural Drawings, or Tenant disapproves any Engineering Drawings that satisfy the Engineering Requirements, or the Tenant Improvement Work is otherwise changed, in each case in a way that increases the Construction Pricing Proposal, or (b) the Construction Pricing Proposal is otherwise increased to reflect the actual cost of all Allowance Items to be incurred by Tenant in connection with the

performance of the Tenant Improvement Work pursuant to the terms hereof, then Tenant shall deliver any resulting Over-Allowance Amount (or any resulting increase in the Over-Allowance Amount) to Landlord immediately upon Landlord's request.

2.7 Revisions. If Tenant requests any revision to the Approved Space Plan, the Approved Additional Programming Information, the Approved Architectural Drawings, or the Approved Engineering Drawings (defined in Section 3.2 below) (collectively, the **"Approved Plans"),** Landlord shall provide Tenant with notice approving or reasonably disapproving such revision, and, if Landlord approves such revision, Landlord shall deliver to Tenant notice of any resulting change in the most recent Construction Pricing Proposal, if any (together with a copy of the revision itself, except in the case of the Approved Additional Programming Information), within five (5) (or, in the case of the Approved Architectural Drawings or the Approved Engineering Drawings, 15) business days after the later of Landlord's receipt of such request or the mutual execution and delivery of this Agreement, whereupon Tenant, within one (1) business day, shall notify Landlord whether it desires to proceed with such revision. If Landlord has begun performing the Tenant Improvement Work, then, in the absence of such authorization, Landlord shall have the option to continue such performance disregarding such revision. Without limitation, it shall be deemed reasonable for Landlord to disapprove any such proposed revision that conflicts with the Landlord Requirements. Landlord shall not revise the Approved Plans without Tenant's consent, which shall not be unreasonably withheld or conditioned. Tenant shall approve, or reasonably disapprove (and state, with reasonable specificity, its reasons for disapproving), any revision to the Approved Plans within two (2) business days after receiving Landlord's request for approval thereof. For purposes hereof, any change order affecting the Approved Plans shall be deemed a revision thereto.

2.8 Tenant's Approval Deadline. Tenant shall approve the Construction Pricing Proposal pursuant to Section 2.6.l above on or before Tenant's Approval Deadline (defined below). As used in this Work Letter, **"Tenant's Approval Deadline"** means the date occurring one (1) week after the mutual execution and delivery of this Agreement; provided, however, that Tenant's Approval Deadline shall be extended by one (1) day for each day, if any, by which Tenant's approval of the Construction Pricing Proposal pursuant to Section 2.6.1 above is delayed by any failure of Landlord to perform its obligations under this Section 2.

3 CONSTRUCTION.

3.1 Contractor. Landlord shall retain a contractor of its choice (the **"Contractor")** to perform the Tenant Improvement Work. In addition, Landlord may select and/or approve of any subcontractors, mechanics and materialmen used in connection with the performance of the Tenant Improvement Work.

3.2 Engineering Drawings.

3.2.1 Preparation. Landlord shall cause the engineering working drawings for the mechanical, electrical, plumbing, fire-alarm and fire sprinkler work in the Premises (the **"Engineering Drawings")** to (a) be prepared by one or more of the Architect, the Contractor, and/or engineers or other consultants selected and/or retained by the Architect, the Contractor or Landlord, and (b) conform to the Approved Space Plan, the Approved Additional Programming Information, the first sentence of Section 4 below, and any then-existing Approved Architectural Drawings (collectively, the **"Engineering Requirements").**

3.2.2 Design Build. Except as provided in Section 3.2.3 below, the Engineering Drawings shall be delivered to Tenant within 15 business days after the later of Tenant's approval of the Architectural Drawings pursuant to Section 2.5 above or the mutual execution and delivery of this Agreement. Tenant shall approve, or reasonably disapprove (and state, with reasonable specificity, its reasons for disapproving), the Engineering Drawings within two (2) business days after the latest of
(a) Tenant's receipt of the Engineering Drawings, (b) Tenant's approval of the Architectural Drawings, or (c) the mutual execution and delivery of this Agreement. After receiving any such notice of reasonable disapproval, Landlord shall cause the Contractor to revise the Engineering Drawings and resubmit them to Tenant, taking into account the reasons for Tenant's disapproval; provided, however, that Landlord shall not be required to make any revision to the Engineering Drawings that conflicts with the Engineering Requirements or the Landlord Requirements or is otherwise reasonably disapproved by Landlord. Such procedure shall be repeated as necessary until Tenant has reasonably approved the Engineering Drawings. Such approved Engineering Drawings shall be referred to herein as the **"Approved Engineering Drawings".**

3.2.3 Design Bid Build. If Landlord, at its option, causes the Engineering Drawings to be delivered to Tenant on or before the date on which the Architectural Drawings are first delivered to Tenant pursuant to Section 2.5 above, then (a) Section 3.2.2 above shall not apply; (b) Tenant's review

and approval of the Engineering Drawings shall be governed by Section 2.5 above as if the Engineering Drawings were part of the Architectural Drawings; and (c) the Engineering Drawings, as approved by Tenant pursuant to Section 2.5 above, shall be referred to herein as the **"Approved Engineering Drawings".**

3.3 Permits. Landlord shall cause the Contractor to submit the Approved Architectural Drawings and the Approved Engineering Drawings (collectively, the **"Approved Construction Drawings")** to the appropriate municipal authorities and otherwise apply for and obtain from such authorities all permits necessary for the Contractor to complete the Tenant Improvement Work (the **"Permits").**

3.4 Construction.

3.4.1 Performance of Tenant Improvement Work. Landlord shall cause the Contractor to perform the Tenant Improvement Work in accordance with the Approved Construction Drawings.

3.4.2 Contractor's Warranties. Tenant waives all claims against Landlord relating to any defects in the Tenant Improvements; provided, however, that if, within 30 days after substantial completion of the Tenant Improvement Work, Tenant provides notice to Landlord of any non-latent defect in the Tenant Improvements, or if, within I I months after substantial completion of the Tenant Improvement Work, Tenant provides notice to Landlord of any latent defect in the Tenant Improvements, then Landlord shall promptly cause such defect to be corrected.

4 COMPLIANCE WITH LAW; SUITABILITY FOR TENANT'S USE. Landlord shall cause the Architect and the Contractor to use the Required Level of Care (defined below) to cause the Architectural Drawings and the Engineering Drawings to comply with law; provided, however, that Landlord shall not be responsible for any violation of law resulting from (a) any particular use of the Premises (as distinguished from general office use), or (b) any failure of the Approved Additional Programming Information to comply with law. As used herein, **"Required Level of Care"** means the level of care that reputable architects and engineers customarily use to cause architectural and engineering plans, drawings and specifications to comply with law where such plans, drawings and specifications are prepared for spaces in buildings comparable in quality to the Building. Except as provided above in this Section 4, Tenant shall be responsible for ensuring that the Approved Plans are suitable for Tenant's use of the Premises and comply with law, and neither the preparation of any of the Approved Plans by the Architect or the Contractor nor Landlord's approval of the Approved Plans shall relieve Tenant from such responsibility. To the extent that either party (the **"Responsible Party")** is responsible under this Section 4 for causing the Approved Plans to comply with law, the Responsible Party may contest any alleged violation of law in good faith, including by seeking a waiver or deferment of compliance, asserting any defense allowed by law, and exercising any right of appeal (provided that the other party incurs no liability as a result of such contest and that, after completing such contest, the Responsible Party makes any modification to the Approved Plans or any alteration to the Premises that is necessary to comply with any final order or judgment).

5 COMPLETION.

5.1 **Substantial Completion.** For purposes of Section 1 .2 of this Agreement, and subject to Section 5.2 below, the Tenant Improvement Work shall be deemed to be **"Substantially Complete"** upon the completion of the Tenant Improvement Work pursuant to the Approved Construction Drawings (as reasonably determined by Landlord), with the exception of any details of construction, mechanical adjustment or any other similar matter the non-completion of which does not materially interfere with Tenant's use of the Premises.

5.2 **Tenant Cooperation; Tenant Delay.** Tenant shall use reasonable efforts to cooperate with Landlord, the Architect, the Contractor, and Landlord's other consultants to complete all phases of the plans and specifications for the Tenant Improvement Work, approve the Construction Pricing Proposal, obtain the Permits, and complete the Tenant Improvement Work as soon as possible, and Tenant shall meet with Landlord, in accordance with a schedule determined by Landlord, to discuss the parties' progress. Without limiting the foregoing, if (i) the Tenant Improvements include the installation of electrical connections for furniture stations to be installed by Tenant, and (ii) any electrical or other portions of such furniture stations must be installed in order for Landlord to obtain any governmental approval required for occupancy of the Premises, then (x) Tenant, upon five (5) business days' notice from Landlord, shall promptly install such portions of such furniture stations in accordance with Sections 7.2 and 7.3 of the Lease, and (y) during the period of Tenant's entry into the Premises for the purpose of performing such installation, all of Tenant's obligations under this Agreement relating to the Premises shall apply, except for the obligation to pay Monthly Rent. In addition, without limiting the foregoing, if the Substantial Completion of the Tenant Improvement Work is delayed (a **"Tenant**

Delay") as a result of (a) any failure of Tenant to approve the Construction Pricing Proposal pursuant to Section 2.6.1 above on or before Tenant's Approval Deadline; (b) any failure of Tenant to timely approve the Engineering Drawings for any reason other than their failure to satisfy the Engineering Requirements; (c) any failure of Tenant to timely approve any other matter requiring Tenant's approval;
(d) any breach by Tenant of this Work Letter or this Agreement; (e) any request by Tenant for any revision to, or for Landlord's approval of any revision to, any portion of the Approved Plans (except to the extent that such delay results from a breach by Landlord of its obligations under Section 2.7 above);
(t) any requirement of Tenant for materials, components, finishes or improvements that are not available in a commercially reasonable time given the anticipated date of Substantial Completion of the Tenant Improvement Work as set forth in this Agreement; (g) any change to the base, shell or core of the Premises or Building required by the Approved Construction Drawings; or (h) any other act or omission of Tenant or any of its agents, employees or representatives, then, notwithstanding any contrary provision of this Agreement, and regardless of when the Tenant Improvement Work is actually Substantially Completed, the Tenant Improvement Work shall be deemed to be Substantially Completed on the date on which the Tenant Improvement Work would have been Substantially Completed if no such Tenant Delay had occurred. Notwithstanding the foregoing, Landlord shall not be required to tender possession of the Premises to Tenant before the Tenant Improvement Work has been Substantially Completed, as determined without giving effect to the preceding sentence.

6 MISCELLANEOUS. Notwithstanding any contrary provision of this Agreement, if Tenant defaults under this Agreement before the Tenant Improvement Work is completed, Landlord's obligations under this Work Letter shall be excused until such default is cured and Tenant shall be responsible for any resulting delay in the completion of the Tenant Improvement Work. This Work Letter shall not apply to any space other than the Premises.

EXHIBITB-1

APPROVED SPACE PLAN

EXHIBIT C

NOTICE OF LEASE TERM DATES

_, 20

To: ___

Re: Third Amendment (the **"Third Amendment"),** dated 2016, to a lease agreement dated November 3, 2014, between **BRE/COH FL LLC, a Delaware limited liability company ("Landlord"),** and **KEMPHARM, INC., a Delaware corporation ("Tenant"),** concerning Suite I 08 on the first (151 floor of the building located at 1180 Celebration Boulevard,

Celebration, Florida (the **"Suite 108 Expansion Space").**

Lease lD: _____
Business Unit Number:--------

Dear-------

In accordance with the Third Amendment, Tenant accepts possession of the Suite 108 Expansion Space and confirms that the Suite I 08 Expansion Effective Date is , 20_ .

Please acknowledge the foregoing by signing all three (3) counterparts of this letter in the space provided below and returning two (2) fully executed counterparts to my attention. Please note that, under Section 2.3 of the Third Amendment, Tenant is required to execute and return (or reasonably object in writing to) this letter within five (5) days after receiving it.

"Landlord":

BRE/COH FL LLC, a Delaware limited liability company

By:__ Name:__ Title: ___

Agreed and Accepted
as of___, 20_.

"Tenant":

KEMPHARM,

corporation

INC., a Delaware

By:__ Name:__ Title: ___

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

1. Registration Statement (Form S-3 No. 333-213926) of KemPharm, Inc.
2. Registration Statement (Form S-8 No. 333-210369) pertaining to the 2014 Equity Incentive Plan of KemPharm, Inc., and
3. Registration Statement (Form S-8 No. 333-203703) pertaining to the Incentive Stock Plan, as amended, and the 2014 Equity Incentive Plan of KemPharm, Inc.

of our report dated March 10, 2017, with respect to the financial statements of KemPharm, Inc. included in this Annual Report (Form 10-K) of KemPharm, Inc. for the year ended December 31, 2016.

/s/ Ernst & Young LLP

Tampa, Florida
March 10, 2017

Exhibit 31.1

CERTIFICATIONS

I, Travis C. Mickle, certify that:

1. I have reviewed this Annual Report on Form 10-K of KemPharm, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 10, 2017

/s/ Travis C. Mickle

Name: Travis C. Mickle, Ph.D.
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, R. LaDuane Clifton, certify that:

1. I have reviewed this Annual Report on Form 10-K of KemPharm, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 10, 2017

/s/ R. LaDuane Clifton

Name: R. LaDuane Clifton, CPA
Title: Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of KemPharm, Inc., (the "Company") for the fiscal year ended December 31, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Travis C. Mickle, Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 10, 2017

/s/ Travis C. Mickle

Name: Travis C. Mickle, Ph.D.
Title: President and Chief Executive Officer
(Principal Executive Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350, is not being "filed" by the Company as part of the Report or as a separate disclosure document and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of KemPharm, Inc., (the “Company”) for the fiscal year ended December 31, 2016, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, R. LaDuane Clifton, Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 10, 2017

/s/ R. LaDuane Clifton

Name: R. LaDuane Clifton, CPA
Title: Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350, is not being "filed" by the Company as part of the Report or as a separate disclosure document and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.