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, 2019

☐ **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.)**
1180 Celebration Boulevard, Suite 103, Celebration, FL 34747	**(321) 939-3416**
(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	**Trading Symbol**	**Name of Each Exchange on Which Registered**
Common Stock, $0.0001 par value	**KMPH**	**The Nasdaq Stock Market LLC (Nasdaq Capital 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 every Interactive Data File required to be submitted 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 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 ☒ Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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 28, 2019, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $38,659,464, based upon the closing sales price for the registrant's common stock, as reported on the Nasdaq Stock Market, on June 28, 2019. The calculation of the aggregate market value of voting and non-voting common equity excludes 6,767,421 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 February 27, 2020, the registrant had 50,684,743 shares of common stock outstanding.

Documents Incorporated by Reference

Portions of the registrant's definitive proxy statement for its 2020 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, 2019. 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. We have based these forward-looking statements largely on our current expectations 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 anticipated in the forward-looking statements. Forward-looking statements contained in this report include, but are not limited to, statements about:

- *our development plan for our ADHD product candidates, including expectations about the timing of our regulatory filings;*
- *the progress of, timing of and expected amount of expenses associated with our research, development and commercialization activities;*
- *our ability to raise additional funds on commercially reasonable terms, or at all, in order to support our continued operations;*
- *the sufficiency of our cash resources to fund our operating expenses and capital investment requirements for any period;*
- *the expected timing of our clinical trials for our product candidates and the availability of data and results of those trials;*
- *our expectations regarding federal, state and foreign regulatory requirements;*
- *the potential therapeutic benefits and effectiveness of our product candidates and partnered assets;*
- *the size and characteristics of the markets that may be addressed by our product candidates and partnered assets;*
- *the potential outcome of any strategic collaborations or partnerships for the development or sale of our product candidates and partnered assets;*
- *our expectations as to future financial performance, expense levels and liquidity sources;*
- *the timing of commercializing our product candidates; 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, APADAZ, LAT 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.

PART I

ITEM 1. BUSINESS.

Overview

We are a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs to treat serious medical conditions through our proprietary Ligand Activated Therapy, or LAT™, technology. We utilize our proprietary LAT technology to generate improved prodrug versions of drugs approved by the U.S. Food and Drug Administration, or FDA, as well as to generate prodrug versions of existing compounds that may have applications for new disease indications. Our product candidate pipeline is focused on the high need areas of attention deficit hyperactivity disorder, or ADHD, and stimulant use disorder, or SUD. Our co-lead clinical development candidates, KP415 and KP484, are both based on a prodrug of d-methylphenidate, or d-MPH, but with differing extended-release, or ER, effect profiles, and are intended for the treatment of ADHD. Our preclinical product candidate for the treatment of SUD is KP879, based on a prodrug of d-MPH. In addition, we have announced our commercial partnership with KVK Tech, Inc., or KVK, of APADAZ®, an FDA approved immediate-release, or IR, combination product of benzhydrocodone, our prodrug of hydrocodone, and acetaminophen, or APAP, for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. We have entered into a collaboration and license agreement with Commave Therapeutics SA (formerly known as Boston Pharmaceuticals S.A.), an affiliate of Gurnet Point Capital, or Commave, for the development, manufacture and commercialization of our product candidates containing serdexmethylphenidate, or SDX, and d-MPH.

We have two commercial partnerships relating to our ADHD program, and APADAZ, our FDA approved IR combination product of benzhydrocodone, our prodrug of hydrocodone, and APAP for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

In October 2018, we entered into our collaboration and license agreement, or the APADAZ License Agreement, with KVK. Under the APADAZ License Agreement, we granted an exclusive license to KVK to conduct regulatory activities for, manufacture and commercialize APADAZ in the United States. In collaboration with KVK, APADAZ was available for sale nationally beginning in November 2019.

In September 2019, we entered into our collaboration and license agreement, or the KP415 License Agreement, with Commave, for the development, manufacture and commercialization of our product candidates containing SDX and d-MPH, including KP415, KP484, and, at the option of Commave, KP879, KP922 or any other product candidate developed by us containing SDX and developed to treat ADHD or any other central nervous system disorder.

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, Inc. was acquired by Shire plc, or Shire, in 2007. Shire was subsequently acquired by Takeda Pharmaceuticals Company Limited, or Takeda, in January 2019.

We employ our proprietary LAT technology to discover and develop prodrugs that are new molecules that can improve one or more of the attributes of approved drugs, such as enhanced bioavailability, extended duration of action, increased safety and reduced susceptibility to abuse. 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 the active form of the drug through a normal metabolic process. Where possible, we seek, 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.

We intend to advance our pipeline of product candidates for the treatment of ADHD and SUD, and we anticipate submitting a new drug application, or NDA, to the FDA for KP415 in the first quarter of 2020, although the timing of the filing is at the discretion of Commave. We also anticipate initiating a pivotal efficacy trial for KP484 in 2021, subject to Commave's approval. We plan to employ our LAT 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.

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 proprietary LAT technology to improve the attributes of widely-prescribed, FDA-approved drugs***. We plan to employ our proprietary LAT technology to discover and develop prodrugs that can improve one or more of the attributes of FDA-approved drugs that are widely-prescribed. We intend to discover and develop prodrugs of FDA-approved drugs in multiple therapeutic areas.

- ***Advance the development of our pipeline product candidates***. We plan, together with Commave, to advance the development of our co-lead product candidates, KP415 and KP484, for the treatment of ADHD. We plan to initiate a pivotal efficacy trial for KP484 in 2021. We also plan to submit an NDA for KP415 in the first quarter of 2020, although the timing of the filing is at the discretion of Commave. In addition, we are developing KP879, our prodrug of d-methylphenidate, for the treatment of SUD.

- ***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.

- ***Commercialize APADAZ.*** We announced that in November 2019, APADAZ and its authorized generic (AG-APADAZ) became available nationally. To date KVK's commercialization strategy has targeted outreach to pharmacy benefit managers, managed care organizations and integrated delivery networks for the exclusive utilization of APADAZ as an alternative to currently available hydrocodone/acetaminophen products. We may also license the international commercial rights to APADAZ to one or more collaborators.

Our Proprietary LAT Technology

We employ our proprietary LAT technology to create prodrugs that are new molecules 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 by the FDA. When the prodrug is administered, 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 proprietary LAT technology offers the following potential benefits:

- ***Improved drug properties***. We seek to discover and develop prodrugs that are new molecules with potentially improved attributes over FDA-approved drugs, such as enhanced bioavailability, extended duration of action, increased safety and reduced susceptibility to abuse.

- ***Composition-of-matter patent protection***. Our prodrugs are new molecules and thus may be eligible for patent protection as novel compositions of matter, provided that all other applicable requirements are met. We seek patent protection not only for our 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 proprietary LAT technology allows us to discover and develop prodrugs that may be eligible to use the 505(b)(2) NDA pathway. Under that regulatory pathway, if we are able to provide an adequate bridge between our product candidates and appropriate FDA-approved drugs, we will then be able to reference the FDA's previous findings of safety and effectiveness of 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 potentially 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 stimulant products. However, we believe there is a significant need for longer duration products. While many of the currently marketed methylphenidate products provide good symptom control for up to 12 hours post-dose, there is increasing attention to addressing late afternoon/early evening behavioral deficits, while maintaining early symptom control.

A study published in a peer-reviewed journal 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 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. As a result, we believe there is a need to develop a methylphenidate product that provides early-morning control of symptoms.

In addition to early onset, patients require sustained, consistent efficacy throughout the day and into the early evening hours. While currently marketed methylphenidate products offer efficacy for up to 12 hours, this duration may not be sufficient for all patients. Particularly adolescents and adults may often require longer effects as they have longer waking hours compared to younger patients. It has been reported in a peer-reviewed journal that these patients are typically using dose-augmentation strategies by taking additional doses of stimulant later in the day. We believe a single dose therapy that provides effective symptom control without requiring additional doses may have several benefits including, potentially, improved dosage compliance by regularly and consistently taking medication as indicated, reduced social embarrassment by avoiding the need to take medication during working hours, and overall improvement in quality of life through more consistent therapy. Based on this evidence, we believe there is a need to develop a methylphenidate product that can deliver long duration of efficacy. There may also be a need to develop a long-duration stimulant with and without very early onset depending on individual patient preference and requirements.

Our Product Candidates and Approved Products

We have employed our proprietary LAT technology to create a portfolio of product candidates and approved products that we believe will offer significant improvements over FDA-approved and widely-prescribed drugs.

A selection of our product candidates and approved products are summarized in the table below:

Selected KemPharm Partnered and Optioned Assets

Parent Drug (Effect Profile) (Indication)	Product Candidate / Product (Status)	Development Status	Key Milestone
Methylphenidate (ER) (ADHD)	KP415 (Partnered)	Clinical	NDA Submission - Q1 2020
Methylphenidate (ER) (ADHD)	KP484 (Partnered)	Clinical	Initiation of Pivotal Efficacy Trial - 2021
Methylphenidate (ER) (SUD)	KP879 (Optioned)	Preclinical	IND Submission - 2021
Hydrocodone / APAP (IR) (Pain)	APADAZ (Partnered)	FDA Approved	Tracking Payor Contracts and TRx's - 2020

Subject to Commave's approval, we intend to seek approval of both KP415 and KP484 under the 505(b)(2) NDA pathway, which will allow us to rely on the FDA's previous findings of safety and effectiveness for one or more approved products. We anticipate submitting a 505(b)(2) NDA for KP415 in the first quarter of 2020, although the timing of the filing is at the discretion of Commave. We anticipate initiating additional pharmacokinetic, or PK, and pivotal efficacy trials for KP484 in 2021, subject to Commave's approval.

KP415 and KP484

Overview

The prodrug in both KP415 and KP484 is SDX, which we are developing for the treatment of ADHD. The ADHD market is largely served by the stimulant products methylphenidate and amphetamine. Both KP415 and KP484 are designed to be extended-duration methylphenidate products.

Subject to Commave's approval, we intend to seek approval of both KP415 and KP484 under the 505(b)(2) NDA pathway, which will allow us to rely on the FDA's previous findings of safety and effectiveness for one or more approved products. We anticipate submitting a 505(b)(2) NDA for KP415 in the first quarter of 2020, although the timing of the filing is at the discretion of Commave, and initiating additional PK and pivotal efficacy trials for KP484 in 2021, subject to Commave's approval.

In September 2019, we entered into the KP415 License Agreement with Commave. Under the KP415 License Agreement, we granted to Commave an exclusive, worldwide license to develop, manufacture and commercialize our product candidates containing SDX and d-MPH, including KP415, KP484, and, at the option of Commave, KP879, KP922 or any other product candidate developed by us containing SDX and developed to treat ADHD or any other central nervous system disorder, or the Additional Product Candidates and, collectively with KP415 and KP484, the Licensed Product Candidates.

Under the terms of the KP415 License Agreement, we granted Commave an exclusive, worldwide license to commercialize and develop the Licensed Product Candidates; provided that such license shall apply to an Additional Product Candidates only if Commave exercises its option under the KP415 License Agreement related thereto. If Commave exercises its option related to any Additional Product Candidate under the KP415 License Agreement, the parties are obligated to negotiate in good faith regarding the economic terms of such Additional Product Candidate. We also granted to Commave a right of first refusal to acquire, license or commercialize any Additional Product Candidate, with such right of first refusal expiring upon the acceptance of a new drug application for such Additional Product Candidate. In addition, we granted Commave a right of first negotiation and a right of first refusal, subject to specified exceptions, for any assignment of our rights under the KP415 License Agreement.

Pursuant to the KP415 License Agreement, Commave paid the Company an upfront payment of $10.0 million and agreed to pay up to $63.0 in milestone payments upon the occurrence of specified regulatory milestones related to the KP415 and KP484. In addition, Commave agreed to make additional payments upon the achievement of specified U.S. sales milestones of up to $420.0 million in the aggregate, depending, among other things, on timing of approval for an NDA for KP415 and its final approved label, if any. Further, Commave will pay us quarterly, tiered royalty payments ranging from a percentage in the high single digits to the mid-twenties of Net Sales (as defined in the KP415 License Agreement) in the United States and a percentage in the low to mid-single digits of Net Sales in each country outside the United States, in each case subject to specified reductions under certain conditions as described in the KP415 License Agreement. Commave is obligated to make such royalty payments on a product-by-product basis until expiration of the Royalty Term (as defined in the KP415 License Agreement) for the applicable product.

Commave agreed to be responsible for and reimburse us for all of development, commercialization and regulatory expenses for the Licensed Product Candidates, subject to certain limitations as set forth in the KP415 License Agreement, including consultation fees to be paid to the Company for services provided to Commave in performing such activities.

The KP415 License Agreement will continue on a product-by-product basis (i) until expiration of the Royalty Term for the applicable Licensed Product Candidate in the United States and (ii) perpetually for all other countries. Commave may terminate the KP415 License Agreement at its convenience upon prior written notice prior to regulatory approval of any Licensed Product Candidate or upon prior written notice after regulatory approval of any Licensed Product Candidate. We may terminate the KP415 License Agreement in full if Commave, any of its sublicensees or any of its or their affiliates challenge the validity of any Licensed Patent (as defined in the KP415 License Agreement) and such challenge is not required under a court order or subpoena and is not a defense against a claim, action or proceeding asserted by us. Either party may terminate the KP415 License Agreement (i) upon a material breach of the KP415 License Agreement by the other party, subject to a cure period, or (ii) if the other party encounters bankruptcy or insolvency. Upon a Serious Material Breach (as defined in the KP415 License Agreement) by us, subject to a cure period, Commave may choose not to terminate the KP415 License Agreement and instead reduce the milestone and royalty payments owed to us. Upon termination, all licenses and other rights granted by us to Commave pursuant to the KP415 License Agreement would revert to us. During the term of the KP415 License Agreement, we may not develop or commercialize any Competing Product (as defined in the KP415 License Agreement).

The KP415 License Agreement established a joint steering committee, which monitors progress in the development of both KP415 and KP484. Subject to the oversight of the joint steering committee, we otherwise retain all responsibility for the conduct of all regulatory activities required to obtain NDA approval of both KP415 and KP484; provided that Commave shall be the sponsor of any clinical trials conducted by us on behalf of Commave.

Under our March 2012 asset purchase agreement with Shire, Shire had a right of first refusal to acquire, license or commercialize KP415 and KP484. In January 2019, Shire was acquired by Takeda to whom this right of first refusal was transferred at that time. Takeda did not exercise this right of first refusal as part of the KP415 License Agreement.

Under our March 2012 termination agreement with Aquestive Therapeutics, or Aquestive, Aquestive has the right to receive a royalty amount equal to 10% of any value generated by KP415, KP484 or KP879, and any product candidates which contain SDX, including royalty payments on any license of KP415, KP484 or KP879, the sale of KP415, KP484 or KP879 to a third party, the commercialization of KP415, KP484 or KP879 and the portion of any consideration that is attributable to the value of KP415, KP484 or KP879 and paid to us or our stockholders in a change of control transaction. In connection with the KP415 License Agreement, we paid Aquestive a royalty equal to 10% of the upfront license payment we received in the third quarter of 2019.

Market Opportunity

We believe the ADHD market would be receptive to new branded drugs that have improved properties when compared to current treatments. We believe a new product in the form of a prodrug that has differentiated features may provide a new treatment option in this large market segment. While methylphenidate is available as a generic product, the branded formulations, including, among others, CONCERTA, FOCALIN XR, QUILLICHEW XR and COTEMPLA XR-ODT.

Key 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:

- ***Faster early-morning symptom control and sustained effectiveness***. In July 2018, we announced top line results from our pivotal efficacy and safety clinical trial of KP415. KP415.E01 was a laboratory classroom clinical trial in children aged 6-12 years old with a diagnosis of ADHD to assess the efficacy and safety of KP415. Subjects who received KP415 met the trial's primary and secondary efficacy endpoint, showing statistically significant improvement on both the SKAMP and PERMP scales.

- ***Reduced abuse potential***. In order to evaluate the potential for reduced abuse of SDX, our prodrug of d-methylphenidate and major component of KP415, we conducted preclinical and clinical studies to compare the exposure to d-methylphenidate following oral, intranasal and intravenous, or IV, administration of the prodrug as compared to oral, intranasal and IV administration of d-methylphenidate hydrochloride. We observed significantly lower concentrations of d-methylphenidate following oral, intranasal and IV administration of the prodrug compared to oral, intranasal and IV administered d-methylphenidate hydrochloride. Consistent with this lower exposure, in human abuse potential studies, we also observed significantly lower abuse-related pharmacodynamic effects compared to d-methylphenidate comparators. Our prodrug of d-methylphenidate incorporates our proprietary LAT technology and, based on our preclinical and clinical studies, we believe it may have lower abuse potential compared to d-methylphenidate.

- ***Once-daily dosing***. PK data from our preclinical studies suggest that the time to maximum plasma concentration of d-methylphenidate after oral administration of KP415 is approximately three times longer than that after oral administration of currently marketed IR d-methylphenidate. We believe our PK studies in human subjects also demonstrate that KP415 affords d-methylphenidate concentrations that are consistent with a once-daily, extended-duration product.

- ***Amenable to patient-friendly formulations***. Our preclinical and clinical data show that KP415 could ultimately be used in a variety of patient-friendly dosage forms such as oral thin film and orally dissolving tablets as a means of increasing patient convenience and dosage compliance by regularly and consistently taking the medication as indicated.

- ***Composition-of-matter patent protection***. We have a U.S. composition-of-matter patent that will expire, after utilizing all appropriate patent term adjustments but excluding possible term extensions, in 2032 that generally covers at least one component of KP415. Our patent strategy is focused primarily on key geographic markets, and we have composition-of-matter patents in multiple countries, including in Canada, China, Europe, Malaysia, Mexico, Indonesia, Israel, Japan, New Zealand, Philippines, Russia, Singapore, South Africa, South Korea and Vietnam, and additional patent filings pending in the United States and foreign jurisdictions. In addition, subject to further discussions with the FDA, we believe additional patent protection 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 contains a prodrug that was given a new chemical name, serdexmethylphenidate, by the U.S. Adopted Names Council, or USAN, which means that there may be no generic equivalent product for KP415 in most states, making drug-equivalent substitution potentially difficult at the pharmacy.

Key Features of KP484

Based on our preclinical and clinical data, we believe KP484, 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:

- ***Super-extended release***. We believe that this KP484 may provide sustained, consistent effectiveness through the day and into the evening hours.

- ***Reduced abuse potential***. The preclinical and clinical studies of SDX, the prodrug of d-methylphenidate, discussed above in the KP415 "Reduced Abuse Potential" subsection are being used by us for the abuse potential evaluation of the KP484 product candidate. Accordingly, we believe serdexmethylphenidate may have attributes that disincentivize certain forms of abuse, as observed in these preclinical and clinical studies.

- ***Once-daily dosing***. PK data from our clinical studies suggest that under fasted conditions, the time to maximum plasma concentration of d-methylphenidate after oral administration of KP484 is potentially five to seven times longer compared to oral administration of currently marketed IR d-methylphenidate. We believe this extended-duration attribute of KP484 may allow for convenient, once-daily dosing.

- ***Amenable to patient-friendly formulations***. Our preclinical and clinical data shows that KP484 could ultimately be used in a variety of patient-friendly dosage forms such as oral thin film and orally dissolving tablets as a means of increasing patient convenience and dosage compliance by regularly and consistently taking the medications as indicated.

- ***Composition-of-matter patent protection***. KP484 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 markets, and we have composition-of-matter patents generally protecting the major component of KP484 in New Zealand, South Africa and select other countries.

- ***No generic equivalent product***. KP484 contains a prodrug that was given a new chemical name, serdexmethylphenidate, by the USAN, which means that there may be no generic equivalent product for KP484 in most states, making drug-equivalent substitution potentially difficult at the pharmacy.

KP879

KP879, a prodrug of d-methylphenidate using our proprietary LAT technology, is our product candidate for the treatment of SUD including, for example, abuse or misuse of cocaine, methamphetamine and prescription stimulants. Currently there are no approved drugs in the United States for SUD.

APADAZ

Overview

In February 2018, we announced that the FDA approved APADAZ for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. APADAZ is an IR combination of our prodrug, benzhydrocodone, and APAP. Benzhydrocodone was developed with our proprietary LAT technology.

In October 2018, we entered into the APADAZ License Agreement with KVK pursuant to which we have granted an exclusive license to KVK to conduct regulatory activities for, manufacture and commercialize APADAZ in the United States.

Pursuant to the APADAZ License Agreement, KVK agreed to pay us certain payments and cost reimbursements of an estimated $3.4 million, which includes a payment of $2.0 million within 10 days of the achievement of a specified milestone related to the initial formulary adoption of APADAZ, or the Initial Adoption Milestone. In addition, KVK has agreed to make additional payments to us upon the achievement of specified sales milestones of up to $53.0 million in the aggregate. Further, we and KVK will share the quarterly net profits of APADAZ by KVK in the United States at specified tiered percentages, ranging from us receiving 30% to 50% of net profits, based on the amount of net sales on a rolling four quarter basis. We are responsible for a portion of commercialization and regulatory expenses for APADAZ until the Initial Adoption Milestone is achieved, after which KVK will be responsible for all expenses incurred in connection with commercialization and maintaining regulatory approval in the United States.

The APADAZ License Agreement will terminate on the later of the date that all of the patent rights for APADAZ have expired in the United States or KVK's cessation of commercialization of APADAZ in the United States. KVK may terminate the APADAZ License Agreement upon 90 days written notice if a regulatory authority in the United States orders KVK to stop sales of APADAZ due to a safety concern. In addition, after the third anniversary of the APADAZ License Agreement, KVK may terminate the APADAZ License Agreement without cause upon 18 months prior written notice. We may terminate the APADAZ License Agreement if KVK stops conducting regulatory activities for or commercializing APADAZ in the United States for a period of six months, subject to specified exceptions, or if KVK or its affiliates challenge the validity, enforceability or scope of any licensed patent under the APADAZ License Agreement. Both parties may terminate the APADAZ License Agreement (i) upon a material breach of the APADAZ License Agreement, subject to a 30-day cure period, (ii) the other party encounters bankruptcy or insolvency or (iii) if the Initial Adoption Milestone is not achieved. Upon termination, all licenses and other rights granted by us to KVK pursuant to the APADAZ License Agreement would revert to us.

The APADAZ License Agreement also established a joint steering committee, which monitors progress of the commercialization of APADAZ.

In November 2019, APADAZ and its authorized generic (AG-APADAZ) became nationally available. To date, KVK's commercialization strategy has targeted outreach to pharmacy benefit managers, managed care organizations and integrated delivery networks for the exclusive utilization of APADAZ as an alternative to currently available hydrocodone/acetaminophen products. We may also license the international commercial rights to APADAZ to one or more collaborators.

Market Opportunity

Typically, patients are instructed to take 4-6 pills per day and prescriptions provide approximately 14 days of therapy. Hydrocodone is associated with more drug abuse and diversion than any other opioid, and IR hydrocodone abuse results in more emergency department visits than any other prescription opioid.

Key Product Features of APADAZ

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

- ***Composition-of-matter patent protection***. APADAZ is protected by a U.S. composition-of-matter patent on benzhydrocodone, the prodrug of hydrocodone contained in APADAZ, that will expire, after utilizing all appropriate patent term adjustments but excluding possible patent term extensions, in 2031. Our patent strategy is focused primarily on key geographic markets and benzhydrocodone has received granted, issued or allowed patent status in multiple foreign jurisdictions and patent applications covering benzhydrocodone were pending in other foreign jurisdictions.

- ***No generic equivalent product***. Benzhydrocodone, the APADAZ active pharmaceutical ingredient, or API, is a prodrug with a new chemical name given by the USAN, benzhydrocodone. APADAZ has a lower prescribed milligram strength of benzhydrocodone than the therapeutic equivalent amount of hydrocodone bitartrate used in existing IR hydrocodone/APAP combination products. The difference in chemical structure and prescription strength means that there is no generic equivalent product for APADAZ in most states (outside of the authorized generic AG-APADAZ), making substitution difficult at the pharmacy.

- ***Convenient dosing***. Based on data from our food-effect PK trial, APADAZ can be administered without regard to food and, accordingly, APADAZ will be as convenient as existing IR hydrocodone/APAP combination products.

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 proprietary LAT 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 proprietary LAT technology. The parent drug and ligand or ligands together may potentially constitute a new molecule and thus may be eligible for composition-of-matter patent protection, among other patent protections, in the United States and abroad.

As of December 31, 2019, we have been granted 31 active patents within the United States, and an additional 84 active foreign patents covering our selected prodrugs and product candidates. The terms of the 31 issued U.S. patents extend to various dates ranging, for example, between 2030 and 2035. The term of our overall domestic and foreign patent portfolio related to our selected prodrugs and product candidates, including patent term adjustments but excluding possible patent term extensions, extend to various dates ranging, for example, between 2030 and 2035, if pending patent applications in each of our patent families issue as patents. As of December 31, 2019, we had 24 pending patent applications under active prosecution in the United States, and an additional 44 pending foreign patent applications potentially covering our selected prodrugs and product candidates. Our issued and granted patents provide protection in jurisdictions that include the United States, Australia, Canada, Chile, China, Colombia, Cuba, European Countries, Hong Kong, India, Indonesia, Israel, Japan, Kazakhstan, Malaysia, Mexico, New Zealand, Philippines, Romania, Russia, Singapore, South Africa, South Korea Ukraine, and Vietnam.

We have received composition-of-matter patents and also additionally filed composition-of-matter patent applications related to the KP415 and KP484 families in the United States and in Argentina, Australia, Brazil, Canada, Chile, China, Egypt, Hong Kong, European Countries, India, Israel, Indonesia, Japan, South Korea, Kazakhstan, Mexico, Malaysia, New Zealand, Philippines, Russia, Singapore, South Africa, Thailand, Ukraine, and Vietnam. We anticipate filing additional patent applications for our prodrugs and product candidates.

In 2013, the United States Patent and Trademark Office, or the USPTO, issued a composition-of-matter patent covering benzhydrocodone, 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 benzhydrocodone in Australia, Canada, Chile, China, Mexico, South Africa, and South Korea. In addition, three U.S. patent applications covering benzhydrocodone-related compositions-of-matter were pending as of December 31, 2019, and patent applications covering benzhydrocodone were pending as of December 31, 2019, in Brazil, EPC, Israel, Thailand, New Zealand, South Korea, and Vietnam.

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 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

In February 2018, we announced that the FDA approved APADAZ for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

In October 2018, we entered into the APADAZ License Agreement with KVK pursuant to which we have granted an exclusive license to KVK to conduct regulatory activities for, manufacture and commercialize APADAZ in the United States. Under the terms of the APADAZ License Agreement we are eligible to receive milestone payments of up to $53.0 million and royalties based on the net profits of APADAZ sales in the United States. In November 2019, APADAZ and its authorized generic (AG-APADAZ) became nationally available. To date, KVK's commercialization strategy has targeted outreach to pharmacy benefit managers, managed care organizations and integrated delivery networks for the exclusive utilization of APADAZ as an alternative to currently available hydrocodone/acetaminophen products. In support of the commercial launch, including the transition of commercial-level manufacturing to KVK, the technology transfer process outlined under the APADAZ License Agreement is underway. As part of this process, in February 2019 we completed the transfer of the NDA for APADAZ to KVK. We may also license the international commercial rights to APADAZ to one or more collaborators in the future.

With the exception of APADAZ, we have not yet begun commercialization activities for 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 similar to those we have entered into with KVK and Commave, 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 which are not currently subject to the APADAZ License Agreement or KP415 License Agreement, 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, 2019 and 2018, we recorded $19.4 million and $41.8 million, respectively, in research and development expenses. We plan to devote a significant portion of our capital towards research and development for the foreseeable future as we continue our efforts to further advance the development of our product candidates and commercialize APADAZ and our product candidates, if approved, subject to the availability of additional funding. However, as part of the KP415 License Agreement, Commave agreed to be responsible for and reimburse us for all of development, commercialization and regulatory expenses for the Licensed Product Candidates, as defined in the KP415 License Agreement, subject to certain limitations as set forth in the KP415 License Agreement.

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. 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 or product candidates and these competitors may also have significantly more resources than us and be more successful than us in manufacturing and marketing their products.

If approved, both KP415 and KP484 will compete against currently marketed, branded and generic methylphenidate products for the treatment of ADHD. Some of these currently marketed products include Janssen's CONCERTA, Tris Pharma's QUILLIVANT XR and QUILLICHEW ER, Novartis' RITALIN, FOCALIN and FOCALIN XR, UCB's METADATE CD, Noven's DAYTRANA, Neos Therapeutics' CONTEMPLA XR-ODT, Ironshore Pharmaceuticals, Inc.'s JORNAY PM and Adlon Therapeutics' ADHANSIA XR, in addition to multiple other branded and generic methylphenidate products. In addition, if approved, KP415 and KP484 will face potential competition from any other methylphenidate products for the treatment of ADHD that are currently in or which may enter into clinical development.

Currently, there are no approved drugs in the United States for the treatment of SUD. If approved, KP879 will face potential competition from any products for the treatment of SUD that are currently in or which may enter into clinical development.

APADAZ competes against currently marketed, branded and generic IR hydrocodone/APAP combination products indicated for the short-term management of acute pain. In addition, APADAZ will face potential competition from any IR or hydrocodone/APAP combination products for the short-term management of acute pain that are currently in or may enter into clinical development.

Manufacturing

Our manufacturing strategy is to rely on contract manufacturers to produce our 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 benzhydrocodone required to manufacture APADAZ under a supply agreement. We have contracted with another third-party manufacturer to supply KP415 and KP484 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 APADAZ, and subject to Commave's approval, KP415 and KP484, 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 benzhydrocodone necessary for clinical trials and commercial sale for a price equal to JMI’s manufacturing cost and to provide process development services for benzhydrocodone. In exchange, we issued shares of our common stock to JMI, provided that the commercial supply arrangement for benzhydrocodone 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 any products which utilize benzhydrocodone as the API. 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 any products which utilize benzhydrocodone as the API, and stability testing for those batches is in process.

Under the Supply Agreement, we retain sole ownership of benzhydrocodone and are required to use commercially reasonable efforts to develop and to pursue FDA marketing approval of any products which utilize benzhydrocodone as the API. We are responsible for product development, including formulation, preclinical studies and clinical trials, and for regulatory approval, quality assurance and commercialization. If any products which utilize benzhydrocodone as the API are subject to a U.S. Drug Enforcement Agency, or DEA, scheduling quota, then each year, both we and JMI are responsible for using commercially reasonable efforts to obtain a quota from the DEA for the production of benzhydrocodone for use with any products that utilize benzhydrocodone as an API.

JMI is responsible for all costs of any benzhydrocodone manufactured during a specified validation process for any products which utilize benzhydrocodone as an API. After completion of the validation process, but prior to the commercial launch of any products that utilize benzhydrocodone as the API, JMI will manufacture batches of benzhydrocodone at a negotiated price. Upon commercial launch, JMI will manufacture and supply benzhydrocodone at a price equal to JMI’s fully allocated manufacturing cost after commercial launch of APADAZ or any other product that may utilize benzhydrocodone as an API, should we obtain approval for marketing from the FDA.

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

The term of the Supply Agreement extends as long as we hold a valid and enforceable patent for benzhydrocodone or until the tenth anniversary of the commercial launch of any product that utilizes benzhydrocodone 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

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. Pursuant to this agreement, we also granted Shire a right of first refusal to acquire, license or commercialize KP415 and KP484. In January 2019, Shire was acquired by Takeda to whom this right of first refusal was transferred at that time. Takeda did not exercise this right of first refusal as part of the KP415 License Agreement.

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 and 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, our product and product candidates 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 & 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 recent legislation 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% currently. To help achieve this reduction, pharmaceutical manufacturers are required to provide quarterly discounts of 50%, and 70% commencing January 1, 2019. In 2020, drug manufacturers will be responsible for a larger share of total drug costs due to an increase to the catastrophic threshold. Such increase will also result in a higher out-of-pocket threshold paid by Part D beneficiaries.

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:

- non-clinical laboratory and animal tests that must be conducted in accordance with good laboratory practices, or GLPs;
- submission of an investigational new drug application, or IND, which must be received by the FDA and become effective before human 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 of a NDA to the FDA;
- 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 human 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. Additional non-clinical studies may be required even after the IND is submitted. The IND 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, 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, or post-market, 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, 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 ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant 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, non-clinical 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 application 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.

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 may refer drugs which present difficult questions of safety, purity or potency to an advisory committee. An advisory committee is a panel that typically 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 a 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 a new molecular entity, or 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 (Class 1 or Class 2). 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.

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 boxed 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 human prescription drug program fee requirements for approved products. 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

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 a new molecule. 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.

APADAZ is currently subject to a REMS requirement, and under the APADAZ License Agreement, KVK is responsible for the maintenance of and all expenses and fees for the APADAZ REMS program.

DEA Regulation

Most of our products and 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 criteria:

- 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.

APADAZ is listed as a Schedule II controlled substance under the CSA, and we expect that most of our other products and product candidates may be listed in the same manner, if approved. 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. 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.

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 APADAZ and most of our current 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 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 substances 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.

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 are 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 federal 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, 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 federal Anti-Kickback Statute, or the specific intent to violate it, to have violated those statutes. 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, which can be enforced by private citizens through civil whistleblower or *qui tam* actions, 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.

The civil monetary penalties statute 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, as defined by such law, 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 significant civil monetary penalties.

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 covered entities, including certain healthcare providers, health plans and healthcare clearinghouses, and their respective business associates, independent contractors or agents of covered entities that receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity, relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH 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 HIPAA 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 and local jurisdictions 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.

Depending on the circumstances, failure to comply with these laws can result in significant penalties, including criminal, civil and/or administrative 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 from 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 remain judicial and congressional challenges to certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by ACA. Concurrently, Congress has considered legislation to repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

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, due to subsequent legislative amendments, including the BBA, will remain in effect through 2029 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 and enacted federal and state legislation 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. At the federal level, the Trump administration's budget proposal for fiscal year 2020 contains further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and, at the same, has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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, 2019, we employed 22 full-time employees. We have never had a work stoppage, and none of our employees are 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, 2019 and 2018.

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 1180 Celebration Boulevard, Suite 103, Celebration, FL 34747 and our telephone number is (321) 939-3416.

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 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 because of factors that are described below and elsewhere in this Annual Report on Form 10-K.

Risks Related to Our Financial Position and Capital Needs

We 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 or cease operations altogether.

Based on our current operating plan, our existing resources and projected revenues are expected to be sufficient to fund our operating expense and capital investment requirements into, but not through, the first quarter of 2021. If revenues are not as we project, we believe our existing resources are sufficient to fund our current operations into but not through the third quarter of 2020. We do not currently have sufficient funds to finance our continuing operations beyond the short-term or to substantially advance our product candidates further into clinical development. We expect that our only source of revenues will be through payments arising from our license agreements with KVK and Commave, and/or through any other future arrangements related to one of our other product candidates. Accordingly, our ability to continue as a going concern will require us to obtain, in the short term, additional financing to fund our operations. In order to substantially advance development of our product candidates, we will need to obtain additional funding in connection with our continuing operations from one or more equity offerings, including pursuant to our purchase agreement, or the Purchase Agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park, debt financings, the APADAZ License Agreement, the KP415 License Agreement or other third-party funding, including potential strategic alliances and licensing or collaboration arrangements, and we cannot guarantee that we will be able to generate sufficient proceeds from sales under the Purchase Agreement, the APADAZ License Agreement or the KP415 License Agreement, or be successful in completing other transactions, that will fund our operating expenses. If we are delayed in obtaining additional funding or are unable to complete a strategic transaction, we may discontinue our development activities on our product candidates or discontinue our operations. Even if we are able to fund continued development and any of our product candidates, beyond APADAZ, are approved, we expect that we will need to complete a strategic transaction or raise substantial additional funding through public or private debt or equity securities to successfully commercialize any product candidate. Our future capital requirements will depend on many factors, including:

- the progress and results of our preclinical studies, clinical trials, chemistry, manufacturing and controls, or CMC, and other product development and commercialization activities;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates;
- the ability to obtain differentiating 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 APADAZ under our APADAZ License Agreement, or any product candidate subject to the terms of the KP415 License agreement or sales of our other product candidates for which we receive marketing approval, which may be affected by market conditions, including obtaining coverage and adequate reimbursement of APADAZ or our product candidates from third-party payors, including government programs and managed care organizations, and competition within the therapeutic class to which APADAZ or our product candidates are assigned;
- our success in developing and commercializing our ADHD product candidates in accordance with the terms of the KP415 License Agreement;
- 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.

The auditor's opinion on our audited financial statements for the fiscal year ended December 31, 2019, included in this annual report on Form 10-K, contains an explanatory paragraph relating to our ability to continue as a going concern.

The auditor's opinion on our audited financial statements for the year ended December 31, 2019 includes an explanatory paragraph stating that our recurring losses from operations, stockholders' deficit and negative operating cash flows raise substantial doubt about our ability to continue as a going concern. While we believe that we will be able to raise the capital we need to continue our operations, there can be no assurances that we will be successful in these efforts or will be able to resolve our liquidity issues or eliminate our operating losses. If we are unable to obtain sufficient funding, we would need to significantly reduce our operating plans and curtail some or all of our product development, commercialization and strategic plans. Accordingly, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

In connection with preparation of our annual financial statements for the fiscal year ended December 31, 2019, we identified a material weakness in our internal control over financial reporting. Any failure to maintain effective internal control over financial reporting could harm us.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. generally accepted accounting principles. In connection with our audit of the fiscal year ended December 31, 2019, we identified a material weakness in our internal controls over financial reporting regarding our ineffective controls over non-routine transactions. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected and corrected on a timely basis. This control deficiency resulted in misstatements to research and development expenses, debt discount, interest expense related to amortization of debt discount, fair value adjustment related to derivative and warrant liability, revenue, accounts and other receivables, accounts payable and accrued expenses, prepaid expenses and other current assets and general and administrative expenses all of which were corrected prior to issuance of our financial statements as of and for the year ended December 31, 2019 included in this annual report on Form 10-K. As this deficiency created a reasonable possibility that a material misstatement would not be prevented or detected in a timely basis, management concluded that the control deficiency represented a material weakness and accordingly our internal control over financial reporting was not effective as of December 31, 2019.

We are still considering the full extent of the procedures to implement in order to remediate the material weakness described above, however, the current remediation plan includes implementing controls over calculations and conclusions associated with non-routine transactions at a more precise level of operation. We cannot assure you that any of our remedial measures will be effective in resolving this material weakness or that we will not suffer from other material weaknesses in the future.

If our management is unable to conclude that we have effective internal control over financial reporting, or to certify the effectiveness of such controls, or if additional material weaknesses in our internal controls are identified in the future, we could be subject to regulatory scrutiny and a loss of public confidence, which could have a material adverse effect on our business and our stock price. In addition, if we do not maintain adequate financial and management personnel, processes and controls, we may not be able to manage our business effectively or accurately report our financial performance on a timely basis, which could cause a decline in our common stock price and adversely affect our results of 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 had negative operating cash flows since our inception and, as of December 31, 2019, had an accumulated deficit of $245.7 million. Our negative operating cash flows for the years ended December 31, 2019 and 2018, were $23.7 million and $54.2 million, respectively. We have financed our operations through December 31, 2019 with funds raised in private placements of redeemable convertible preferred stock, in the issuance of convertible promissory notes and term debt, our initial public offering and other public and private offerings of our common stock, as well as through revenue received under the KP415 License Agreement.

In February 2019, we entered into a purchase agreement with Lincoln Park, or the Prior Purchase Agreement, which provided that, upon the terms and subject to the conditions and limitations set forth therein, we could sell to Lincoln Park up to $15.0 million of shares of our common stock, from time to time over the 36-month term of the Prior Purchase Agreement, and upon execution of the Prior Purchase Agreement we issued 120,200 shares of our common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Prior Purchase Agreement. We terminated the Prior Purchase Agreement in February 2020 in connection with entering into the Purchase Agreement. We sold 3,401,271 shares of our common stock to Lincoln Park under the Prior Purchase Agreement for approximately $5.4 million in gross proceeds prior to termination.

In February 2020, we entered into a new purchase agreement with Lincoln Park, or the Purchase Agreement, which provides that, upon the terms and subject to the conditions and limitations set forth therein, we may sell to Lincoln Park up to $4.0 million of shares of our common stock, from time-to-time over the 12-month term of the Purchase Agreement, and upon execution of the Purchase Agreement we issued 308,637 shares of our common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Purchase Agreement. There are no assurances whether we will utilize any portion of, or receive any proceeds from, the Purchase Agreement.

Our negative cash flows from operations and accumulated deficit raise substantial doubt about our ability to continue as a going concern. The perception of our inability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials. We are in various stages of development of our product candidates, and we have only completed development of, and received regulatory approval for, one product, APADAZ. We expect to continue to incur significant expenses and operating losses over the next several years and our net losses may fluctuate significantly from quarter to quarter and year to year 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 product candidates;
- seek to discover and develop additional product candidates either internally or in partnership with other pharmaceutical companies;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio;
- incur additional legal, accounting and other expenses in operating as a public company; and
- add operational systems and personnel, if needed, to support any future commercialization efforts.

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, whether ourselves or through a license with a third party, any of our product candidates for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We are in various stages of these activities for our product candidates and we cannot guarantee that any strategy we adopt will be successful. For instance, in October 2018, we entered into the APADAZ License Agreement with KVK pursuant to which we granted an exclusive license to KVK to commercialize APADAZ in the United States. We cannot guarantee that KVK will be able to successfully commercialize APADAZ or that we will ever receive any payments under the APADAZ License Agreement from commercial sales of APADAZ. In addition, in September 2019, we entered into the KP415 License Agreement with Commave pursuant to which we granted an exclusive, worldwide license to Commave to develop, manufacture and commercialize KP415 and KP484 worldwide. Even if approved, we cannot guarantee that Commave will be able to successfully develop, manufacture or commercialize KP415 or KP484 or that we will ever receive any future payments under the KP415 License Agreement. We may never succeed in commercialization 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.

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 not 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, APADAZ or our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of prodrug products. We cannot guarantee that KVK will be able to successfully commercialize APADAZ, that Commave will be able to successfully commercialize any product candidates subject to the KP415 License Agreement, even if approved, or that we will ever receive any payments under the APADAZ License Agreement from commercial sales of APADAZ or any future payments under the KP415 License Agreement. 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. We previously entered into a credit facility, dated as of June 2, 2014, as subsequently amended, or the Deerfield Facility Agreement with Deerfield Private Design Fund III, LP, or Deerfield, and certain other holders of our senior secured convertible promissory notes. The Deerfield Facility Agreement 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. The Deerfield Facility Agreement also includes high yield discount obligation protections that went into effect in June 2019. Going forward, if at any interest payment date our outstanding indebtedness under the Deerfield Facility Agreement would qualify as an "applicable high yield discount obligation" under the Internal Revenue Code of 1986, as amended, or the Code, then we are obligated to prepay in cash on each such date the amount necessary to avoid such classification. Under the terms of the Deerfield Facility Agreement periodic interest is paid-in-kind and added to principal, we are required to make payments of all paid-in-kind interest and principal upon maturity. In this regard, if holders of the notes do not convert their notes prior to the maturity date, we will be required to repay the principal amount of all then outstanding notes plus any paid-in-kind, accrued and unpaid interest. We may also be required to repurchase the 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 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 substantial indebtedness may limit cash flow available to invest in the ongoing needs of our business.

We have a significant amount of indebtedness. As of February 1, 2020, we had $75.2 million of outstanding borrowings under the Deerfield Facility Agreement. Amounts outstanding under the Deerfield Facility Agreement bear interest at a rate of 6.75% per annum, and all outstanding principal and accrued interest for our outstanding borrowings under the Deerfield Facility Agreement are due and payable on March 31, 2021. Our obligations under the Deerfield Facility Agreement are secured by substantially all of our assets. We could in the future incur additional indebtedness beyond our borrowings under our Deerfield Facility Agreement.

Our debt combined with our other financial obligations and contractual commitments could have significant adverse consequences, including:

- requiring us to dedicate a substantial portion of cash flow from operations, if any, or cash on hand to the payment of interest on, and principal of, our debt, which will reduce the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and our industry; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

We may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt and funds from external sources may not be available on acceptable terms, if at all. In addition, a failure to comply with the covenants under the Deerfield Facility Agreement could result in an event of default and acceleration of amounts due. If an event of default occurs and the lenders accelerate the amounts due under the Deerfield Facility Agreement, we may not be able to make accelerated payments, and the lender could seek to enforce security interests in the collateral securing such indebtedness.

We may be unable to issue securities under our shelf registration statement, which may have an adverse effect on our liquidity.

We have filed shelf registration statements on Form S-3 with the SEC. Based on the market value of our outstanding common stock held by non-affiliates as of February 28, 2020, the date we filed this Annual Report on Form 10-K for the year ended December 31, 2019, in order to issue securities on Form S-3, we must rely on Instruction I.B.6. of Form S-3, which imposes a limitation on the maximum amount of securities that we may sell pursuant to the registration statements during any twelve-month period. At the time we sell securities pursuant to the applicable registration statement, the amount of securities to be sold plus the amount of any securities we have sold during the prior twelve months in reliance on Instruction I.B.6. may not exceed one-third of the aggregate market value of our outstanding common stock held by non-affiliates as of a day during the 60 days immediately preceding such sale, as computed in accordance with Instruction I.B.6. This calculation is updated immediately upon filing our Annual Report on Form 10-K for the year ended December 31, 2019. As of filing this Annual Report, based on this calculation, the amount of securities we are able to sell under a registration statement on Form S-3 is approximately $10.9 million, of which we (i) have filed a prospectus supplement to register approximately $4.0 million for sales under the Purchase Agreement (as defined below); and (ii) have previously sold an aggregate of $5.7 million of shares of common stock in prior offering on Form S-3 in the previous 12 months. Based on this calculation, we expect that we will be unable to sell additional securities beyond those amounts on Form S-3 in the near term, unless and until the market value of our outstanding common stock held by non-affiliates increases significantly. In addition, under the terms of the Purchase Agreement, stockholder approval may be required to access a portion of the amounts available under the Purchase Agreement. If we cannot sell securities on Form S-3, we may be required to utilize more costly and time-consuming means of accessing the capital markets, which could materially adversely affect our liquidity and cash position.

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. To date, we have only one product approved by the FDA, APADAZ for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. We have not yet demonstrated an ability to 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. Further, we cannot guarantee that KVK will be able to successfully commercialize APADAZ, that Commave will be able to successfully commercialize any product candidates subject to the KP415 License Agreement, if approved, or that we will ever receive any payments under the APADAZ License Agreement or the KP415 License Agreement from commercial sales of APADAZ or any other approved product candidates, if any. 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 activities are 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 proprietary LAT 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. As our scientific efforts are primarily focused on discovering novel prodrugs with new molecular structures, the 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 those product candidates into 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, for reasons including 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 a Complete Response Letter, or CRL, from the FDA for the APADAZ new drug application, or NDA. Following a Formal Dispute Resolution Request, or FDRR, process and detailed discussions with the FDA, we responded to the CRL by submitting an amended NDA for APADAZ. In February 2018, we announced that the FDA approved the NDA for APADAZ. If APADAZ is not successfully commercialized under our APADAZ License Agreement and we do not successfully develop and commercialize our product candidates based upon our proprietary LAT 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 non-clinical 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. In February 2018, we announced that the FDA approved the NDA for APADAZ for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Even with the regulatory approval of APADAZ by the FDA, we cannot guarantee that the FDA will approve any of our other product candidates for commercial sale. For example, our NDA submission for KP415 may not be accepted for filing by FDA, may encounter review difficulties, and may ultimately receive a Complete Response Letter for any deficiencies in nonclinical, clinical or manufacturing of KP415. 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, institutional review boards, or 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;
- 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 submissions 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 non-clinical 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 4 for the approval of APADAZ, but voted 18 to two against inclusion of abuse-deterrent labeling for APADAZ. Additionally, in June 2016, we received a CRL from the FDA for the APADAZ NDA. Following a FDRR process and detailed discussions with the FDA, we responded to the CRL we received in June 2016 by submitting an amended NDA for APADAZ for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. In February 2018, we announced that the FDA approved the NDA for APADAZ.

Any product candidates 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 for that indication, and our ability to generate revenue will be impaired.

We are early in our development efforts and have only one product which has completed development and obtained regulatory approval by the FDA, APADAZ. All our other active product candidates are in clinical or preclinical development. If commercialization of APADAZ or our product candidates is not successful, or we experience significant delays in commercialization, our business will be harmed.

We are early in our development efforts and have only one product that has completed development and been approved by the FDA, APADAZ. All of our other active product candidates are in clinical or preclinical development. We currently generate no commercial revenue from the sale of any prodrugs and we may never be able to successfully commercialize a prodrug product. For instance, while we have entered into the APADAZ License Agreement with KVK pursuant to which we granted an exclusive license to KVK to commercialize APADAZ in the United States, we cannot guarantee that KVK will be able to successfully commercialize APADAZ or that we will ever receive any payments under the APADAZ License Agreement from commercial sales of APADAZ. In addition, we entered into the KP415 License Agreement with Commave pursuant to which we granted an exclusive, worldwide license to Commave to develop, manufacture and commercialize KP415 and KP484 worldwide. We cannot guarantee that Commave will be able to successfully develop, manufacture or commercialize KP415 or KP484 or that we will ever receive any future payments under the KP415 License Agreement. We have invested substantially all our efforts and financial resources in the development of our proprietary LAT technology, the identification of potential product candidates and the development of our product candidates. Our ability to generate revenue from APADAZ under the APADAZ License Agreement and generate revenue from our product candidates will depend heavily on their successful development and eventual commercialization. The success of APADAZ and 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 APADAZ and our product candidates are outweighed by the benefits;
- successful development of our manufacturing processes for APADAZ under the APADAZ License Agreement and for our other 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 APADAZ and 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 differentiating claims in the labels for our product candidates;
- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for APADAZ and our product candidates and otherwise protecting our rights in our intellectual property portfolio;
- maintaining compliance with regulatory requirements, including cGMPs;
- launching commercial sales of APADAZ under the APADAZ License Agreement and launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with Commave or others;
- acceptance of APADAZ and 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.

Although APADAZ obtained regulatory approval in February 2018, it is possible that none of our other 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 KVK could experience an inability to successfully commercialize APADAZ or we could experience an inability to successfully commercialize our product candidates approved for marketing in the future, if any, which would harm our business.

If we, subject to the approval of Commave, or Commave themselves attempt to rely on Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act 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 or Commave to pursue the 505(b)(2) NDA pathway as anticipated, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and the FDA may not ultimately approve our product candidates.

A key element of our strategy is to seek FDA approval for most of our product candidates under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, otherwise known as the 505(b)(2) NDA pathway with any NDA submitted thereunder a 505(b)(2) NDA, where possible. The 505(b)(2) NDA 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, subject to Commave approval, we currently plan on relying on the 505(b)(2) pathway for any NDA submitted for KP415 or KP484. However, we do not anticipate that the 505(b)(2) pathway will be available for every product candidate. For instance, it is possible we will only be permitted to utilize the 505(b)(2) NDA pathway for either KP415 or KP484, but not both. 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 abbreviated new drug application, or ANDA, which is used for the development of generic drug products.

In addition, notwithstanding the approval of several 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 boxed warning, may be subject to other conditions of approval, or may contain requirements for costly post-marketing clinical trials, testing and surveillance to monitor the safety or efficacy of the products, or other post-market requirements, such as a Risk Evaluation and Mitigation Strategy, or REMS. The FDA also may not approve a product candidate with a label that includes the labeling claims necessary or desirable for the successful commercialization of that product candidate. Based upon currently approved products, we anticipate that we will be required to conduct Phase 4 studies and to implement a REMS and will have a boxed warning for at least some of our product candidates, including APADAZ.

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 submit 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 Federal Food, Drug and Cosmetic Act or the FDA's regulations;
- the NDA does not contain a statement that each non-clinical laboratory study was conducted in compliance with good laboratory practices 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 current 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 a CRL for the APADAZ NDA. 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-deterrent studies of APADAZ. Following a FDRR process and detailed discussions with the FDA, we responded to the CRL we received in June 2016 by submitting an amended NDA for APADAZ. In February 2018, we announced that the FDA approved the NDA for APADAZ for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Despite this, the final approved product labeling for APADAZ concluded that the overall results of the clinical program did not demonstrate abuse-deterrence by current measurement standards.

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. Additionally, if we do not successfully develop any product candidates subject to the KP415 License Agreement, we may not be eligible to receive any future payments under the KP415 License Agreement. 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 the 505(b)(2) NDA pathway, 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.

Regarding any NDA that we may submit under the 505(b)(2) NDA pathway, 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 considerable 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 may not be successful in our efforts to develop a prodrug-based product that might allow us to seek a rare pediatric disease priority review voucher.

The FDA has awarded rare pediatric disease priority review vouchers to sponsors of drug candidates to treat rare pediatric disease, if the treatment sponsors apply for this designation and meet certain criteria. Under this program, upon the approval of a qualifying NDA, for the treatment of a rare pediatric disease, the sponsor of such an application would be eligible for a rare pediatric disease priority review voucher that can be used to obtain priority review for a subsequent NDA. The priority review voucher may be sold or transferred an unlimited number of times.

We previously announced a technology licensing agreement with Genco Sciences, LLC to develop prodrug-based therapy for potential rare pediatric indications of Tourette’s Syndrome with ADHD. We cannot guarantee that we will be successful in this effort to develop such a prodrug-based therapy. Additionally, we cannot guarantee that the FDA would grant us a rare pediatric disease designation for such a prodrug-based product candidate. Even if the FDA grants us a rare pediatric disease designation for one of our prodrug-based product candidates, designation of a drug as a drug for a rare pediatric disease does not guarantee that an NDA for such drug will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved.

APADAZ is subject to mandatory REMS programs, which could increase the cost, burden and liability associated with the commercialization of APADAZ and certain product candidates.

The FDA has indicated that opioid analgesic 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. In September 2018, the FDA approved the Opioid Analgesic REMS for extended-release, long-acting, or ER/LA, and IR opioids as one strategy among multiple national and state efforts to reduce the risk of abuse, misuse, addiction, overdose and deaths due to prescription opioid analgesics. The Opioid Analgesic REMS affects more than 60 companies that manufacture these products. Under this REMS, companies are required to make training available to all healthcare providers who are involved in the management of patients with pain, including nurses and pharmacists. To meet this requirement, drug companies with approved opioid analgesics will provide unrestricted grants to accredited continuing education providers for the development of education courses for healthcare providers based on the FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain. The REMS program 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.

APADAZ is subject to this REMS, and we anticipate that any opioid product candidates we may choose to develop in the future, if approved by the FDA, are likely to also 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. In October 2018, we entered into the APADAZ License Agreement with KVK pursuant to which we granted an exclusive license to KVK to commercialize APADAZ in the United States. As part of this agreement KVK has assumed most regulatory and commercialization costs, including this REMS requirement.

APADAZ and 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 any of our product candidates, if approved, 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. For APADAZ, the DEA has completed its process for determining the controlled substance schedule and determined it to be a Schedule II drug. We expect that most of our product candidates, including KP415, KP484 and KP879, if approved, will be regulated as "controlled substances" as defined in the Controlled Substances Act, or 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 current product candidates may be listed by the DEA as Schedule II controlled substances under the CSA. If our product candidates are listed as Schedule II controlled substances, then the importation of the APIs for our product candidates, as well as the manufacture, shipping, storage, sales and use of the products, will be subject to a high degree of regulation. In addition to maintaining an importer and/or exporter registration, importers and exporters of controlled substances must obtain a permit for every import of a Schedule I or II substance and a narcotic substance in Schedule III, IV and V, as well as every export of a Schedule I or II substance and a narcotic substance in Schedule III and IV. For all other drugs in Schedule III, IV and V, importers and exporters must submit an import or export declaration. Schedule II drugs are subject to the strictest requirements for registration, security, recordkeeping and reporting. Also, distribution and dispensing of these drugs are highly regulated. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription. Electronic prescriptions may also be permissible depending on the state, so long as the prescription complies with the DEA's requirements for electronic prescriptions.

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

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

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Because most of our product candidates may be regulated as Schedule II controlled substances, they may be subject to the DEA's production and procurement quota scheme. The DEA establishes annually an aggregate quota for how much of a controlled substance may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. Manufacturers of Schedule I and II controlled substances are required to apply for quotas on an annual basis. If we or our contract manufacturers or suppliers do not obtain a sufficient quota from 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 affect 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 APADAZ or our other applicable 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 the ability to commercialize APADAZ under the APADAZ License Agreement or to commercialize our other applicable product candidates. Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of hydrocodone or other opioid drugs and stimulants, 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 APADAZ or our other applicable 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 formulations with improved attributes 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 APADAZ and our other applicable product candidates. For example, in April 2014, the FDA approved class-wide labeling changes to the indications for use of all approved ER/LA opioids, so that ER/LA 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. These changes have reduced the number of prescriptions for opioids written by physicians and negatively impact the potential market for APADAZ or our other applicable 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 previously 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 APADAZ or our other applicable product candidates.

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 regulatory standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, 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 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 partnered product and product candidates that utilize benzhydrocodone and SDX as the API used in our clinical trials and with a sole source supplier for the manufacture of bulk quantities of benzhydrocodone and SDX used in the partnered product and 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 benzhydrocodone and SDX, 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. We procure the bulk drug substances for KP415, KP484, APADAZ and KP879 from sole-source, third-party manufacturers and the partnered product and 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 product candidates, as well as for commercial manufacture of APADAZ or our product candidates should they receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of benzhydrocodone, SDX, other bulk drug substances or our partnered product or 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 APADAZ and 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.

We do not, other than through our contractual arrangements, control the manufacturing process of APADAZ or our product candidates, and we 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 manufacturing of APADAZ or 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 APADAZ or our product candidates, if approved.

Further, for APADAZ and our product candidates, if approved, our suppliers will be subject to regulatory requirements, covering manufacturing, testing, quality control and record keeping relating to APADAZ or our product candidates, if approved, 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 KP415, KP484 or KP879 bulk drug substance. If our current contract manufacturer for KP415, KP484 or KP879 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 have entered into collaborations with KVK, for the commercialization of APADAZ in the United States, and Commave, to develop, manufacture and commercialize KP415 and KP484 worldwide. In addition, we may seek collaborations with third parties for the development or commercialization of our other product candidates, or in other territories. If those collaborations are not successful, we may not be able to capitalize on the market potential of APADAZ or KP415, KP484 or other product candidates, if approved.

We have entered into the APADAZ License Agreement with KVK pursuant to which we granted an exclusive license to KVK to commercialize APADAZ in the United States. We cannot guarantee that our collaboration with KVK will be successful or that we will ever receive any payments under the APADAZ License Agreement. For instance, if the Initial Adoption Milestone is not achieved, KVK may terminate the APADAZ License Agreement without making any payments to us. Further, even if the Initial Adoption Milestone under the APADAZ License Agreement is achieved, we cannot guarantee that we will receive any additional milestone or royalty payments under the APADAZ License Agreement. Further, under the APADAZ License Agreement, we have limited control over the amount and timing of resources that KVK will dedicate to the commercialization of APADAZ, and we may not always agree with KVK's commercialization efforts. Our ability to generate revenue under the APADAZ License Agreement will depend on KVK's ability to successfully perform the functions assigned to it under the APADAZ License Agreement. The commercialization strategy under the APADAZ License Agreement is novel and untested, and, even if successful we expect that the pricing for any sales of APADAZ will be at or near the prices of currently available generic equivalent drugs. As a result, even if KVK does successfully perform its functions under the APADAZ License Agreement, we cannot guarantee that there will be sufficient market demand for APADAZ for us to receive any revenue under the APADAZ License Agreement.

In addition, we entered into the KP415 License Agreement with Commave pursuant to which we granted an exclusive, worldwide license to Commave to develop, manufacture and commercialize KP415 and KP484. We cannot guarantee that the K415 License Agreement with Commave will be successful or that we will receive any future payments under the KP415 License Agreement. For instance, Commave has the option to terminate the KP415 License Agreement, in its entirety or on a product-by-product and country-by-country basis, at their convenience either (i) prior to the first regulatory approval of a product upon sixty days prior written notice or (ii) subsequent to the first regulatory approval of a product upon one hundred twenty days prior written notice. Further, even if Commave does not terminate the KP415 License Agreement, we cannot guarantee that we will receive any additional milestone or royalty payments under the KP415 License Agreement. In addition, under the KP415 License Agreement, we have limited control over the amount and timing of resources that Commave will dedicate to the development, manufacturing or commercialization of KP415 and KP484, and we may not always agree with Commave's efforts. Our ability to generate revenue under the KP415 License Agreement will depend, in part, on Commave's ability to successfully perform the functions assigned to it under the KP415 License Agreement.

We may also seek additional third-party collaborators for the commercialization of APADAZ outside of the United States or for the development or commercialization of our other product candidates, which are not subject to the KP415 License Agreement, or those that are subject to the KP415 License Agreement but the option is not exercised by Commave. In such cases, our likely collaborators would include large and mid-size pharmaceutical companies, regional, national and international pharmaceutical companies and biotechnology companies. If we do enter into any such 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 APADAZ outside of the United States or our other 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.

Our collaborations with KVK and Commave, or combined the Collaborators, pose the following risks to us:

- The Collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- The Collaborators may not perform their obligations as expected;
- The Collaborators may not pursue commercialization of APADAZ the products covered under the KP415 License Agreement, if approved, or may elect not to continue or renew commercialization programs based on post-approval clinical trial results, changes in the Collaborator's strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- The Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with APADAZ or the products covered under the KP415 License Agreement, as applicable, 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;
- APADAZ and the products covered under the KP415 License Agreement may be viewed by the Collaborators as competitive with their own product candidates or products, which may cause the Collaborators to cease to devote resources to the commercialization of APADAZ or the products covered under the KP415 License Agreement, if approved;
- The Collaborators may not commit sufficient resources to the development, marketing and distribution of APADAZ and the products covered under the KP415 License Agreement, as applicable;
- disagreements with the Collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development or commercialization, might cause delays or termination of the development or commercialization of APADAZ or the products covered under the KP415 License Agreement, as applicable, might lead to additional responsibilities for us with respect to APADAZ or the products covered under the KP415 License Agreement, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- The 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;
- The Collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- the license agreements may be terminated by the Collaborators under specified circumstances and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of APADAZ or the products covered under the KP415 License Agreement.

If we enter into any future collaborations we will face similar risks with any future collaborators as well.

The APADAZ License Agreement, KP415 License Agreement and any other licensing or collaboration agreements we may enter into may not lead to commercialization of APADAZ or development or commercialization of KP415, KP484 or of our other product candidates in the most efficient manner or at all. If KVK, Commave or a 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 for our product candidates, we may have to alter our development and commercialization plans.

Our prodrug development programs and the potential commercialization of our product candidates, if approved, will require substantial additional capital. For our product candidates, which are not subject to the terms of the APADAZ License Agreement or KP415 License Agreement, 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 of our product candidates or reduce the scope of any sales or marketing activities of our product candidates, or increase our expenditures and undertake development or commercialization activities at our own expense of our product candidate. 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 our product candidates to market and generate product revenue.

Provisions in our agreements with Aquestive Therapeutics and Commave may inhibit our ability to enter into future collaborations with third parties.

We are party to a termination agreement with Aquestive that may limit the value of any sale, license or commercialization of KP415, KP484 or KP879. Under this termination agreement, Aquestive has the right to receive a royalty amount equal to 10% of any value generated by KP415, KP484 or KP879, and any product candidates which contain SDX, including royalty payments on any license of KP415, KP484 or KP879, the sale of KP415, KP484 or KP879 to a third party or the commercialization of KP415, KP484 or KP879. As part of the KP415 License Agreement, we paid Aquestive a royalty equal to 10% of the license upfront payment we received in the third quarter of 2019.

We also granted to Commave a right of first refusal to acquire, license or commercialize any Additional Product Candidate, with such right of first refusal expiring upon the acceptance of a new drug application for such Additional Product Candidate. We also granted Commave a right of first negotiation and a right of first refusal, subject to specified exceptions, for any assignment of our rights under the KP415 License Agreement. We cannot predict if these obligations will limit the value we may receive from any future sale or license of any Additional Product Candidate.

Provisions in the Deerfield Facility Agreement 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 Agreement, we may not enter into specified transactions, including any joint venture, partnership or any other profit-sharing arrangement, without the prior approval of the holders of a majority of our senior secured convertible promissory notes. The interests of our noteholders may not always coincide with our corporate interests or the interests of our other stockholders, and our noteholders 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 our noteholders do not approve our entry into specified transactions, it could significantly delay or inhibit the commercialization of our product candidates. For instance, our noteholders consented to our entry into the APADAZ License Agreement and KP415 License Agreement, but we cannot guarantee that sufficient noteholders will consent to any future collaboration agreement for commercialization of APADAZ outside of the United States or for the development or commercialization of any of our other 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, APADAZ, KP415, KP484 and our other 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, APADAZ, KP415, KP484 and our other product candidates, if approved, may be impaired.

Our success depends in large part on our ability to obtain and maintain trade secret protection of our proprietary LAT technology as well as patent protection in the United States and other countries with respect to APADAZ, KP415, KP484 and our other 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. As part of the APADAZ License Agreement, KVK obtained from us an exclusive license to certain patents that cover APADAZ. In addition, as part of the KP415 License Agreement, Commave obtained from us an exclusive, worldwide license to certain patents that cover KP415 and KP484.

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

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

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

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

- we may fail to seek patent protection for inventions that are important to our success;
- our pending patent applications may not result in issued patents;
- we cannot be certain that we are the first to invent the inventions covered by pending patent applications or that we are the first to file such applications and, if we are not, we may be subject to priority disputes or lose rights;
- we may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications;
- we may file patent applications but have claims restricted or we may not be able to supply sufficient data to support our claims and, as a result, may not obtain the original claims desired or we may receive restricted claims; alternatively, it is possible that we may not receive any patent protection from an application;
- even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, and may not be of sufficient scope or strength to provide us with any commercial advantage;
- our competitors may be able to design around our owned or licensed patents by developing similar or alternative technologies or drugs without infringing on our intellectual property rights;
- we could inadvertently abandon a patent or patent application, resulting in the loss of protection of intellectual property rights in a particular country, and we, our collaborators or our patent counsel may take action resulting in a patent or patent application becoming abandoned which may not be able to be reinstated or if reinstated, may suffer patent term adjustments;
- the claims of our issued patents or patent applications when issued may not cover our product candidates;
- no assurance can be given that our patents would be declared by a court to be valid or enforceable or that a competitor's technology or product would be found by a court to infringe our patents and our patents or patent applications may be challenged by third parties in patent litigation or in proceedings before the United States Patent and Trademark Office, or 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 proprietary LAT 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 proprietary LAT 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.

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.

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 our 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 license agreements 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 another 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 APADAZ and any of our product candidates that are approved for marketing from the products of our competitors. We have registered trademarks for APADAZ and KemPharm. In addition, we have solicited and applied for trademarks for the KemPharm Logo, LAT and several potential tradenames and logos for KP415. For our other product candidates, we have not yet solicited trademarks and have not yet begun the process of applying to register trademarks. 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. If 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 APADAZ and 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 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 Partnered Product and Product Candidates

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

We have only a limited sales and 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. While we entered into the APADAZ License Agreement to establish a collaboration for the commercialization of APADAZ and we entered into the KP415 License Agreement to establish a collaboration for the commercialization of any product candidates subject to such agreement, we may not choose to enter into a collaboration for any future approved product. 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. For instance, under the APADAZ License Agreement, we and KVK will share the quarterly net profits of APADAZ by KVK in the United States at specified tiered percentages, with the portion we receive ranging from 30% to 50% of net profits. As a result, we will be entitled to a smaller portion of the net profits of any sales of APADAZ in the United States than if we had decided to sell, market and distribute APADAZ ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates in the future, or may be unable to do so on terms that are favorable to us, including as a result of restrictions in the Deerfield Facility Agreement. We likely will have little control over such third parties, including KVK and Commave, and any of them may fail to devote the necessary resources and attention to sell and market APADAZ, KP415, KP484 or our other product candidates, if approved, effectively. Further, we may be liable for conduct of third parties, including KVK and Commave, acting on our behalf, including failure to comply with legal requirements applicable to sales and marketing of our product or product candidates, if approved. 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 APADAZ, KP415, KP484 or our other product candidates, if approved.

APADAZ, or any of our product candidates that may receive marketing approval, 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.

APADAZ, or any of our product candidates that may receive marketing approval, may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Despite the fact that APADAZ is now nationally available, we cannot guarantee that it will receive significant, if any, market acceptance in the United States. If APADAZ, or any other product candidates, if approved for commercial sale, do not achieve an adequate level of market acceptance, they may not generate significant product revenue and we may not become profitable. For instance, under the APADAZ License Agreement, we are entitled to milestone and royalty payments only if APADAZ sales in the United States are above specified levels. If APADAZ does not achieve an adequate level of market acceptance, it is unlikely that sales will satisfy these thresholds and we may not be entitled to any payments under the APADAZ License Agreement. Additionally, the commercialization strategy under the APADAZ License Agreement is novel and untested, and, even if successful we expect that the pricing for any sales of APADAZ will be at or near the prices of currently available generic equivalent drugs. Accordingly, we expect that APADAZ will need to achieve broad market acceptance in order for this strategy to be successful. The degree of market acceptance of APADAZ, or 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 differentiating 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 APADAZ and 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 APADAZ or 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 or product candidates and these competitors may also have significantly more resources than us and be more successful than us in manufacturing and marketing their products.

If approved, KP415 and KP484 will compete against currently marketed, branded and generic methylphenidate products for the treatment of ADHD. Some of these currently marketed products include Janssen's Concerta, Tris Pharma's QUILLIVANT XR and QUILLICHEW ER, Novartis' RITALIN, FOCALIN and Focalin XR, UCB's METADATE CD, Noven's Daytrana, nEOS tHERAPEUTICS' CONTEMPLA XR-ODT, Ironshore Pharmaceuticals, Inc.'s JORNAY PM and Adlon Therapeutics' Adhansia XR, in addition to multiple other branded and generic methylphenidate products. In addition, if approved, KP415 and KP484 will face potential competition from any other methylphenidate products for the treatment of ADHD that are currently in or which may enter into clinical development.

Currently, there are no approved drugs in the United States for the treatment of SUD. If approved, KP879 will face potential competition from any products for the treatment of SUD that are currently in or which may enter into clinical development.

APADAZ competes against currently marketed, branded and generic IR hydrocodone/APAP combination products indicated for the short-term management of acute pain. In addition, APADAZ will face potential competition from any IR or hydrocodone/APAP combination products for the short-term management of acute pain that are currently in or may enter into clinical development.

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 products for 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 drugs with improved attributes 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.

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 products for the treatment of ADHD, pain 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 a new chemical entity or three-year FDA regulatory exclusivity.

The FDA provides periods of regulatory exclusivity following their approval of an NDA, which provide the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug. Five-year exclusivity precludes approval of 505(b)(2) applications or ANDAs by delaying the submission or approval of the application, while three-year exclusivity precludes the approval of the application. We intend to seek new chemical entity, or NCE, status for any of our 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 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 competitive differentiating mechanisms or may be able to obtain approval for similar products without a competitive differentiating mechanism.

Even if we or our collaborators are able to commercialize APADAZ, or any of our product candidates, they may be subject to unfavorable pricing regulations, third-party coverage and reimbursement policies.

The successful commercialization of APADAZ and any of our product candidates will depend, in part, on the extent to which coverage and adequate reimbursement for APADAZ, or 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, APADAZ, or 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 APADAZ under the APADAZ License Agreement, or 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 APADAZ, or 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 the ability to sell APADAZ under the APADAZ License Agreement, or our ability to sell any of 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 our improved attribute 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 APADAZ or 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 as APADAZ, and any prodrug products that may be approved in the future, are commercialized. This includes the risk that our products may be misused. For example, APADAZ does, and we anticipate that any other product candidates we may choose to develop in the future, if approved may, carry a boxed warning regarding lethality if our oral tablets or capsules 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 on behalf of ourselves. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for APADAZ and 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 successfully commercialize APADAZ or 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 upon commencement of commercialization of any product approved in the future. 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;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- 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 APADAZ and 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 APADAZ and our product candidates internationally could affect our business.

We may seek regulatory approval for APADAZ and 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.

APADAZ is, and 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 or our collaborators fail to comply with regulatory requirements or if we or our collaborators experience unanticipated problems with APADAZ, or our product candidates when and if any of them are approved.

APADAZ is, and any product candidate for which we obtain marketing approval could 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. For example, we are required to conduct pediatric studies related to APADAZ to determine its safety and effectiveness for the claimed indication in pediatric patients. Under the APADAZ License Agreement, KVK will be responsible for these regulatory activities going forward, and we cannot guarantee they will be complied with. 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.

APADAZ is, and if marketing approval of a product candidate is granted 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. For example, in September 2018, the FDA approved the Opioid Analgesic REMS for ER/LA and IR opioids as one strategy among multiple national and state efforts to reduce the risk of abuse, misuse, addiction, overdose, and deaths due to prescription opioid analgesics. APADAZ is subject to this REMS, and we anticipate that any of our other opioid product candidates that we may choose to develop in the future, if approved by the FDA, are likely to also be subject to a REMS requirement.

APADAZ does, and if any of our product candidates receive marketing approval they may, have a label that limits their 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 boxed 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 boxed warnings, including warnings regarding tampering, lethality if our oral tablets or capsules 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. APADAZ is subject to a post-marketing requirement for four deferred pediatric assessments that must be completed pursuant to the FDA's February 2018 approval letter. 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 Federal Food, Drug and Cosmetic Act relating to the promotion of prescription drugs may lead to a number of actions and penalties, including warning letters, cyber letters, or untitled letters, adverse publicity, the requirement for dear-health-care-provider letters or other corrective information, fines and other monetary penalties, civil or criminal prosecution, including False Claims Act liability, restrictions on our operations and other operating requirements through consent decrees or corporate integrity agreements, debarment, exclusion from participation in federal health care programs and refusal of government contracts or future orders under existing contracts, among other consequences.

In addition, later discovery of previously unknown adverse events or other problems with our 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, significant civil, criminal and administrative penalties including False Claims Act liability, damages, monetary fines, disgorgement, restitution, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, corporate integrity agreements, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, among other consequences, any of which could adversely affect our ability to operate.

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

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the Anti-Kickback Statute and the 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 False Claims Act, which impose criminal and civil penalties, including through 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 False Claims Act, for violations of the federal 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;

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

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations, which impose obligations on covered entities, including certain 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 Affordable Care Act, or the ACA, and its implementing regulations, which imposes new annual reporting requirements for 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, as defined by such law, 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.

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, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, corporate integrity agreements or similar agreements to resolve allegations of non-compliance with these laws, 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 significant 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 our product candidates and increase the cost to commercialize APADAZ and any of our product candidates that may be approved in the future and affect the prices thereof.

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 the ability to profitably sell APADAZ under the APADAZ License Agreement and 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 federal 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 70% 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, 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 remain judicial and congressional challenges to numerous provisions of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA, and we expect there will be additional challenges and amendments in the future. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provision of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act includes a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and 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, due to subsequent legislative amendments, including the BBA, will stay in effect through 2029 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 and enacted federal and state legislation 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. At the federal level, the Trump administration's budget proposal for fiscal year 2020 contains further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, establish an international price index for Medicare Part B pricing and to eliminate the Medicaid drug rebate cap. Further, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and, at the same, has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. 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, R. LaDuane Clifton, CPA, our chief financial officer, and Sven Guenther, Ph.D., our executive vice president research and development, 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.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our product candidate 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 a low of $0.27 to a high of $26.15 through February 26, 2020. 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, including without limitation changes in the structure of healthcare payment systems;
- 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 4 for the approval of APADAZ but voted 18 to 2 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 Nasdaq. Additionally, when we announced in June 2016 that the FDA had issued a CRL for the APADAZ NDA, the trading price of our common stock on Nasdaq 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 in the Iowa District Court in Johnson County by a stockholder 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. In June 2018, the case was dismissed without prejudice to members of the putative class. Future litigation could cause us to incur substantial costs and divert management's attention and resources from our business. Further, companies listed on The Nasdaq Capital 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 we fail to maintain compliance with the listing requirements of The Nasdaq Stock Market, we may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is currently listed on The Nasdaq Capital Market. To maintain the listing of our common stock on The Nasdaq Capital Market, we are required to meet certain listing requirements.

If we fail to satisfy the continued listing requirements of The Nasdaq Capital Market, The Nasdaq Capital Market may take steps to delist our common stock, which could have a materially adverse effect on our ability to raise additional funds as well as the price and liquidity of our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair our stockholders' ability to sell or purchase our common stock when they wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement, or prevent future non-compliance with The Nasdaq Capital Market's listing requirements.

On January 15, 2020, we announced that the Nasdaq Listing Qualifications Panel, or Nasdaq Listings Panel, of the Nasdaq Stock Market, LLC, or Nasdaq, granted us an extension, until May 13, 2020, to regain compliance with the Market Value of Listed Securities, or MVLS, continued listing requirement of The Nasdaq Capital Market, conditioned upon achievement of certain milestones included in a plan of compliance which we previously submitted to the Nasdaq Listings Panel. Previously, on May 17, 2019, we received notice from the Listing Qualification Department of Nasdaq that we were not in compliance with the continued listing requirement of The Nasdaq Global Market to maintain a minimum MVLS of $50.0 million. By transferring the listing of our common stock to The Nasdaq Capital Market, we will regain compliance with the MVLS continued listing requirement of The Nasdaq Capital Market by reaching a minimum MVLS of $35.0 million for ten consecutive trading days on or before May 13, 2020. Should we fail to demonstrate compliance with the MVLS continued listing requirement by that date, Nasdaq will issue a final delisting determination and we will be suspended from trading on the Nasdaq Stock Market. In order to maintain the listing of our common stock on The Nasdaq Capital Market, we must also regain compliance for all other continued listing standards within the applicable compliance period.

For instance, on September 27, 2019, we received notice from Nasdaq that we were not in compliance with the continued listing requirement to maintain a minimum bid price of $1.00. The initial compliance period for this continued listing requirement ends on March 25, 2020. If we fail to increase our bid price above $1.00 for at least ten consecutive trading days prior to this time, then our bid price deficiency may be an additional ground for delisting by Nasdaq.

Additionally, on December 19, 2019, we received notice that we were not in compliance with the continued listing requirement of The Nasdaq Global Market to maintain a minimum Market Value of Publicly Held Shares, or MVPHS, of $15.0 million. However, upon transferring to The Nasdaq Capital Market, the Company became subject to its MVPHS continued listing requirement, which is $1.0 million. Based on the lower requirement, the Company has maintained a MVPHS greater than $1.0 million since transferring The Nasdaq Capital Market.

If we do not regain compliance within the allotted compliance period(s), including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our shares of common stock will be subject to delisting. At such time, we may appeal the delisting determination to a hearings panel pursuant to the procedures set forth in the applicable Nasdaq Listing Rules.

There can be no assurance that we will be successful in maintaining the listing of our common stock on The Nasdaq Capital Market. This could impair the liquidity and market price of our common stock. In addition, the delisting of our common stock from a national exchange could have a material adverse effect on our access to capital markets, and any limitation on market liquidity or reduction in the price of our common stock as a result of that delisting could adversely affect our ability to raise capital on terms acceptable to us, or at all.

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

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

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

Our outstanding senior secured convertible promissory notes and the warrant we issued to Deerfield under the Deerfield Facility Agreement, or the Deerfield Warrant, each include conversion or exercise, as applicable, price protection provision, pursuant to which the conversion or exercise, as applicable, price of each note or the Deerfield Warrant will be adjusted downward on a broad-based weighted-average basis if we issue or sell any shares of common stock, convertible securities, warrants or options at a sale or exercise price per share less than the greater of (i) $5.85 per share, which represents the Deerfield Warrant's exercise price and the conversion price of our outstanding senior secured convertible promissory notes or (ii) the closing sale price of our common stock as reported on The Nasdaq Capital 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, 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 our outstanding senior secured convertible promissory notes 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, provided that this anti-dilution adjustment will not apply to any sales made under the Purchase Agreement, the Second ATM Agreement or the September 2019 Exchange Agreement, as amended, or the September 2019 Exchange Agreement, that we entered into with Deerfield and Deerfield Special Situations Fund, or the Deerfield Lenders.

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

We expect that we will need significant additional capital in the short term to continue as a going concern and in the future to fund our planned future 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.

The holders of our senior secured convertible promissory notes may convert all or any portion of the outstanding principal and any accrued but unpaid interest on such notes into shares of our common stock at a conversion price of $5.85 per share.

According to the terms of our outstanding senior secured convertible promissory notes in no event may any holder thereof convert such holder's note to the extent such conversion would result in such holder beneficially owning more than 4.985% of the then issued and outstanding shares of our common stock, provided that this limitation is 19.985% of our issued and outstanding common stock for any holder of our senior secured convertible promissory note who owned more than 4.985% of our issued and outstanding common stock at the time the issuance of such note. 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 noteholder is only able to convert such holder's senior secured convertible promissory note into a limited number of shares due to this conversion limitation, such 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 such holder sells some of its existing shares.

In September 2019, we entered into the September 2019 Exchange Agreement, which was subsequently amended in December 2019. Under the September 2019 Exchange Agreement, we issued an aggregate of 1,499,894 shares of our common stock and an aggregate of 1,576 shares of our Series B-1 Preferred Stock in exchange for the cancellation of an aggregate of $3,000,000 principal amount of our then outstanding convertible debt. As of February 1, 2020, 1,576 shares of Series B-1 Preferred Stock have been converted into 1,659,996 shares of common stock. The September 2019 Exchange Agreement provides the Deerfield Lenders the option to exchange the principal amount of their outstanding senior secured convertible promissory notes for shares of common stock or shares of our Series B-2 convertible preferred stock, subject to the terms and conditions set forth in the September 2019 Exchange Agreement. In December 2019, we amended the September 2019 Exchange Agreement, to, among other things, (i) to allow the Deerfield Lenders to effect optional exchanges of all their outstanding senior secured convertible promissory notes under the terms of the September 2019 Exchange Agreement; (ii) amend the common stock exchange price under the September 2019 Exchange Agreement to be a per share price equal to the greater of (x) $0.60, subject to adjustment to reflect stock splits and similar events, or (y) the average of the volume-weighted average prices of our common stock on the Nasdaq Capital Market on each of the 15 trading days immediately preceding such exchange, (iii) provide that no more than 28,439,015 of shares of our common stock shall be issued pursuant to optional exchanges under the September 2019 Exchange Agreement (whether by common stock exchange or upon conversion of shares of Series B-2 convertible preferred stock), subject to adjustment to reflect stock splits and similar events and (iv) eliminate limitations regarding the timing and aggregate amount of principal which may be exchanged under the September 2019 Exchange Agreement. If the Deerfield Lenders choose to exchange any portion of their senior secured convertible promissory notes for shares of Series B-2 convertible preferred stock, such exchange will be effected at an exchange price of $1,000 per share. As of February 1, 2020, there was an aggregate of 17,439,015 shares of our common stock issuable (i) in exchange of the then outstanding principal amount of our senior secured convertible promissory notes held by the Deerfield Lenders, or (ii) upon conversion of the Series B-2 convertible preferred stock issuable in exchange of the then outstanding principal amount of such senior secured convertible promissory notes.

If Deerfield Lenders elect to exchange their senior secured convertible promissory notes for shares of our common stock (or convert any shares of our Series B-2 preferred stock for shares of common stock), or the holders of our senior secured convertible promissory notes elect to convert such notes into common stock, your ownership interest will be diluted and the market price of our common stock may be materially and adversely effected.

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

In February 2020, we entered into the Purchase Agreement with Lincoln Park which provides that, upon the terms and subject to the conditions and limitations set forth therein, we may sell to Lincoln Park up to $4.0 million of shares of our common stock, from time to time over the 12-month term of the Purchase Agreement, and we issued an additional 308,637 shares of our common stock to Lincoln Park as commitment shares under the Purchase Agreement. Concurrently with entering into the Purchase Agreement, we also entered into the Registration Rights Agreement, pursuant to which we agreed to register the sale of the shares of our common stock that have been and may be issued to Lincoln Park under the Purchase Agreement pursuant to our Current Registration Statement or a new registration statement.

The accounting method for the Deerfield Warrant, our outstanding senior secured convertible promissory notes and the warrant we issued to KVK under the APADAZ License Agreement could have a material effect on our reported financial results.

The Deerfield Warrant, our outstanding senior secured convertible promissory notes and the warrant we issued to KVK under the APADAZ License Agreement contain embedded derivatives, which require 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.

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.

Deerfield has the right, subject to some conditions, to require us to file one or more registration statements covering its shares of our common stock, including shares issued or issuable upon conversion or exercise of its senior secured convertible promissory note issued in June 2014 and the Deerfield Warrant, as applicable, or to include such 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 Aquestive and our outstanding senior secured convertible promissory notes, the Deerfield Warrant and Deerfield Facility Agreement, may 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 Aquestive will be entitled to a royalty equal to 10% of the price being paid to us and our stockholders in such transaction which is attributable to the value of KP415, KP484 or KP879, as was the case with the KP415 License Agreement. Pursuant to the Deerfield Facility Agreement, we may not enter into any major transaction without the prior approval of a majority of the holders of our outstanding senior secured convertible promissory notes, including a merger, asset sale or change of control transaction, and pursuant to the terms of such notes, each holder thereof has the option to demand repayment of all outstanding principal, and any unpaid interest accrued thereon, of such 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. A takeover of us may trigger the requirement that we repurchase our outstanding senior secured convertible promissory notes and the Deerfield Warrant, which could make it more costly for a potential acquirer to engage in a business combination transaction with us.

Finally, in the event of a sale of the Company the holders of our Series B-2 convertible preferred stock, if any, will share ratably in any distribution of our assets or other proceeds with holders of common stock on an as-converted basis without giving effect to any limitation on conversion of the Series B-2 convertible preferred stock. This would in turn reduce the distribution to the holders of our common stock in such change of control.

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 (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) 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 (iv) any action asserting a claim against us that is governed by the internal affairs doctrine. While these choice of forum provisions do not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction, 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 Our Business Startups Act, or the JOBS Act, and we take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

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

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 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 $1.00 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, 2019, we had federal net operating loss carryforwards of approximately $217.1 million, due to prior period losses, $138.1 million of 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. On December 22, 2017, the U.S. government enacted H.R. 1, "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018" (informally titled the Tax Cuts and Jobs Act). Under the Tax Cuts and Jobs Act, U.S. federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act. To the extent that we continue to generate taxable losses in the United States, unused losses will carry forward to offset future taxable income (subject to any applicable limitations), if any. In addition, under Section 382 and Section 383 of the Code, 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 performed a Section 382 ownership change analysis in 2017 and determined that we experienced an ownership change in 2010, which resulted in a portion of our net operating loss carryforwards being subject to an annual limitation under Section 382 through 2012. No other ownership changes or limitations on our historical net operating loss carryforwards were noted through the year ended December 31, 2017. 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 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.

Changes in tax laws or regulations that are applied adversely to us may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic earnings, if any. Any new taxes could adversely affect our business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, significantly revised the Internal Revenue Code of 1986, as amended. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Cuts and Jobs Act may affect us, and certain aspects of the Tax Cuts and Jobs Act could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Cuts and Jobs Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

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 of 2002, or 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 controls over financial reporting. For our fiscal year ended December 31, 2019, we performed system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K, as required by Section 404 of the Sarbanes-Oxley Act. We will be required to perform this evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting on an annual basis. This requires 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 controls 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.

For example, management identified a control deficiency as of December 31, 2019 regarding our ineffective controls over non-routine transactions that constituted a material weakness. For more information regarding the material weakness refer to our risk factor titled "In connection with preparation of our annual financial statements for the fiscal year ended December 31, 2019, we identified a material weakness in our internal control over financial reporting. Any failure to maintain effective internal control over financial reporting could harm us" and Item 9A of this annual report on Form 10-K. We are still considering the full extent of the procedures to implement in order to remediate this material weakness. We can give no assurances that any additional material weakness will not arise in the future due to our failure to implement and maintain adequate internal controls over financial reporting. In addition, even if we are successful in strengthening our controls and procedures to resolve this material weakness, those controls and procedures may not be adequate to prevent or identify irregularities or ensure the fair presentation of our financial statements included in our periodic reports filed with the SEC.

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 Facility Agreement, 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

As of December 31, 2019, we occupied approximately 17,000 square feet of headquarters 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 February 2020, we agreed to sublease approximately 6,000 square feet of office space in Celebration, Florida to a third-party, under a non-cancelable lease agreement that expires in February 2026. In addition, we occupy leased laboratory space in Coralville, Iowa and Blacksburg, Virginia. We believe that our facilities are adequate for our current needs.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Common Stock Listing

From April 16, 2015 until January 14, 2020, our common stock was listed on The Nasdaq Global Market under the symbol “KMPH”. Effective January 15, 2020, our common stock was listed on The Nasdaq Capital Market under the symbol “KMPH”. Prior to April 16, 2015, there was no public trading market for our common stock.

Holders of our Common Stock

As of February 26, 2020, we had 132 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 Agreement limits 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.

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 specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs to treat serious medical conditions through our proprietary Ligand Activated Therapy, or LAT™, technology. We utilize our proprietary LAT technology to generate improved prodrug versions of drugs approved by the U.S. Food and Drug Administration, or FDA, as well as to generate prodrug versions of existing compounds that may have applications for new disease indications. Our product candidate pipeline is focused on the high need areas of attention deficit hyperactivity disorder, or ADHD, and stimulant use disorder, or SUD. Our co-lead clinical development candidates, KP415 and KP484, are both based on a prodrug of d-methylphenidate, or d-MPH, but with differing extended-release, or ER, effect profiles, and are intended for the treatment of ADHD. Our preclinical product candidate for the treatment of SUD is KP879, based on a prodrug of d-MPH. In addition, we have announced our commercial partnership with KVK Tech, Inc., or KVK, of APADAZ®, an FDA approved immediate-release, or IR, combination product of benzhydrocodone, our prodrug of hydrocodone, and acetaminophen, or APAP, for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

We expect that our only source of revenues will be through payments arising from our license agreements with KVK and Commave, and through any other future arrangements we might enter into related to one of our other product candidates. To date, we have only generated revenue from the KP415 License Agreement in the form of the non-refundable upfront payment of $10.0 million, of which we paid Aquestive $1.0 million as a royalty payment, reimbursement of out-of-pocket third-party research and development costs and payments related to the performance of consulting services. We had negative cash flows from operations since our inception and, as of December 31, 2019, had an accumulated deficit of $245.7 million. Our negative cash flows from operations for the years ended December 31, 2019 and 2018 were $23.7 million and $54.2 million, respectively.

We expect to continue to incur significant expenses and negative operating cash flows 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 fluctuate 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 either internally or in partnership with other pharmaceutical companies;
- 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 APADAZ or any other product candidates for which we obtain regulatory approval. In October 2018, we entered into the APADAZ License Agreement with KVK, pursuant to which we granted an exclusive license to KVK to commercialize APADAZ in the United States, and in September 2019, we entered into the KP415 License Agreement, pursuant to which we granted an exclusive, worldwide license to Commave to develop, manufacture and commercialize our product candidates containing SDX and d-MPH, including KP415 and KP484. We cannot guarantee that KVK or Commave will be able to successfully commercialize APADAZ or our product candidates covered under the KP415 License Agreement, or that we will ever receive any payments under the APADAZ License Agreement from commercial sales of APADAZ or any future payments under the KP415 License Agreement. We also do not know when, if ever, any other product candidate 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, 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.

Our recurring negative cash flows from operations and stockholders' deficit raise substantial doubt about our ability to continue as a going concern. We expect that our only source of revenues will be through payments arising from our license agreements with KVK and Commave, and through any other future arrangements related to one of our other product candidates. Accordingly, our ability to continue as a going concern will require us to obtain additional financing to fund our operations. The perception of our inability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees. 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, 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

APADAZ License Agreement

In October 2018, we entered into the APADAZ License Agreement with KVK pursuant to which we have granted an exclusive license to KVK to conduct regulatory activities for, manufacture and commercialize APADAZ in the United States.

Pursuant to the APADAZ License Agreement, KVK has agreed to pay us certain payments and cost reimbursements of an estimated $3.4 million, which includes a payment of $2.0 million within 10 days of the achievement of a specified milestone related to the initial formulary adoption of APADAZ, or the Initial Adoption Milestone. In addition, KVK has agreed to make additional payments to us upon the achievement of specified sales milestones of up to $53.0 million in the aggregate. Further, we and KVK will share the quarterly net profits of APADAZ by KVK in the United States at specified tiered percentages, ranging from us receiving 30% to 50% of net profits, based on the amount of net sales on a rolling four quarter basis. We are responsible for a portion of commercialization and regulatory expenses for APADAZ until the Initial Adoption Milestone is achieved, after which KVK will be responsible for all expenses incurred in connection with commercialization and maintaining regulatory approval in the United States.

The APADAZ License Agreement will terminate on the later of the date that all of the patent rights for APADAZ have expired in the United States or KVK’s cessation of commercialization of APADAZ in the United States. KVK may terminate the APADAZ License Agreement upon 90 days written notice if a regulatory authority in the United States orders KVK to stop sales of APADAZ due to a safety concern. In addition, after the third anniversary of the APADAZ License Agreement, KVK may terminate the APADAZ License Agreement without cause upon 18 months prior written notice. We may terminate the APADAZ License Agreement if KVK stops conducting regulatory activities for or commercializing APADAZ in the United States for a period of six months, subject to specified exceptions, or if KVK or its affiliates challenge the validity, enforceability or scope of any licensed patent under the APADAZ License Agreement. Both parties may terminate the APADAZ License Agreement (i) upon a material breach of the APADAZ License Agreement, subject to a 30-day cure period, (ii) the other party encounters bankruptcy or insolvency or (iii) if the Initial Adoption Milestone is not achieved. Upon termination, all licenses and other rights granted by us to KVK pursuant to the APADAZ License Agreement would revert to us.

The APADAZ License Agreement also established a joint steering committee, which monitors progress of the commercialization of APADAZ.

KP415/484 License Agreement

In September 2019, we entered into the KP415 License Agreement with Commave. Under the KP415 License Agreement, we granted to Commave an exclusive, worldwide license to develop, manufacture and commercialize our product candidates containing SDX and d-MPH, including KP415, KP484, and, at the option of Commave, KP879, KP922 or any other product candidate developed by us containing SDX and developed to treat ADHD or any other central nervous system disorder, or the Additional Product Candidates and, collectively with KP415 and KP484, the Licensed Product Candidates.

Under the terms of the KP415 License Agreement, we granted Commave an exclusive, worldwide license to commercialize and develop the Licensed Product Candidates; provided that such license shall apply to an Additional Product Candidates only if Commave exercises its option under the KP415 License Agreement related thereto. If Commave exercises its option related to any Additional Product Candidate under the KP415 License Agreement, the parties are obligated to negotiate in good faith regarding the economic terms of such Additional Product Candidate. We also granted to Commave a right of first refusal to acquire, license or commercialize any Additional Product Candidate, with such right of first refusal expiring upon the acceptance of a new drug application for such Additional Product Candidate. We also granted Commave a right of first negotiation and a right of first refusal, subject to specified exceptions, for any assignment of our rights under the KP415 License Agreement.

Pursuant to the KP415 License Agreement, Commave paid us an upfront payment of $10.0 million and agreed to pay up to $63.0 million in milestone payments upon the occurrence of specified regulatory milestones related to the KP415 and KP484. In addition, Commave agreed to make additional payments upon the achievement of specified U.S. sales milestones of up to $420.0 million in the aggregate, depending, among other things, on timing of approval for a new drug applicable for KP415 and its final approved label, if any. Further, Commave will pay us quarterly, tiered royalty payments ranging from a percentage in the high single digits to the mid-twenties of Net Sales (as defined in the KP415 License Agreement) in the United States and a percentage in the low to mid-single digits of Net Sales in each country outside the United States, in each case subject to specified reductions under certain conditions as described in the KP415 License Agreement. Commave is obligated to make such royalty payments on a product-by-product basis until expiration of the Royalty Term (as defined in the KP415 License Agreement) for the applicable product.

Commave agreed to be responsible for and reimburse us for all of development, commercialization and regulatory expenses for the Licensed Product Candidates, subject to certain limitations as set forth in the KP415 License Agreement.

The KP415 License Agreement will continue on a product-by-product basis (i) until expiration of the Royalty Term for the applicable Licensed Product Candidate in the United States and (ii) perpetually for all other countries. Commave may terminate the KP415 License Agreement at its convenience upon prior written notice prior to regulatory approval of any Licensed Product Candidate or upon prior written notice after regulatory approval of any Licensed Product Candidate. We may terminate the KP415 License Agreement in full if Commave, any of its sublicensees or any of its or their affiliates challenge the validity of any Licensed Patent (as defined in the KP415 License Agreement) and such challenge is not required under a court order or subpoena and is not a defense against a claim, action or proceeding asserted by us. Either party may terminate the KP415 License Agreement (i) upon a material breach of the KP415 License Agreement by the other party, subject to a cure period, or (ii) if the other party encounters bankruptcy or insolvency. Upon a Serious Material Breach (as defined in the KP415 License Agreement) by us, subject to a cure period, Commave may choose not to terminate the KP415 License Agreement and instead reduce the milestone and royalty payments owed to us. Upon termination, all licenses and other rights granted by us to Commave pursuant to the KP415 License Agreement would revert to us. During the term of the KP415 License Agreement, we may not develop or commercialize any Competing Product (as defined in the KP415 License Agreement).

The KP415 License Agreement also established a joint steering committee, which monitors progress of the development of both KP415 and KP484. Subject to the oversight of the joint steering committee, we otherwise retain all responsibility for the conduct of all regulatory activities required to obtain new drug application approval of KP415 and KP484; provided that Commave shall be the sponsor of any clinical trials conducted by us on behalf of Commave.

JMI Agreement

In November 2009, we entered into the Supply Agreement with JMI, whereby JMI has agreed to supply us with all the benzhydrocodone 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 benzhydrocodone. In exchange, we issued shares of our common stock to JMI, provided that the commercial supply arrangement for benzhydrocodone would be exclusive to JMI in the United States and agreed to pay JMI royalties on the net sales of any products that utilize benzhydrocodone as the API. The percentage royalty rate ranges from the high teens at low volumes to the mid-single digits at higher volumes. Our FDA-approved drug, APADAZ, contains benzhydrocodone.

We are responsible for all costs of any benzhydrocodone manufactured during a specified validation process for APADAZ. After completion of the validation process, but prior to the commercial launch of any products that utilize benzhydrocodone as the API JMI will manufacture batches of benzhydrocodone 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 benzhydrocodone at a price equal to JMI's fully allocated manufacturing cost after commercial launch of APADAZ.

We must purchase all our U.S. benzhydrocodone needs from JMI and JMI cannot supply benzhydrocodone to other companies. After the commercial launch of any product that utilizes benzhydrocodone as the API, JMI is required to identify a secondary manufacturing site and qualify and validate that site to produce benzhydrocodone.

The term of the supply agreement extends as long as we hold a valid and enforceable patent for benzhydrocodone or until the tenth anniversary of the commercial launch of any product that utilizes benzhydrocodone 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.

Other Third-Party Agreements

Under our March 2012 asset purchase agreement with Shire, Shire had a right of first refusal to acquire, license or commercialize KP415 and KP484. In early 2019, Shire was acquired by Takeda to whom this right of first refusal was transferred at that time. Takeda did not exercise this right of first refusal in connection with our entry into the KP415 License Agreement.

Under our March 2012 termination agreement with Aquestive, Aquestive has the right to receive a royalty amount equal to 10% of any value generated by KP415, KP484 or KP879, and any product candidates containing SDX, including royalty payments on any license of KP415, KP484 or KP879, the sale of KP415, KP484 or KP879 to a third party, the commercialization of KP415, KP484 or KP879 and the portion of any consideration that is attributable to the value of KP415, KP484 or KP879 and paid to us or our stockholders in a change of control transaction. In connection with the KP415 License Agreement, we paid Aquestive a royalty equal to 10% of the upfront license payment we received in the third quarter of 2019.

Components of our Results of Operations

Revenue

Our commercial revenue, if any, will be derived from sales of APADAZ or any other product candidates for which we obtain regulatory approval. We expect that our only source of revenues will be through payments arising from our license agreements with KVK and Commave, and through any other future arrangements related to one of our other product candidates. To date, we have only generated revenue from the KP415 License Agreement in the form of the non-refundable upfront payment of $10.0 million, of which we paid Aquestive $1.0 million as a royalty payment, reimbursement of out-of-pocket third-party research and development costs and payments related to the performance of consulting services. We cannot guarantee that KVK or Commave will be able to successfully commercialize APADAZ or our product candidates covered under the KP415 License Agreement, or that we will ever receive any payments under the APADAZ License Agreement from commercial sales of APADAZ or any future payments under the KP415 License Agreement. We also do not know when, if ever, any other product candidate will be commercially available.

Royalties and Contract Costs

The components of our royalties and contract costs are royalties and expenses directly attributable to revenue. To date, we have only generated revenue from the KP415 License Agreement in the form of the non-refundable upfront payment of $10.0 million, reimbursement of out-of-pocket third-party research and development costs and payments related to the performance of consulting services. In connection with the KP415 License Agreement, we paid Aquestive a royalty equal to 10% of the upfront license payment we received in the third quarter of 2019 and capitalized incremental costs directly attributable to the KP415 License Agreement, these costs are amortized to royalties and contract costs as revenue is recognized.

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 costs for the years ended December 31, 2019 and 2018 (in thousands):

	Year Ended December 31,	
	2019	**2018**
Outsourced development costs directly identified to programs:		
KP415	$ 7,831	$ 28,798
KP484	24	195
APADAZ	3,866	4,150
Total outsourced development costs directly identified to programs	11,721	33,143
Research and development costs not directly identified to programs:		
Personnel costs including cash compensation, benefits and stock-based compensation	5,204	6,244
Facilities costs	599	473
Other costs	1,891	1,899
Total research and development costs not directly allocated to programs	7,694	8,616
Total research and development expenses	$ 19,415	$ 41,759

We anticipate that our research and development expense will fluctuate for the foreseeable future as we continue our efforts to advance the development of our product candidates, subject to the availability of additional funding. In accordance with the KP415 License Agreement, Commave has also agreed to be responsible and reimburse us for all of development, commercialization and regulatory expenses for the Licensed Product Candidates, subject to certain limitations as set forth in the KP415 License Agreement.

The successful commercialization of APADAZ and our product candidates, 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 APADAZ or our product candidates, if approved, and complete the remaining development of any product candidates. This is due to the numerous risks and uncertainties associated with the commercialization and development of products and 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 fluctuate as we continue to operate as a public reporting company and continue to develop our product candidates. We believe that these fluctuations will likely include costs related to the hiring of additional personnel and fees for outside consultants, lawyers and accountants. We also expect to continue to incur costs to comply with corporate governance, internal controls, investor relations, disclosure and similar requirements applicable to public reporting companies.

Severance Expense

Severance expense consisted of severance payments and stock-based compensation paid to our former executive vice president, government and public relations who resigned in August 2018. We had no severance expense in 2019. We anticipate that we will have additional severance expense in 2020 for severance payments and stock-based compensation to be paid to our former chief business officer who ceased to serve in this role in February 2020.

Other (Expense) Income

Other (expense) income consists primarily of non-cash costs associated with fair value adjustments to our derivative and warrant liability and amortization of debt issuance costs and debt discount to interest expense. Other (expense) income also includes interest expense incurred on our outstanding borrowings, as well as, interest and other income consisting primarily of interest earned on investments. Additionally, we recognized a gain on extinguishment of debt for the year ended December 31, 2019, related to the exchange of $9.6 million of principal on the 2021 Notes for Series A Preferred Stock in October 2018. These items are unrelated to our core business and thus are recognized as other (expense) income in our statements of operations.

Income Tax Benefit

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

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2018 (in thousands):

	Year Ended December 31,		Period-to
	2019	2018	Period Change
Revenue	$ 12,839	$ -	$ 12,839
Operating expenses:			
Royalties and contract costs	2,945	-	2,945
Research and development	19,415	41,759	(22,344)
General and administrative	10,816	12,508	(1,692)
Severance expense	-	1,636	(1,636)
Total operating expenses	33,176	55,903	(22,727)
Loss from operations	(20,337)	(55,903)	35,566
Other (expense) income:			
Gain on extinguishment of debt	-	2	(2)
Interest expense related to amortization of debt issuance costs and discount	(1,656)	(1,618)	(38)
Interest expense on principal	(4,858)	(5,469)	611
Fair value adjustment related to derivative and warrant liability	1,998	5,976	(3,978)
Interest and other income, net	309	420	(111)
Total other (expense) income	(4,207)	(689)	(3,518)
Loss before income taxes	(24,544)	(56,592)	32,048
Income tax benefit	22	126	(104)
Net loss	$ (24,522)	$ (56,466)	$ 31,944

Net Loss

Net loss for the year ended December 31, 2019 was $24.5 million, a decrease of $31.9 million compared to net loss for the year ended December 31, 2018 of $56.5 million. The decrease was primarily attributable to a decrease in loss from operations of $35.6 million and a decrease in net interest expense and other items of $0.4 million, partially offset by a decrease in non-cash fair value adjustment income of $4.0 million related changes to the derivative and warrant liability.

Revenue

Revenue for the year ended December 31, 2019 was $12.8 million, which was comprised of a $10.0 million non-refundable up-front payment, $1.1 million of reimbursements for out-of-pocket third-party research and development costs and $1.7 million of consulting fees earned, all related to the KP415 License Agreement. We had no revenue for the year ended December 31, 2018.

Royalties and Contract Costs

Royalties and contract costs for the year ended December 31, 2019 was $2.9 million, which was comprised of a royalty payment to Aquestive related to the $10.0 million non-refundable upfront payment under the KP415 License Agreement and $1.9 million of contract costs which were directly attributable to the revenue recognized. We had no royalties and contract costs for the year ended December 31, 2018.

Research and Development

Research and development expenses decreased by $22.3 million, from $41.8 million for the year ended December 31, 2018, to $19.4 million for the year ended December 31, 2019. This decrease was primarily attributable to a decrease in net third-party research and development costs and personnel-related costs.

General and Administrative

General and administrative expenses decreased by $1.7 million, from $12.5 million for the year ended December 31, 2018, to $10.8 million for the year ended December 31, 2019. This decrease was primarily attributable to a decrease in personnel-related costs.

Severance Expense

Severance expense of $1.6 million was recognized for the year ended December 31, 2018 due to the resignation of our executive vice president, government and public relations in August 2018. Severance expense is comprised of $0.4 million of severance payments and $1.2 million of stock compensation expense related to the acceleration of vesting on certain stock options upon termination. We had no severance expense for the year ended December 31, 2019.

Other (Expense) Income

Other (expense) income increased by $3.5 million, from expense of $0.7 million for the year ended December 31, 2018, to expense of $4.2 million for the year ended December 31, 2019. This period-to-period increase in expense was primarily attributable to a decrease in non-cash fair value adjustment income related to our derivative and warrant liability, partially offset by a decrease in net interest expense and other items.

Liquidity and Capital Resources

Sources of Liquidity

Through December 31, 2019, we have funded our research and development and operating activities primarily through the issuance of debt, private placements of redeemable convertible preferred stock and the sale of common stock in our initial public offering, at-the-market offering, underwritten public offerings, through our Prior Purchase Agreement with Lincoln Park, and from revenue received under the KP415 License Agreement. As of December 31, 2019, we had cash and cash equivalents of $3.2 million and restricted cash of $0.3 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 and/or warrants, which was declared effective by the Securities and Exchange Commission, or SEC, on October 17, 2016, or the Current Registration Statement. In October 2019, the Company filed a registration on Form S-3 covering the sale of up to $80.0 million of the Company's common stock, preferred stock, and debt and/or warrants, or the Replacement Registration Statement. Once the Replacement Registration Statement is declared effective by the SEC, the Company will no longer make any sales under the Current Registration Statement.

Based on the market value of our outstanding common stock held by non-affiliates as of February 28, 2020, the date we filed this Annual Report on Form 10-K for the year ended December 31, 2019, in order to issue securities under the Current Registration Statement and the Replacement Registration Statement, once effective, we must rely on Instruction I.B.6. of Form S-3, which imposes a limitation on the maximum amount of securities that we may sell pursuant to the registration statements during any twelve-month period. At the time we sell securities pursuant to the applicable registration statement, the amount of securities to be sold plus the amount of any securities we have sold during the prior twelve months in reliance on Instruction I.B.6. may not exceed one-third of the aggregate market value of our outstanding common stock held by non-affiliates as of a day during the 60 days immediately preceding such sale, as computed in accordance with Instruction I.B.6. This calculation is updated immediately upon filing this Annual Report on Form 10-K for the year ended December 31, 2019. As of filing this Annual Report, based on this calculation, the amount of securities we are able to sell under a registration statement on Form S-3 is approximately $10.9 million, of which we (i) have filed a prospectus supplement to register approximately $4.0 million for sales under the Purchase Agreement (as defined below); and (ii) have previously sold an aggregate of $5.7 million of shares of common stock in prior offering on Form S-3 in the previous 12 months. Based on this calculation, we expect that we will be unable to sell additional securities beyond those amounts pursuant to our Current Registration Statement or the Replacement Registration Statement, once effective, in the near term, unless and until the market value of our outstanding common stock held by non-affiliates increases significantly. In addition, under the terms of the Purchase Agreement, stockholder approval may be required to access a portion of the amounts available under the Purchase Agreement.

In September 2018, we entered into the Second ATM Agreement with RBCCM, 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 RBCCM as our sales agent. The registration statement on Form S-3 originally contemplated under the Second ATM Agreement includes a prospectus supplement covering the offering of up to $50,000,000 of shares of common stock in accordance with the Second ATM Agreement, but in February 2020, we filed a prospectus supplement to our registration statement on Form S-3 to terminate this offering in its entirety. As a result, we do not anticipate making any sales under the Second ATM Agreement in the near term, if at all. Through the date of termination we did not sell any shares of common stock under the Second ATM Agreement.

In October 2018, we entered into an underwriting agreement with RBCCM pursuant to which we sold 8,333,334 shares of our common stock in an underwritten public offering pursuant to our registration statement on Form S-3. Our net proceeds from the offering were approximately $23.1 million after deducting underwriting discounts and commissions and estimated offering expenses.

In February 2019, we entered into the Prior Purchase Agreement with Lincoln Park, which provided that, upon the terms and subject to the conditions and limitations set forth therein, we may sell to Lincoln Park up to $15.0 million of shares of our common stock, from time to time over the 36-month term of the Prior Purchase Agreement, and upon execution of the Prior Purchase Agreement we issued an additional 120,200 shares of our common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Prior Purchase Agreement. Concurrently with entering into the Prior Purchase Agreement, we also entered into a registration rights agreement with Lincoln Park, pursuant to which we agreed to register the sale of the shares of our common stock that have been and may be issued to Lincoln Park under the Prior Purchase Agreement pursuant to our existing shelf registration statement on Form S-3 or a new registration statement. Upon entering into the Purchase Agreement with Lincoln Park, we terminated the Prior Purchase Agreement and we filed a prospectus supplement to our registration statement on Form S-3 to terminate this offering in its entirety. As a result, we will not make any future sales under the Prior Purchase Agreement. Through the date of termination we sold 3,401,271 shares of our common stock to Lincoln Park under the Prior Purchase Agreement for approximately $5.4 million in gross proceeds.

In September 2019, we entered into the KP415 License Agreement with Commave and Commave paid us a non-refundable upfront payment of $10.0 million.

In February 2020, we entered into the Purchase Agreement with Lincoln Park, which provided that, upon the terms and subject to the conditions and limitations set forth therein, we may sell to Lincoln Park up to $4.0 million of shares of our common stock, from time to time over the 12-month term of the Purchase Agreement, and upon execution of the Purchase Agreement we issued an additional 308,637 shares of our common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Purchase Agreement. Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement with Lincoln Park, pursuant to which we agreed to register the sale of the shares of our common stock that have been and may be issued to Lincoln Park under the Purchase Agreement pursuant to our existing shelf registration statement on Form S-3 or a new registration statement.

We had negative operating cash flows since our inception and, as of December 31, 2019, had an accumulated deficit of $245.7 million. We anticipate that we will continue to incur negative operating flows for at least the next several years. Our recurring negative cash flows from operations and stockholders' deficit raise substantial doubt about our ability to continue as a going concern. We expect that our only source of revenues will be through payments arising from our license agreements with KVK and Commave, or through any other future arrangements related to one of our other product candidates. Accordingly, our ability to continue as a going concern may require us to obtain additional financing to fund our operations. The perception of our inability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees. 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, 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.

Convertible Debt

As of December 31, 2019, we had $80.2 million of convertible notes outstanding, consisting of (i) senior secured convertible promissory notes issued under the Deerfield Facility Agreement in the aggregate principal amount of $77.2 million and (ii) one 5.50% Senior Convertible Note due 2021, or the 2021 Note, in the principal amount of $3.0 million.

Deerfield Facility Agreement

In June 2014, we entered into the Deerfield Facility Agreement as a $60.0 million multi-tranche credit facility with Deerfield. At the time we entered into the Deerfield Facility Agreement, we borrowed the first tranche, which consisted of a $15.0 million term note and the $10.0 million convertible note, or the Deerfield Convertible Note. We used approximately $18.6 million of the net proceeds from the offering of the 2021 Notes to repay in full the $15.0 million original principal amount on the term note issued under the Deerfield Facility Agreement 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 Agreement.

The Deerfield Convertible Note originally bore interest at 9.75% per annum, but was subsequently reduced to 6.75%. Interest accrued on the outstanding balance under the Deerfield Convertible Note was due quarterly in arrears. We originally had to repay one-third of the outstanding principal amount of the Deerfield Convertible Note on the fourth and fifth anniversaries of the Deerfield Facility Agreement (June 2018 and June 2019). In June 2018, Deerfield agreed to convert the $3,333,333 of the principal amount then due, plus $168,288 of accrued interest, into 598,568 shares of our common stock. In September 2019, we entered into an amendment with Deerfield in order to (i) reduce the interest rate applicable under the Deerfield Facility Agreement from 9.75% to 6.75%, (ii) provide for “payment in kind” of interest on the Loans (as defined in the Deerfield Facility Agreement), and (iii) defer the Loan payments due pursuant to the Deerfield Facility Agreement until June 1, 2020. In December 2019, we entered into another amendment with Deerfield in order to (i) defer the Loan payments due pursuant to the Deerfield Facility Agreement until March 31, 2021 and (ii) allow for the entries of additional debt and debt holders under the Deerfield Facility Agreement (as discussed in more detail below). We are also obligated to repay principal in the amount of $6,980,824 plus any capitalized interest to date on March 31, 2021. Prepayment of the outstanding balance is not allowed without written consent of Deerfield.

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

We also issued to Deerfield the Deerfield Warrant to purchase 14,423,076 shares of our Series D Preferred at an initial exercise price of $0.78 per share, or the Deerfield Warrant. 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 Agreement, we may not enter into specified transactions, including a debt financing in the aggregate value of $750,000 or more, other than permitted indebtedness under the Deerfield Facility Agreement, 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 the Required Lenders (as defined in the Deerfield Facility Agreement). 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 Convertible 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 Agreement also includes high yield discount obligation protections that went into effect in June 2019. Going forward, if at any interest payment date our outstanding indebtedness under the Deerfield Facility Agreement would qualify as an "applicable high yield discount obligation" under the Code, then we are obligated to prepay in cash on each such date the amount necessary to avoid such classification.

2021 Notes

In February 2016, we issued the 2021 Notes in aggregate principal amount of $86.3 million. The 2021 Notes were originally issued to Cowen and Company LLC and RBCCM 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 was 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 originally matured on February 1, 2021 unless earlier converted or repurchased.

The 2021 Notes were not redeemable prior to the maturity date, and no sinking fund was provided for the 2021 Notes. The 2021 Notes were 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 was equal to an initial conversion price of approximately $17.11 per share of our common stock.

If we underwent 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.

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

As described in more detail below, in multiple exchanges occurring in October 2018, December 2019 and January 2020, all outstanding 2021 Notes were exchanged by the holders thereof for either shares of our common stock or senior secured convertible promissory notes issued under the terms of the Deerfield Facility Agreement.

2021 Note Exchanges

2021 Note Exchange Effected in October 2018

In October 2018, we entered into an exchange agreement, or the October 2018 Exchange Agreement, with the Deerfield Lenders Under the October 2018 Exchange Agreement, the Deerfield Lenders exchanged an aggregate of $9,577,000 principal amount of our 2021 Notes for an aggregate of 9,577 shares of our Series A Convertible Preferred Stock, par value $0.0001, or the Series A Preferred Stock.

As a condition to closing of the October 2018 Exchange Agreement, we filed a Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, or the Series A Certificate of Designation, with the Secretary of State of the State Delaware, setting forth the preferences, rights and limitations of the Series A Preferred Stock.

Each share of Series A Preferred Stock has an aggregate stated value of $1,000 and is convertible into shares of our common stock at a price equal to $3.00 per share (subject to adjustment to reflect stock splits and similar events). Immediately following the exchange under the October 2018 Exchange Agreement, an aggregate of 3,192,333 shares of common stock were issuable upon conversion of the Series A Preferred Stock. As of December 31, 2019, all 9,577 shares of Series A Preferred Stock issued under the October 2018 Exchange Agreement have been converted into an aggregate 3,192,333 shares of our common stock.

2021 Note Exchange Effected in September 2019

In September 2019, we entered into the September 2019 Exchange Agreement with the Deerfield Lenders. Under the September 2019 Exchange Agreement, we issued an aggregate of 1,499,894 shares of our common stock and an aggregate of 1,576 shares of our Series B-1 Convertible Preferred Stock, par value $0.0001 per share, or the Series B-1 Preferred Stock**,** (such shares of common stock and Series B-1 Preferred Stock, the Initial Exchange Shares), in exchange for the cancellation of an aggregate of $3,000,000 principal amount of the 2021 Notes. The September 2019 Exchange Agreement provided the Deerfield Lenders the option to exchange up to an additional aggregate of $27,000,000 principal amount of the 2021 Notes, or the Optional Exchange Principal Amount, for shares of common stock or shares of our Series B-2 Convertible Preferred Stock, par value $0.0001 per share, or the Series B-2 Preferred Stock**,** and, together with the Series B-1 Preferred Stock, the Series B Preferred Stock, subject to the terms and conditions set forth in the September 2019 Exchange Agreement, including limits as to the principal amount that can be exchanged prior to specified dates therein. If the Deerfield Lenders choose to exchange any portion of the Optional Exchange Principal Amount for shares of Series B-2 Preferred Stock, such exchange will be effected at an exchange price of $1,000 per share. If the Deerfield Lenders choose to exchange any portion of the Optional Exchange Principal Amount for shares of common stock, such exchange will be effected at an exchange price equal to the greater of (i) $0.9494 or (ii) the average of the volume-weighted average price of the common stock on the Nasdaq Capital Market on each of the 15 trading days immediately preceding such exchange.

As a condition to closing of the September 2019 Exchange Agreement, we filed a Certificate of Designation of Preferences, Rights and Limitations of Series B-1 Convertible Preferred Stock, or the Series B-1 Certificate of Designation**,** and a Certificate of Designation of Preferences, Rights and Limitations of Series B-2 Convertible Preferred Stock, or the Series B-2 Certificate of Designation**,** with the Secretary of State of the State Delaware, setting forth the preferences, rights and limitations of the Series B-1 Preferred Stock and the Series B-2 Preferred Stock, respectively.

Each share of Series B-1 Preferred Stock has an aggregate stated value of $1,000 and is convertible into shares of common stock at a per share price equal to $0.9494 per share (subject to adjustment to reflect stock splits and similar events). There was an aggregate of 1,659,996 shares of common stock issuable upon conversion of the Series B-1 Preferred Stock (without giving effect to the limitation on conversion described below). Each share of Series B-2 Preferred Stock has an aggregate stated value of $1,000 and is convertible into shares of common stock at a per share price equal to the greater of (i) $0.9494 (subject to adjustment to reflect stock splits and similar events), or (ii) the average of the volume-weighted average prices of the common stock on the Nasdaq Capital Market on each of the 15 trading days immediately preceding such exchange. Immediately following the exchange under the September 2019 Exchange Agreement, there was an aggregate of 28,439,015 shares of Common Stock issuable (i) in exchange of the Optional Exchange Principal Amount, or (ii) upon conversion of the Series B-2 Preferred Stock issuable in exchange of the Optional Exchange Principal Amount (in each case without giving effect to the limitation on conversion described below).

The Series B Preferred Stock is convertible at any time at the option of the Deerfield Lenders; provided that the Deerfield Lenders are prohibited from converting shares of Series B Preferred Stock into shares of common stock if, as a result of such conversion, such holders (together with certain affiliates and "group" members of such holders) would beneficially own more than 4.985% of the total number of shares of common stock then issued and outstanding. The Series B Preferred Stock is not redeemable. In the event of the Company's liquidation, dissolution or winding up, the Deerfield Lenders will receive an amount equal to $0.0001 per share, plus any declared but unpaid dividends, and thereafter will share ratably in any distribution of our assets with holders of common stock and with the holders of any shares of any other class or series of capital stock of us entitled to share in such remaining assets of us (including our Series A Preferred Stock on an as-converted basis. With respect to rights upon liquidation, the Series B Preferred Stock ranks senior to the common stock, on parity with the Series A Preferred Stock, if any is outstanding, and junior to existing and future indebtedness. Except as otherwise required by law (or with respect to approval of certain actions involving our organizational documents that materially and adversely affect the holders of Series B Preferred Stock), the Series B Preferred Stock does not have voting rights. The Series B Preferred Stock is not subject to any price-based anti-dilution protections and does not provide for any accruing dividends, but provides that holders of Series B Preferred Stock will participate in any dividends on the common stock on an as-converted basis (without giving effect to the limitation on conversion described above). The Series B-1 Certificate of Designation and the Series B-2 Certificate of Designation also provide for partial liquidated damages in the event that the Company fails to timely convert shares of Series B-1 Preferred Stock or Series B-2 Preferred Stock, respectively, into common stock in accordance with the applicable Certificate of Designation.

As of December 31, 2019, 1,576 shares of Series B-1 Preferred Stock have been converted into 1,659,996 shares of common stock, and there were no shares of Series B-2 Preferred Stock outstanding.

2021 Note Exchange Effected in December 2019

In December 2019, we entered into the December 2019 Exchange Agreement and Amendment to Facility Agreement, Senior Secured Convertible Notes and Warrants, or the December 2019 Exchange Agreement, with the Deerfield Lenders and Delaware Street Capital Master Fund, L.P., or DSC and, collectively with the Deerfield Lenders, the December 2019 Holders. Under the December 2019 Exchange Agreement, we issued senior secured convertible promissory notes under the Deerfield Facility Agreement in the aggregate principal amount of $71,418,011, or the December 2019 Notes, in exchange for the cancellation of an aggregate of $71,418,011 principal amount and accrued interest of the 2021 Notes. Upon entering into the December 2019 Exchange Agreement, we agreed to pay the December 2019 Holders, in the aggregate, an interest payment of $745,011, which represents 50% of the accrued interest, as of December 18, 2019, on the 2021 Notes owned by the December 2019 Holders. The remainder of such interest was included in the principal amount of the December 2019 Notes.

The December 2019 Notes bear interest at 6.75% per annum. The December 2019 Notes were originally convertible into shares of our common stock at an initial conversion price of $17.11 per share (which represents the conversion price of the 2021 Notes), subject to adjustment in accordance with the terms of the December 2019 Notes. As of the date of issuance, the December 2019 Notes were convertible, by their terms, into an aggregate of 4,174,051 shares of our common stock. We subsequently amended the December 2019 Notes to provide that such notes shall be convertible into shares of our common stock at a conversion price of $5.85 per share (which represents the conversion price of the Deerfield Convertible Note). The conversion price of the December 2019 Notes 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 December 2019 Notes' conversion price or the closing sale price of our common stock as reported on the Nasdaq Stock 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. However, if we effect an "at the market offering" as defined in Rule 415 of the Securities Act or 1933, as amended, or the Securities Act, of our common stock, the conversion price of the December 2019 Notes 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, provided that this anti-dilution adjustment will not apply to any sales made under (x) the Purchase Agreement, (y) Second ATM Agreement, or (z) the September 2019 Exchange Agreement (as amended). Notwithstanding anything in the contrary in the December 2019 Notes, the anti-dilution adjustment of such notes shall not result in the conversion price of the December 2019 Notes being less than $0.583 per share. The December 2019 Notes are convertible at any time at the option of the holders thereof, provided that a holder of a December 2019 Note is prohibited from converting such note into shares of our common stock if, as a result of such conversion, such holder (together with certain affiliates and "group" members) would beneficially own more than 4.985% of the total number of shares of common stock then issued and outstanding. However, the December 2019 Note issued to DSC, due to the fact DSC was a beneficial owner of more than 4.985% of the total number of shares of our common stock then issued and outstanding, has a beneficial ownership cap equal to 19.985% of the total number of shares of our common stock then issued and outstanding. Pursuant to the December 2019 Notes, the December 2019 Holders have the option to demand repayment of all outstanding principal, and any unpaid interest accrued thereon, in connection with a Major Transaction (as defined in the December 2019 Notes), which shall include, among others, any acquisition or other change of control of the Company; a liquidation, bankruptcy or other dissolution of the Company; or if at any time after March 31, 2021, shares of our common stock are not listed on an Eligible Market (as defined in the December 2019 Notes). The December 2019 Notes are subject to specified events of default, the occurrence of which would entitle the December 2019 Holders to immediately demand repayment of all outstanding principal and accrued interest on the December 2019 Notes. Such events of default include, among others, failure to make any payment under the December 2019 Notes when due, failure to observe or perform any covenant under the Deerfield Facility Agreement or the other transaction documents related thereto (subject to a standard cure period), the failure of the Company to be able to pay debts as they come due, the commencement of bankruptcy or insolvency proceedings against the Company, a material judgement levied against the Company and a material default by the Company under the Deerfield Warrant, the December 2019 Notes or the Deerfield Convertible Note.

The December 2019 Exchange Agreement amends the Deerfield Facility Agreement, in order to, among other things, (i) provide for the Deerfield Facility Agreement to govern the December 2019 Notes received by the December 2019 Holders pursuant to the December 2019 Exchange Agreement, (ii) extend the maturity of the Deerfield Convertible Note from February 14, 2020 and June 1, 2020, as applicable, to March 31, 2021, (iii) defer interest payments on the Deerfield Convertible Note and December 2019 Notes until March 31, 2021 (which such interest shall accrue as "payment-in-kind" interest), (iv) designate DSC as a Lender under (and as defined in the Deerfield Facility Agreement), (v) name Deerfield as the "Collateral Agent" for all Lenders and (vi) modify the terms and conditions under which the Company may issue additional pari passu and subordinated indebtedness under the Deerfield Facility Agreement (subject to certain conditions specified in the Deerfield Facility Agreement).

The December 2019 Exchange Agreement also amends and restates that the Deerfield Convertible Note to conform the definitions of "Eligible Market" and "Major Transactions" to the definition in the December 2019 Notes, to remove provisions that were only applicable prior to our initial public offering and to make certain other changes to conform to the December 2019 Notes. The conversion price for the Deerfield Convertible Note remains $5.85 per share, subject to adjustment on the same basis as the December 2019 Notes, but subject to a floor price of $0.583.

The December 2019 Exchange Agreement also amends Deerfield Warrant to conform the definitions of "Eligible Market" and "Major Transaction" in the Warrant with the definitions of such terms in the December 2019 Notes.

In connection with entering into the December 2019 Exchange Agreement, we also amended and restated the Guaranty and Security Agreement, dated June 2, 2014, by and between the Company and the other parties thereto, or the GSA, to, among other things, (i) provide that all of the notes will be secured by the liens securing the indebtedness under the Deerfield Facility Agreement, and (ii) name Deerfield as the "Collateral Agent" under the GSA.

In connection with entering into the December 2019 Exchange Agreement, we also entered into an amendment, or the September 2019 Exchange Agreement Amendment, to the September 2019 Exchange Agreement to, among other things, (i) amend and restate Annex I of the September 2019 Exchange Agreement to allow the Deerfield Lenders to effect optional exchanges of the December 2019 Notes and the Deerfield Convertible Note under the terms of the September 2019 Exchange Agreement; (ii) amend the common stock exchange price under the September 2019 Exchange Agreement to be a per share price equal to the greater of (x) $0.60, subject to adjustment to reflect stock splits and similar events, or (y) the average of the volume-weighted average prices of our common stock on the Nasdaq Stock Market on each of the 15 trading days immediately preceding such exchange, (iii) provide that no more than 28,439,015 of shares of the Company's common stock shall be issued pursuant to optional exchanges under the September 2019 Exchange Agreement (whether by common stock exchange or upon conversion of Series B-2 Shares (as defined in the September 2019 Exchange Agreement Amendment)), subject to adjustment to reflect stock splits and similar events and (iv) eliminate limitations regarding the timing and aggregate amount of principal which may be exchanged under the September 2019 Exchange Agreement.

In connection with entering into the September 2019 Exchange Agreement Amendment, we filed an amendment to the Certificate of Designation of Preferences, Rights and Limitations of Series B-2 Convertible Preferred Stock, or the Series B-2 Certificate of Designation Amendment, with the Secretary of State of the State Delaware. The Series B-2 Certificate of Designation Amendment provides that each share of the Series B-Preferred Stock is convertible into shares of the Company's common stock at a per share price equal to the common stock exchange price under the September 2019 Exchange Agreement, which equals the greater of (i) $0.60 (subject to adjustment to reflect stock splits and similar events), or (ii) the average of the volume-weighted average prices of the Company's common stock on the Nasdaq Stock Market on each of the 15 trading days immediately preceding such exchange.

As of December 31, 2019, the Deerfield Lenders have converted $1.2 million of principal on the December 2019 Notes into 2,000,000 shares of common stock.

2021 Note Exchange Effected in January 2020

In January 2020, we entered into a January 2020 Exchange Agreement, or the January 2020 Exchange Agreement, with M. Kingdon Offshore Master Fund, LP, or Kingdon. Under the January 2020 Exchange Agreement, we issued a senior secured convertible note in the aggregate principal amount of $3,037,354, or the January 2020 Note, in exchange for the cancellation of an aggregate of $3,037,354 principal amount and accrued interest of the 2021 Note then owned by Kingdon. Upon entering into the January 2020 Exchange Agreement, we agreed to pay Kingdon an interest payment of $37,354, which represents 50% of the accrued and unpaid interest, as of January 13, 2020, on Kingdon's 2021 Note. The remainder of such interest was included in the principal amount of the January 2020 Note.

The January 2020 Note was issued with substantially the same terms and conditions as the December 2019 Notes (as amended by the amendment described in more detail below).

In connection with entering into the January 2020 Exchange Agreement, we entered into an Amendment to Facility Agreement and December 2019 Notes and Consent, or the December 2019 Note Amendment, with the December 2019 Holders that, among other things, (i) amended the December 2019 Notes to (a) reduce the Conversion Price (as defined in the December 2019 Notes) from $17.11 to $5.85 per share d (b) increased the Floor Price (as defined in the December 2019 Notes) from $0.38 to $0.583 per share, and (ii) amended Deerfield Facility Agreement to (x) provide for the Kingdon to join the Deerfield Facility Agreement as a Lender (as defined in the Deerfield Facility Agreement) and (y) provide that the 2020 Note and shall constitute a "Senior Secured Convertible Note" (as defined in the Deerfield Facility Agreement) for purposes of the Deerfield Facility Agreement and other Transaction Documents (as defined in the Deerfield Facility Agreement). As a result of the December 2019 Note Amendment, the December 2019 Notes were convertible, by their terms, into an aggregate of 11,753,016 shares of the Company's common stock, assuming a conversion date of January 13, 2020.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2019 and 2018 (in thousands):

	Year Ended December 31,		Period-to
	2019	2018	Period Change
Net cash used in operating activities	$ (23,737)	$ (54,203)	$ 30,466
Net cash provided by investing activities	3,234	33,332	(30,098)
Net cash provided by financing activities	4,939	28,019	(23,080)
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (15,564)	$ 7,148	$ (22,712)

Operating Activities

For the year ended December 31, 2019, net cash used in operating activities of $23.7 million consisted of a net loss of $24.5 million, primarily attributable to our spending on research and development programs, partially offset by revenue received under the KP415 License Agreement, and $5.1 million in changes in working capital; partially offset by $5.9 million in adjustments for non-cash items. The adjustments for non-cash items primarily consisted of stock-based compensation expense of $4.4 million, non-cash interest expense of $1.4 million, amortization of debt issuance costs and debt discount of $1.7 million and $0.4 million related to depreciation, amortization and other items; partially offset by non-cash income related to the change in the fair value of our derivative and warrant liabilities of $2.0 million. The changes in working capital consisted of $1.7 million related to a change in accounts and other receivables, $3.8 million related to a change in accounts payable and accrued expenses, $1.5 million related to operating lease right-of-use assets and $0.8 million related to a change in other liabilities; partially offset by $0.5 million related to a change in prepaid expenses and other assets and $2.2 million related to operating lease liabilities.

For the year ended December 31, 2018, net cash used in operating activities of $54.2 million consisted of a net loss of $56.5 million, primarily attributable to our spending on research and development programs, and $2.3 million in changes in working capital, partially offset by $4.5 million in adjustments for non-cash items. The changes in working capital consisted of $1.6 million related to an increase in accounts payable and accrued expenses, $0.5 million related to an increase in prepaid expenses and other assets and $0.1 million related to other liabilities. The adjustments for non-cash items primarily consisted of stock-based compensation expense of $6.5 million, non-cash interest expense of $2.1 million, amortization of debt issuance costs and debt discount of $1.6 million and $0.3 million related to depreciation, amortization and other items, partially offset by non-cash income related to the change in the fair value of our derivative and warrant liabilities of $6.0 million.

Investing Activities

For the year ended December 31, 2019, net cash provided by investing activities was $3.2 million, which was primarily attributable to maturities of marketable securities.

For the year ended December 31, 2018, net cash provided by investing activities was $33.3 million, which was primarily attributable to maturities of marketable securities of $33.4 million, partially offset by purchases of property and equipment of $0.1 million.

Financing Activities

For the year ended December 31, 2019, net cash provided by financing activities was $4.9 million, which was primarily attributable to proceeds from sales of our common stock under the Prior Purchase Agreement of $5.4 million; partially offset by repayment of principal on finance lease liabilities of $0.2 million and payment of debt issuance costs of $0.3 million.

For the year ended December 31, 2018, net cash provided by financing activities was $28.0 million. This consisted of proceeds from the issuance of common stock under the underwritten public offering in October 2018, net of commissions, of $23.5 million, proceeds from the issuance of common stock under the First ATM agreement, net of commissions, of $4.8 million and proceeds from the exercise of common stock options of $0.1 million, partially offset by repayment of $0.2 million of obligations under capital lease arrangements and payment of $0.2 million of deferred offering costs.

Future Funding Requirements

We anticipate that we will need substantial additional funding in connection with our continuing operations. Based upon our current operating plan, revenue projections and existing cash resources as of December 31, 2019, we believe our cash resources will be sufficient to fund operating expense and capital investment requirements into, but not through, the first quarter of 2021. If revenues are not as we project, we believe our existing resources are sufficient to fund our current operations into but not through the third quarter of 2020.

Potential near-term sources of additional funding include:

- sales of common stock under the Purchase Agreement;
- any revenues generated under the APADAZ License Agreement; and
- any out-of-pocket third-party research and development cost reimbursements, consulting services revenue or short-term milestone payments generated under the KP415 License Agreement.

We cannot guarantee that we will be able to generate sufficient proceeds from any of these potential sources to fund our operating expenses. For instance, pursuant to the terms of the Purchase Agreement, stockholder approval may be required to access a portion of the amounts available under the Purchase Agreement. Accordingly, we cannot guarantee that we will be able to sell the full $4.0 million subject to the terms of the Purchase Agreement.

To date, we have only generated revenue from the non-refundable upfront payment and consulting services under the KP415 License Agreement. We do not know when, or if, we will generate any additional revenue. We expect that our only source of revenues will be through payments arising from our license agreements with KVK and Commave, or through any other future arrangements related to one of our product candidates. While we have entered into the APADAZ License Agreement to commercialize APADAZ in the United States, and entered into the KP415 License Agreement to develop, manufacture and commercialize KP415 and KP484, we cannot guarantee that this, or any strategy we adopt in the future, will be successful. We also expect to continue to incur additional costs associated with operating as a public company. If we are unable to generate revenue in the short term under our license agreements, we will need substantial additional funding in order to continue our operations.

Our audited financial statements for the year ended December 31, 2019, includes an explanatory paragraph, within Note A, stating that our recurring losses, negative operating cash flows and stockholders' deficit raise substantial doubt about our ability to continue as a going concern. We expect that our only source of revenues will be through payments arising from our license agreements with KVK and Commave, or through any other future arrangements related to one of our other product candidates. Accordingly, our ability to continue as a going concern will require us to obtain additional financing to fund our operations. The perception of our inability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees. 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, 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.

We have based our estimates of our cash needs and cash runway on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect and we cannot guarantee that we will be able to generate sufficient proceeds from our license agreements with KVK and Commave, sales under our Purchase Agreement or other funding transactions to fund our operating expenses. To meet any additional cash requirements, we may seek to sell additional equity or convertible securities that may result in dilution to our stockholders, issue additional debt or seek other third-party funding, including potential strategic transactions, such as licensing or collaboration arrangements. Because of the numerous risks and uncertainties associated with the development and commercialization of product candidates and products, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the commercialization and development of our partnered product or product candidates, should they obtain regulatory approval.

We have filed shelf registration statements on Form S-3 with the SEC. Based on the market value of our outstanding common stock held by non-affiliates as of the date we filed this Annual Report on Form 10-K for the year ended December 31, 2019, in order to issue securities under our Current Registration Statement or our Replacement Registration Statement, once effective, we must rely on Instruction I.B.6. of Form S-3, which imposes a limitation on the maximum amount of securities that we may sell pursuant to the registration statements during any twelve-month period. At the time we sell securities pursuant to the applicable registration statement, the amount of securities to be sold plus the amount of any securities we have sold during the prior twelve months in reliance on Instruction I.B.6. may not exceed one-third of the aggregate market value of our outstanding common stock held by non-affiliates as of a day during the 60 days immediately preceding such sale, as computed in accordance with Instruction I.B.6. This calculation is updated immediately upon filing our Annual Report on Form 10-K for the year ended December 31, 2019. As of filing this Annual Report, based on this calculation, the amount of securities we are able to sell under a registration statement on Form S-3 is approximately $10.9 million, of which we (i) have filed a prospectus supplement to register approximately $4.0 million for sales under the Purchase Agreement; and (ii) have previously sold an aggregate of $5.7 million of shares of common stock in prior offering on Form S-3 in the previous 12 months. Based on this calculation, we expect that we will be unable to sell additional securities beyond those amounts pursuant to the Current Registration Statement or the Replacement Registration Statement, once effective, in the near term, unless and until the market value of our outstanding common stock held by non-affiliates increases significantly. In addition, under the terms of the Purchase Agreement, stockholder approval may be required to access a portion of the amounts available under the Purchase Agreement.

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

- the progress and results of our preclinical studies, clinical trials, chemistry , manufacturing and controls, or CMC, and other product development and commercialization activities;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates;
- the ability to obtain differentiated claims in the labels for our product candidates;
- the number and development requirements of 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 for our product candidates;
- the revenue, if any, received from commercial sales of APADAZ under the APADAZ License Agreement, or any product candidate subject to the terms of the KP415 License Agreement or sales of our other product candidates for which we receive marketing approval, which may be affected by market conditions, including obtaining coverage and adequate reimbursement of APADAZ and our product candidates from third-party payors, including government programs and managed care organizations, and competition within the therapeutic class to which APADAZ and our product candidates are assigned;
- our success in developing and commercializing our ADHD product candidates in accordance with the terms of the KP415 License Agreement;
- 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 products or product candidates and technologies.

Our commercial revenue, if any, will likely be derived from payments under the APADAZ License Agreement in connection with sales of APADAZ or payments under the KP415 License Agreement any other product candidates for which we obtain regulatory approval subject to the terms of such agreement. We cannot guarantee that KVK or Commave will be able to successfully commercialize APADAZ or our product candidates covered under the KP415 License Agreement, if approved, or that we will ever receive any payments under the APADAZ License Agreement from commercial sales of APADAZ or any future payments under the KP415 License Agreement. We also do not know when, if ever, any other product candidate 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, the terms of these securities or this debt may restrict our ability to operate. The Deerfield Facility Agreement 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 Judgements 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 judgements 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 judgements 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,	
	2019	**2018**
Research and development	$ 1,459	$ 1,608
General and administrative	2,951	3,651
Severance expense	-	1,236
Total stock-based compensation	$ 4,410	$ 6,495

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:

- historically we have not had sufficient experience to estimate the volatility of our common stock. As such, we calculated the expected volatility based on reported data for selected similar publicly traded companies for which the historical information is available, or peer volatility, and blended it with our historical volatility, or leverage-adjusted peer volatility. 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 utilized this leverage-adjusted peer volatility for grants prior to the initial public offering, as well as grants within the two-year period immediately following the initial public offering. For grants after the second anniversary of the initial public offering we utilized our historical volatility to determine the expected volatility;

- 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 grant date 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.

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,	
	2019	**2018**
Risk-free interest rate	1.75% - 2.61%	2.43% - 2.91%
Expected term (in years)	5.50 - 10.00	5.50 - 6.79
Expected volatility	84.82% - 85.93%	83.10% - 85.05%
Expected dividend yield	0%	0%

Based upon the stock price of $0.38 per share, which is the last sale price of our common stock reported on The Nasdaq Stock Market as of December 31, 2019 outstanding options to purchase shares of our common stock as of December 31, 2019 had no intrinsic value; and there was also no aggregate intrinsic value of outstanding options to purchase shares of our common stock as of December 31, 2018.

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 Stock Market on the date of grant to determine the exercise price of stock options.

Fair Value of Financial Instruments

We have a common stock warrant issued to Deerfield, put options embedded within those Deerfield warrants, fundamental change and make-whole interest provisions embedded within the 2021 Notes, a conversion feature within the Deerfield Convertible Note and common stock warrants issued to KVK that meet the definition of derivative financial instruments and are accounted for as derivatives. The fair value of the common stock warrant issued to Deerfield, put options embedded within the Deerfield Warrants, fundamental change and make-whole interest provisions embedded within the 2021 Notes and the conversion feature within the Deerfield Convertible Note are based on Monte Carlo simulations, while the common stock warrant issued to KVK is valued using a probability-weighted Black-Scholes option pricing model. These derivatives are fair valued at each reporting period.

The derivative liability for the Deerfield common stock warrant was $0.1 million and $1.6 million at December 31, 2019 and 2018, respectively. The derivative liability for the put options embedded within the Deerfield common stock warrant was $19,000 and $154,000 at December 31, 2019 and 2018, respectively. The derivative liability for the fundamental change and make-whole interest provisions embedded within the 2021 Notes had no value at either December 31, 2019 and 2018, respectively. The conversion feature within the Deerfield Convertible Note had no value at December 31, 2019 and $0.1 million at December 31, 2019 and 2018. The derivative liability for the KVK common stock warrant was $24,000 and $273,000 at December 31, 2018, respectively. A 10% increase in the enterprise value would result in an increase of $19,000 in the estimated fair value of the Deerfield common stock warrant, no change in the estimated fair value of the put options embedded within the Deerfield common stock warrant, no change in the estimated fair value of the fundamental change and make-whole interest provisions embedded within the 2021 Notes, an increase of $2,000 in the estimated fair value of the conversion feature within the Deerfield Convertible Note and an increase of $5,000 in the estimated fair value of the KVK common stock warrant at December 31, 2019.

Upon exercise of the warrants, we will adjust the associated derivative liability to fair value with any changes recorded in other (expense) income. 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, 2019, we had federal net operating loss, or NOL, carryforwards of approximately $138.1 million with expiration dates from 2027 to 2037 and $78.9 million with no expiration. We also had research and development credit carryforwards of $3.8 million with expiration dates ranging from 2027 to 2037 and $2.6 million with no expiration.

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 performed a Section 382 ownership change analysis in 2017 and determined that we experienced an ownership change in 2010, which resulted in a portion of our net operating loss carryforwards being subject to an annual limitation under Section 382 through 2012. No other ownership changes or limitations on our historical net operating loss carryforwards were noted through the year ended December 31, 2017. 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 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.

Emerging Growth Company Status

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

Recent Accounting Pronouncements

In April 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 could have elected 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 irrevocably 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 February 2016, the FASB issued ASU 2016-02, *Leases (Topic* 842*)*, or ASU 2016-02, which requires lessees to recognize operating and finance lease liabilities and corresponding right-of-use assets on the balance sheet and to provide enhanced disclosures surrounding the amount, timing and uncertainty of cash flows arising from leases. We lease office space and laboratory facilities under non-cancelable operating leases. In addition, we lease various laboratory equipment, furniture and office equipment and leasehold improvements that are accounted for as capital leases. We adopted the new standard effective January 1, 2019 on a modified retrospective basis and did not restate comparative periods. We elected the package of practical expedients permitted under the transition guidance, which allowed us to carryforward our historical lease classification and our assessment on whether a contract is or contains a lease for any leases that existed prior to adoption of the new standard. We also elected to combine lease and non-lease components and to keep leases with an initial term of 12 months or less off the balance sheet and recognize the associated lease payments in the condensed statements of operations on a straight-line basis over the lease term. We did not elect the hindsight practical expedient, which would have allowed us to use hindsight in determining the lease term and in assessing any impairment of right-of-use assets during the lookback period. The adoption of ASU 2016-02 resulted in the recognition of total right-of-use assets and total lease liabilities of approximately $2.6 million on the condensed balance sheets as of January 1, 2019.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic* 260*)*, *Distinguishing Liabilities from Equity (Topic* 480*)*, *Derivatives and Hedging (Topic* 815*) – I. Accounting for Certain Financial Instruments with Down Round Features and II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*, or ASU 2017-11, which addresses the complexity of accounting for certain financial instruments with down round features and addresses the difficulty of navigating Topic 480 because of the existence of extensive pending content in the ASC as a result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. This update applies to all entities that issue financial instruments that include down round features and entities that present earnings per share in accordance with Topic 260. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. The adoption of ASU 2017-11 did not have a material impact on our financial statements and disclosures.

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation (Topic 820) – Improvements to Nonemployee Share-Based Payment Accounting*, or ASU 2018-07, which simplifies several aspects of the accounting for nonemployee share-based payment transactions resulting from expanding the scope of Topic 718, Compensation—Stock Compensation, to include share-based payment transactions for acquiring goods and services from nonemployees. This update applies to all entities that enter into share-based payment transactions for acquiring goods and services from nonemployees. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. The amendments in this ASU expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost (that is, the period of time over which share-based payment awards vest and the pattern of cost recognition over that period). The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The adoption of ASU 2018-07 did not have a material impact on our financial statements and disclosures.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820) – Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, or ASU 2018-13, which modifies the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement, based on the concepts in the FASB Concepts Statement, *Conceptual Framework for Financial Reporting—Chapter 8: Notes to Financial Statements*, which the FASB finalized on August 28, 2018, including the consideration of costs and benefits. This update applies to all entities that are required, under existing U.S. generally accepted accounting principles, to make disclosures about recurring or nonrecurring fair value measurements. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. Early adoption is permitted. An entity is permitted to early adopt any removed or modified disclosures and delay adoption of the additional disclosures until their effective date. We do not expect the adoption of ASU 2018-13 to have a material impact 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, 2019. Based on the evaluation of our disclosure controls and procedures as of December 31, 2019, our chief executive officer and our chief financial officer concluded that, as of such date, our disclosure controls and procedures were not effective due to a material weakness in our controls over financial reporting, described below.

Nevertheless, based on the performance of additional procedures by management designed to ensure reliability of financial reporting our management has concluded that, notwithstanding the material weakness described below, the financial statements fairly present in all material respects, our financial position, results of operations and cash flows as of the dates, and for the periods presented, inconformity with accounting principles generally accepted in the United States.

Management's Report on Internal Controls over Financial Reporting

Internal controls 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 controls 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 controls 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 controls over financial reporting. Based on its evaluation, management has concluded that our internal controls over financial reporting were not effective as of December 31, 2019, which was the end of our most recent fiscal year, because certain controls over non-routine transactions were not designed at the appropriate level of precision to ensure the accuracy of calculations supporting non-routine transactions, and subsequently to ensure that appropriate conclusions related to accounting treatment were reached.

A material weakness is a deficiency, or a combination of deficiencies, in internal controls over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

This control deficiency resulted in misstatements to research and development expenses, debt discount, interest expense related to amortization of debt discount, fair value adjustment related to derivative and warrant liability, revenue, accounts and other receivables, accounts payable and accrued expenses, prepaid expenses and other current assets, royalty and direct contract acquisition costs and general and administrative expenses all of which were corrected prior to issuance of our financial statements as of and for the year ended December 31, 2019 included in this annual report on Form 10-K. As this deficiency created a reasonable possibility that a material misstatement would not be prevented or detected in a timely manner, management concluded that the control deficiency represented a material weakness and accordingly our internal controls over financial reporting were not effective as of December 31, 2019.

.Our independent registered public accounting firm has not performed an evaluation of our internal controls 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 controls over financial reporting.

Changes in Internal Controls over Financial Reporting

Other than the material weakness described above that occurred during our fiscal year ended December 31, 2019, there was no change in our internal controls 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 controls over financial reporting.

Remediation

We are still considering the full extent of the procedures to implement in order to remediate the material weakness described above, however, the current remediation plan includes implementing controls over calculations and conclusions associated with non-routine transactions at a more precise level of operation.

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 controls 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 controls 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 2020 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 proposal with the heading “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

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

Opinion on the Financial Statements
We have audited the accompanying balance sheets of KemPharm, Inc. (the Company) as of December 31, 2019 and 2018, the related statements of operations, changes in stockholders' deficit and cash flows for the years then ended, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Emphasis of Matter Regarding Going Concern Uncertainty
The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note A to the financial statements, the Company has recurring losses from operations, negative operating cash flows and a stockholders' deficit and its existing cash and cash equivalents and restricted cash are not sufficient to fund the Company's operating expenses and capital expenditure requirements for at least one year from the date these financial statements are issued. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note A. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis of Opinion
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ RSM US LLP

We have served as the Company's auditor since 2017.

Orlando, Florida
February 28, 2020

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

	As of December 31, 2019	As of December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 3,217	$ 18,409
Marketable securities	-	3,260
Accounts and other receivables	1,865	140
Prepaid expenses and other current assets	1,552	1,912
Total current assets	6,634	23,721
Property and equipment, net	1,471	1,753
Operating lease right-of-use assets	1,537	-
Restricted cash	338	710
Other long-term assets	527	562
Total assets	$ 10,507	$ 26,746
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,911	$ 8,342
Current portion of convertible notes	-	3,333
Current portion of capital lease obligation	-	214
Current portion of operating lease liabilities	284	-
Other current liabilities	236	115
Total current liabilities	5,431	12,004
Convertible notes, less current portion, net	77,343	78,105
Derivative and warrant liability	120	2,118
Capital lease obligation, less current portion	-	396
Operating lease liabilities, less current portion	1,901	-
Other long-term liabilities	168	689
Total liabilities	84,963	93,312
Commitments and contingencies (Note H)		
Stockholders' deficit:		
Preferred stock:		
Series A convertible preferred stock, $0.0001 par value, 9,578 shares authorized, 9,577 shares issued and no shares outstanding as of December 31, 2019; 9,577 shares issued and 3,337 shares outstanding as of December 31, 2018	-	-
Series B-1 convertible preferred stock, $0.0001 par value, 1,576 shares authorized, 1,576 shares issued and no shares outstanding as of December 31, 2019; no shares authorized, issued or outstanding as of December 31, 2018	-	-
Series B-2 convertible preferred stock, $0.0001 par value, 27,000 shares authorized, no shares issued or outstanding as of December 31, 2019; no shares authorized, issued or outstanding as of December 31, 2018	-	-
Undesignated preferred stock, $0.0001 par value, 9,961,846 shares authorized, no shares issued or outstanding as of December 31, 2019; 9,990,422 shares authorized, no shares issued or outstanding as of December 31, 2018	-	-
Common stock, $0.0001 par value, 250,000,000 shares authorized, 36,350,785 shares issued and outstanding as of December 31, 2019; 26,455,352 shares issued and outstanding as of December 31, 2018	4	3
Additional paid-in capital	171,254	154,623
Accumulated deficit	(245,714)	(221,192)
Total stockholders' deficit	(74,456)	(66,566)
Total liabilities and stockholders' deficit	$ 10,507	$ 26,746

See accompanying notes to financial statements

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

	Year Ended December 31,	
	2019	**2018**
Revenue	$ 12,839	$ -
Operating expenses:		
Royalty and direct contract acquisition costs	2,945	-
Research and development	19,415	41,759
General and administrative	10,816	12,508
Severance expense	-	1,636
Total operating expenses	33,176	55,903
Loss from operations	(20,337)	(55,903)
Other (expense) income:		
Gain on extinguishment of debt	-	2
Interest expense related to amortization of debt issuance costs and discount	(1,656)	(1,618)
Interest expense on principal	(4,858)	(5,469)
Fair value adjustment related to derivative and warrant liability	1,998	5,976
Interest and other income, net	309	420
Total other (expense) income	(4,207)	(689)
Loss before income taxes	(24,544)	(56,592)
Income tax benefit	22	126
Net loss	$ (24,522)	$ (56,466)
Net loss per share of common stock:		
Basic and diluted	$ (0.83)	$ (3.15)
Weighted average number of shares of common stock outstanding:		
Basic and diluted	29,654,968	17,930,023

See accompanying notes to financial statements

KEMPHARM, INC.
STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT
(in thousands)

	Preferred Stock							
	Series A Convertible Preferred Stock	Series B-1 Convertible Preferred Stock	Series B-2 Convertible Preferred Stock	Undesignated Preferred Stock	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance as of January 1, 2018	$ -	$ -	$ -	$ -	$ 1	$ 107,209	$ (164,726)	$ (57,516)
Net loss	-	-	-	-	-	-	(56,466)	(56,466)
Stock-based compensation expense	-	-	-	-	-	6,495	-	6,495
Issuance of common stock in connection with ATM, net of commissions	-	-	-	-	1	4,827	-	4,828
Offering expenses charged to equity	-	-	-	-	-	(554)	-	(554)
Conversion of principal and interest on Deerfield Convertible Note	-	-	-	-	-	3,502	-	3,502
Exercise of stock options	-	-	-	-	-	68	-	68
Issuance of common stock in connection with underwritten public offering, net of commissions	-	-	-	-	1	23,499	-	23,500
Conversion of principal on 2021 Notes	-	-	-	-	-	9,577	-	9,577
Balance as of December 31, 2018	$ -	$ -	$ -	$ -	$ 3	$ 154,623	$ (221,192)	$ (66,566)
Net loss	-	-	-	-	-	-	(24,522)	(24,522)
Stock-based compensation expense	-	-	-	-	-	4,410	-	4,410
Issuance of common stock in connection with equity line of credit	-	-	-	-	-	5,446	-	5,446
Issuance of common stock in connection with Deerfield Optional Conversion Feature	-	-	-	-	1	1,199		1,200
Conversion of principal on 2021 Notes	-	-	-	-	-	3,000	-	3,000
Change in fair value of embedded conversion feature in connection with debt modification	-	-	-	-	-	2,311	-	2,311
Recognition of deferred offering costs in connection with equity line of credit	-	-	-	-	-	300	-	300
Offering expenses charged to equity	-	-	-	-	-	(151)	-	(151)
Change in estimated deferred offering costs	-	-	-	-	-	116	-	116
Balance as of December 31, 2019	$ -	$ -	$ -	$ -	$ 4	$ 171,254	$ (245,714)	$ (74,456)

See accompanying notes to financial statements

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

	Year Ended December 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (24,522)	$ (56,466)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on extinguishment of debt	-	(2)
Stock-based compensation expense	4,410	6,495
Non-cash interest expense	1,417	2,089
Amortization of debt issuance costs and debt discount	1,656	1,618
Depreciation and amortization expense	304	324
Fair value adjustment related to derivative and warrant liability	(1,998)	(5,976)
Write-off of deferred offering costs	116	-
Change in assets and liabilities:		
Accounts and other receivables	(1,725)	-
Prepaid expenses and other assets	544	(548)
Operating lease right-of-use assets	(1,537)	-
Accounts payable and accrued expenses	(3,789)	(1,635)
Operating lease liabilities	2,185	-
Other liabilities	(798)	(102)
Net cash used in operating activities	(23,737)	(54,203)
Cash flows from investing activities:		
Purchases of property and equipment	(26)	(21)
Maturities and sales of marketable securities	3,260	33,353
Net cash provided by investing activities	3,234	33,332
Cash flows from financing activities:		
Proceeds from equity line of credit	5,446	-
Proceeds from at-the-market offering, net of commissions	-	4,828
Proceeds from underwritten public offering, net of commissions	-	23,500
Repayment of obligations under capital lease	-	(193)
Payment of deferred offering costs	-	(184)
Repayment of principal on finance lease liabilities	(207)	-
Payment of debt issuance costs	(300)	-
Proceeds from exercise of common stock options	-	68
Net cash provided by financing activities	4,939	28,019
Net (decrease) increase in cash, cash equivalents and restricted cash	(15,564)	7,148
Cash, cash equivalents and restricted cash, beginning of year	19,119	11,971
Cash, cash equivalents and restricted cash, end of year	$ 3,555	$ 19,119
Supplemental cash flow information:		
Cash paid for interest	$ 5,362	$ 5,539
Deerfield Convertible Note principal and interest converted to common stock	-	3,502
2021 Notes principal converted to preferred stock	1,537	9,577
2021 Notes principal converted to common stock	1,463	-
2019 Notes principal converted to common stock	1,200	-
Commitment shares issued in connection with equity line of credit included in deferred offering costs	300	-
Deferred offering costs included in accounts payable and accrued expenses	-	181
Property and equipment financed under a lease agreement	-	52
Property and equipment included in accounts payable and accrued expenses	4	-

See accompanying notes to financial statements

A. Description of Business and Basis of Presentation

Organization

KemPharm, Inc. (the "Company") is a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs to treat serious medical conditions through its proprietary Ligand Activated Therapy ("LAT™") technology. The Company utilizes its proprietary LAT technology to generate improved prodrug versions of U.S. Food and Drug Administration (the "FDA") approved drugs as well as to generate prodrug versions of existing compounds that may have applications for new disease indications. The Company's product candidate pipeline is focused on the high need areas of attention deficit hyperactivity disorder ("ADHD") and stimulant use disorder ("SUD"). The Company's clinical product candidates for the treatment of ADHD include KP415 and KP484, and the Company's preclinical product candidate for the treatment of SUD includes KP879. The Company was formed and incorporated in Iowa in October 2006 and reorganized in Delaware in May 2014.

Going Concern

The financial statements have been prepared on a going concern basis which assumes that the Company will be able to realize its assets and discharge its liabilities in the normal course of business for the foreseeable future. The Company has experienced recurring negative operating cash flows and has a stockholders' deficit, and its existing cash and cash equivalents and restricted cash are not sufficient to fund the Company's operating expenses and capital expenditure requirements for at least one year from date these financial statements are issued. Various internal and external factors will affect whether and when product candidates become approved drugs and how significant the market share of those approved products will be. The length of time and cost of developing and commercializing these product and product candidates and/or failure of them at any stage of the drug approval or commercialization process will materially affect the Company's financial condition and future operations. The Company's ability to continue as a going concern will likely need additional financing to fund its operations. The perception of the Company's inability to continue as a going concern may make it more difficult to obtain financing for the continuation of operations and could result in the loss of confidence by investors, suppliers and employees. Adequate additional financing may not be available to the Company on acceptable terms, or at all.

Management believes these conditions raise substantial doubt about the Company's ability to continue as a going concern within the twelve months after the date these financial statements are issued. Based upon the Company's current operating plan and projected revenue, the Company believes its cash resources will be sufficient to fund operating expense and capital investment requirements into, but not through, the first quarter of 2021. A significant portion of the Company's projected revenue is based upon the achievement of milestones in the KP415 and APADAZ license agreements. Certain of the milestones are associated with regulatory matters that are outside the control of the Company an the Company does not have a history of achieving milestones in their license agreements. If revenues are not as the Company projects, the Company believes its existing resources are sufficient to fund its current operations into but not through the third quarter of 2020. The ability to continue as a going concern is dependent upon profitable future operations, positive cash flows, the forebearance of the Company's lenders and additional financing. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Management intends to finance operating costs over the next twelve months with existing cash and cash equivalents and restricted cash, as well as anticipated payments arising from the Company's license agreements and additional financing through the Company's active registration statement on Form S-3 covering the sale of up to $150.0 million of the Company's common stock, preferred stock, and debt and/or warrants, if available (the "Current Registration Statement"). In October 2019, the Company filed a registration on Form S-3 covering the sale of up to $80.0 million of the Company's common stock, preferred stock, and debt and/or warrants (the "Replacement Registration Statement"). Once the Replacement Registration Statement is declared effective by the SEC, the Company will no longer make any sales under the Current Registration Statement.

After the Company files this Annual Report on Form 10-K for the fiscal year ended December 31, 2019 (the "Annual Report"), in order to issue securities under the Current Registration Statement or the Replacement Registration Statement, once effective, it must rely on Instruction I.B.6. of Form S-3, which imposes a limitation on the maximum amount of securities that the Company may sell pursuant to the registration statements during any twelve-month period. At the time it sells securities pursuant to the applicable registration statement, the amount of securities to be sold plus the amount of any securities it has sold during the prior twelve months in reliance on Instruction I.B.6. may not exceed one-third of the aggregate market value of its outstanding common stock held by non-affiliates as of a day during the 60 days immediately preceding such sale, as computed in accordance with Instruction I.B.6. As of filing this Annual Report, based on this calculation, the amount of securities the Company is able to sell under a registration statement on Form S-3 is approximately $10.9 million, of which the Company (i) has filed a prospectus supplement to register approximately $4.0 million for sales under the Purchase Agreement (as defined below); and (ii) has previously sold an aggregate of $5.7 million of shares of common stock in prior offering on Form S-3 in the previous 12 months. Based on this calculation, the Company expects it will be unable to sell additional securities beyond those amounts pursuant to the Current Registration Statement or the Replacement Registration Statement, once effective, in the near term, unless and until the market value of its outstanding common stock held by non-affiliates increases significantly. In addition, under the terms of the Purchase Agreement, stockholder approval may be required to access a portion of the amounts available under the Purchase Agreement. As of December 31, 2019, the Company has sold 3,401,271 shares of common stock registered under the Current Registration Statement for approximately $5.4 million in gross proceeds under the Prior Purchase Agreement.

Entry into First ATM Agreement

In October 2016, the Company entered into a Common Stock Sales Agreement (the "First ATM Agreement") with Cowen and Company, LLC ("Cowen"). The First ATM Agreement was terminated in September 2018. Prior to termination of the First ATM Agreement, the Company sold an aggregate of 762,338 shares of common stock under the First ATM Agreement resulting in gross proceeds to the Company of $4.9 million. The Company paid Cowen a commission of up to three percent (3.0%) of the gross sales proceeds for such sales of common stock. Pursuant to the terms of the First ATM Agreement, specified obligations of the parties, including the Company's indemnification obligations to Cowen, survive the termination of the First ATM Agreement.

Entry into Second ATM Agreement

In September 2018, the Company entered into a Common Stock Sales Agreement (the "Second ATM Agreement") with RBC Capital Markets, LLC ("RBCCM") 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 RBCCM as its sales agent. The Company's registration statement on Form S-3 contemplated under the Second ATM Agreement was declared effective by the SEC on October 17, 2016. The registration statement on Form S-3 includes a prospectus supplement covering the offering of up to $50,000,000 of shares of common stock in accordance with the Second ATM Agreement. In March 2019, the Company filed an updated prospectus supplement regarding the Second ATM Agreement covering the offering of up to $3.2 million of shares of common stock in order to be in compliance with Instruction I.B.6 of Form S-3. In February 2020, the Company terminated this offering. As of December 31, 2019, the Company has not sold any shares of common stock under the Second ATM Agreement.

Underwritten Public Offering

In October 2018, the Company entered into an underwriting agreement (the "Underwriting Agreement") with RBCCM, pursuant to which, on October 10, 2018, the Company sold 8,333,334 shares of common stock of the Company in an underwritten public offering pursuant to the Company's registration statement on Form S-3, filed with the SEC on October 17, 2016, and a related prospectus and prospectus supplement, filed with the SEC on October 17, 2016 and October 5, 2018, respectively. The offering price to the public was $3.00 per share. The Company's net proceeds from the offering were approximately $23.1 million, after deducting underwriting discounts and commissions and estimated offering expenses.

Entry into Prior Purchase Agreement

In February 2019, the Company entered into a purchase agreement (the "Prior Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") which provided that, upon the terms and subject to the conditions and limitations set forth therein, the Company previously could sell to Lincoln Park up to $15.0 million of shares of common stock from time to time over the 36-month term of the Prior Purchase Agreement, and upon execution of the Prior Purchase Agreement the Company issued an additional 120,200 shares of common stock to Lincoln Park as commitment shares in accordance with the closing conditions within the Prior Purchase Agreement. Concurrently with entering into the Prior Purchase Agreement, the Company also entered into a registration rights agreement with Lincoln Park pursuant to which the Company agreed to register the sale of the shares of common stock that have been and may be issued to Lincoln Park under the Prior Purchase Agreement pursuant to the Company's existing shelf registration statement on Form S-3 or a new registration statement. As of December 31, 2019, the Company has sold 3,401,271 shares of common stock to Lincoln Park under the Prior Purchase Agreement for approximately $5.4 million in gross proceeds. In February 2020, and in connection with entering into the Purchase Agreement (see discussion below), the Company terminated the Prior Purchase Agreement.

Entry into APADAZ License Agreement

In October 2018, the Company entered into a Collaboration and License Agreement (the "APADAZ License Agreement") with KVK Tech, Inc. ("KVK") pursuant to which we have granted an exclusive license to KVK to conduct regulatory activities for, manufacture and commercialize APADAZ in the United States.

Pursuant to the APADAZ License Agreement, KVK agreed to pay the Company certain payments and cost reimbursements of an estimated $3.4 million, which includes a payment of $2.0 million within 10 days of the achievement of a specified milestone related to the initial formulary adoption of APADAZ (the "Initial Adoption Milestone"). In addition, KVK has agreed to make additional payments to the Company upon the achievement of specified sales milestones of up to $53.0 million in the aggregate. Further, the Company and KVK will share the quarterly net profits of APADAZ by KVK in the United States at specified tiered percentages, ranging from the Company receiving 30% to 50% of net profits, based on the amount of net sales on a rolling four quarter basis. The Company is responsible for a portion of commercialization and regulatory expenses for APADAZ until the Initial Adoption Milestone is achieved, after which KVK will be responsible for all expenses incurred in connection with commercialization and maintaining regulatory approval in the United States.

The APADAZ License Agreement will terminate on the later of the date that all of the patent rights for APADAZ have expired in the United States or KVK's cessation of commercialization of APADAZ in the United States. KVK may terminate the APADAZ License Agreement upon 90 days written notice if a regulatory authority in the United States orders KVK to stop sales of APADAZ due to a safety concern. In addition, after the third anniversary of the APADAZ License Agreement, KVK may terminate the APADAZ License Agreement without cause upon 18 months prior written notice. The Company may terminate the APADAZ License Agreement if KVK stops conducting regulatory activities for or commercializing APADAZ in the United States for a period of six months, subject to specified exceptions, or if KVK or its affiliates challenge the validity, enforceability or scope of any licensed patent under the APADAZ License Agreement. Both parties may terminate the APADAZ License Agreement (i) upon a material breach of the APADAZ License Agreement, subject to a 30-day cure period, (ii) the other party encounters bankruptcy or insolvency or (iii) if the Initial Adoption Milestone is not achieved. Upon termination, all licenses and other rights granted by the Company to KVK pursuant to the APADAZ License Agreement would revert to the Company.

The APADAZ License Agreement also established a joint steering committee, which monitors progress of the commercialization of APADAZ.

Entry into KP415 License Agreement

In September 2019, the Company entered into a Collaboration and License Agreement (the "KP415 License Agreement") with Commave Therapeutics SA, an affiliate of Gurnet Point Capital ("Commave"). Under the KP415 License Agreement, the Company granted to Commave an exclusive, worldwide license to develop, manufacture and commercialize the Company's product candidates containing serdexmethylphenidate ("SDX") and d-methylphenidate ("d-MPH"), including KP415, KP484, and, at the option of Commave, KP879, KP922 or any other product candidate developed by the Company containing SDX and developed to treat ADHD or any other central nervous system disorder (the "Additional Product Candidates" and, collectively with KP415 and KP484, the "Licensed Product Candidates"). Pursuant to the KP415 License Agreement, Commave (i) paid the Company an upfront payment of $10.0 million; (ii) agreed to pay milestone payments of up to $63.0 million upon the occurrence of specified regulatory milestones related to the KP415 and KP484; (iii) agreed to pay additional payments of up to $420.0 million upon the achievement of specified U.S. sales milestones; and (iv) has agreed to pay the Company quarterly, tiered royalty payments ranging from a percentage in the high single digits to the mid-twenties of Net Sales (as defined in the KP415 License Agreement) in the United States and a percentage in the low to mid-single digits of Net Sales in each country outside the United States, in each case subject to specified reductions under certain conditions as described in the KP415 License Agreement. Commave is obligated to make such royalty payments on a product-by-product basis until expiration of the Royalty Term (as defined in the KP415 License Agreement) for the applicable product.

Commave has also agreed to be responsible and reimburse the Company for all of development, commercialization and regulatory expenses for the Licensed Product Candidates, subject to certain limitations as set forth in the KP415 License Agreement.

The KP415 License Agreement also established a joint steering committee, which monitors progress of the development of both KP415 and KP484. Subject to the oversight of the joint steering committee, the Company otherwise retains all responsibility for the conduct of all regulatory activities required to obtain new drug application approval of KP415 and KP484; provided that Commave shall be the sponsor of any clinical trials conducted by the Company on behalf of Commave.

In accordance with the terms of the Company's March 20, 2012 Termination Agreement with Aquestive Therapeutics (formerly known as MonoSol Rx, LLC), Aquestive Therapeutics has the right to receive an amount equal to 10% of any royalty or milestone payments made to the Company related to KP415, KP484 or KP879 under the KP415 License Agreement.

Entry into Purchase Agreement

In February 2020, the Company entered into a purchase agreement with Lincoln Park (the "Purchase Agreement"), which provided that, upon the terms and subject to the conditions and limitations set forth therein, the Company may sell to Lincoln Park up to $4.0 million of shares of its common stock, from time to time over the 12-month term of the Purchase Agreement, and upon execution of the Purchase Agreement the Company issued an additional 308,637 shares of its common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Purchase Agreement. Concurrently with entering into the Purchase Agreement, the Company also entered into a registration rights agreement with Lincoln Park, pursuant to which the Company agreed to register the sale of the shares of its common stock that have been and may be issued to Lincoln Park under the Purchase Agreement pursuant to the Company's existing shelf registration statement on Form S-3 or a new registration statement.

B. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("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 and assumptions, including those related to revenue recognition, the useful lives of property and equipment, the recoverability of long-lived assets, the incremental borrowing rate for leases, 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.

Reclassifications

During 2019, the Company began presenting accounts and other receivables as a separate line item on the balance sheets and statements of cash flows. In prior periods, accounts and other receivables were reported within the prepaid expenses and other current assets line items in the balance sheets and statements of cash flows. In accordance with GAAP, the change in current period presentation requires a reclassification of prior period balances. The reclassification of prior period balances resulted in a reduction of prepaid expenses and other current assets of $0.1 million on the Company's balance sheet for the period ended December 31, 2018 and a reduction in change in prepaid expenses and other assets of $0.1 million on the statement of cash flows for the year ended December 31, 2018. This reclassification had no effect on the statements of operations.

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 maintained investment securities that were classified as trading securities. These securities were carried at fair value with unrealized gains and losses included in other (expense) income on the statements of operations. The securities primarily consisted of certificates of deposit, U.S. Treasury securities and U.S. government-sponsored agency securities.

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 ten 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 the statements of operations.

Debt Issuance Costs

Debt issuance costs incurred in connection with financing arrangements are recorded as a reduction of the related debt on the balance sheet and 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 and product candidates. These arrangements also may include a share of future revenue if related product or product candidates reach commercialization. Costs under these supply arrangements, if any, are expensed as incurred (Note I).

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, 2019 or 2018.

Fair Value of Financial Instruments

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.

Revenue Recognition

The Company commenced recognizing revenue in accordance with the provisions of ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), starting January 1, 2018. However, the Company had no revenue at that time.

Arrangements with Multiple-Performance Obligations

From time to time, the Company enters into arrangements for research and development, manufacturing and/or commercialization services. Such arrangements may require the Company to deliver various rights, services, including intellectual property rights/licenses, research and development services, and/or commercialization services. The underlying terms of these arrangements generally provide for consideration to the Company in the form of nonrefundable upfront license fees, development and commercial performance milestone payments, royalty payments, and/or profit sharing.

In arrangements involving more than one performance obligation, each required performance obligation is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on its respective relative stand-alone selling price. The estimated selling price of each deliverable reflects the Company's best estimate of what the selling price would be if the deliverable was regularly sold by the Company on a stand-alone basis or using an adjusted market assessment approach if selling price on a stand-alone basis is not available.

The consideration allocated to each distinct performance obligation is recognized as revenue when control of the related goods or services is transferred. Consideration associated with at-risk substantive performance milestones is recognized as revenue when it is probable that a significant reversal of the cumulative revenue recognized will not occur. Should there be royalties, the Company utilizes the sales and usage-based royalty exception in arrangements that resulted from the license of intellectual property, recognizing revenues generated from royalties or profit sharing as the underlying sales occur.

Licensing Agreements

The Company enters into licensing agreements with licensees that fall under the scope of ASC 606.

The terms of the Company's licensing agreements typically include one or more of the following: (i) upfront fees; (ii) milestone payments related to the achievement of development, regulatory, or commercial goals; and (iii) royalties on net sales of licensed products. Each of these payments may result in licensing revenues.

As part of the accounting for these agreements, the Company must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligations. Generally, the estimation of the stand-alone selling price may include such estimates as, independent evidence of market price, forecasted revenues or costs, development timelines, discount rates, and probability of regulatory success. The Company evaluates each performance obligation to determine if they can be satisfied at a point in time or over time, and it measures the services delivered to the licensee which are periodically reviewed based on the progress of the related program. The effect of any change made to an estimated input component and, therefore revenue or expense recognized, would be recorded as a change in estimate. In addition, variable consideration (e.g., milestone payments) must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

Up-front Fees: If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from the transaction price allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time.

Milestone Payments: At the inception of each arrangement that includes milestone payments (variable consideration), the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or the licensee's control, such as non-operational developmental and regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of milestones that are within its or the licensee's control, such as operational developmental milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues and earnings in the period of adjustment. Revisions to the Company's estimate of the transaction price may also result in negative licensing revenues and earnings in the period of adjustment.

KP415 License Agreement

In September 2019, the Company entered into the KP415 License Agreement with Commave under which the Company granted to Commave an exclusive, worldwide license to develop, manufacture and commercialize the Company's product candidates containing SDX and d-MPH, including KP415, KP484, and, at the option of Commave, KP879, KP922 and/or any other product candidate developed by the Company containing SDX and developed to treat ADHD or any other central nervous system disorder. The license granted to Commave is distinct from other performance obligations as Commave can benefit from the license either on its own or together with other resources that are readily available and the license is separately identifiable from other promises in the KP415 License Agreement.

In exchange for the exclusive, worldwide license, discussed above, Commave paid the Company a non-refundable upfront payment of $10.0 million. The Company is also entitled to additional payments from Commave of up to $63.0 million, conditioned upon the achievement of specified regulatory milestones related to KP415 and KP484. In addition, the Company is entitled to payments from Commave of up to $420.0 million in the aggregate, conditioned upon the achievement of certain U.S. sales milestones, which are dependent upon, among other things, the timing of approval for a new drug application for KP415 and its final approved label, if any. Further, Commave will pay the Company quarterly, tiered royalty payments ranging from a percentage in the high single digits to mid-twenties of Net Sales (as defined in the KP415 License Agreement) in the U.S. and a percentage in the low to mid-single digits of Net Sales in each country outside of the U.S., in each case subject to specified reductions under certain conditions as described in the KP415 License Agreement

Commave also agreed to be responsible for and reimburse the Company for all of development, commercialization and regulatory expenses incurred on the licensed products, subject to certain limitations as set forth in the KP415 License Agreement. As part of this agreement the Company is obligated to perform consulting services on behalf of Commave related to the licensed products. For these consulting services, Commave has agreed to pay the Company a set rate per hour on any consulting services performed on behalf of Commave for the benefit of the licensed products.

The KP415 License Agreement is within the scope of ASC 606, as the transaction represents a contract with a customer where the the participants function in a customer / vendor relationship and are not exposed equally to the risks and rewards of the activities contemplated under the KP415 License Agreement. Using the concepts of ASC 606, the Company has identified the grant of the exclusive, worldwide license and the performance of consulting services, which includes the reimbursement of out-of-pocket third-party research and development costs, as its only two performance obligations. The Company further determined that the transaction price under the agreement was $10.0 million upfront payment plus the fair value of the Development Costs (as defined in the KP415 License Agreement) which was allocated among the performance obligations based on their respective related stand-alone selling price.

The consideration allocated to the grant of the exclusive, worldwide license was $10.0 million, which reflects the standalone selling price. The Company utilized the adjusted market assessment approach to determine this standalone selling price which included analyzing prospective offers received from various entities throughout our licensing negotiation process as well as the consideration paid to other competitors in the market for a similar type transaction. The Company determined that the intellectual property licensed under the KP415 License Agreement represented functional intellectual property and it has significant standalone functionality and therefore should be recognized at a point in time as opposed to over time. The revenue related to the grant of the exclusive, worldwide license was recognized at a point in time at the inception of the KP415 License Agreement.

The consideration allocated to the performance of consulting services, which includes the reimbursement of out-of-pocket third-party research and development costs, was the fair value of the Development Costs (as defined in the KP415 License Agreement), which reflects the standalone selling price. The Company utilized a blended approach which took into consideration the adjusted market assessment approach and the expected cost plus a margin approach to determine this standalone selling price. This blended approach utilized the adjusted market approach and expected cost plus margin approach to value the performance of consulting services which included analyzing hourly rates of vendors in the a market who perform similar services to those of the Company to develop a range and then analyzing the average cost per hour of our internal resources and applying a margin which placed the value in the median of the previously identified range. For the reimbursement of out-of-pocket third-party research and development costs the Company utilized the expected cost plus a margin approach, which included estimating the actual out-of-pocket cost the Company expects to pay to third-parties for research and development costs and applying a margin, if necessary. The Company determined that no margin was necessary of these out-of-pocket third-party research and development costs as these are purely pass-through costs and the margin for managing these third-party activities is included within the value of the performance of consulting services. The Company determined that the performance of consulting services, including reimbursement of out-of-pocket third-party research and development costs, is a performance obligation that is satisfied over time as the services are performed and the reimbursable costs are paid. As such, the revenue related to the performance obligation will be recognized as the consulting services are performed and the services associated with the reimbursable out-of-pocket third-party research and development costs are incurred and paid by the Company, in accordance with the practical expedient allowed under ASC 606 regarding an entity's right to consideration from a customer in an amount that corresponds directly to the value to the customer of the entity's performance completed to date. As discussed above, the combination of the standalone selling price of these consulting services and certain out-of-pocket third-party research and development costs for KP415 was the fair value of the Development Costs at inception. These Development Costs effectively created a cap on certain consulting services and out-of-pocket third-party research and development costs identified in the initial product development plan for KP415 which was anticipated at the inception date of the KP415 License Agreement. As of December 31, 2019, the Company has recognized approximately 66% of the consulting services and out-of-pocket third-party research and development costs under this cap.

Under the KP415 License Agreement, Commave was granted an exclusive option to include Additional Products as Product(s) (both as defined in the KP415 License Agreement) under the KP415 License Agreement (the "Additional Product Option"). In addition to the Additional Product Option, Commave was also granted a right of first refusal ("ROFR") to acquire, license and/or commercialize any of the Additional Product Candidates should they choose not to exercise the Additional Product Option. Should Commave choose to exercise the Additional Product Option on any Additional Product Candidates, Commave and the Company shall negotiate in good faith regarding the economic terms of such Additional Product. Further, should Commave exercise the ROFR on any Additional Product Candidate, the economic terms of the agreement shall be the same as those offered to the third-party. Under ASC 606 an option to acquire additional goods or services gives rise to a performance obligation if the option provides a material right to the customer. The Company concluded that the above described Additional Product Option and ROFR do not constitute material rights to the customer as Commave would acquire the goods or services at a to be negotiated price, which the Company expects to approximate fair value and therefore Commave would not receive a material discount on these goods or services compared to market rates.

The Company is entitled to additional payments from Commave conditioned upon the achievement of specified regulatory milestones related to KP415 and KP484 and the achievement of certain U.S. sales milestones, which are dependent upon, among other things, the timing of approval for a new drug application for KP415 and its final approved label, if any. Further, Commave will pay the Company quarterly, tiered royalty payments ranging from a percentage in the high single digits to mid-twenties of Net Sales (as defined in the KP415 License Agreement) in the U.S. and a percentage in the low to mid-single digits of Net Sales in each country outside of the U.S., in each case subject to specified reductions under certain conditions as described in the KP415 License Agreement. The Company concluded that these regulatory milestones, sales milestones and royalty payments each contain a significant uncertainty associated with a future event. As such, these milestone and royalty payments are constrained at contract inception and are not included in the transaction price as the Company could not conclude that it is probable a significant reversal in the amount of cumulative revenue recognized will not occur surrounding these payments. At the end of each reporting period, the Company updates its assessment of whether the milestone and royalty payments are constrained by considering both the likelihood and magnitude of the potential revenue reversal.

For the year ended December 31, 2019, the Company recognized revenue of $12.8 million, which is comprised of a $10.0 million non-refundable payment for an exclusive, worldwide license, $1.1 million of reimbursement of out-of-pocket third-party research and development costs and $1.7 million for the performance of consulting services. In addition, as of December 31, 2019, the Company had receivables in the amount of $1.4 million and $0.2 million related to the performance of consulting services and the reimbursement of out-of-pocket third-party research and development costs, respectively. In connection with the $10.0 million non-refundable payment the Company received under the KP415 License Agreement, the Company paid Aquestive Therapeutics a royalty equal to 10% of the upfront license payment received in the third quarter of 2019. In addition, under the guidance provided in ASC 340-40, Contracts with Customers, the Company capitalized approximately $2.8 million of incremental costs incurred in obtaining the KP415 License Agreement and will amortize these costs as the revenue associated with the exclusive worldwide license, reimbursement of out-of-pocket third-party research and development costs and consulting services is recognized. As of December 31, 2019, the Company has recognized approximately $1.9 million of these incremental costs, which are recorded in the line item titled royalties and contract costs in the statement of operations along with the royalty discussed above. The remaining incremental contract costs to be amortized are recorded in prepaid expense and other currents on the balance sheet. There was no revenue recognized, or associated receivables and cost revenue, for the year ended or as of December 31, 2018. There was no deferred revenue related to this agreement as of December 31, 2019 or 2018.

Accounts and Other Receivables

Accounts and other receivables consists of receivables under the KP415 License Agreement, as well as income tax and other receivables due to the Company. Receivables under the KP415 License Agreement are recorded for amounts due to the Company related to reimbursable out-of-pocket third-party research and development costs and performance of consulting services. These receivables are evaluated to determine if any reserve or allowance should be established at each reporting date. As of December 31, 2019 and 2018 no reserve or allowance has been established.

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, 2019 and 2018.

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 2014, although carryforward attributes that were generated prior to 2014 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, inclusive of the modifications made by ASU 2018-07. The Company values equity instruments and stock options granted using the Black-Scholes option pricing model.

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 convertible preferred stock and select warrants 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 ("CODM") in deciding how to allocate resources and in assessing performance. The Company’s 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, 2019 and 2018.

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.

In April 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 could have elected 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 irrevocably 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 February 2016, the FASB issued ASU 2016-02, *Leases (Topic* 842*)* ("ASU 2016-02"), which requires lessees to recognize operating and finance lease liabilities and corresponding right-of-use assets on the balance sheet and to provide enhanced disclosures surrounding the amount, timing and uncertainty of cash flows arising from leases. The Company leases office space and laboratory facilities under non-cancelable operating leases. In addition, the Company leases various laboratory equipment, furniture and office equipment and leasehold improvements that are accounted for as capital leases. The Company adopted the new standard effective January 1, 2019 on a modified retrospective basis and did not restate comparative periods. The Company elected the package of practical expedients permitted under the transition guidance, which allowed the Company to carryforward its historical lease classification and its assessment on whether a contract is or contains a lease for any leases that existed prior to adoption of the new standard. The Company also elected to combine lease and non-lease components and to keep leases with an initial term of 12 months or less off the balance sheet and recognize the associated lease payments in the statements of operations on a straight-line basis over the lease term. The Company did not elect the hindsight practical expedient, which would have allowed the Company to use hindsight in determining the lease term and in assessing any impairment of right-of-use assets during the lookback period. The adoption of ASU 2016-02 resulted in the recognition of total right-of-use assets and total lease liabilities of approximately $2.6 million on the balance sheets as of January 1, 2019.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic* 260*), Distinguishing Liabilities from Equity (Topic* 480*), Derivatives and Hedging (Topic* 815*) – I. Accounting for Certain Financial Instruments with Down Round Features and II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception* ("ASU 2017-11"), which addresses the complexity of accounting for certain financial instruments with down round features and addresses the difficulty of navigating Topic 480 because of the existence of extensive pending content in the ASC as a result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. This update applies to all entities that issue financial instruments that include down round features and entities that present earnings per share in accordance with Topic 260. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. The adoption of ASU 2017-11 did not have a material impact on the Company's financial statements and disclosures.

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation (Topic 820) – Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"), which simplifies several aspects of the accounting for nonemployee share-based payment transactions resulting from expanding the scope of Topic 718, Compensation—Stock Compensation, to include share-based payment transactions for acquiring goods and services from nonemployees. This update applies to all entities that enter into share-based payment transactions for acquiring goods and services from nonemployees. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. The amendments in this ASU expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost (that is, the period of time over which share-based payment awards vest and the pattern of cost recognition over that period). The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The adoption of ASU 2018-07 did not have a material impact on the Company's financial statements and disclosures.

Application of New or Revised Accounting Standards—Not Yet Adopted

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820) – Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which modifies the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement, based on the concepts in the FASB Concepts Statement, *Conceptual Framework for Financial Reporting—Chapter 8: Notes to Financial Statements*, which the FASB finalized on August 28, 2018, including the consideration of costs and benefits. This update applies to all entities that are required, under existing GAAP, to make disclosures about recurring or nonrecurring fair value measurements. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. Early adoption is permitted. An entity is permitted to early adopt any removed or modified disclosures and delay adoption of the additional disclosures until their effective date. The Company does not expect the adoption of ASU 2018-13 to have a material impact on the Company's financial statements and disclosures.

C. Accounts and Other Receivables

Accounts and other receivables consist of the following (in thousands):

	December 31,	
	2019	2018
Accounts receivable	$ 1,681	$ -
Other receivables	184	140
Total accounts and other receivables	$ 1,865	$ 140

D. Prepaid Expenses and Other Current Assets

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

	December 31,	
	2019	2018
Prepaid insurance	$ 250	$ 224
Deferred direct contract acquisition costs	805	-
Prepaid offering costs	266	-
Other prepaid expenses and current assets	231	1,688
Total prepaid expenses and other current assets	$ 1,552	$ 1,912

E. Property and Equipment

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

	December 31,	
	2019	2018
Laboratory equipment	$ 638	$ 1,035
Furniture and office equipment	119	655
Computers and hardware	303	299
Leasehold improvements	958	1,017
Finance lease right-of-use assets	1,013	-
Total property and equipment	3,031	3,006
Less: accumulated depreciation and amortization	(1,560)	(1,253)
Property and equipment, net	$ 1,471	$ 1,753

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 finance leases, was approximately $304,000 and $324,000 for the years ended December 31, 2019 and 2018, respectively.

F. Accounts Payable and Accrued Expenses

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

	December 31,	
	2019	2018
Accrued interest	$ 359	$ 1,921
Accrued banking fees	700	700
Accrued severance	-	193
Accrued payroll	1	731
Accrued professional fees	2,364	230
Accounts payable	1,140	3,715
Other accrued expenses	347	852
Total accounts payable and accrued expenses	$ 4,911	$ 8,342

G. Debt Obligations

As of December 31, 2019 and 2018, the Company had convertible notes outstanding, in the aggregate principal amounts, as follows (in thousands):

	December 31,	
	2019	2018
Deerfield Convertible Note	$ 6,981	$ 6,667
2021 Notes	3,000	76,673
December 2019 Notes	70,218	-
Total outstanding principal on debt obligations	80,199	83,340
Less: debt issuance costs and discounts	(2,856)	(1,902)
Convertible notes, net	$ 77,343	$ 81,438

Deerfield Facility Agreement

In June 2014, the Company entered into a $60 million multi-tranche credit facility (the “Deerfield Facility Agreement”) with Deerfield Private Design Fund III, LP (“Deerfield”). At the time the Company entered into the Deerfield Facility Agreement, the Company borrowed the first tranche, which consisted of a term loan of $15 million (the “Term Note”) and a senior secured loan of $10 million (the “Deerfield Convertible Note”). Deerfield is no longer obligated to provide the Company any additional disbursements under the Deerfield Facility Agreement. Deerfield may convert any portion of the outstanding principal and any accrued but unpaid interest on the Deerfield Convertible Note into shares of the Company’s common stock at an initial conversion price of $5.85 per share (the "Deerfield Note Put Option").

The Deerfield Convertible Note originally bore interest at 9.75% per annum, but was subsequently reduced to 6.75%. Interest accrued on the outstanding balance under the Deerfield Convertible Note was due quarterly in arrears. The Company originally had to repay one-third of the outstanding principal amount of the Deerfield Convertible Note on the fourth and fifth anniversaries of the Deerfield Facility Agreement (June 2018 and June 2019). In June 2018, Deerfield agreed to convert the $3,333,333 of the principal amount then due, plus $168,288 of accrued interest, into 598,568 shares of our common stock (as discussed below in the section entitled "Facility Agreement Waiver and Fifth Amendment to Senior Secured Convertible Note"). In September 2019, the Company entered into an amendment with Deerfield in order to (i) reduce the interest rate applicable under the Deerfield Facility Agreement from 9.75% to 6.75%, (ii) provide for “payment in kind” of interest on the Loans (as defined in the Deerfield Facility Agreement), and (iii) defer the Loan payments due pursuant to the Deerfield Facility Agreement until June 1, 2020 (as discussed below in the section entitled "2021 Note Exchange Effected in September 2019"). In December 2019, the Company entered into another amendment with Deerfield in order to (i) defer the Loan payments due pursuant to the Deerfield Facility Agreement until March 31, 2021 and (ii) allow for the entries of additional debt and debt holders under the Deerfield Facility Agreement (as discussed below in the section entitled "2021 Note Exchange Effected in December 2019"). The Company is also obligated to repay principal of the Deerfield Convertible Note in the amount of $6,980,824 plus any capitalized interest to date on March 31, 2021. Prepayment of the outstanding balance is not allowed without written consent of Deerfield.

Pursuant to the Deerfield Facility Agreement, the Company issued to Deerfield 1,923,077 shares of Series D redeemable convertible preferred stock ("Series D Preferred") as consideration for the loans provided to the Company thereunder. Upon completion of the initial public offering, these shares of Series D Preferred automatically reclassified into 256,410 shares of the Company’s common stock.

The Company also issued to Deerfield a warrant to purchase 14,423,076 shares of Series D Preferred at an initial exercise price of $0.78 per share, which is exercisable until June 2, 2024 (the “Deerfield Warrant”). Upon completion of the Company's initial public offering, 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 net loss per share calculation (Note J). If a Major Transaction occurs (as defined in the Deerfield Facility Agreement) 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 “Warrant Put Option”).

The Company recorded the fair value of the shares of Series D Preferred to debt issuance costs on the date of issuance. The Company also recorded the fair value of the Deerfield Warrant and the embedded Warrant 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 related to amortization of debt issuance costs and discount 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, other than permitted indebtedness under the Deerfield Facility Agreement, 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 the Required Lenders (as defined in the Deerfield Facility Agreement). 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 each warrant issued pursuant to the Deerfield Facility Agreement, Deerfield has the right to demand that the Company redeem the warrant for a cash amount equal to the Black-Scholes value of a portion of the warrant upon the occurrence of specified events, including a merger, an asset sale or any other change of control transaction.

The Deerfield Facility Agreement also includes high yield discount obligation protections that went into effect in June 2019. Going forward, if at any interest payment date our outstanding indebtedness under the Deerfield Facility Agreement would qualify as an "applicable high yield discount obligation" under the Internal Revenue Code of 1986 (the" Code") then the Company is obligated to prepay in cash on each such date the amount necessary to avoid such classification.

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

In February 2016, the Company issued $86.3 million aggregate principal amount of its 5.50% Senior Convertible Notes due 2021 (the “2021 Notes”) to Cowen 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.

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 (the "Trustee"). Interest on the 2021 Notes was 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 had an original maturity of February 1, 2021 unless earlier converted or repurchased.

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 Note, plus all accrued but unpaid interest, a make-whole interest payment and a prepayment premium on the Term Note.

The 2021 Notes were not redeemable prior to the maturity date, and no sinking fund was provided for the 2021 Notes. The 2021 Notes were 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.

If the Company underwent a “fundamental change” (as defined in the Indenture), holders could have required 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. As December 31, 2019, 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 M).

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

As described in more detail below, in multiple exchanges occurring in October 2018, December 2019 and January 2020, all outstanding 2021 Notes were exchanged by the holders thereof for either shares of our common stock or senior secured convertible promissory notes issued under the terms of the Deerfield Facility Agreement.

Facility Agreement Waiver and Fifth Amendment to Senior Secured Convertible Note

In June 2018, the Company entered into the Facility Agreement Waiver and Fifth Amendment (the "Fifth Amendment") to the Deerfield Convertible Note with Deerfield. The Fifth Amendment, among other things, provided that (i) $3,333,333 of the principal amount, plus $168,288 of accrued interest, of the Deerfield Convertible Note issued pursuant to the terms of the Deerfield Facility Agreement was converted into 598,568 shares of the Company's common stock, with such principal conversion amount being applied against and in full satisfaction of the amortization payment due June 2, 2018; (ii) Deerfield waived specified rights under the Deerfield Facility Agreement with regards to such principal and interest amount; and (iii) amended specified provisions of the Deerfield Convertible Note as they relate to the delivery of shares of the Company's common stock in connection with any conversion of the Deerfield Convertible Note.

2021 Note Exchange Effected in October 2018

In October 2018, the Company entered into an exchange agreement (the "October 2018 Exchange Agreement") with Deerfield and Deerfield Special Situations Fund, L.P. (the "Deerfield Lenders"). Under the October 2018 Exchange Agreement, the Deerfield Lenders exchanged an aggregate of $9,577,000 principal amount of the 2021 Notes for an aggregate of 9,577 shares of Series A Convertible Preferred Stock, par value $0.0001 ("Series A Preferred Stock").

As a condition to closing of the October 2018 Exchange Agreement, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (the "Series A Certificate of Designation") with the Secretary of State of the State Delaware, setting forth the preferences, rights and limitations of the Series A Preferred Stock.

Each share of Series A Preferred Stock has an aggregate stated value of $1,000 and is convertible into shares of common stock at a price equal to $3.00 per share (subject to adjustment to reflect stock splits and similar events). Immediately following the exchange under the October 2018 Exchange Agreement, there were an aggregate of 3,192,333 shares of common stock issuable upon conversion of the then outstanding Series A Preferred Stock (without giving effect to the limitation on conversion described below). As of December 31, 2019, all 9,577 shares of Series A Preferred Stock issued under the October 2018 Exchange Agreement have been converted into an aggregate 3,192,333 shares of the Company's common stock.

2021 Note Exchange Effected in September 2019

In September 2019, the Company entered into an Exchange Agreement and Amendment to Facility Agreement (the "September 2019 Exchange Agreement") with the Deerfield Lenders. Under the September 2019 Exchange Agreement, the Company issued an aggregate of 1,499,894 shares of the Company's common stock and an aggregate of 1,576 shares of the Company's Series B-1 Convertible Preferred Stock, par value $0.0001 per share ("Series B-1 Preferred Stock") (such shares of common stock and Series B-1 Preferred Stock, the "Initial Exchange Shares"), in exchange for the cancellation of an aggregate of $3,000,000 principal amount of the Company's 2021 Notes. The September 2019 Exchange Agreement provided the Deerfield Lenders the option to exchange up to an additional aggregate of $27,000,000 principal amount of the 2021 Notes (the "Optional Exchange Principal Amount") for shares of common stock or shares of the Company's Series B-2 Convertible Preferred Stock, par value $0.0001 per share (the "Series B-2 Preferred Stock" and, together with the Series B-1 Preferred Stock, the "Series B Preferred Stock"), subject to the terms and conditions set forth in the September 2019 Exchange Agreement, including limits as to the principal amount that can be exchanged prior to specified dates therein. If the Deerfield Lenders choose to exchange any portion of the Optional Exchange Principal Amount for shares of Series B-2 Preferred Stock, such exchange will be effected at an exchange price of $1,000 per share. If the Deerfield Lenders choose to exchange any portion of the Optional Exchange Principal Amount for shares of common stock, such exchange will be effected at an exchange price equal to the greater of (i) $0.9494, or (ii) the average of the volume-weighted average price of the common stock on the Nasdaq Capital Market on each of the 15 trading days immediately preceding such exchange.

As a condition to closing of the September 2019 Exchange Agreement, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series B-1 Convertible Preferred Stock (the "Series B-1 Certificate of Designation") and a Certificate of Designation of Preferences, Rights and Limitations of Series B-2 Convertible Preferred Stock (the "Series B-2 Certificate of Designation") with the Secretary of State of the State Delaware, setting forth the preferences, rights and limitations of the Series B-1 Preferred Stock and the Series B-2 Preferred Stock, respectively.

Each share of Series B-1 Preferred Stock has an aggregate stated value of $1,000 and is convertible into shares of common stock at a per share price equal to $0.9494 per share (subject to adjustment to reflect stock splits and similar events). Immediately following the exchange under the September 2019 Exchange Agreement, there were an aggregate of 1,659,996 shares of common stock issuable upon conversion of the then outstanding Series B-1 Preferred Stock (without giving effect to the limitation on conversion described below). Each share of Series B-2 Preferred Stock has an aggregate stated value of $1,000 and is convertible into shares of common stock at a per share price equal to the greater of (i) $0.9494 (subject to adjustment to reflect stock splits and similar events), or (ii) the average of the volume-weighted average prices of the common stock on the Nasdaq Capital Market on each of the 15 trading days immediately preceding such exchange. Immediately following the exchange under the September 2019 Exchange Agreement there was an aggregate of 28,439,015 shares of Common Stock issuable (i) in exchange of the Optional Exchange Principal Amount, or (ii) upon conversion of the Series B-2 Preferred Stock issuable in exchange of the Optional Exchange Principal Amount (in each case without giving effect to the limitation on conversion described below).

The Series B Preferred Stock is convertible at any time at the option of the Deerfield Lenders; provided that the Deerfield Lenders are prohibited from converting shares of Series B Preferred Stock into shares of common stock if, as a result of such conversion, such holders (together with certain affiliates and "group" members of such holders) would beneficially own more than 4.985% of the total number of shares of common stock then issued and outstanding. The Series B Preferred Stock is not redeemable. In the event of the Company's liquidation, dissolution or winding up, the Deerfield Lenders will receive an amount equal to $0.0001 per share, plus any declared but unpaid dividends, and thereafter will share ratably in any distribution of the Company's assets with holders of common stock and with the holders of any shares of any other class or series of capital stock of the Company entitled to share in such remaining assets of the Company (including the Series A Preferred Stock on an as-converted basis). With respect to rights upon liquidation, the Series B Preferred Stock ranks senior to the common stock, on parity with the Series A Preferred Stock, if any is outstanding, and junior to existing and future indebtedness. Except as otherwise required by law (or with respect to approval of certain actions involving the Company's organizational documents that materially and adversely affect the holders of Series B Preferred Stock), the Series B Preferred Stock does not have voting rights. The Series B Preferred Stock is not subject to any price-based anti-dilution protections and does not provide for any accruing dividends, but provides that holders of Series B Preferred Stock will participate in any dividends on the common stock on an as-converted basis (without giving effect to the limitation on conversion described above). The Series B-1 Certificate of Designation and the Series B-2 Certificate of Designation also provide for partial liquidated damages in the event that the Company fails to timely convert shares of Series B-1 Preferred Stock or Series B-2 Preferred Stock, respectively, into common stock in accordance with the applicable certificate of designation.

As of December 31, 2019, 1,576 shares of Series B-1 Preferred Stock have been converted into 1,659,966 shares of common stock, and there were no shares of Series B-2 Preferred Stock outstanding.

The September 2019 Exchange Agreement also amended the Deerfield Facility Agreement, in order to (i) reduce the interest rate applicable under the Deerfield Facility Agreement from 9.75% to 6.75%, (ii) provide for "payment in kind" of interest on the Loans (as defined in the Deerfield Facility Agreement), and (iii) defer the Loan payments pursuant to the Deerfield Facility Agreement until June 1, 2020. The September 2019 Exchange Agreement contains customary representations, warranties and covenants made by the Company and the Holders. The September 2019 Exchange Agreement also requires the Company to reimburse the Holders for up to $150,000 of expenses relating to the transactions contemplated by the September 2019 Exchange Agreement.

The Company determined the changes to the Deerfield Facility Agreement met the definition of a troubled debt restructuring under ASC 470-60, *Troubled Debt Restructurings by Debtors*, as the Company was experiencing financial difficulties and Deerfield granted a concession. The amendments to the terms of the Deerfield Facility Agreement resulted in no gain on restructuring because the total cash outflows required under the amended Deerfield Facility Agreement exceeded the carrying value of the original Deerfield Facility Agreement immediately prior to amendment. Prospectively, the Deerfield Facility Agreement, and the associated Deerfield Convertible Note will continue to be carried net of the associated discount and debt issuance costs which will be amortized and recorded as interest expense using a modified effective interest rate based on the amendments.

The changes to the 2021 Notes, under the September 2019 Exchange Agreement, were accounted for as a debt modification with the $2.3 million change in fair value of the embedded conversion feature, associated with the Optional Exchange Principal Amount, recorded as an increase to additional paid in capital and as a debt discount to be amortized to interest expense under the effective interest method over the remaining term of the 2021 Notes.

2021 Note Exchange Effected in December 2019

In December 2019, the Company entered into the December 2019 Exchange Agreement and Amendment to Facility Agreement, Senior Secured Convertible Notes and Warrants (the "December 2019 Exchange Agreement") with the Deerfield Lenders and Delaware Street Capital Master Fund, L.P. ("DSC" and, collectively with the Deerfield Lenders, the "December 2019 Holders"). Under the December 2019 Exchange Agreement, the Company issued senior secured convertible promissory notes under the Deerfield Facility Agreement in the aggregate principal amount of $71,418,011 (the "December 2019 Notes"), in exchange for the cancellation of an aggregate of $71,418,011 principal amount and accrued interest of the Company's 2021 Notes. Upon entering into the December 2019 Exchange Agreement, the Company agreed to pay the December 2019 Holders, in the aggregate, an interest payment of $745,011 which represents 50% of the accrued interest, as of December 18, 2019, on the 2021 Notes owned by the December 2019 Holders. The remainder of such interest was included in the principal amount of the December 2019 Notes.

The December 2019 Notes bear interest at 6.75% per annum. The December 2019 Notes are convertible into shares of the Company's common stock at an initial conversion price of $17.11 per share (which represents the conversion price of the 2021 Notes), subject to adjustment in accordance with the terms of the December 2019 Notes. As of the date of issuance, the December 2019 Notes were convertible, by their terms, into an aggregate of 4,174,051 shares of the Company's common stock. The Company subsequently amended the December 2019 Notes to provide that such notes shall be convertible into shares of the Company's common stock at a conversion price of $5.85 per share (which represents the conversion price of the Deerfield Convertible Note). The conversion price of the December 2019 Notes will be adjusted downward if the Company issues or sells any shares of common stock, convertible securities, warrants or options at a sale or exercise price per share less than the greater of the December 2019 Notes' conversion price or the closing sale price of the Company's common stock as reported on the Nasdaq Stock 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 the Company and the underwriters for such offering. However, if the Company effects an "at the market offering" as defined in Rule 415 of the Securities Act or 1933, as amended (the "Securities Act"), of its common stock, the conversion price of the December 2019 Notes 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, provided that this anti-dilution adjustment will not apply to any sales made under (x) the Purchase Agreement, (y) the Second ATM Agreement, or (z) the September 2019 Exchange Agreement (as amended). Notwithstanding anything in the contrary in the December 2019 Notes, the anti-dilution adjustment of such notes shall not result in the conversion price of the December 2019 Notes being less than $0.583 per share. The December 2019 Notes are convertible at any time at the option of the holders thereof, provided that a holder of a December 2019 Note is prohibited from converting such note into shares of the Company's common stock if, as a result of such conversion, such holder (together with certain affiliates and "group" members) would beneficially own more than 4.985% of the total number of shares of common stock then issued and outstanding. However, the December 2019 Note issued to DSC, due to the fact DSC was a beneficial owner of more than 4.985% of the total number of shares of the Company's common stock then issued and outstanding, has a beneficial ownership cap equal to 19.985% of the total number of shares of the Company's common stock then issued and outstanding. Pursuant to the December 2019 Notes, the December 2019 Holders have the option to demand repayment of all outstanding principal, and any unpaid interest accrued thereon, in connection with a Major Transaction (as defined in the December 2019 Notes), which shall include, among others, any acquisition or other change of control of the Company; a liquidation, bankruptcy or other dissolution of the Company; or if at any time after March 31, 2021, shares of the Company's common stock are not listed on an Eligible Market (as defined in the December 2019 Notes). The December 2019 Notes are subject to specified events of default, the occurrence of which would entitle the December 2019 Holders to immediately demand repayment of all outstanding principal and accrued interest on the December 2019 Notes. Such events of default include, among others, failure to make any payment under the December 2019 Notes when due, failure to observe or perform any covenant under the Deerfield Facility Agreement (as defined below) or the other transaction documents related thereto (subject to a standard cure period), the failure of the Company to be able to pay debts as they come due, the commencement of bankruptcy or insolvency proceedings against the Company, a material judgement levied against the Company and a material default by the Company under the Deerfield Warrant, the December 2019 Notes or the Deerfield Convertible Note.

The December 2019 Exchange Agreement amends the Deerfield Facility Agreement in order to, among other things, (i) provide for the Deerfield Facility Agreement to govern the December 2019 Notes received by the December 2019 Holders pursuant to the December 2019 Exchange Agreement, (ii) extend the maturity of the Deerfield Convertible Note from February 14, 2020 and June 1, 2020, as applicable, to March 31, 2021, (iii) defer interest payments on the Deerfield Convertible Note until March 31, 2021 (which such interest shall accrue as "payment-in-kind" interest), (iv) designate DSC as a Lender under (and as defined in the Deerfield Facility Agreement), (v) name Deerfield as the "Collateral Agent" for all Lenders and (vi) modify the terms and conditions under which the Company may issue additional pari passu and subordinated indebtedness under the Deerfield Facility Agreement (subject to certain conditions specified in the Deerfield Facility Agreement).

The December 2019 Exchange Agreement also amends and restates the Deerfield Convertible Note to conform the definitions of "Eligible Market" and "Major Transactions" to the definition in the December 2019 Notes, to remove provisions that were only applicable prior to the Company's initial public offering and to make certain other changes to conform to the December 2019 Notes. The conversion price for the Deerfield Convertible Note remains $5.85 per share, subject to adjustment on the same basis as the existing senior secured convertible notes, but subject to a floor price of $0.583.

The December 2019 Exchange Agreement also amends the Deerfield Warrant to conform the definitions of "Eligible Market" and "Major Transaction" in the Warrant with the definitions of such terms in the December 2019 Notes.

The December 2019 Exchange Agreement contains customary representations, warranties and covenants made by the Company and the December 2019 Holders, including a covenant of the Company to, upon request, use commercially reasonable efforts to use its technology to discover a product based upon a compound that may be identified by the Deerfield Lenders in a manner that is reasonably acceptable to the Deerfield Lenders, or one of their affiliates, with the terms of such discovery plan, including the Company's compensation thereunder, to be mutually agreed to by the parties.

In connection with entering into the December 2019 Exchange Agreement, on December 18, 2019, the Company amended and restated that certain Guaranty and Security Agreement, dated June 2, 2014, by and between the Company and the other parties thereto (the "GSA") to, among other things, (i) provide that all of the notes will be secured by the liens securing the indebtedness under the Deerfield Facility Agreement, and (ii) name Deerfield as the "Collateral Agent" under the GSA.

In connection with entering into the December 2019 Exchange Agreement, the Company also entered into an amendment (the "September 2019 Exchange Agreement Amendment") to the September 2019 Exchange Agreement to, among other things, (i) amend and restate Annex I of the September 2019 Exchange Agreement to allow the Deerfield Lenders to effect optional exchanges of the December 2019 Notes and the Deerfield Convertible Note under the terms of the September 2019 Exchange Agreement; (ii) amend the common stock exchange price under the September 2019 Exchange Agreement to be a per share price equal to the greater of (x) $0.60, subject to adjustment to reflect stock splits and similar events, or (y) the average of the volume-weighted average prices of the Company's common stock on the Nasdaq Stock Market on each of the 15 trading days immediately preceding such exchange, (iii) provide that no more than 28,439,015 of shares of the Company's common stock shall be issued pursuant to optional exchanges under the September 2019 Exchange Agreement (whether by common stock exchange or upon conversion of Series B-2 Shares (as defined in the September 2019 Exchange Agreement Amendment)), subject to adjustment to reflect stock splits and similar events and (iv) eliminate limitations regarding the timing and aggregate amount of principal which may be exchanged under the September 2019 Exchange Agreement. These changes in the September 2019 Exchange Agreement Amendment significantly modified the Optional Exchange Principal Amount, as such after giving effect to the September Exchange Agreement Amendment the Optional Exchange Principal Amount ceases to exist the new optional exchanges are referred to as the Deerfield Optional Conversion Feature.

In connection with entering into the September 2019 Amendment, the Company filed an amendment to the Series B-2 Certificate of Designation (the "Series B-2 Certificate of Designation Amendment") with the Secretary of State of the State Delaware. The Series B-2 Certificate of Designation Amendment provides that each share of the Company's Series B-2 preferred stock is convertible into shares of the Company's common stock at a per share price equal to the common stock exchange price under the September 2019 Exchange Agreement, which equals the greater of (i) $0.60 (subject to adjustment to reflect stock splits and similar events), or (ii) the average of the volume-weighted average prices of the Company's common stock on the Nasdaq Stock Market on each of the 15 trading days immediately preceding such exchange.

As of December 31, 2019, the Deerfield Lenders have converted $1.2 million of principal under the December 2019 Notes into 2,000,000 shares of common stock.

The Company determined the changes to the Deerfield Convertible Note met the definition of a troubled debt restructuring under ASC 470-60, *Troubled Debt Restructurings by Debtors*, as the Company was experiencing financial difficulties and Deerfield granted a concession. The amendments to the terms of the Deerfield Convertible Note resulted in no gain on restructuring because the total cash outflows required under the amended Deerfield Convertible Note exceeded the carrying value of the original Deerfield Convertible Note immediately prior to amendment. Prospectively, the Deerfield Convertible Note will continue to be carried net of the associated discount and debt issuance costs which will be amortized and recorded as interest expense using a modified effective interest rate based on the amendments.

The changes to the 2021 Notes, under the December 2019 Exchange Agreement, referred to after as the December 2019 Notes, were accounted for as a debt modification, prospectively, the December 2019 Notes will be carried net of the associated discount and debt issuance costs which will be amortized and recorded as interest expense using a modified effective interest rate based on the amendments.

2021 Note Exchange Effected in January 2020

In January 2020, we entered into the January 2020 Exchange Agreement (the "January 2020 Exchange Agreement") with M. Kingdon Offshore Master Fund, LP ("Kingdon"). Under the January 2020 Exchange Agreement, the Company issued a senior secured convertible note in the aggregate principal amount of $3,037,354 (the "January 2020 Note") in exchange for the cancellation of an aggregate of $3,037,354 principal amount and accrued interest of the 2021 Note then owned by Kingdon. Upon entering into the January 2020 Exchange Agreement, the Company agreed to pay Kingdon an interest payment of $37,354, which represents 50% of the accrued and unpaid interest, as of January 13, 2020, on Kingdon's 2021 Note. The remainder of such interest was included in the principal amount of the January 2020 Note.

The January 2020 Note was issued with substantially the same terms and conditions as the December 2019 Notes (as amended by the amendment described in more detail below).

In connection with entering into the January 2020 Exchange Agreement, the Company entered into an Amendment to Facility Agreement and December 2019 Notes and Consent (the "December 2019 Note Amendment") with the December 2019 Holders that, among other things, (i) amended the December 2019 Notes to (a) reduce the Conversion Price (as defined in the December 2019 Notes) from $17.11 to $5.85 per share and (b) increased the Floor Price (as defined in the December 2019 Notes) from $0.38 to $0.583 per share, and (ii) amended the Deerfield Facility Agreement to (x) provide for Kingdon to join the Deerfield Facility Agreement as a Lender (as defined in the Deerfield Facility Agreement) and (y) provide that the 2020 Note and shall constitute a "Senior Secured Convertible Note" (as defined in the Deerfield Facility Agreement) for purposes of the Deerfield Facility Agreement and other Transaction Documents (as defined in the Deerfield Facility Agreement).

Convertible Notes

Future minimum principal payments under convertible notes as of December 31, 2019, were as follows (in thousands):

Year Ending December 31,	Convertible Notes
2020	$ -
2021	80,199
Total minimum principal payments	80,199
Less: debt issuance costs and discounts	(2,856)
Convertible notes, net	$ 77,343

Line of Credit

During the second quarter of 2016, the Company opened a line of credit to support several irrevocable letters of credit. In March 2019, the line of credit was closed. The irrevocable letters of credit and associated money market account remain and the money market account is reported as restricted cash on the balance sheets.

H. 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, 2019 and 2018, no accruals have been made related to commitments and contingencies.

Lease Agreements

We have operating and finance leases for office space, laboratory facilities and various laboratory equipment, furniture and office equipment and leasehold improvements. Our leases have remaining lease terms of 1 year to 6 years, some of which include options to extend the leases for up to 5 years, and some which include options to terminate the leases within 1 year.

Florida

The Company leases office space in Florida, comprised of two contiguous office suites, under non-cancelable operating leases, which expire in August 2025 and February 2026, as to each space respectively, and include the right to extend the term of the leases for two successive five-year terms upon expiration. In February 2020, the Company agreed to sublease office space in Florida, comprised of one of the two contiguous suites, under a non-cancelable operating lease, which expires in February 2026.

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 2020 and includes a renewal option that could extend the lease for successive one-year terms upon expiration.

Virginia

The Company leases office and laboratory facilities in Virginia under a non-cancelable operating lease. The Company's lease for its Virginia facilities expires in August 2020.

North Carolina

The Company leased office space in North Carolina under a non-cancelable operating lease. The original expiration date of the Company's lease was May 2020. During the second quarter of 2017, the Company subleased its office space in North Carolina under a non-cancelable operating lease to a third-party tenant. The sublease term with the third-party runs concurrent with the lease term the Company has with the landlord. In October 2019, the Company terminated the head lease with the landlord and the sublease with the subtenant so that the landlord and subtenant could enter directly into a lease.

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, 2019 and 2018, the interest rates for assets under remaining capital leases range from 7.19% to 9.57%.

The components of lease expense were as follows (in thousands):

Lease Cost	Year Ended December 31, 2019
Finance lease cost:	
Amortization of right-of-use assets	$ 123
Interest on lease liabilities	40
Total finance lease cost	163
Operating lease cost	473
Short-term lease cost	232
Variable lease cost	48
Less: sublease income	(84)
Total lease costs	$ 832

Rent expense for non-cancelable operating leases was $0.7 million for the year ended December 31, 2019 and 2018.

Supplemental cash flow information related to leases was as follows (in thousands):

	Year Ended December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from finance leases	$ 40
Financing cash flows from finance leases	207
Operating cash flows from operating leases	435
Operating cash flows from short-term leases	232
Operating cash flows from variable lease costs	48
Right-of-use assets obtained in exchange for lease liabilities:	
Finance leases	$ 757
Operating leases	1,852

Supplemental balance sheet information related to leases was as follows (in thousands, except weighted average remaining lease term and weighted average discount rate):

	December 31, 2019
Finance Leases	
Property and equipment, at cost	$ 1,013
less: accumulated depreciation and amortization	(398)
Property and equipment, net	$ 615
Other current liabilities	$ 236
Other long-term liabilities	168
Total finance lease liabilities	$ 404
Operating Leases	
Operating lease right-of-use assets	$ 1,537
Total operating lease right-of-use assets	$ 1,537
Current portion of operating lease liabilities	$ 284
Operating lease liabilities, less current portion	1,901
Total operating lease liabilities	$ 2,185
Weighted Average Remaining Lease Term	
Finance leases	2 years
Operating leases	6 years
Weighted Average Discount Rate	
Finance leases	7.7%
Operating leases	7.5%

Maturities on lease liabilities were as follows (in thousands):

Year Ending December 31,	Finance Leases	Operating Leases
2020	$ 260	$ 438
2021	163	449
2022	11	461
2023	-	472
2024	-	484
Thereafter	-	420
Total lease payments	434	2,724
Less: future interest expense	(30)	(539)
Lease liabilities	$ 404	$ 2,185

I. Supply Arrangement

As of December 31, 2019 and 2018, 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 benzhydrocodone 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 benzhydrocodone. The Company's FDA-approved drug, APADAZ, contains benzhydrocodone. Expense of $3.2 million and $3.6 million was recorded under this agreement for the year ended December 31, 2019, respectively. The Company must purchase all of its U.S. benzhydrocodone needs from JMI and JMI cannot supply benzhydrocodone to other companies. The term of the Supply Agreement extends as long as the Company holds a valid and enforceable patent for benzhydrocodone or until the tenth anniversary of a commercial launch of a FDA-approved drug incorporating benzhydrocodone, 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 benzhydrocodone. No reliable estimate of the future payments can be made at this time.

J. Preferred Stock and Warrants

Authorized, Issued, and Outstanding Preferred Stock

As of December 31, 2019, the Company had 10,000,000 shares of authorized preferred stock, of which 9,578 shares were designated as Series A Preferred Stock, 1,576 shares were designated as Series B-1 Preferred Stock and 27,000 shares were designated as Series B-2 Preferred Stock. Of the designated preferred stock 9,577 shares of Series A Preferred Stock and 1,576 shares of Series B-1 Preferred Stock were issued as of December 31, 2019. No shares of Series A Preferred Stock or Series B-1 Preferred Stock were outstanding as of December 31, 2019. As of December 31, 2018, 9,577 shares of Series A Preferred Stock were issued and 3,337 were outstanding and no shares of Series B-1 Preferred stock were authorized, issued or outstanding. No shares of Series B-2 Preferred Stock were issued or outstanding as of December 31, 2019 or December 31, 2018 and no shares were authorized as of December 31, 2018.

In October 2018, the Company entered into the October 2018 Exchange Agreement. Under the October 2018 Exchange Agreement the Company issued to the Holders 9,577 shares of Series A Preferred Stock. Each share of Series A Preferred Stock has an aggregate stated value of $1,000 and is convertible into shares of common stock at a price equal to $3.00 per share (subject to adjustment to reflect stock splits and similar events). Immediately following the exchange under the October 2018 Exchange Agreement, there were an aggregate of 3,192,333 shares of common stock issuable upon conversion of the Series A Preferred Stock (without giving effect to the limitation on conversion described below), and as of December 31, 2019 all issued shares of Series A Preferred Stock had been converted into shares of common stock.

In September 2019, the Company entered into the September 2019 Exchange Agreement. Under the September 2019 Exchange Agreement the Company issued to the Holders 1,576 shares of Series B-1 Preferred Stock. Each share of Series B-1 Preferred Stock had an aggregate stated value of $1,000 and was convertible into shares of common stock at a price equal to the greater of (i) $0.9494, or (ii) the average of the volume-weighted average price of the Common Stock on the Nasdaq Capital Market on each of the 15 trading days immediately preceding such exchange (subject to adjustment to reflect stock splits and similar events). Immediately following the exchange under the September 2019 Exchange Agreement, there were an aggregate of 1,659,996 shares of common stock issuable upon conversion of the Series B-1 Preferred Stock (without giving effect to the limitation on conversion described below). The Series B Preferred Stock is convertible at any time at the option of the Holders; provided that the Holders are prohibited from converting shares of Series B Preferred Stock into shares of common stock if, as a result of such conversion, such Holders (together with certain affiliates and "group" members of such Holders) would beneficially own more than 4.985% of the total number of shares of common stock then issued and outstanding. The Series B Preferred Stock is not redeemable. In the event of the Company's liquidation, dissolution or winding up, the Holders will receive an amount equal to $0.0001 per share, plus any declared but unpaid dividends, and thereafter will share ratably in any distribution of the Company's assets with holders of common stock and with the holders of any shares of any other class or series of capital stock of the Company entitled to share in such remaining assets of the Company (including Series A Preferred Stock on an as-converted basis. With respect to rights upon liquidation, the Series B Preferred Stock ranks senior to the common stock, on parity with the Series A Preferred Stock, if any is then outstanding, and junior to existing and future indebtedness. Except as otherwise required by law (or with respect to approval of certain actions involving the Company's organizational documents that materially and adversely affect the holders of Series B Preferred Stock), the Series B Preferred Stock does not have voting rights. The Series B Preferred Stock is not subject to any price-based anti-dilution protections and does not provide for any accruing dividends, but provides that holders of Series B Preferred Stock will participate in any dividends on the common stock on an as-converted basis (without giving effect to the limitation on conversion described above). The Series B-1 Certificate of Designation and the Series B-2 Certificate of Designation also provide for partial liquidated damages in the event that the Company fails to timely convert shares of Series B-1 Preferred Stock or Series B-2 Preferred Stock, respectively, into Common Stock in accordance with the applicable Certificate of Designation. As of December 31, 2019, 1,576 shares of Series B-1 Preferred Stock have been converted into 1,659,996 shares of common stock.

K. Common Stock and Warrants

Authorized, Issued, and Outstanding Common Shares

As of December 31, 2019 and 2018, the Company had authorized shares of common stock of 250,000,000 shares. Of the authorized shares, 36,350,785 and 26,455,352 shares of common stock were issued and outstanding as of December 31, 2019 and 2018, respectively.

As of December 31, 2019 and 2018, the Company had reserved authorized shares of common stock for future issuance as follows:

	December 31,	
	2019	**2018**
Conversion of Deerfield Convertible Note	1,213,606	1,167,607
Conversion of 2021 Notes	175,336	4,481,182
Conversion of 2019 Notes not subject to the Deerfield Optional Conversion Feature	3,186,770	-
Outstanding awards under equity incentive plans	5,192,222	3,704,755
Outstanding common stock warrants	2,423,077	2,527,763
Conversion of Series A Preferred Stock	-	1,112,334
In exchange for the Deerfield Optional Conversion Feature*	26,439,015	-
Possible future issuances under the Prior Purchase Agreement	9,553,046	-
Possible future issuances under equity incentive plans	84,616	648,272
Total common shares reserved for future issuance	48,267,688	13,641,913

Common Stock Activity

The following table summarizes common stock activity for the years ended December 31, 2019 and 2018:

	Shares of Common Stock
Balance as of January 1, 2018	14,657,430
Common stock sold under First ATM Agreement	762,338
Common stock issued as a result of Deerfield Convertible Note principal and interest conversion	598,568
Common stock options exercised	23,682
Common stock sold under underwritten public offering	8,333,334
Common stock issued as a result of Series A Preferred Stock conversion	2,080,000
Balance as of December 31, 2018	26,455,352
Common stock issued under the Prior Purchase Agreement	3,521,471
Restricted stock vested during the period	101,739
Common stock issued as a result of 2021 Notes principal conversion	1,499,894
Common stock issued as a result of Series B-1 Preferred Stock conversion	1,659,996
Common stock issued as a result of Series A Preferred Stock conversion	1,112,333
Common stock issued as a result of Deerfield Optional Conversion Feature conversion	2,000,000
Balance as of December 31, 2019	36,350,785

In September 2018, the Company terminated the First ATM Agreement with Cowen. Prior to termination of the First ATM Agreement, the Company sold an aggregate of 762,338 shares of common stock under the First ATM Agreement resulting in gross proceeds to the Company of $4.9 million. As of December 31, 2019, the Company has not sold any shares of common stock under the Second ATM Agreement. Refer to Note A for a further discussion of the First and Second ATM Agreements.

In October 2018, the Company entered into an underwriting agreement with RBCCM pursuant to which the Company issued and sold 8,333,334 shares of common stock of the Company in an underwritten public offering pursuant to the Company's registration statement on Form S-3. Refer to Note A for a further discussion of the underwritten public offering.

Also in October 2018, the Company entered into the October 2018 Exchange Agreement pursuant to which the Company issued to the Holders 9,577 shares of Series A Preferred Stock. As of December 31, 2019, 9,577 shares of Series A Preferred Stock have been converted into 3,192,333 shares of common stock. Refer to Note G for a further discussion of the October 2018 Exchange Agreement.

On September 3, 2019, the Company entered into the September 2019 Exchange Agreement pursuant to which the Company issued to the Holders 1,499,894 shares of common stock and 1,576 shares of Series B-1 Preferred Stock. As of December 31, 2019, 1,576 shares of Series B-1 Preferred Stock have been converted into 1,659,966 shares of common stock. Refer to Note G for a further discussion of the September 2019 Exchange Agreement.

Warrants

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 requirements (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. 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 expired on June 2, 2019.

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 (Note G). 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 over the term of the Deerfield Convertible Note and the expense is recorded as interest expense related to amortization of debt issuance costs and discount in the condensed statements of operations.

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 condensed statements of operations as a fair value adjustment (Note M).

In connection with a Collaboration and License Agreement (the "APADAZ License Agreement") with KVK Tech, Inc. ("KVK"), in October 2018, the Company issued to KVK a warrant to purchase up to 500,000 shares of common stock of the Company at an exercise price of $2.30 per share, which reflected the closing price of the Company's common stock on the Nasdaq Global Market on the execution date of the APADAZ License Agreement (the "KVK Warrant"). The KVK Warrant is initially not exercisable for any shares of common stock. Upon the achievement of each of four specified milestones under the KVK Warrant, the KVK Warrant will become exercisable for an additional 125,000 shares, up to an aggregate of 500,000 shares of the Company's common stock. The exercise price and the number and type of shares underlying the KVK Warrant are subject to adjustment in the event of specified events, including a reclassification of the Company's common stock, a subdivision or combination of the Company's common stock, or in the event of specified dividend payments. The KVK Warrant is exercisable until October 24, 2023. Upon exercise, the aggregate exercise price may be paid, at KVK's election, in cash or on a net issuance basis, based upon the fair market value of the Company's common stock at the time of exercise.

The Company determined that, since KVK qualifies as a customer under ASC 606, the KVK Warrant should be recorded as a contract asset and recognized as contra-revenue as the Company recognizes revenue from the APADAZ License Agreement. In addition, the Company determined that the KVK Warrant qualifies as a derivative under ASC 815 and should be recorded as a liability and stated at fair value each reporting period. The Company calculates the fair value of the KVK Warrant using a probability-weighted Black-Scholes option pricing model. Changes in fair value resulting from changes in the inputs to the Black Scholes model are accounted for as changes in the fair value of the derivative under ASC 815 and are recorded as fair value adjustment related to derivative and warrant liability in the statements of operations. Changes in the number of shares that are expected to be issued are treated as changes in variable consideration under ASC 606 and are recorded as a change in contract asset in the balance sheets.

L. 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 of Directors of the Company ("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 5,076,694 as of December 31, 2019. 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, 2020, the common stock reserved for issuance under the 2014 Plan automatically increased by 1,454,031 shares.

During the second quarter of 2019, the Company granted to each non-employee member of the Company's board of directors (each a "non-employee Director") two separate fully vested restricted stock awards ("RSAs") under the 2014 Plan. The RSAs were granted in lieu of the quarterly cash compensation payable under the Company's Third Amended and Restated Non-Employee Director Compensation Policy to each non-employee Director for service as a member of the Company's board of directors, and applicable committees thereof, in the first and second quarters of 2019. For the first and second quarter of 2019, RSAs were granted for a total of 42,436 and 39,284 shares of common stock, respectively.

In addition, the Company granted to a consultant fully vested RSAs under the 2014 Plan. The RSAs were granted as part of the monthly compensation package to the consultant for services performed. As of December 31, 2019, RSAs were granted for a total of 20,019 shares of common stock for this purpose.

During the year ended December 31, 2019 no stock options were exercised. During the year ended December 31, 2019 and 2018, stock options to acquire 23,682 shares of common stock were exercised for approximately $68,000 with an intrinsic value of approximately $69,000.

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,	
	2019	2018
Research and development	$ 1,459	$ 1,608
General and administrative	2,951	3,651
Severance expense	-	1,236
Total stock-based compensation expense	$ 4,410	$ 6,495

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 for options granted prior to the second anniversary of the IPO is based on a blend of historical volatilities for publicly traded stock of comparable companies and the Company over the estimated expected term of the stock options. For options granted after the second anniversary of the IPO, expected volatility is based on the Company's historical volatility 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, 2019 and 2018, fair value was $1.43 and $4.05 per share, respectively. The assumptions used to estimate fair value are as follows:

	Year Ended December 31,	
	2019	2018
Risk-free interest rate	1.75% - 2.61%	2.43% - 2.91%
Expected term (in years)	5.50 - 10.00	5.50 - 6.79
Expected volatility	84.82% - 85.93%	83.10% - 85.05%
Expected dividend yield	0%	0%

The activity under the Incentive Stock Plan and the 2014 Plan for the year ended December 31, 2019, is summarized as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Avg Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding balance at January 1, 2019	3,704,755	$ 9.35	7.48	$ -
Granted	2,291,820	$ 1.84		
Exercised or released	(101,739)	$ -		
Canceled or forfeited	(675,950)	$ 8.80		
Expired	(26,664)	$ 4.80		
Outstanding balance at December 31, 2019	5,192,222	$ 6.31	7.63	$ -
Exercisable at December 31, 2019	2,154,640	$ 10.80	6.04	$ -
Vested and expected to vest at December 31, 2019	4,503,063	$ 7.16	7.30	$ -

Information regarding currently outstanding and exercisable options as of December 31, 2019, is as follows:

	Options Outstanding		Options Exercisable	
Exercise Price	Number of Shares	Weighted Avg Remaining Contractual Term	Number of Shares	Weighted Avg Remaining Contractual Term
$0.52 to $5.00	2,902,995	8.72	479,039	7.19
$5.01 to $10.00	1,102,844	6.74	599,969	5.62
$10.01 to $15.00	471,833	5.94	381,208	5.90
$15.01 to $20.00	379,550	5.70	359,424	5.67
$20.01 to $20.45	335,000	5.68	335,000	5.68
	5,192,222	7.63	**2,154,640**	6.04

The total fair value of stock options vested during the years ended December 31, 2019 and 2018, was $4.9 million and $5.9 million, respectively.

Unvested stock options as of December 31, 2019 and 2018, were as follows:

	Number of Unvested Shares December 31,	
Exercise Price	2019	2018
$0.52 to $5.00	2,423,956	634,751
$5.01 to $10.00	502,875	818,900
$10.01 to $15.00	90,625	186,584
$15.01 to $20.00	20,126	139,988
$20.01 to $20.45	-	86,950
Total number of unvested stock options	**3,037,582**	**1,867,173**

As of December 31, 2019, there was $3.8 million of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under the 2014 Plan. That compensation cost is expected to be recognized over a weighted-average period of 2.29 years.

There was no stock-based compensation expense related to performance-based awards recognized during the years ended December 31, 2019 or 2018.

M. Fair Value of Financial Instruments

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

The fair value of the Deerfield Convertible Note was $6.0 million and $6.2 million, respectively, as of December 31, 2019 and 2018. The fair value of the 2021 Notes was $2.4 million and $51.2 million, respectively, as of December 31, 2019 and 2018. The fair value of the December 2019 Notes was $57.0 million as of December 31, 2019. The Deerfield Convertible Note, 2021 Notes and December 2019 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 Note, 2021 Notes and December 2019 Notes as of December 31, 2019 and 2018.

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, 2019 and 2018 (in thousands):

	Balance at December 31, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Deerfield Warrant liability	$ 77	$ -	$ -	$ 77
Embedded Warrant Put Option	19	-	-	19
Fundamental change and make-whole interest provisions embedded within 2021 Notes	-	-	-	-
Deerfield Note Conversion Feature	-	-	-	-
KVK Warrant liability	24	-	24	-
Total liabilities	$ 120	$ -	$ 24	$ 96

	Balance at December 31, 2018	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Deerfield Warrant liability	$ 1,557	$ -	$ -	$ 1,557
Embedded Warrant Put Option	154	-	-	154
Fundamental change and make-whole interest provisions embedded within 2021 Notes	-	-	-	-
Deerfield Note Conversion Feature	134	-	-	134
KVK Warrant liability	273	-	273	-
Total liabilities	$ 2,118	$ -	$ 273	$ 1,845
Trading securities:				
Certificates of deposit	246	246	-	-
U.S. Treasury securities	3,014	3,014	-	-
Total assets	$ 3,260	$ 3,260	$ -	$ -

The Company's Deerfield Warrant liability, embedded Warrant Put Option, the fundamental change and the make-whole interest provisions embedded in the 2021 Notes and the embedded Deerfield Note Put Option, as well as the trading securities are measured at fair value on a recurring basis. As of December 31, 2019 and December 31, 2018, the Deerfield Warrant liability, embedded Warrant Put Option, the fundamental change and make-whole interest provisions embedded in the 2021 Notes and the embedded Deerfield Note Put Option are reported on the balance sheets in derivative and warrant liability. As of December 31, 2018, the trading securities are reported on the balance sheets in marketable securities. The Company used a Monte Carlo simulation to value the Deerfield Warrant liability, embedded Warrant Put Option, the fundamental change and make-whole interest provisions embedded in the 2021 Notes and the embedded Deerfield Note Put Option as of December 31, 2019 and December 31, 2018. 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 and a present value discount rate. Changes in the fair value of the Deerfield Warrant liability, embedded Warrant Put Option, the fundamental change and make-whole interest provisions embedded in the 2021 Notes and the embedded Deerfield Note Put Option are reflected in the statements of operations for the years ended December 31, 2019 and 2018 as a fair value adjustment related to derivative and warrant liability.

The Company's KVK Warrant liability is measured at fair value on a recurring basis. As of December 31, 2019 and December 31, 2018, the KVK Warrant liability is reported on the balance sheets in derivative and warrant liability. The Company estimates the fair value of the KVK Warrant using a probability-weighted Black-Scholes option-pricing model, which requires the use of subjective assumptions, including the expected term of the warrant, the expected stock price volatility, expected dividend yield and the risk-free interest rate for the expected term of the warrant. The expected term represents the period of time the warrant is expected to be outstanding. For the KVK Warrant, the Company used an expected term equal to the contractual term of the warrant. Expected volatility is based on the Company's historical volatility since the IPO. 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. Changes in the fair value of the KVK Warrant liability are reflected in the statements of operations for the years ended December 31, 2019 and 2018 as a fair value adjustment related to derivative and warrant liability.

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):

	2019	2018
Balance as of beginning of period	$ 1,845	$ 7,709
Gain on extinguishment of debt	-	(2)
Adjustment to fair value	(1,749)	(5,862)
Balance as of end of period	$ 96	$ 1,845

N. Income Taxes

The Company's financial statements include a total state tax benefit related to research and development credits of $22,000 and $126,000 on a loss before income taxes of approximately $24.2 million and $56.6 million for the years ended December 31, 2019 and 2018, 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, except amounts pertaining to rate which are shown as a percentage):

	Year ended December 31,	
	2019	**2018**
Federal statutory rate	21.00	21.00
Effect of:		
Change in valuation allowance	(28.52)	(30.44)
Return to provision and deferred true-up	-	0.38
Change in rate	(0.33)	0.03
State tax benefit (net of federal)	3.39	4.35
Warrant liability	1.71	2.02
State research and development credit	0.09	0.22
Federal research and development credit	1.44	3.30
Amortization	(0.29)	-
Stock-based compensation	(1.10)	(0.63)
Other	2.70	(0.01)
Federal income tax provision effective rate	0.09	0.22

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

	December 31,	
	2019	**2018**
Deferred tax assets relating to:		
Net operating loss carryforwards	$ 56,827	$ 51,269
Research and development tax carryforward	6,411	5,657
Other deferred tax assets	4,488	3,437
Total gross deferred tax assets	67,726	60,363
Deferred tax liabilities relating to:		
Property and equipment	-	161
Other deferred tax liabilities	540	10
Total gross deferred tax liabilities	540	171
Deferred tax assets less liabilities	67,186	60,192
Valuation allowance	(67,186)	(60,192)
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, 2019 (in thousands):

Year Incurred	Net Operating Loss CF	Research Activities Cr.	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	15,897	894	2034
2015	23,496	598	2035
2016	41,580	745	2036
2017	34,776	652	2037
2018	56,155	2,272	Indefinite
2019	22,784	352	Indefinite
	$ 217,085	$ 6,412	

The Company also has certain state net operating loss carryforwards totaling $136.0 million that expire between 2027 and 2037. Due to potential ownership changes that may have occurred or would occur in the future, Internal Revenue Code Section 382 may place additional limitations on the Company’s ability to utilize the net operating loss carryforward.

ASC 740-10, *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.

O. Net Loss Per Share

Under the two-class method, for periods with net income, basic net income per share of common stock is computed by dividing the net income attributable to shares of common stock by the weighted average number of shares of common stock outstanding during the period. Net income attributable to shares of common stock is computed by subtracting from net income the portion of current period earnings that participating securities would have been entitled to receive pursuant to their dividend rights had all of the period'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 income (loss) per share of common stock is computed under the two-class method by using the weighted average number of shares of common stock outstanding plus the potential dilutive effects of stock options and warrants. In addition, the Company analyzes the potential dilutive effect of the outstanding convertible securities under the if-converted method when calculating diluted income (loss) per share of common stock in which it is assumed that the outstanding convertible securities convert into common stock at the beginning of the period or date of issuance, if the convertible security was issued during the period. The Company reports the more dilutive of the approaches (two-class or if-converted) as its diluted net income (loss) per share of common stock during the period.

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

	Year Ended December 31,	
	2019	**2018**
Net loss - basic and diluted	$ (24,522)	$ (56,466)
Weighted average number of shares of common stock - basic and diluted	29,654,968	17,930,023
Net loss per share - basic and diluted	$ (0.83)	$ (3.15)

Diluted net loss per share of common stock is the same as basic net loss per share of common stock 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 number of shares of common stock outstanding because their effect is anti-dilutive:

	December 31,	
	2019	**2018**
Deerfield Convertible Note	1,213,606	1,167,607
2021 Notes	175,336	4,481,182
2019 Notes*	29,625,785	-
Awards under equity incentive plans	5,192,222	3,704,755
Common stock warrants	2,423,077	2,527,763
Series A Convertible Preferred Stock	-	1,112,334
Total securities excluded from the calculation of weighted average number of shares of common stock outstanding	38,630,026	12,993,641

* Inclusive of 26,439,015 of shares of Common Stock issuable (i) in exchange of the Deerfield Optional Conversion Feature, or (ii) upon conversion of the Series B-2 Preferred Stock issuable in exchange of the Deerfield Optional Conversion Feature.

P. Severance Expense

On August 31, 2018, Daniel L. Cohen resigned from his position as the executive vice president, government and public relations of the Company, effective immediately. In connection with his resignation, Mr. Cohen and the Company entered into a separation and release agreement which included among other items, severance benefits. The severance benefits consisted of personnel and other related charges of approximately $0.4 million and stock compensation expense of approximately $1.2 million related to the acceleration of vesting on unvested shares subject to certain stock options and the extension of the exercise period for certain stock options. These severance benefits are presented as severance expense in the statement of operations for the fiscal year ended December 31, 2018. As of December 31, 2018, the Company had accrued severance expense recorded within accounts payable and accrued expenses in the amount of $0.2 million. No severance expense or accrued severance expense is recorded for the year ended or as of December 31, 2019.

On February 7, 2020, the Company eliminated the chief business officer role and Gordon K. Johnson was separated from the Company. As a result, the Company anticipates recognizing additional severance expense of approximately $1.0 million over the twelve months following the separation date, comprised of severance payments and non-cash stock-based compensation expense of approximately $0.4 million and $0.6 million, respectively

Q. 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 $133,000 and $212,000 for the years ended December 31, 2019 and 2018, 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 2019 or 2018.

EXHIBITS

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).
3.1.1	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of KemPharm, Inc. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on October 5, 2018).
3.1.2	Certificate of Designation of Preferences, Rights and Limitations of Series B-1 Convertible Preferred Stock of KemPharm, Inc. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on September 4, 2019).
3.1.3	Certificate of Designation of Preferences, Rights and Limitations of Series B-2 Convertible Preferred Stock of KemPharm, Inc. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on September 4, 2019).
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).
4.3.1	First Supplemental Indenture, dated November 20, 2018, between the Company and U.S. Bank National Association, as trustee (as incorporated herein by reference to the Company's Current Report on Form 8-K as filed with the SEC on November 20, 2018).
4.4	Senior Secured Convertible Note, dated as of January 13, 2020 (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on January 13, 2020).
4.5	Registration Rights Agreement dated February 28, 2019 by and between the Company and Lincoln Park Capital Fund, LLC (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 1, 2019)..
4.6	Registration Rights Agreement dated February 17, 2020 by and between the Registrant and Lincoln Park Capital Fund, LLC (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on February 18, 2020).
4.7	Form of Senior Secured Convertible Note, with a schedule of noteholders (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on December 18.2019).
4.8	Amended and Restated Senior Secured Convertible Note issued to Deerfield Private Design Fund III, L.P., dated as of December 18, 2019 (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on December 18.2019).
4.9*	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.
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).
10.2.4	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated June 3, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 13, 2019).
10.2.5	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated June 17, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 13, 2019)
10.2.6	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated June 24, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 13, 2019)
10.2.7	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated June 28, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 13, 2019)
10.2.8	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated July 15, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 13, 2019)
10.2.9	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated July 31, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 13, 2019)
10.2.10	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated August 9, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 13, 2019)
10.2.11	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated August 16, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on November 14, 2019)
10.2.12	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated August 23, 2019. (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on November 14, 2019)
10.2.13	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated August 30, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on November 14, 2019)
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).

EXHIBITS, CONTINUED

Exhibit No.	Description
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).
10.3.3	Facility Agreement Waiver and Fifth Amendment to Senior Secured Convertible Note by and between Registrant and Deerfield Private Design Fund III, L.P., dated as of June 11, 2018 (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on June 11, 2018).
10.3.4	Amendment to Convertible Note and Warrant Agreement, dated November 20, 2018, between the Company and Deerfield Private Design Fund III, L.P. (as incorporated herein by reference to the Company's Current Report on Form 8-K filed with the SEC on November 20, 2018).
10.3.5	Seventh Amendment to Senior Secured Convertible Note and Sixth Amendment to Warrant, dated February 28, 2019, between the Company and Deerfield Private Design Fund III, L.P. (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 1, 2019).
10.3.6	Amendment to December 2019 Notes and Consent, dated as of January 12, 2020, by and among the Registrant and the signatories party thereto (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on January 13, 2020)
10.3.7	Amendment to Senior Secured Convertible Notes and Amendment to Warrant, dated as of February 17, 2020, by and among Registrant and the noteholders party thereto (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on February 18, 2020)
10.4	Amended and Restated Investors' Rights Agreement, dated as of February 19, 2015, by and among the Registrant and certain of its stockholders (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.5	Warrant to Purchase Shares of Series D Preferred Stock issued to Deerfield Private Design Fund III, L.P., dated as of June 2, 2014 (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.6	Form of Stock Purchase Warrant to purchase shares of Series D Convertible Preferred Stock issued in bridge financing, along with a schedule of warrant holders (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.7+	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).
10.8#	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).
10.9#	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).
10.10#	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).
10.11#	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).
10.12#	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).
10.13#	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).
10.14#	Fourth Amended and Restated Non-Employee Director Compensation Policy (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on November 14, 2019)
10.15#	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).
10.16#	Amended and Restated Employment Agreement by and between the Registrant and R. LaDuane Clifton, dated as of June 25, 2015 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 14, 2015).
10.16.1#	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).
10.17#	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).
10.17.1#	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).
10.18#	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).
10.18.1#	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).
10.19#	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).
10.19.1#	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).
10.20#	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).
10.21	Lease Agreement, by and between KemPharm, Inc. and BRE/COH FL LLC, dated as of November 3, 2014 (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 10, 2017).
10.21.1	First Amendment to the Lease Agreement, by and between KemPharm, Inc. and BRE/COH FL LLC, dated as of April 21, 2015 (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 10, 2017).
10.21.2	Second Amendment to the Lease Agreement, by and between KemPharm, Inc. and BRE/COH FL LLC, dated as of December 22, 2015 (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 10, 2017).

EXHIBITS, CONTINUED

Exhibit No.	Description
10.21.3	Third Amendment to the Lease Agreement, by and between KemPharm, Inc. and BRE/COH FL LLC, dated as of July 15, 2016 (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 10, 2017).
10.21.4*	Agreement to Sublease, by and between KemPharm, Inc. and Ciber Global, LLC, dated as of January 15, 2020.
10.22	Common Stock Sales Agreement, dated September 4, 2018, by and between KemPharm, Inc. and RBC Capital Markets, LLC (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on September 4, 2018).
10.23+	Collaboration and License Agreement by and between the Company and KVK Tech, Inc. dated as of October 25, 2018 (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 1, 2019).
10.24+	Warrant to Purchase Shares of Common Stock issued to KVK Tech, Inc. dated October 25, 2018 (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 1, 2019).
10.25	Purchase Agreement dated February 28, 2019 by and between the Company and Lincoln Park Capital Fund, LLC. (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 1, 2019).
10.26	Purchase Agreement, dated February 17, 2020, by and between the KemPharm, Inc. and Lincoln Park Capital Fund, LLC. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on February 18, 2020).
10.27	Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under 2014 Equity Incentive Plan (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on May 14, 2019)
10.28	September 2019 Exchange Agreement and Amendment to Facility Agreement, dated as of September 3, 2019, by and among KemPharm, Inc., Deerfield Private Design Fund III, L.P. and Deerfield Special Situations Fund, L.P. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on September 4, 2019)
10.28.1	Amendment to September 2019 Exchange Agreement and Amendment to Facility Agreement, dated as of December 17, 2019, by and among KemPharm, Inc., Deerfield Private Design Fund III, L.P. and Deerfield Special Situations Fund, L.P. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on December 18.2019)
10.29+	Collaboration and License Agreement, dated as of September 3, 2019, by and between KemPharm, Inc. and Boston Pharmaceuticals Holdings SA.(incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on September 4, 2019)
10.30	December 2019 Exchange Agreement and Amendment to Facility Agreement, Senior Secured Convertible Notes and Warrants, dated as of December 17, 2019, by and among KemPharm, Inc., Deerfield Private Design Fund III, L.P., Deerfield Special Situations Fund, L.P. and Delaware Street Capital Master Fund, L.P. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on December 18, 2019)
10.31	Amended and Restated Guaranty and Security Agreement, dated as of December 18, 2019, by and among KemPharm, Inc., each other Grantor party thereto, each Guarantor party thereto and Deerfield Private Design Fund III, L.P., as collateral agent (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on December 18.2019)
23.1*	Consent of RSM US 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, formatted in XBRL (Extensible Business Reporting Language): (i) Balance Sheets, (ii) Statements of Operations, (iii) Statements of Changes in 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.
+	Certain portions of the exhibit, identified by the mark, "[*]", have been omitted because such portions contained information that is both (i) not material and (ii) would likely cause competitive harm if publicly disclosed.
(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.

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: February 28, 2020

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

Dated: February 28, 2020

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)	February 28, 2020
/s/ R. LaDuane Clifton R. LaDuane Clifton, CPA	Chief Financial Officer, Secretary and Treasurer (Principal Financial Officer)	February 28, 2020
/s/ Timothy J. Sangiovanni Timothy J. Sangiovanni, CPA	Vice President, Corporate Controller (Principal Accounting Officer)	February 28, 2020
/s/ Matthew R. Plooster Matthew R. Plooster	Director	February 28, 2020
/s/ Richard W. Pascoe Richard W. Pascoe	Director	February 28, 2020
/s/ Joseph B. Saluri Joseph B. Saluri	Director	February 28, 2020
/s/ David S. Tierney David S. Tierney	Director	February 28, 2020

Exhibit 4.9

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

KemPharm, Inc. ("we," "our," or "us") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended, our common stock, par value $0.0001 per share, or common stock. The following description of our capital stock is a summary and does not purport to be complete. It is qualified in its entirety by, and should be read in conjunction with, our amended and restated certificate of incorporation, amended and restated bylaws and applicable Delaware law.

General

Under our amended and restated certificate of incorporation we are authorized to issue up to 250,000,000 shares of common stock and 10,000,000 shares of preferred stock, $0.0001 par value per share, of which 9,578 shares have been designated Series A preferred stock, or the Series A Preferred Stock, 1,576 shares have been designated as Series B-1 preferred stock, or the Series B-1 Preferred Stock, and 27,000 shares have been designated as Series B-2 preferred stock, or the Series B-2 Preferred Stock (and together with the Series B-1 Preferred Stock, the Series B Preferred Stock). Our board of directors may establish the rights and preferences of the undesignated preferred stock from time to time.

Common Stock

Voting Rights

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

Dividends

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

Liquidation

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

Rights and Preferences

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

Preferred Stock

Undesignated

Pursuant to our amended and restated certificate of incorporation, our board of directors has the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of us and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of common stock until the board of directors determines the specific rights attached to that preferred stock.

Series A Preferred Stock

In October 2018, we filed a Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, or the Series A Certificate of Designation, with the Secretary of State of the State Delaware, setting forth the preferences, rights and limitations of the Series A Preferred Stock. Our board of directors designated 9,578 shares of preferred stock as Series A Preferred Stock. As of December 31, 2019, there were no shares of Series A Preferred Stock outstanding

Each share of Series A Preferred Stock has an aggregate stated value of $1,000 and is convertible into shares of our common stock at a per share price equal to $3.00 per share (subject to adjustment to reflect stock splits and similar events). The Series A Preferred Stock is convertible at any time at the option of the holders thereof, provided that the holders of Series A Preferred Stock are prohibited from converting shares of Series A Preferred Stock into shares of our common stock if, as a result of such conversion, such holders (together with certain affiliates and "group" members of such holders) would beneficially own more than 4.985% of the total number of shares of our common stock then issued and outstanding. The Series A Preferred Stock is not redeemable. In the event of our liquidation, dissolution or winding up, the holders of our Series A Preferred Stock will receive an amount equal to $0.0001 per share, plus any declared but unpaid dividends, and thereafter will share ratably in any distribution of our assets with the holders of our common stock, on an as-converted basis. With respect to rights upon liquidation, the Series A Preferred Stock ranks senior to our common stock and junior to existing and future indebtedness. Except as otherwise required by law (or with respect to approval of certain actions involving our organizational documents that materially and adversely affect the holders of Series A Preferred Stock), the Series A Preferred Stock does not have voting rights. The Series A Preferred Stock is not subject to any price-based anti-dilution protections and does not provide for any accruing dividends, but provides that holders of Series A Preferred Stock will participate in any dividends on our common stock on an as-converted basis (without giving effect to the limitation on conversion described above). The Series A Certificate of Designation also provides for partial liquidated damages in the event that we fail to timely convert shares of Series A Preferred Stock into shares of our common stock in accordance with the Series A Certificate of Designation**.**

Series B-1 Preferred Stock and Series B-2 Preferred Stock

In September 2019, we filed a Certificate of Designation of Preferences, Rights and Limitations of Series B-1 Convertible Preferred Stock, or the Series B-1 Certificate of Designation, and a Certificate of Designation of Preferences, Rights and Limitations of Series B-2 Convertible Preferred Stock, or the Series B-2 Certificate of Designation, in each case with the Secretary of State of the State Delaware, setting forth the preferences, rights and limitations of the Series B-1 Preferred Stock and the Series B-2 Preferred Stock, respectively. Our board of directors designated 1,576 shares of preferred stock as Series B-1 Preferred Stock and 27,000 shares of preferred stock as Series B-2 Preferred Stock. As of December 31, 2019, there were no shares of Series B-1 Preferred Stock or Series B-2 Preferred Stock outstanding.

Each share of Series B-1 Preferred Stock has an aggregate stated value of $1,000 and is convertible into shares of our common stock at a per share price equal to $0.9494 per share (subject to adjustment to reflect stock splits and similar events). Each share of Series B-2 Preferred Stock has an aggregate stated value of $1,000 and is convertible into shares of our common stock at a per share price equal to the greater of (i) $0.60 (subject to adjustment to reflect stock splits and similar events), or (ii) the average of the volume-weighted average prices of our common stock on the Nasdaq Capital Market on each of the 15 trading days immediately preceding such exchange.

The Series B Preferred Stock is convertible at any time at the option of the holders thereof; provided that such holders are prohibited from converting shares of Series B Preferred Stock into shares of our common stock if, as a result of such conversion, such holders (together with certain affiliates and "group" members of such holders) would beneficially own more than 4.985% of the total number of shares of our common stock then issued and outstanding. The Series B Preferred Stock is not redeemable. In the event of our liquidation, dissolution or winding up, the holders of Series B Preferred Stock will receive an amount equal to $0.0001 per share, plus any declared but unpaid dividends, and thereafter will share ratably in any distribution of our assets with the holders of our common stock and with the holders of any shares of any other class or series of our capital stock entitled to share in such remaining assets (including the holders of the Series A Preferred Stock) on an as-converted basis. With respect to rights upon liquidation, the Series B Preferred Stock ranks senior to our common stock, on parity with the Series A Preferred Stock and junior to existing and future indebtedness. Except as otherwise required by law (or with respect to approval of certain actions involving our organizational documents that materially and adversely affect the holders of Series B Preferred Stock), the Series B Preferred Stock does not have voting rights. The Series B Preferred Stock is not subject to any price-based anti-dilution protections and does not provide for any accruing dividends, but provides that holders of Series B Preferred Stock will participate in any dividends on our common stock on an as-converted basis (without giving effect to the limitation on conversion described above). The Series B-1 Certificate of Designation and the Series B-2 Certificate of Designation also provide for partial liquidated damages in the event that the Company fails to timely convert shares of Series B-1 Preferred Stock or Series B-2 Preferred Stock, respectively, into shares of our common stock in accordance with the applicable Certificate of Designation.

Convertible Notes

In June 2014, we issued to Deerfield Private Design Fund III, L.P., or Deerfield, a secured convertible note in the principal amount of $10.0 million, or the Deerfield Note. As of December 31, 2019, the outstanding principal amount of the Deerfield Note was approximately $7.0 million. In December 2019 and January 2020, we issued senior secured convertible promissory notes, or the Senior Secured Notes, to Deerfield, Deerfield Special Situations Fund, L.P., Delaware Street Capital Master Fund, L.P. and M. Kingdon Offshore Master Fund, LP in the aggregate principal amount of $74.5 million. We refer to the Deerfield Note and the Senior Secured Notes together as the Convertible Notes. The Convertible Notes bear interest at 6.75% per annum. The Convertible Notes are convertible into shares of our common stock at an initial conversion price of $5.85 per share, subject to adjustment in accordance with the terms of the Convertible Notes. The conversion price of the Convertible Notes will be adjusted downward if we issue or sell any shares of our common stock, convertible securities, warrants or options at a sale or exercise price per share less than the greater of the conversion price of the Convertible Notes or the closing sale price of our common stock as reported on the Nasdaq Capital 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. If we effect an "at the market offering" as defined in Rule 415 of the Securities Act of our common stock, the conversion price of the Convertible Notes 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, provided that this anti-dilution adjustment will not apply to any sales made (x) the Purchase Agreement, dated February 17, 2020, by and between us and Lincoln Park Capital Fund, LLC, (y) that certain Common Stock Sales Agreement, dated as of September 4, 2018, by and between the Company and RBC Capital Markets, LLC, or (z) the September 2019 Exchange Agreement and Amendment to Facility Agreement, dated as of September 3, 2019, by and among us, Deerfield and Deerfield Special Situations Fund, L.P. (as amended). Notwithstanding anything in the contrary in the Convertible Notes, the anti-dilution adjustment of the Convertible Notes shall not result in the conversion price of the Convertible Notes being less than $0.583 per share. The Convertible Notes are convertible at any time at the option of the holders thereof, provided that each holder is prohibited from converting the Convertible Notes into shares of our common stock if, as a result of such conversion, such holder (together with certain affiliates and "group" members of such holder) would beneficially own more than 4.985% of the total number of shares of our common stock then issued and outstanding. However, the Convertible Note issued to Delaware Street Capital Master Fund, L.P., due to the fact Delaware Street Capital Master Fund, L.P. was a beneficial owner of more than 4.985% of the total number of shares of our common stock then issued and outstanding, has a beneficial ownership cap equal to 19.985% of the total number of shares of the Company's common stock then issued and outstanding. Pursuant to the Convertible Notes, the holders thereof have the option to demand repayment of all outstanding principal, and any unpaid interest accrued thereon, in connection with a Major Transaction (as defined in the Convertible Notes), which shall include, among others, any acquisition or other change of control of us; a liquidation, bankruptcy or other dissolution of us; or if at any time after March 31, 2021, shares of our common stock are not listed on an Eligible Market (as defined in the Convertible Notes). The Convertible Notes are subject to specified events of default, the occurrence of which would entitle the holders thereof to immediately demand repayment of all outstanding principal and accrued interest on the Convertible Notes. Such events of default include, among others, failure to make any payment under the Convertible Notes when due, failure to observe or perform any covenant under the Facility Agreement (as defined in the Convertible Notes) or the other transaction documents related thereto (subject to a standard cure period), our failure to be able to pay debts as they come due, the commencement of bankruptcy or insolvency proceedings against us, a material judgement levied against us and a material default by us under the Warrant or the Notes (each as defined in the Facility Agreement).

The foregoing information is qualified entirely by reference to the applicable provisions of the terms of the Facility Agreement and the Convertible Notes, which are each incorporated by reference and included as exhibits to the Annual Report on Form 10-K to which this exhibit is a part.

Warrants

As of December 31, 2019, we had outstanding immediately exercisable warrants to purchase 2,423,077 shares of our common stock at a weighted average exercise price of $5.12 per share and which expire between October 24, 2023 and June 2, 2024. The warrants include a net exercise provision and contain provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of each warrant in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations. We have also granted registration rights to Deerfield, as more fully described below under "—Registration Rights."

In June 2014, in connection with our entering into the Facility Agreement we issued to Deerfield a warrant, or the Deerfield 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. 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. According to the terms of the Deerfield Warrant, in no event may Deerfield exercise this warrant if such exercise would result in Deerfield beneficially owning more than 4.985% of the then issued and outstanding shares of our common stock. This exercise limitation may not be waived and any purported exercise that is inconsistent with this exercise limitation is null and void. This exercise limitation will not apply to any exercise made immediately prior to a change of control transaction. If Deerfield is only able to exercise the Deerfield Warrant for a limited number of shares due to this exercise limitation, the Deerfield Warrant could subsequently become exercisable to purchase the remainder of the shares as a result of a variety of events. This could occur, for example, if we issue more shares or Deerfield sells some of its existing shares. The Deerfield Warrant includes a net exercise provision and contains provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrant in the event of certain stock dividends, stock splits, recapitalizations, reclassifications and consolidations. Under the Deerfield Warrant, Deerfield also has the right to demand upon the occurrence of specified events, including a merger, asset sale or other change of control transaction, that we redeem the Deerfield Warrant for a cash amount equal to the Black-Scholes value of the portion of the Deerfield Warrant to be redeemed. If Deerfield chooses not to redeem the Deerfield Warrant upon the occurrence of such an event, we may not enter into any such transaction unless our successor entity assumes in writing all our obligations under both the Deerfield Warrant and the Deerfield facility and provides Deerfield with certain registration rights.

The Deerfield Warrant includes certain exercise price protection provisions pursuant to which the exercise price of the Deerfield Warrant will be adjusted downward on a broad-based weighted average basis if we issue or sell any shares of common stock, convertible securities, warrants or options, including in this offering, at a sale or exercise price per share less than the greater of the Deerfield Warrant's exercise price or the closing sale price of our common stock as reported on the Nasdaq Capital 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. The sale price for purposes of this adjustment is measured after giving effect to any underwriting discounts and commissions. This exercise price adjustment does not apply to any offering deemed by the SEC to constitute an "at the market offering" as defined in Rule 415 of the Securities Act of our common stock, the conversion price of the Deerfield Warrant 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, provided that this anti-dilution adjustment will not apply to any sales made under (x) the purchase agreement, dated February 17, 2020, by and between us and Lincoln Park Capital Fund, LLC, (y) that certain Common Stock Sales Agreement, dated as of September 4, 2018, by and between the Company and RBC Capital Markets, LLC, or (z) the September 2019 Exchange Agreement and Amendment to Facility Agreement, dated as of September 3, 2019, by and among us, Deerfield and Deerfield Special Situations Fund, L.P. (as amended).

The foregoing information is qualified entirely by reference to the applicable provisions of the terms of the warrants, which are each incorporated by reference and included as exhibits to the Annual Report on Form 10-K to which this exhibit is a part.

Registration Rights

We and the holders of shares of our common stock issued upon the conversion or reclassification of our redeemable convertible preferred stock have entered into an investors' rights agreement. The registration rights provisions of this agreement expired as to all holders of our capital stock, other than Deerfield, on the second anniversary of our initial public offering. The registration rights provisions of our investors' rights agreement currently provide Deerfield with the registration rights described in more detail below. The following information is qualified entirely by reference to the applicable provisions of the investors' rights agreement, which is incorporated by reference and included as an exhibit to the Annual Report on Form 10-K to which this exhibit is a part.

Piggyback Registration Rights

If we propose to register any of our securities under the Securities Act either for our own account or for the account of other stockholders, Deerfield will be entitled to include its shares of common stock in the registration statement. These piggyback registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under specified circumstances.

Registration on Form S-3

Deerfield is entitled, upon its written request, to have such shares registered by us on a Form S-3 registration statement at our expense, subject to other specified conditions and limitations.

Expenses of Registration

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

Termination of Registration Rights

The registration rights granted under the investors' rights agreement terminated as to all the holders of our capital stock, other than Deerfield, on the two-year anniversary of our initial public offering. These registration rights will terminate as to Deerfield upon the earliest to occur of (i) written consent of Deerfield, (ii) such time that the Deerfield Warrant and Deerfield Note have been exercised or converted, as applicable, in full and Rule 144 or another similar exemption under the Securities Act of 1933, as amended, is available for the sale of all shares of our capital stock held by Deerfield without limitation during a three-month period without registration or (iii) six-months following the later to occur of (x) the expiration of the Deerfield Warrant and (y) payment in full or termination of the Deerfield Note.

Anti-Takeover Effects of Provisions of Delaware Law and Our Charter Documents

Section 203 of the Delaware General Corporation Law

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

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

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

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

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

Certificate of Incorporation and Bylaws

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

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

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

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

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

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

Choice of Forum

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for:

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

except that these choice of forum provisions do not apply to suits brought to enforce a duty or liability created by the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or any other claim for which the federal courts have exclusive jurisdiction.

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

Transfer Agent and Registrar

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

Listing on the Nasdaq Capital Market

Our common stock is listed on the Nasdaq Capital Market under the symbol "KMPH."

AGREEMENT OF SUBLEASE

BETWEEN

KEMPHARM, INC., AS SUBLANDLORD,

AND

CIBER GLOBAL, LLC AS SUBTENANT

SUITE 108

CELEBRATION OFFICE CENTER I

1180 CELEBRATION BOULEVARD

CELEBRATION, FLORIDA 34747

AGREEMENT OF SUBLEASE

This **AGREEMENT OF SUBLEASE** (this "Sublease"), made as of January 15, 2020, between **KEMPHARM, INC.**, a Delaware corporation (the "Sublandlord") and **CIBER GLOBAL, LLC,** a Michigan limited liability company (the "Subtenant").

W I T N E S S E T H

WHEREAS, by that certain Office Lease dated as of November 3, 2014 (the "Original Lease") between BRIDGE III FL CELEBRATION, LLC, a Delaware limited liability company, successor-in-interest to BRE/COH FL LLC, a Delaware limited liability company, (the "Prime Landlord") and Sublandlord, as tenant, as amended by that certain First Amendment dated April 21, 2015 (the "First Amendment"), as further amended by that certain Second Amendment dated December 22, 2015 (the "Second Amendment"), and as further amended by that certain Third Amendment dated July 15, 2016 (the "Third Amendment" and together with the Original Lease, the First Amendment and the Second Amendment, the "Prime Lease"), Prime Landlord leased to Sublandlord Suite 103, Suite 104 and Suite 108 containing a total of approximately 17,074 rentable square feet (the "Premises") and located on the first floor of the building known as Celebration Office Center I and located at 1180 Celebration Boulevard, Celebration, Florida 34747 (the "Building"), as more particularly described in the Prime Lease (a copy of the Prime Lease is annexed hereto as Exhibit A and made a part hereof); and

WHEREAS, Sublandlord desires to sublease to Subtenant, and Subtenant desires to sublease from Sublandlord, a portion of the Premises consisting of the approximately 6,302 rentable square feet contained in Suite 108 (the "Sublease Premises") as depicted on Exhibit B attached hereto and made a part hereof, all on the terms and conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, it is hereby agreed as follows:

1. Sublease. Sublandlord hereby subleases to Subtenant and Subtenant hereby subleases from Sublandlord the Sublease Premises, subject to the terms and conditions set forth herein.

2. Condition of Sublease Premises. On the Commencement Date (as hereinafter defined), Sublandlord shall deliver the Sublease Premises, and Subtenant agrees to accept the Sublease Premises, in its "AS IS, WITH ALL FAULTS" condition as of such date and Sublandlord shall not be obligated to alter, repair or perform any work or furnish any materials on or about the Sublease Premises in order to prepare the Sublease Premises for Subtenant's use or occupancy or otherwise. Subtenant hereby acknowledges that Sublandlord has made no representations or warranties with respect to the condition of the Sublease Premises, including, without limitation the suitability of the Sublease Premises for Subtenant's intended use, and that Sublandlord shall not, nor or at any time in the future, be required to make any expenditures whatsoever with respect to the Sublease Premises. It shall be the responsibility of Subtenant to maintain and keep the Sublease Premises in as good an order and condition as existed on the date hereof. Subtenant shall at Sublandlord's written request promptly make, at Subtenant's sole cost and expense, all repairs to the Sublease Premises or Building, whenever damage or injury thereto shall be caused by Subtenant or its employees, agents, contractors, licensees or invitees. If any maintenance or repair is not completed by Subtenant as outlined herein, and Sublandlord chooses to perform said maintenance or repair, then Subtenant shall promptly reimburse Sublandlord upon demand for any costs and expenses incurred by Sublandlord in taking any such action. This obligation shall survive the expiration or earlier termination of the Sublease.

3. Term of Sublease. The term ("Term") of this Sublease shall commence on the date on which Prime Landlord executes the Prime Landlord Consent in accordance with Section 4 hereof, or March 1, 2020 (the "Commencement Date") and shall expire at noon on February 28, 2026 (the "Expiration Date"), unless this Sublease is sooner terminated by operation of law or pursuant to any of the terms, covenants or conditions of this Sublease. The "Rent Commencement Date" as such term is used in this Sublease shall be the date the Prime Landlord Consent has been fully executed in accordance with Section 4 hereof. Notwithstanding the foregoing, Subtenant acknowledges that (x) such installation is subject to the terms and conditions of this Sublease, including, without limitation, Section 16, and (y) Subtenant shall not be permitted to enter the Sublease Premises until Subtenant has delivered to Sublandlord the insurance certificates required hereunder and paid the first installment of Fixed Rent and the Security Deposit as provided in Section 5 hereof, and the Prime Landlord Consent has been fully executed in accordance with Section 4 hereof.

4. Prime Landlord's Consent. Notwithstanding anything in this Sublease to the contrary, this Sublease is subject to and conditioned upon Sublandlord obtaining the written consent of Prime Landlord to this Sublease, in accordance with the provisions of the Prime Lease (the "Prime Landlord Consent"). Subtenant agrees to promptly execute and deliver a consent agreement in a form reasonably requested by Prime Landlord, provided that such consent does not contain any provisions that would materially increase the obligations of either party under this Sublease, or increase in any fashion the amount to be paid hereunder by Subtenant. Sublandlord shall in no event be required to (A) incur any cost or expense in connection with such consent, except any fees, costs and/or expenses incurred or imposed by Prime Landlord under the Prime Lease in connection with granting such consent and/or reviewing Sublandlord's request for such consent, (B) alter any of the provisions of the Prime Lease, or (C) commence any action or proceedings against Prime Landlord. Subtenant shall (i) cooperate with Sublandlord and use commercially reasonable efforts to assist Sublandlord in obtaining such consent as soon as practicable and (ii) provide all information concerning Subtenant that Prime Landlord shall reasonably require in connection with Sublandlord's request for such consent. If such consent is refused, or conditioned in such a manner not acceptable to Sublandlord, or if Prime Landlord shall otherwise fail to grant such consent by the date that is thirty (30) days following the date of this Sublease, then either party may, by written notice to the other, given at any time prior to the granting of such consent, terminate and cancel this Sublease, provided that if Prime Landlord consents in a manner acceptable to Sublandlord, then neither party's right of termination shall be of any further effect. Upon the timely delivery of such written notice of termination in accordance with the terms hereof, neither party shall have any further rights or obligations hereunder, except for those rights and obligations expressly set forth herein to survive the expiration or earlier termination of this Sublease. In addition, the Sublandlord shall promptly return to Subtenant any Rent prepaid.

5. Rent.

A. Subtenant covenants and agrees to pay to Sublandlord fixed rent ("Fixed Rent") for the Term in the amount of $955,194.14 as follows:

Period	Monthly Installment*	Period Rent*
Rent Commencement Date 3/1/2020 through 2/28/2021	$12,304.66	$147,655.86
3/1/2021 through 2/28/2022	$12,677.52	$152,130.28
3/1/2022 through 2/28/2023	$13,055.64	$156,667.72
3/1/2023 through 2/28/2024	$13,449.52	$161,394.22
3/1/2024 through 2/28/2025	$13,848.65	$166,183.74
3/1/2025 through 2/28/2026	$14,263.53	$171,162.32
		Total Fixed Rent: $955,194.14

*Plus applicable Florida sales tax.

†The rent table above assumes a Rent Commencement Date of 3/1/2020. If the Rent Commencement Date occurs on a day other than the first day of a calendar month, Fixed Rent for such partial month shall be prorated on a per diem basis.

The monthly installments of Fixed Rent shall be due and payable on the first day of each month of the Term commencing on the Rent Commencement Date. Notwithstanding anything in the Prime Lease or Sublease to the contrary, the Fixed Rent shall not be abated or reduced for any reason. Subtenant shall pay to Sublandlord $25,615.52 upon execution of this Sublease, which is comprised of the Security Deposit ($12,807.76) and the first monthly installment of Fixed Rent ($11,947.54) plus applicable Florida sales tax ($860.22).

B. All of the amounts payable by Subtenant pursuant to this Sublease, including, without limitation, the Fixed Rent and all other fees, costs, expenses, charges, sums and deposits payable by Subtenant to Sublandlord hereunder shall constitute "Rent" under this Sublease and such Rent shall be payable to Sublandlord or its designee at such address as Sublandlord shall from time to time direct in writing.

C. Subtenant shall promptly pay the Rent as and when the same shall become due and payable without setoff, offset or deduction of any kind whatsoever and, in the event Subtenant shall fail to pay same when due, Sublandlord shall, in addition to all of the rights and remedies provided for in this Sublease and/or at law or in equity, have all of the rights and remedies provided for in the Prime Lease in the case of non-payment of any rent due thereunder. Except as expressly set forth herein, Subtenant's obligation to pay Rent shall survive the expiration or sooner termination of this Sublease.

D. If Sublandlord shall be charged with respect to the Sublease Premises for overtime, excess consumption, or other services requested by Subtenant, then Subtenant shall be liable for such costs, sums or charges. Sublandlord shall provide Subtenant written substantiation of any and all such costs, sums, or charges.

6. Use. Subtenant shall not use or occupy the Sublease Premises for any purpose other than as permitted by the Prime Lease, and Subtenant shall not use or occupy the Sublease Premises in violation of any provision set forth in the Prime Lease, including, without limitation, Section 1.7 of the Original Lease.

7. Subordination to and Incorporation of the Prime Lease.

A. This Sublease and all of Subtenant's rights hereunder are and shall remain in all respects subject and subordinate to (i) all of the terms, conditions and provisions of the Prime Lease, (ii) any and all amendments, supplements or modifications to the Prime Lease hereafter made between Prime Landlord and Sublandlord, and (iii) any and all matters to which the tenancy of Sublandlord, as tenant under the Prime Lease, is subordinate. The foregoing provisions shall be self-operative and no further instrument of subordination shall be necessary to effectuate such provisions. Subtenant hereby acknowledges and agrees that it has been furnished with a true, correct and complete copy of the Prime Lease and is familiar with the terms and conditions set forth therein. To the extent that the terms of the Sublease and the Prime Lease conflict, the terms of this Sublease shall control, provided that this Sublease shall not be construed to modify the terms of the Prime Lease or limit any rights of Prime Landlord or Sublandlord under the Prime Lease.

B. Except as otherwise expressly provided in this Sublease, Subtenant assumes and shall keep, observe and perform every term, provision, covenant and condition on Sublandlord's part pertaining to the Sublease Premises that is required to be kept, observed and performed pursuant to the Prime Lease and which arises or accrues during the term of this Sublease, except that Fixed Rent shall be paid in lieu of Base Rent, Tenant's Share of the Expense Excess, and Tenant's Share of the Tax Excess. Any right or option to renew, extend or terminate the Prime Lease or expand or contract the Premises, shall have no force and effect as between Sublandlord and Subtenant and which rights are reserved solely by Sublandlord who may elect to exercise or not exercise such rights in Sublandlord's sole and absolute discretion.

C. Except as otherwise expressly provided in this Sublease, the terms, provisions and conditions contained in the Prime Lease are incorporated in this Sublease by reference and are made a part hereof as if herein set forth at length, the term "Sublandlord" being substituted for the term "Landlord" under the Prime Lease, the term "Subtenant" being substituted for the term "Tenant" under the Prime Lease, the term "Sublease" being substituted for the term "Lease" under the Prime Lease, the term "Fixed Rent" being substituted for the term "Base Rent" under the Prime Lease and the term "Sublease Premises" being substituted for the term "Premises" under the Prime Lease, and the terms "Commencement Date" "Rent Commencement Date" "Expiration Date" "Security Deposit" "Term" and "Broker" having the meaning set forth in this Sublease. The parties agree that the following provisions of the Prime Lease are not so incorporated herein by reference (although any terms used in the Prime Lease which are defined in such provisions are incorporated in this Sublease by reference to the extent such terms are used in the provisions of the Prime Lease which are incorporated herein by reference): Original Lease: Section 1.15 (Tenant Improvements), Section 6.3 (Interruption), Section 14.8 (Permitted Transfers), Section 21.2 (Security Deposit Reduction), Section 25.2 (Force Majeure), Section 25.7 (Brokers), Exhibit B (Work Letter), Exhibit E (Right of First Offer), and Exhibit F (Potential Offering Space); First Amendment: Section 7.2 (Responsibility for Improvements) and Exhibit B (Work Letter); Second Amendment: Section 4 (Additional Security Deposit), Section 7.2 (Responsibility for Improvements), Section 9 (Extension Options), Section 10 (Right of Refusal), Section 11.4 (Signage), Section 11.6 (Landlord's Waiver and Consent), Exhibit B (Work Letter), and Exhibit D (Landlord's Waiver and Consent); and Third Amendment: Section 2, last paragraph (Rent Abatement), Section 3 (Additional Security Deposit), Section 6.2 (Responsibility for Improvements), Section 7.4 (Extension Options), and Exhibit B (Work Letter).

D. The time limits set forth in the Prime Lease for the giving of notices, making demands, performance of any act, condition or covenant, or the exercise of any right, remedy or option, are changed for the purposes of incorporation into this Sublease, by lengthening or shortening the same in each instance by the lesser of (i) five (5) days, or (ii) one-half of the applicable time limit set forth in the Prime Lease, so that notices may be given, demands made, or any act, condition or covenant performed, or any right, remedy or option hereunder exercised, by Sublandlord or Subtenant, as the case may be, within two (2) business days prior to the expiration of the time limit, taking into account the applicable grace period, if any, relating thereto contained in the Prime Lease. Each party shall promptly deliver to the other party copies of all notices, requests or demands which relate to the Sublease Premises or the use or occupancy thereof after receipt of same from Prime Landlord.

E. Sublandlord shall have, in addition to all rights and remedies set forth in this Sublease, the same rights and remedies with respect to a breach of this Sublease by Subtenant as Prime Landlord has with respect to a breach of the Prime Lease as if the same were more fully set forth at length herein, and Sublandlord shall have, with respect to Subtenant, this Sublease and the Sublease Premises, all of the rights, powers, privileges and immunities as are possessed by Prime Landlord under the Prime Lease in addition to all of the rights, powers, privileges and immunities of Sublandlord set forth in this Sublease. Sublandlord herein shall not be responsible for any breach of the Prime Lease by Prime Landlord or any non-performance or non-compliance with any provisions thereof by Prime Landlord, provided that Sublandlord shall comply with the provisions of Section 12 hereof.

F. If the Prime Lease is terminated for any reason other than a default of Sublandlord under the Prime Lease which was not otherwise caused by Subtenant's default hereunder, Sublandlord shall not be liable in any manner whatsoever for such termination. Sublandlord shall immediately forward to Subtenant any default or termination notice with respect to the Prime Lease received by Sublandlord and this Sublease shall terminate in the event of any such termination of the Prime Lease. Subtenant shall forward to Sublandlord, promptly upon receipt thereof by Subtenant or delivery to Prime Landlord, a copy of each notice of default or in any way affecting the Prime Lease or the Sublease Premises received by Subtenant from Prime Landlord or sent by Subtenant to Prime Landlord under the Prime Lease.

G. So long as this Sublease is in effect and Subtenant is not in default, Sublandlord shall not take or omit to take any action that would constitute a default under the Prime Lease.

H. Subtenant hereby expressly agrees that the obligations of indemnity and any duty to defend on the part of the "Tenant" described in the Prime Lease shall be for the benefit of both Sublandlord and Prime Landlord, and with reference to the waivers of subrogation set forth in the Prime Lease, Subtenant hereby agrees that the waiver described therein as they pertain to Subtenant shall be for the benefit of both Sublandlord and Prime Landlord. All waivers of claims and limitations of liability against or releases or exculpations of Prime Landlord contained in the Prime Lease shall run in favor of both Prime Landlord and Sublandlord.

8. Attornment. Notwithstanding anything to the contrary set forth in this Sublease, if the Prime Lease and Sublandlord's leasehold interest in the Sublease Premises shall be terminated, Subtenant shall, if so requested in writing by Prime Landlord, attorn to Prime Landlord and shall, during the term of this Sublease, perform all of the terms, covenants and conditions of this Sublease on the part of Subtenant to be performed. In the event of any such attornment, Prime Landlord shall not be (A) liable for any act or omission or default of any prior sublessor (including, without limitation, Sublandlord), (B) subject to any offsets or defenses which Subtenant might have against any prior sublessor (including without limitation, Sublandlord), (C) bound by any Rent which Subtenant might have paid more than thirty (30) days in advance of when due hereunder to any prior sublessor (including, without limitation, Sublandlord), (D) bound by any obligation to make any payment to or on behalf of Subtenant for any obligation which accrued hereunder prior to termination of the Prime Lease, (E) bound to return the Security Deposit, if any, until the Security Deposit has come into Prime Landlord's actual possession and Subtenant is entitled to such Security Deposit pursuant to the provisions of this Sublease, or (F) bound by any amendment or modification of this Sublease made without Prime Landlord's consent. The foregoing shall be self-operative without the necessity of the execution of any further instruments but Subtenant agrees, upon the demand of Prime Landlord, to execute, acknowledge and deliver any instrument or instruments confirming such attornment.

9. Quiet Enjoyment. Sublandlord covenants that as long as Subtenant shall pay the Rent due hereunder and shall duly perform all of the terms, covenants and conditions of this Sublease on Subtenant's part to be performed and observed in each case prior to the expiration of all applicable notice, grace and cure periods, Subtenant shall peaceably and quietly have, hold and enjoy the Sublease Premises during the Term without molestation or hindrance by Sublandlord, subject to the terms, provisions and conditions of the Prime Lease and this Sublease and Landlord's rights under the Prime Lease.

10. Representations and Warranties.

A. Sublandlord represents and warrants to Subtenant as of the date hereof that, (i) subject to obtaining the Prime Landlord Consent, Sublandlord has full right, power and authority to enter into this Sublease and perform its obligations and consummate the transactions contemplated hereunder, and (ii) this Sublease has been duly executed and delivered by Sublandlord and constitutes a valid and binding agreement of Sublandlord, enforceable against Sublandlord in accordance with the terms.

B. Subtenant represents and warrants to Sublandlord as of the date hereof that (i) Subtenant has full right, power and authority to enter into this Sublease and perform its obligations and consummate the transactions contemplated hereunder, and (ii) this Sublease has been duly executed and delivered by Subtenant and constitutes a valid and binding agreement of Subtenant, enforceable against Subtenant in accordance with the terms hereof.

11. Landlord Obligations. The Prime Lease describes Prime Landlord's duties and obligations. Notwithstanding anything in this Sublease to the contrary, Subtenant expressly agrees that Sublandlord is not obligated to perform any of Prime Landlord's obligations or duties. Without limiting the foregoing, except as provided in Section 12 hereof, Subtenant agrees that Sublandlord shall have no obligation to render or supply any services to Subtenant or perform any other obligations under the Prime Lease, including, without limitation (A) the furnishing of utilities, services, electricity, heat, ventilation, water, air conditioning, elevator service, access, lighting, amenities, parking, signage, janitorial cleaning, window washing or rubbish removal services, (B) making any alterations, maintenance, repairs, construction, improvements or restorations, (C) complying with any laws or requirements of any governmental authorities, (D) procuring any insurance or providing any indemnification, (E) taking any action that Prime Landlord has agreed to provide, make, comply with or take, or cause to be provided, made, complied with or taken under the Prime Lease, or (F) giving any reimbursements or abatements that Landlord has agreed to under the Prime Lease (collectively "Landlord's Obligations"). Subtenant hereby agrees that Subtenant shall look solely to the Prime Landlord for the performance of any and all Landlord's Obligations, subject to the terms and conditions of this Sublease. Sublandlord shall in no event be liable to Subtenant, nor shall the obligations of Subtenant hereunder be impaired or the performance thereof excused because of any failure or delay on Prime Landlord's part in furnishing Landlord's Obligations, unless such failure or delay results from Sublandlord's willful misconduct or default under Section 12 hereof and/or default under the Prime Lease (which default is not the result of or attributable to, any corresponding default of Subtenant under this Sublease).

12. Enforcement of Prime Lease Against Prime Landlord. If Prime Landlord shall default in any of its obligations to Sublandlord with respect to the Sublease Premises beyond all applicable notice and cure periods, Sublandlord shall not be obligated to bring any action or proceeding or to take any steps to enforce Sublandlord's rights against Prime Landlord other than, upon the written request of Subtenant, making a demand upon Prime Landlord to perform its obligations under the Prime Lease with respect to the Sublease Premises. If, after receipt of such notice, Prime Landlord does not perform its obligations under the Prime Lease, and such failure goes uncured for thirty (30) days, Subtenant may declare a default and pursue all remedies provided in the Prime Lease. In no event shall Sublandlord incur any liability, or otherwise be responsible, nor shall there be any set-off, deduction or abatement of Rent, arising from Prime Landlord's failure to comply with its obligations or duties.

13. Default By Subtenant; Remedies.

A. Subtenant agrees that each of the following events shall be considered an **"**Event of Default**"** hereunder:

1. Subtenant shall be adjudged an involuntary bankrupt, or a decree or order approving, as properly filed, a petition or answer filed against Subtenant asking reorganization of Subtenant under the Federal bankruptcy laws as now or hereafter amended, or under the laws of any State, shall be entered, and any such decree or order shall not have been vacated or stayed or set aside within thirty (30) days from the date of the entry or granting thereof; or

2. Subtenant shall file, or admit the jurisdiction of the court and the material allegations contained in, any petition in bankruptcy, or any petition pursuant or purporting to be pursuant to the Federal bankruptcy laws now or hereafter amended, or Subtenant shall institute any proceedings for relief of Subtenant under any bankruptcy or insolvency laws or any laws relating to the relief of debtors, readjustment of indebtedness, reorganization, arrangements, composition or extension, or is adjudicated insolvent; or

3. Subtenant has filed against it a petition in bankruptcy, or any petition pursuant or purporting to be pursuant to the Federal bankruptcy laws now or hereafter amended, and such petition shall not have been dismissed within thirty (30) days from the filing thereof; or

4. Subtenant shall make any assignment for the benefit of creditors or shall apply for or consent to the appointment of a receiver for Subtenant or any of the property of Subtenant; or

5. Subtenant shall admit in writing its inability to pay its debts as they become due; or

6. A decree or order appointing a receiver of the property of Subtenant shall be made and such decree or order shall not have been vacated, stayed or set aside within thirty (30) days from the date of entry or granting thereof; or

7. Subtenant shall fail to make any payment of Rent required to be made by Subtenant hereunder when due as herein provided and such failure goes uncured for ten business days after receipt of written notice of such failure by Sublandlord; or

8. Subtenant shall default with respect to lien claims as set forth in Section 16 of this Sublease or shall default in securing insurance or in providing evidence of insurance as set forth in Section 17 of this Sublease and either such default shall continue for three (3) days after notice thereof in writing to Subtenant; or

9. Subtenant shall, by its act or omission to act, cause a breach or default under the Prime Lease; or

10. Subtenant shall fail to perform any of the other covenants and agreements in the Prime Lease or this Sublease to be kept, observed and performed by Subtenant.

B. If an Event of Default shall have occurred, Sublandlord shall have, in its sole discretion, the right to pursue all available remedies at law and equity and shall also be permitted to pursue any rights and remedies set forth in the Prime Lease, including without limitation Section 19 of the Original Lease, against Subtenant, the Sublease or the Sublease Premises, as the case may be. In addition, in the event Subtenant fails to observe or perform any of the terms, covenants, conditions and agreements of this Sublease or the Prime Lease, Sublandlord shall have the right to cure such default. Subtenant shall reimburse Sublandlord as additional Rent, within ten (10) days of written demand therefor, any and all amounts reasonably expended by Sublandlord to cure any such default by Subtenant. No termination of this Sublease, by operation of law or otherwise, and no repossession of the Sublease Premises or any part thereof, and no reletting of the Sublease Premises or any part thereof, and no payment of any amounts by Subtenant as damages, except to the extent of such payment, and the exercise by Sublandlord of any of its other rights under this Section 13 shall relieve Subtenant of either (i) its other liabilities and obligations hereunder, all of which shall survive the exercise of Sublandlord’s remedies, or (ii) any other liabilities under this Sublease which by express provision of this Sublease survive the exercise of Sublandlord’s remedies.

C. The remedies described in this Section 13 and the Prime Lease are cumulative and in addition to and without waiver of all remedies allowed Sublandlord by this Sublease, case law, common law and/or statute now or hereafter in effect, and are not mutually exclusive. Subtenant agrees that the rights and remedies granted Sublandlord in this Section 13 are commercially reasonable.

14. Assignment, Subletting and Encumbrances.

A. Without the prior written consent of Sublandlord, which consent may be withheld in Sublandlord's sole and absolute discretion with or without cause, and Prime Landlord, to the extent required under the Prime Lease, Subtenant shall not (i) assign this Sublease (by operation of law or otherwise), (ii) sub-sublease all or any part of the Sublease Premises, (iii) mortgage, pledge, hypothecate or otherwise encumber its interest in this Sublease or the Sublease Premises or any interest therein, (iv) grant any concession, license or otherwise permit the Sublease Premises to be used or occupied by anyone other than Subtenant, or (v) take any other such action that is in violation of the Prime Lease, including, without limitation, Section 14 of the Original Lease. Any such assignment, sublease, mortgage, pledge, hypothecation or other encumbrance of or under this Sublease without such prior written consent shall be invalid and without force and effect and shall constitute an immediate Event of Default which is not subject to cure.

B. Any proposed assignment of this Sublease, or sub-subletting of the Sublease Premises, shall be subject to and conditioned upon compliance by Subtenant with the terms and conditions of the Prime Lease.

C. If this Sublease is assigned, or if the Sublease Premises or any part thereof is sub-sublet or occupied by anyone other than Subtenant, whether or not Subtenant shall have been granted any consent, Sublandlord may, after default by Subtenant which continues beyond the expiration of all applicable notice, grace and cure periods, collect rent and other charges from such assignee, sub-sublessee or other occupant, and apply the net amount collected to Rent and other charges herein reserved, but no such assignment, sub-subletting, occupancy or collection shall be deemed to be a waiver of the requirements of this Section 14 or an acceptance of the assignee, sub-sublessee or other occupant as sub-sublessee under this Sublease. No consent by Sublandlord to an assignment or subletting shall in any way be construed to relieve Subtenant from obtaining consent to any further assignment or sub-subletting. In each sub-subletting permitted by the Prime Lease, and this Section 14, and in each further sub-subletting with the consent of Sublandlord and Prime Landlord, Subtenant shall include, or cause to be included, in the sub-sublease a provision prohibiting the assignment of the sub-sublease or sub-subletting thereunder without the consent of Sublandlord and Prime Landlord in each instance. No assignment or sub-subletting shall, in any way, release, relieve or modify the liability of Subtenant under this Sublease and Subtenant shall be and remain liable under all of the terms, conditions, and covenants hereof.

D. If Subtenant shall at any time request the consent of Sublandlord to any proposed assignment of this Sublease, sub-subletting, or other third party use of all or any portion of the Sublease Premises, Subtenant shall pay on demand the costs and expenses incurred by Sublandlord and Prime Landlord, including, without limitation, architects', engineers' and reasonable attorneys' fees and disbursements, charges under the Prime Lease, and a reasonable administrative fee for review and/or preparation of documents in connection with any proposed or actual assignment of this Sublease or sub-subletting of the Sublease Premises or any part thereof.

15. Indemnification.

A. Subject to the terms and provisions of Section 15(B) hereof, Sublandlord, Prime Landlord and the employees, agents, contractors, licensees and invitees of each (collectively, "Indemnified Parties"), shall not be liable to Subtenant, and Subtenant shall indemnify and hold harmless the Indemnified Parties from and against any and all suits, claims, demands, liabilities, damages, costs and expenses of every kind and nature (including, without limiting the generality of the foregoing, reasonable attorneys' fees, disbursements and court costs, penalties and fines suffered or paid by Prime Landlord and/or Sublandlord in any action or proceeding between or among Subtenant and Prime Landlord and/or Sublandlord, any third party and/ Prime Landlord and/or Sublandlord, or otherwise) arising out of the following:

1. any injury or damage to any person happening in the Sublease Premises, or for any injury or damage to the Sublease Premises, Building or the Furniture (as hereinafter defined), or to any property of Subtenant or of any other natural person or persons, partnership, corporation, limited liability company, firm, association or other form of business or legal association or entity (each, a "Person") on or about the Sublease Premises, but in all of the aforementioned cases, only to the extent any such damage or injury is not cause by the negligent acts or omissions of Sublandlord or Prime Landlord, or by Sublandlord or Prime Landlord's failure to abide by the terms and conditions of the Sublease or the Prime Lease, as applicable;

2. default by Subtenant in the payment of the Rent or any other default by Subtenant in the observance or performance of, or compliance with any of the terms, provisions or conditions of this Sublease or the Prime Lease, including, without limitation, such matters relating to obtaining the possession of the Sublease Premises following any such default;

3. the exercise by Subtenant or any Person claiming through or under Subtenant of any claims against Prime Landlord not permitted by this Sublease;

4. any holdover beyond the expiration or sooner termination of the Term of this Sublease; or

5. any negligent or willful acts or omissions of Subtenant or of any employees, agents, contractors, licensees or invitees of Subtenant or any such Person, in or about the Sublease Premises or the Building.

B. Subtenant's obligations in this Section 15 are in addition to, not in lieu of, the indemnity obligations in the Prime Lease and all of the foregoing obligations shall survive the expiration or earlier termination of this Sublease.

16. Alterations.

A. Notwithstanding anything to the contrary in the Prime Lease, Subtenant shall make no alterations, installations, additions, changes or improvements (collectively, "Alterations") in or about the Sublease Premises without the prior written consent of Sublandlord and Prime Landlord, in each instance, which consent shall not be unreasonably withheld. Any Alterations consented to by Sublandlord shall be performed by Subtenant at its sole cost and expense and in compliance with all of the provisions of this Sublease and the Prime Lease, including, without limitation, Section 7 of the Original Lease and any other provisions that may require the Prime Landlord's consent, and also in compliance with any other reasonable requirements of Sublandlord and Prime Landlord. To the extent required under the Prime Lease, Subtenant shall pay to Prime Landlord any and all amounts payable to Prime Landlord in connection with Prime Landlord's review and/or inspection of (a) any plans and/or specifications relating to any proposed Alterations, and (b) any Alterations during and subsequent to the making thereof.

B. Subtenant shall be responsible for the payment of all repairs, replacements and maintenance costs in and to the Sublease Premises that would otherwise have been the responsibility of Sublandlord absent this Sublease, including, without limitation, costs for any repairs due to work performed by Subtenant, the installation, use or operation of the Sublease Premises by Subtenant, the moving of any property of Subtenant in or out of the Sublease Premises, and any act, omission, neglect or misuse by Subtenant or any of its employees, agents, contractors, invitees or licensees, and any fees due to Prime Landlord under the Prime Lease in connection with the performance of such repairs.

C. Prior to commencing any Alterations, Subtenant shall obtain builder's risk, general liability, and other insurance in form and amount satisfactory to Sublandlord (and also to the extent required by the Prime Lease or Prime Landlord). No Alterations shall be commenced until Subtenant has delivered to Sublandlord certificates of insurance or other evidence of insurance satisfactory to Sublandlord and Prime Landlord.

D. Subtenant shall keep the Sublease Premises and all parts thereof at all times free of mechanic's liens and any other lien for labor, services, supplies, equipment or material purchased or procured, directly or indirectly, by or for Subtenant, including, without limitation, all and any Alterations, (collectively, **"**Subtenant's Work**"**). Subtenant further agrees that, with respect to Subtenant's Work, Subtenant shall promptly pay, satisfy, bond against and/or discharge all liens of contractors, subcontractors, mechanics, laborers, materialmen, and other items of like character and provide such security to Sublandlord as it may require or Prime Landlord as is required under the Prime Lease. Further, without limiting Subtenant's other indemnity obligations under the Prime Lease or Sublease, Subtenant shall indemnify, defend (by counsel acceptable to Sublandlord and Prime Landlord) and hold Sublandlord and Prime Landlord harmless against (i) all costs and expenses incurred by Sublandlord or Prime Landlord in respect of any such lien and in the defense of any suit in discharging the Sublease Premises or any part thereof from any liens, judgments, or encumbrances relating to Subtenant's Work, (ii) claims or demands of any of Subtenant's contractors or subcontractors or anyone claiming by, through or under any such party, related to the completion of the Subtenant's Work, and (iii) liability for injury, loss, accident, or damage to any person or property, including, without limitation, bodily injury and/or death, and from any claims, actions, proceedings and expenses and costs in connection therewith (including, without limitation, reasonable counsel fees) arising from the acts or omissions of Subtenant, its agents, employees, contractors or subcontractors, in completing the Subtenant's Work. All materialmen, contractors, mechanics and laborers are hereby charged with notice that they must look solely to Subtenant, and not to Sublandlord, Prime Landlord or their interest in the Sublease Premises, Premises or Building, to secure the payment of any bill for work done or material furnished at the request or instruction of Subtenant.

E. Subtenant's Work shall be completed in a good and workmanlike manner and in compliance with all applicable laws and all lawful ordinances, regulations, orders, permits and approvals of governmental authority and insurers of the Sublease Premises. Sublandlord and Prime Landlord shall have the right, in their sole and absolute discretion, to approve all subcontractors and contractors used by Subtenant in connection with Subtenant's Work.

F. Subtenant shall not remove the Subtenant's Work upon the expiration or earlier termination of the Sublease, unless required by the Prime Landlord including without limitation pursuant to the terms of the Prime Lease. Notwithstanding the foregoing, prior to the expiration of the Sublease Term, Subtenant shall remove at its sole cost and expense all of its all wiring and cabling from the point of origin to the termination point, including without limitation any low voltage telecommunications/data cabling and wiring used by Subtenant, and Subtenant shall repair any damage caused by such removal.

17. Insurance. Subtenant, at Subtenant's sole cost and expense, shall maintain for the benefit of Sublandlord and Prime Landlord such policies of insurance (and in such form) as are required of Sublandlord by the Prime Lease with respect to the Sublease Premises during Subtenant's use and occupancy thereof, including, without limitation, Section 10 of the Original Lease, which policies shall be reasonably satisfactory to Sublandlord as to coverage and insurer, provided that Subtenant shall, at its sole cost and expense, maintain during the Sublease Term each of the following insurance policies, as follows: (a) commercial general liability insurance, including blanket contractual liability, with limits of not less than $1 Million per occurrence and $2 Million in the aggregate, protecting Sublandlord, Prime Landlord and Subtenant against all claims and liabilities for injury or damage to persons or property occurring in, on or about the Sublease Premises or the Building, caused by or resulting from or in connection with any act or omission of Subtenant and/or Subtenant's employees, agents, contractors, licensees or invitees, (b) commercial automotive liability with limits of not less than $1 Million per occurrence, (c) property insurance covering all of Subtenant's property located on or about the Premises or Building, and (d) Subtenant worker's compensation insurance with at least statutory minimum required limits. Each of the aforesaid Subtenant's insurance policies shall be upon terms and conditions as approved by Sublandlord, provided however Subtenant agrees to maintain such policies with insurers and with amounts, forms, terms, conditions and endorsements which shall be in compliance with the requirements of the Prime Lease should the Prime Lease requirements exceed those required in this Sublease; and shall contain an endorsement on all such policies that insurer shall provide at least thirty (30) days prior written notice to Sublandlord of material changes in terms of insurance or cancellation thereof, which shall be written with insurance companies reasonably acceptable to Landlord and Sublandlord and licensed to do business in the state where the Sublease Premises is located. Subtenant shall include Sublandlord, Prime Landlord and any other parties required by Sublandlord as "additional insureds" on all liability insurance policies required to be maintained by Subtenant, shall provide for a waiver of subrogation against Sublandlord and Prime Landlord on all property insurance policies required to be maintained by Subtenant, shall provide Sublandlord and Prime Landlord with duplicate originals of all policies and endorsements or a certificate thereof, and shall provide Sublandlord notices and other documents provided to Prime Landlord in satisfaction of the requirements of the Prime Lease at such time as the same are provided to the Prime Landlord.

18. Access to Sublease Premises; Right to Make Repairs. In the event Sublandlord shall require access to the Sublease Premises to perform any of its obligations under the Prime Lease or to show the Sublease Premises to proposed subtenants or for any other reasonable purpose, Subtenant hereby agrees that it shall provide immediate access to Sublandlord and any prospective subtenants, and the affiliates, agents, brokers, and representatives of each of the foregoing upon one (1) hour prior notice which may be oral or written. In addition, Subtenant agrees to provide access to the Sublease Premises to Sublandlord, Prime Landlord, their agents and contractors, as required under the Prime Lease. In addition, the event Subtenant fails to perform any of its obligations under this Sublease or the Prime Lease with respect to the maintenance, repair, replacement and/or restoration of the Sublease Premises, Building or Furniture (as hereinafter defined), then, in either such event, Sublandlord may immediately re-enter the Sublease Premises for the purpose of making such correction, and may, but shall not be required to, make such correction. In any such event, Subtenant shall promptly reimburse Sublandlord on demand for any costs and expenses incurred by Sublandlord in taking any such action. This obligation shall survive the expiration or earlier termination of the Sublease.

19. Destruction by Fire or Other Casualty; Condemnation.

A. If the Sublease Premises and/or the Building are partially or totally damaged or destroyed by fire or other casualty, except as expressly provided herein, Subtenant shall have no right to terminate this Sublease and this Sublease shall not be terminated by reason of such casualty unless the Prime Lease is terminated by Sublandlord or Prime Landlord pursuant to the provisions of the Prime Lease. Sublandlord shall give Subtenant prompt written notice of any such termination.

B. This Sublease shall be considered an express agreement governing any case of damage or destruction of the Building or any part thereof by fire or other casualty, and any law providing for such contingency in the absence of such express agreement, now or hereafter enacted, shall have no application in such case.

C. If the Prime Lease is terminated as the result of a taking of all or any portion of the Building by condemnation (or deed in lieu thereof), this Sublease shall likewise terminate. In such event, Subtenant shall have no claim to any share of the award, except to file a separate claim for the value of any alterations and improvements made by Subtenant. The foregoing shall be self-operative without the necessity of the execution of any further instruments.

20. Security Deposit. Subtenant has deposited with Sublandlord the sum of $11,947.54 as security for the faithful performance and observance by Subtenant of the terms, provisions and conditions of this Sublease ("Security Deposit"). Any interest accruing on the Security Deposit shall be the sole property of Sublandlord. It is agreed that in the event Subtenant defaults in respect of any of the terms, provisions and conditions of this Sublease, including, but not limited to, the payment of Rent, Sublandlord may, after notice to Subtenant and the expiration of any applicable grace period with respect to such default, if any, use, apply or retain the whole or any part of the Security Deposit to the extent required for the payment of any Rent or any other sum as to which Subtenant is in default or for any sum which Sublandlord may expend or may be required to expend by reason of Subtenant's default in respect of any of the terms, covenants and conditions of this Sublease, including but not limited to, any damages or deficiency in the re-letting of all or a portion of the Sublease Premises. In any such event, Subtenant shall promptly on demand deposit with Sublandlord so much of the Security Deposit as shall have been so expended so that Sublandlord shall at all times have the full Security Deposit required hereunder. If Subtenant shall fully and faithfully comply with all of the terms, provisions, covenants and conditions of this Sublease, the Security Deposit shall be returned to Subtenant, without interest, within thirty (30) days after the Expiration Date and after delivery of possession of the Sublease Premises to Sublandlord at the time and in the condition required in accordance herewith. Sublandlord shall not be obligated to deposit the Security Deposit in a separate account.

21. **Brokers**. Each party warrants and represents to the other party hereto that it has not dealt with any brokers in connection with this Sublease other than Cresa, who has represented Sublandlord, and Jones Lang LaSalle, who has represented Subtenant (together, the "Broker"). Each party hereby agrees to indemnify, defend, and hold the other party hereto harmless from any and all loss, damage, claim, liability, cost or expense (including, but not limited to, reasonable attorneys' fees, disbursements and court costs) arising out of or in connection with any breach of the foregoing warranty and representation. The provisions of this Section 21 shall survive the expiration or earlier termination of this Sublease.

22. **Notices**. All notices, consents, approvals or other communications (collectively a "Notice") required to be given under this Sublease or pursuant to law shall be in writing and, unless otherwise required by law, shall be either personally delivered, or sent by reputable overnight courier service, or sent by registered or certified mail, return receipt requested, postage prepaid, addressed to the Sublandlord as the as set forth below, or such other address(es) as each such party may designate by Notice to the other.

If to Sublandlord:

KemPharm, Inc.
1180 Celebration Blvd.
Suite 103
Celebration, FL 34747
Attention: R. LaDuane Clifton, CFO

If to Subtenant:

Ciber Global, LLC
3270 W. Big Beaver Rd.
Suite 120
Troy, MI 48084
Attention: Contract Admin.

Any Notice given pursuant hereto shall be deemed to have been received on delivery if personally delivered, or one (1) business day following delivery to a reputable overnight courier service, or three (3) business days after the mailing thereof if mailed in accordance with the terms hereof, such mailing to be effected by depositing the Notice in any post office, branch post office or official depository regularly maintained by the United States Postal Service. If a party shall refuse to accept a Notice, then delivery shall be deemed to have occurred upon such refusal.

23. **No Waivers**. Failure by either party in any instance to insist upon the strict performance of any one or more of the obligations of the other party under this Sublease, or to exercise any election herein contained, or acceptance of payment of any kind with knowledge of a default by the other party shall in no manner be or be deemed to be a waiver by such party of any defaults or breaches hereunder or of any of its rights and remedies by reason of such defaults or breaches, or a waiver or relinquishment for the future of the requirement of strict performance of any and all of the defaulting party's obligations hereunder. Except as may be agreed by Sublandlord to the contrary in writing, no payment by Subtenant or receipt by Sublandlord of a lesser amount than the correct amount of Rent due hereunder shall be deemed to be other than a payment on account, nor shall any endorsement or statement on any check or any letter accompanying any check or payment be deemed to effect or evidence an accord and satisfaction, and Sublandlord may accept any checks or payments as made without prejudice to Sublandlord's right to recover the balance or pursue any other remedy in this Sublease or otherwise provided at law or in equity.

24. **Consent**. If Subtenant shall request Sublandlord's consent to any matter and such consent is withheld or delayed, Subtenant shall not be entitled to any damages by reason thereof, it being intended that the sole remedy therefor shall be an action for specific performance or injunction and that such remedy shall only be available when Sublandlord has agreed herein not to unreasonably withhold or delay such consent or when, as a matter of law, such consent may not be unreasonably withheld or delayed.

25. **Expiration of Term**. Upon the expiration or sooner termination of the Term, Subtenant shall quit and surrender the Sublease Premises to Sublandlord in the same condition as each of the foregoing was in on the Commencement Date, reasonable wear and tear excepted, and Subtenant shall, at its sole cost and expense, remove all of Subtenant's movable fixtures and movable partitions, telephone and other equipment, furniture, furnishings and other items of movable personal property and shall otherwise comply with the provisions of the Prime Lease. Subtenant's obligation to observe or perform this covenant shall survive the Expiration Date or sooner termination of the Term of this Sublease. Subtenant's failure to comply with its covenant set forth in this Section 25 shall entitle Sublandlord to all of its rights hereunder, including, without limitation, the right to indemnification pursuant to Section 15 hereof for damages arising out of Subtenant's failure to surrender the Sublease Premises when and in the condition required herein.

26. **Holdover**. Subtenant will not be permitted to hold over possession of the Sublease Premises after the expiration or earlier termination of the Term without the express written consent of Sublandlord, which consent Sublandlord may withhold in its sole and absolute discretion with or without cause. If Subtenant holds over after the expiration or earlier termination of the Term with or without the express written consent of Sublandlord, then, in addition to all other remedies available to Sublandlord, Subtenant shall become a tenant at sufferance only, upon the terms and conditions set forth in this Sublease, but at a monthly Fixed Base Rent equal to one hundred fifty percent (150%) of the Monthly Rent under the Prime Lease applicable to the Sublease Premises. Any such holdover Rent shall be paid on a per month basis without reduction for partial months during the holdover. Acceptance by Sublandlord of Rent after such expiration or earlier termination shall not constitute consent to a hold over hereunder or result in an extension of this Sublease. This Section 26 shall not be construed to create any express or implied right to holdover beyond the expiration of the Term or any extension thereof. Subtenant shall be liable, and shall pay to Sublandlord within ten (10) days of demand, for all losses and damages incurred by Sublandlord as a result of such holdover, and shall indemnify, defend and hold Sublandlord harmless from and against all liabilities, damages, losses, claims, suits, costs and expenses (including reasonable attorneys' fees and costs) arising from or relating to any such holdover tenancy, including without limitation, any claim for damages made by Prime Landlord or a succeeding subtenant. Subtenant's indemnification obligation hereunder shall survive the expiration or earlier termination of this Sublease, or upon the early termination of Subtenant's right to occupy the Sublease Premises. The foregoing provisions of this Section 26 are in addition to, and do not affect, Sublandlord's right of re-entry or any other rights of Sublandlord hereunder or otherwise at law or in equity.

27. **Furniture**. Sublandlord and Subtenant acknowledge and agree that certain furniture, fixtures, and equipment exists in the Sublease Premises as of the Sublease Commencement Date (collectively, the "Furniture"). Sublandlord and Subtenant have mutually prepared a list of all Furniture on or before the Commencement Date, a copy of which is annexed hereto as Exhibit B and made a part hereof. Sublandlord makes no representation or warranty whatsoever as to the condition of or title to the Furniture. Subtenant shall purchase all of the Furniture from Sublandlord, and Sublandlord shall convey the Furniture to Subtenant, on the Commencement Date through a bill of sale for a total sale price of One Dollar ($1.00). Subtenant (i) agrees to accept the Furniture in its "as-is" condition as of the Commencement Date, (ii) shall maintain the Furniture in good condition and repair throughout the Term, and (iii) shall be solely responsible for any and all costs associated with the Furniture (including, but not limited to, repair, maintenance and property taxes). During the Term, the Furniture shall remain in the Sublease Premises at all times and shall not be utilized in any location other than the Sublease Premises. Subtenant shall indemnify, defend and hold Sublandlord harmless from and against any and all losses, claims, and damages arising out of or resulting from, or in any way connected with Subtenant's failure to comply with this Section 27, and/or the use of the Furniture by Subtenant, or any officer, agent, employee, contractor, servant, invitee or guest of Subtenant, and such obligations shall survive the expiration or earlier termination of the Sublease.

28. **Parking**. Provided Subtenant is not in default under the terms and provisions of this Sublease, Subtenant shall have the non-exclusive right during the Term to use up to thirty (30) of the unreserved parking spaces provided to Sublandlord by Landlord in the Landlord-controlled surface parking lot servicing the Building, provided that such use shall be in common with others on a "first-come, first-served" basis and shall at all times be subject to the terms and conditions of the Prime Lease, including, without limitation, Section 24 of the Original Lease.

29. **Signage**. Subtenant may not install any signage, window coverings, blinds or similar items that are visible from outside the Premises without the prior written consent of Sublandlord and Prime Landlord, which consent may be withheld in each party's sole and absolute discretion. Notwithstanding the foregoing, if Prime Landlord consents to the installation of standard building signage for Subtenant and Subtenant provides Sublandlord with proof of its payment of out-of-pocket expenses in connection with such signage installation, then Sublandlord shall reimburse Subtenant for such out-of-pocket expenses up to, but not exceeding, an amount equal to Five Hundred and No/100 Dollars ($500.00). Such reimbursement shall, at Sublandlord's option, be made as a credit against Subtenant's Fixed Rent payment next coming due.

30. **Prohibited Persons and Transactions**. Subtenant represents and warrants to Sublandlord that Subtenant is not a party with whom Sublandlord is prohibited from doing business pursuant to the regulations of the Office of Foreign Assets Control ("OFAC") of the U.S. Department of the Treasury, including those parties named on OFAC's Specially Designated Nationals and Blocked Persons List. Subtenant is currently in compliance with, and shall at all times during the Sublease term remain in compliance with, the regulations of OFAC and any other governmental requirement relating thereto. In the event of any violation of this section, Sublandlord shall be entitled to immediately terminate this Sublease and take such other actions as are permitted or required to be taken under law or in equity. SUBTENANT SHALL DEFEND, INDEMNIFY AND HOLD HARMLESS SUBLANDLORD FROM AND AGAINST ANY AND ALL CLAIMS, DAMAGES, LOSSES, RISKS, LIABILITIES AND EXPENSES (INCLUDING ATTORNEYS' FEES AND COSTS) INCURRED BY SUBLANDLORD ARISING FROM OR RELATED TO ANY BREACH OF THE FOREGOING CERTIFICATIONS. These indemnity obligations shall survive the expiration or earlier termination of this Sublease.

31. **Miscellaneous**.

A. This Sublease shall be governed by and construed in accordance with the laws of the state in which the Sublease Premises is located without regard to the conflicts of law principles thereof. All disputes arising under this Sublease shall be submitted to the exclusive jurisdiction of the appropriate state and federal courts of the state in which the Sublease Premises is located. Time shall be of the essence with respect to the performance of all Subtenant's obligations hereunder.

B. The Section headings in this Sublease are inserted only as a matter of convenience for reference and are not to be given any effect in construing this Sublease.

C. If any of the provisions of this Sublease or the application thereof to any person or circumstance shall, to any extent, be held to be invalid or unenforceable, the remainder of this Sublease shall not be affected thereby and shall be valid and enforceable to the fullest extent permitted by law.

D. All of the terms and provisions of this Sublease shall be binding upon and inure to the benefit of the parties hereto and their respective permitted successors and assigns.

E. All prior negotiations and agreements relating to this Sublease and the Sublease Premises are merged into this Sublease. This Sublease may not be amended, modified or terminated, in whole or in part, nor may any of the provisions be waived, except by a written instrument executed by both parties hereto, and unless the same is permitted under the terms and provisions of the Prime Lease.

F. This Sublease shall have no binding force and effect and shall not confer any rights or impose any obligations upon either party unless and until both parties have executed it and Sublandlord shall have obtained Prime Landlord's written consent to this Sublease and delivered to Subtenant an executed copy of such consent. Under no circumstances shall the submission of this Sublease in draft form by or to either party be deemed to constitute an offer for the subleasing of the Premises by Sublandlord.

G. Capitalized terms not defined in this Sublease shall have the meanings ascribed thereto in the Prime Lease.

H. At any time and from time to time Subtenant shall, within ten (10) days after a written request by Sublandlord, execute, acknowledge and deliver to Sublandlord a written statement certifying (i) that this Sublease has not been modified and is in full force and effect or, if modified, that this Sublease is in full force and effect as modified, and specifying such modifications, (ii) the dates to which the Rent and other charges have been paid, and (iii) that to the best of Subtenant's knowledge, no defaults exist under this Sublease or, if any do exist, the nature of such default.

I. Subtenant agrees that in executing this Sublease, it has not relied upon any statements, representations, covenants or warranties made by Sublandlord or any person acting on behalf of Sublandlord other than those, if any, expressly set forth in this Sublease and on such investigations, examinations and inspections as Subtenant has chosen to make or has made.

J. This Sublease may be executed in any number of counterparts with the same effect as if both parties had signed the same documents. All counterparts shall be construed together and shall constitute one Sublease. Signatures of this Sublease that are transmitted by either or both electronic or telephonic means (including, without limitation, facsimile, PDF and email) are valid for all purposes.

K. This Sublease shall be construed without regard to any presumption or other rule requiring construction against the party causing this Sublease to be drafted. Each covenant, agreement, obligation or other provision of this Sublease shall be deemed and construed as a separate and independent covenant of the party bound by, undertaking or making the same, which covenant, agreement, obligation or other provision shall be construed and interpreted in the context of the Sublease as a whole. All terms and words used in this Sublease, regardless of the number or gender in which they are used, shall be deemed to include any other number and any other gender as the context may require.

L. The parties hereby waive any rights that they may have to trial by jury in any action or proceeding or counterclaim arising out of or in any way connected with this Sublease, the Sublease Premises and the use and occupancy thereof, to the extent permitted under applicable law.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have duly executed this Sublease as a sealed instrument and have hereunto set their hands and seals as of the day and year first above written.

SUBLANDLORD:

SUBLANDLORD:

KEMPHARM, INC.

WITNESSES:

/s/ Susan Smoker
Print Name: Susan Smoker

/s/ Timothy Sangiovanni
Print Name: Timothy Sangiovanni

By: /s/ R. LaDuane Clifton
Name: R. LaDuane Clifton
Title: CFO
Date of Execution: 15 Jan 2020

SUBTENANT:

CIBER GLOBAL, LLC

WITNESSES:

/s/ Marie C Smith
Print Name: Marie C Smith

/s/ Sarah Lombardi-Johe
Print Name: Sarah Lombardi-Johe

By: /s/ Sutbir Randhawa
Name: Sutbir Randhawa
Title: VP
Date of Execution: 22 Jan 2020

EXHIBIT A

Prime Lease

[To be attached]

EXHIBIT B

Sublease Premises

Suite 108

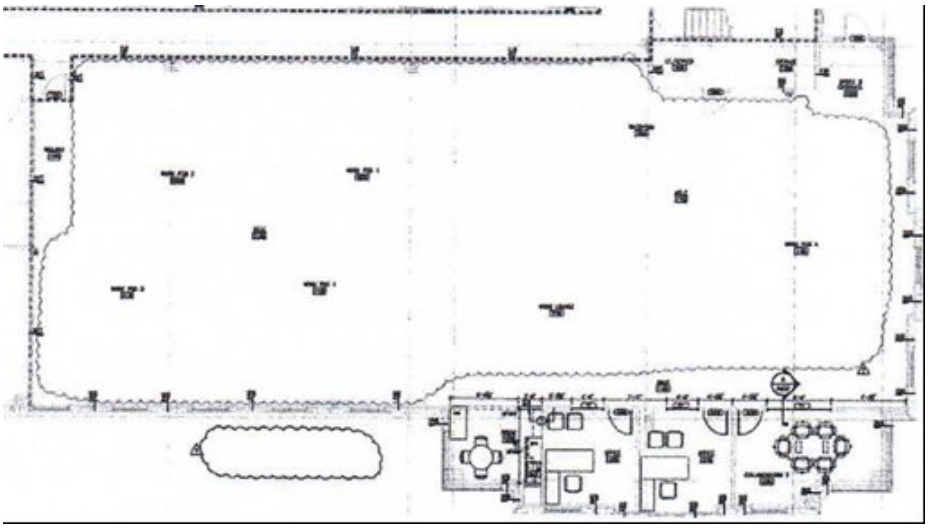

EXHIBIT C

Furniture

	OPEN AREA
9	L-shape desk
3	Two drawer lateral cabinets
6	Two doors cabinets
9	Visitor Chairs
18	Mesh high back chairs
2	Sixty inches book case
2	Forty inches book case
1	Large conference table
1	Four doors storage credenza
1	Recepton desk
	KITCHEN AREA
1	Round lunch table with four chair:
1	Redridgerator
1	Microwave
	OFFICE 1 AND 2
2	L-shape desk
2	One shelf bookcase
2	Two doors cabinets
4	Visitor Chairs
2	Mesh high back chairs
2	Forty inches book case
	CONFERENCE ROOM
1	Small conference table
6	Mesh Chairs
1	65-inches TV
1	Four doors storage credenza

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements (No. 333-234235 and No. 333-213926) on Form S-3 and Registration Statements (No. 333-203703, No. 333-210369, No. 333-216858, No. 333-224062 and No. 333-230041) on Form S-8 of KemPharm, Inc. of our report dated February 28, 2020 relating to the financial statements of KemPharm, Inc., appearing in this Annual Report on Form 10-K of KemPharm, Inc. for the year ended December 31, 2019.

/s/ RSM US LLP

Orlando, Florida
February 28, 2020

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.

February 28, 2020

/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.

February 28, 2020

/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, 2019, 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.

February 28, 2020

/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, 2019, 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.

February 28, 2020

/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.