6,765,463 Shares of Common Stock
Warrants to Purchase up to 7,692,307 Shares of Common Stock
Pre-Funded Warrants to Purchase up to 926,844 Shares of Common Stock

This prospectus supplement updates and should be read in conjunction with the prospectus dated January 8, 2021, or the Prospectus, relating to the offering of up to 6,765,463 shares of our common stock, warrants to purchase up to 7,692,307 shares of our common stock and pre-funded warrants to purchase 926,844 shares of our common stock, as well as an option to the underwriter in the offering to purchase up to an additional 1,153,846 shares of common stock and/or warrants to purchase up to 1,153,846 shares of our common stock, in any combination thereof. To the extent that there is any conflict between the information contained herein and the information contained in the Prospectus, the information contained herein supersedes and replaces such information.

Current Report

This prospectus supplement incorporates into the Prospectus the information contained in our attached annual report on Form 10-K that we filed with the Securities and Exchange Commission on March 11, 2021, or the Form 10-K. The Form 10-K, as filed, is set forth below.

The information contained in this Prospectus Supplement No. 5 supplements and supersedes, in relevant part, the information contained in the Prospectus, as amended and supplemented to date. This Prospectus Supplement No. 5 is incorporated by reference into, and should be read in conjunction with, the Prospectus, as amended and supplemented to date, and is not complete without, and may not be delivered or utilized except in connection with, the Prospectus, as amended and supplemented to date.

The Prospectus, together with Prospectus Supplement No.1, Prospectus Supplement No. 2, Prospectus Supplement No. 3, Prospectus Supplement No. 4 and this Prospectus Supplement No. 5, constitutes the prospectus required to be delivered by Section 5(b) of the Securities Act of 1933, as amended, with respect to offers and sales of the securities as set forth in the Prospectus, as amended and supplemented. All references in the Prospectus to “this prospectus” are amended to read “this prospectus (as supplemented and amended to date).”

Our common stock is traded on the Nasdaq Capital Market under the symbol “KMPH.” The last reported sale price of our common stock on March 10, 2021 was $10.30 per share. You are urged to obtain current market quotations for our common stock.

Investing in our securities is highly speculative and involves a significant degree of risk. See “Risk Factors” beginning on page 9 of the Prospectus and the Risk Factors identified in our Annual Report for the year ended December 31, 2020 for a discussion of information that should be considered before making a decision to purchase our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is March 11, 2021.

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, 2020

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

Commission File No. 001-36913

KemPharm, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware **(State or Other Jurisdiction of Incorporation or Organization)**	**20-5894398** **(I.R.S. Employer Identification No.)**
1180 Celebration Boulevard, Suite 103, Celebration, FL 34747 **(Address of Principal Executive Offices and Zip Code)**	**(321) 939-3416** **(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

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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 such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2020, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $18.5 million, based upon the closing sales price for the registrant's common stock, as reported on the OTC Markets Venture Market, or OTCQB, on June 30, 2020. The calculation of the aggregate market value of voting and non-voting common equity excludes 170,390 shares of common stock the registrant held by executive officers, directors and stockholders that the registrant concluded were affiliates of the registrant on that date. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of management or policies of the registrant or that such person is controlled by or under common control with the registrant.

As of March 10, 2021, the registrant had 28,376,321 shares of common stock outstanding.

Documents Incorporated by Reference

Portions of the registrant's definitive proxy statement for its 2021 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, 2020. 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:

- *the progress of, outcome or and timing of any regulatory approval for any of our product candidates and the expected amount or timing of any payment related thereto under any of our collaboration agreements;*
- *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 products and product candidates;*
- *the size and characteristics of the markets that may be addressed by our products and product candidates;*
- *our intention to seek to establish, and the potential benefits to us from, any strategic collaborations or partnerships for the development or sale of our products and product candidates;*
- *our expectations as to future financial performance, expense levels and liquidity sources;*
- *the timing of commercializing our products and 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.

RISK FACTORS SUMMARY

The risk factors summarized below could materially harm our business, operating results, and/or financial condition, impair our future prospects, and/or cause the price of our common stock to decline. These risks are discussed more fully in the section titled "Risk Factors". Material risks that may affect our business, financial condition, results of operations, and trading price of our common stock include the following:

- *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.*
- *If we are not able to obtain required regulatory approvals for our product candidates, or the approved labels are not sufficiently differentiated from other competing products, we will not be able to commercialize them and our ability to generate revenue or profits or to raise future capital could be limited.*
- *If commercialization of AZSTARYS, APADAZ or our other product candidates is not successful, or we experience significant delays in commercialization, our business will be harmed.*
- *Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.*
- *We may 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.*
- *We have incurred significant recurring negative net operating losses since our inception. We expect to incur operating losses over the next several years and may never achieve or maintain profitability.*
- *If we are unable to obtain and maintain trade secret protection or patent protection for our technology, AZSTARYS, KP879 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, AZSTARYS, KP879 and our other product candidates, if approved, may be impaired.*
- *If we, subject to the approval of Commave Therapeutics, S.A., 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.*
- *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.*
- *We have entered into collaborations with Commave to develop, manufacture and commercialize AZSTARYS 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 AZSTARYS or KP484 or other product candidates, if approved.*
- *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.*

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, 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 contains statistical data, estimates and forecasts that are based on independent industry publications or other publicly available information, as well as other information based on our internal sources. While we believe the industry and market data included in this Annual Report on Form 10-K is reliable and is based on reasonable assumptions, this data involves many assumptions and limitations, and you are cautioned not to give undue weight to these estimates. We have not independently verified the accuracy or completeness of the data contained in these industry publications and other publicly available information. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled "Risk Factors" and "Special Note Regarding Forward-Looking Statements" included in this Annual Report on Form 10-K.

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, and idiopathic hypersomnia, or IH. Our newly approved product, AZSTARYS™, formerly referred to as 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 lead clinical development product candidate, KP879, is also based on a prodrug of d-MPH and is intended for the treatment of stimulant use disorder, or SUD. Our preclinical prodrug product candidate for the treatment of ideopathic hypersomnia, or IH, is KP1077. 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 AZSTARYS, and any other of our product candidates containing serdexmethylphenidate, or SDX, and d-MPH. In addition, we have entered into a commercial partnership with KVK-Tech, Inc., or KVK, for 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.

On March 2, 2021, we announced that the FDA approved the NDA for AZSTARYS, a once-daily product for the treatment of ADHD in patients ranging from six years and older. Corium will lead the commercialization of AZSTARYS per the KP415 License Agreement. Corium expects to make AZSTARYS commercially available in the U.S. as early as the second half of 2021.

In July 2020, we entered into a consultation services arrangement, or the Corium Consulting Agreement, with Corium, Inc., or Corium, under which Corium engaged us to guide the product development and regulatory activities for certain current and potential future products in Corium's portfolio, as well as to continue supporting preparation for the potential commercial launch of AZSTARYS. Corium is a portfolio company of Gurnet Point Capital and has been tasked with leading all commercialization activities for AZSTARYS under the KP415 License Agreement.

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 AZSTARYS and KP484. In addition, the KP415 License Agreement provides Commave a right of first negotiation upon the completion of a Phase 1 proof-of-concept study for KP879, KP922 or any other product candidate developed by us containing SDX and intended to treat ADHD or any other central nervous system disorder.

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 first available for sale nationally beginning in November 2019. In December 2020, KVK, began a regional pilot launch of APADAZ in the state of Alabama, with plans to expand into additional geographic regions during 2021.

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, SUD and IH, and we anticipate initiating a Phase 1 proof-of-concept study for KP879 in 2021. We plan to employ our LAT technology and development expertise to develop additional product candidates that address significant unmet medical needs in therapeutic indications which have few existing product options. 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 has the potential to reduce drug development time, risk and expense.

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 a few of the currently-marketed methylphenidate products are labeled as providing some level symptom control for up to 12 hours post-dose, there is increasing attention to addressing late afternoon/early evening behavioral deficits, while also providing symptom control sooner following dosing.

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 Other Development Assets

Parent Drug (Effect Profile) (Indication)	Product Candidate / Product (Status)	Development Status	Next Milestone
Methylphenidate (ER) (ADHD)	AZSTARYS (Partnered)	FDA Approved	Commercial Launch - as early as H2 2021
Methylphenidate (ER) (ADHD)	KP484 (Partnered)	Clinical	Initiation of Pivotal Efficacy Trial - TBD by Partner
Methylphenidate (ER) (SUD)	KP879*	Clinical	Initiation of Clinical Program - 2021
Prodrug (IH)	KP1077	Preclinical	Pre-IND Meeting - H1 2021
Hydrocodone / APAP (IR) (Pain)	APADAZ (Partnered)	FDA Approved	Tracking Payor Contracts and TRx's

* This product candidate is subject to a right of first negotiation upon completion of a Phase 1 proof-of-concept study in favor of Commave under the terms of the KP415 License Agreement, but is not currently licensed to Commave, thereunder.

AZSTARYS and KP484

Overview

The prodrug in both AZSTARYS and KP484 is serdexmethylphenidate, or SDX, and both product candidates are intended for the treatment of ADHD. The ADHD market is largely served by the stimulant products methylphenidate and amphetamine. Both AZSTARYS and KP484 are designed to be extended-duration methylphenidate products.

On March 2, 2021, we announced that the FDA approved the NDA for AZSTARYS, a once-daily product for the treatment of ADHD in patients ranging from six years and older. Subject to Commave's approval, we intend to seek approval of 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. The timing for initiating additional PK and pivotal efficacy trials for KP484 is subject to Commave's direction as provided under the KP415 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 AZSTARYS and KP484. In addition, the KP415 License Agreement provides a right of first negotiation upon completion of a Phase 1 proof-of-concept study for 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 AZSTARYS 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 right to first negotiation 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 us 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 AZSTARYS, including FDA approval and specified conditions with respect to the final approval label, and KP484. As a result of the FDA's approval of the AZSTARYS NDA, we have earned a regulatory milestone payment following FDA approval as provided under the KP415 License Agreement, and we have invoiced Commave for such payment, which is payable within thirty (30) days following the PDUFA date for AZSTARYS, which was March 2, 2021. 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. 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 us 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 AZSTARYS 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 AZSTARYS 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 AZSTARYS 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, Aquestive has the right to receive a royalty amount equal to 10% of any value generated by AZSTARYS, KP484 or KP879, and any product candidates which contain SDX, including royalty payments on any license of AZSTARYS, KP484 or KP879, the sale of AZSTARYS, KP484 or KP879 to a third party, the commercialization of AZSTARYS, KP484 or KP879 and the portion of any consideration that is attributable to the value of AZSTARYS, 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 and the regulatory milestone payment we received in the second quarter of 2020. Aquestive will be due to receive a royalty equal to 10% of the of the regulatory milestone payment for the approval of the AZSTARYS NDA upon receipt from Commave.

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, JORNAY PM, QUILLICHEW XR and COTEMPLA XR-ODT rely on formulation alone in attempting to provide differentiation from generics.

Key Features of AZSTARYS

We believe AZSTARYS has valuable product features and may provide significant benefits to patients, physicians, and society when compared to other FDA-approved and widely-prescribed methylphenidate products:

- ***Earlier onset and extended duration.***
- ***Once-daily dosing.***
- ***Available to treat patients six years and older.***
- ***Amenable to patient-friendly formulations.*** Patients can take AZSTARYS with or without food and can swallow capsules whole or open and sprinkle onto food or add to water.
- ***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 2037 that generally covers at least one component of AZSTARYS. 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.
- ***No generic equivalent product.*** AZSTARYS 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 AZSTARYS 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. We filed an IND with the FDA for KP879 in December 2020. In January 2021, the FDA completed its review of the KP879 IND, concluding that we may proceed with its planned clinical investigation of the product candidate. We expect to initiate the clinical program for KP879 in 2021.

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.

- ***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.

KP1077

KP1077 is our prodrug preclinical product candidate for the treatment of IH, an underserved, orphan disease indication. Currently there are no approved drugs in the United States for IH. We expect to hold a pre-IND meeting with the FDA in 2021.

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 acetaminophen, or 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 became nationally available. To date, KVK has utilized targeted non-traditional efforts to build product awareness for APADAZ as a responsible alternative to currently available hydrocodone/acetaminophen products. For example, in December 2020, KVK began a collaboration with Sure Med Compliance, a provider of compliance and decision support software designed to assist physicians in evaluating the appropriateness of opioid treatment, to provide a patient/provider support program, referred to as Perspectives in Care, to provide education to physicians, pharmacies and patients regarding responsible opioid therapy. The Perspectives in Care program was initially launched as a pilot program for APADAZ in Alabama. We may also license the international commercial rights to APADAZ to one or more collaborators.

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, 2020, we have been granted 48 active patents within the United States, and an additional 78 active foreign patents covering our selected prodrugs and product candidates. The terms of the 48 issued U.S. patents extend to various dates ranging, for example, between 2030 and 2037. 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 2037, if pending patent applications in each of our patent families issue as patents. As of December 31, 2020, we had 13 pending patent applications under active prosecution in the United States, and an additional 28 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, European Countries, Hong Kong, India, Indonesia, Israel, Japan, Kazakhstan, Malaysia, Mexico, New Zealand, Philippines, Romania, Russia, Singapore, South Africa, South Korea, and Vietnam.

We have received composition-of-matter patents and also additionally filed composition-of-matter and method of treatment patent applications related to the AZSTARYS 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.

Since 2013, the United States Patent and Trademark Office, or the USPTO, has issued 14 composition-of-matter or method of treatment patents 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, Israel, Mexico, South Africa, and South Korea. Patent applications covering benzhydrocodone were pending as of December 31, 2020, in Thailand 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

On March 2, 2021, we announced that the FDA approved the NDA for AZSTARYS, a once-daily product for the treatment of ADHD in patients ranging from six years and older. Corium will lead the commercialization of AZSTARYS per the KP415 License Agreement. Corium expects to make AZSTARYS commercially available in the United States as early as the second half of 2021.

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. In November 2019, APADAZ and its authorized generic (AG-APADAZ) became nationally available. In December 2020, KVK, in collaboration with Sure Med Compliance, initiated a regional launch of the Perspectives in Care program to provide education to physicians, pharmacies and patients regarding responsible opioid therapy and launched a pilot program for APADAZ in Alabama.

With the exception of AZSTARYS and APADAZ, commercialization activities for our product candidates in active development have not yet begun. 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 Commave and KVK, 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 KP415 License Agreement or the APADAZ 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, 2020 and 2019, we recorded $8.8 million and $19.4 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.Under 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. We are responsible for the development costs required to bring Additional Product Candidates to the successful completion of a Phase 1 proof-of-concept study, or if Commave does not exercise its right of first negotiation at that point, or Commave's exercise of its right of first negotiation does not culminate in economic terms which are mutually agreeable between Commave and the Company, any additional development costs which would be required to pursue the approval of such product candidate.

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.

AZSTARYS and, if approved, 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, AZSTARYS and, if approved, 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.

Currently, there are no approved drugs in the United States for the treatment of IH. If approved, KP1077 could face potential competition from any products for the treatment of IH that are currently in or which 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 AZSTARYS and KP484 to be used in our non-clinical, clinical and formulation development programs necessary to support an NDA filing. We expect that our commercial partners under the KP415 License Agreement and the APADAZ License Agreement will continue to rely initially on these manufacturers to manufacture commercial quantities of AZSTARYS, KP484 and APADAZ for sale in the United States, following 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.

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 AZSTARYS 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, and therefore we entered into the KP415 License Agreement with Commave.

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, reimbursement 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 70%, which commenced January 1, 2019. In 2020, drug manufacturers became 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 new chemical entities, or 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, and the FDA has recommended that AZSTARYS should be, listed as a Schedule II controlled substance under the CSA, and we expect that 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 AZSTARYS, APADAZ and our other current product candidates currently under development 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 and Privacy Regulatory Frameworks

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 as well as privacy and information security laws, including those described below. Compliance with government regulations requires the expenditure of substantial time and financial resources.

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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) 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. Beginning in 2022, applicable manufacturers will also be required to report information regarding payments and other transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants, and certified nurse-midwives.

In addition, we may be subject to data privacy and security regulation by foreign, federal, state and local governments. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes requirements on 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, and their covered subcontractors, 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, U.S. state and foreign law equivalents may govern the privacy and security of personal information (including key-coded data and health information_, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Efforts to ensure that our current and future business arrangements comply with applicable privacy and data security laws and regulations will involve substantial costs. For example, the European General Data Protection Regulation, or GDPR, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. European data protection laws, such as the GDPR, also impose strict rules on the transfer of personal data out of the European Economic Area, Switzerland and United Kingdom. Further, the GDPR authorizes the imposition of penalties (such as restrictions or prohibitions on personal data processing) and large fines for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The GDPR has increased our responsibility and potential liability in relation to personal data that we process or control compared to prior EU law, including in clinical trials, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR and similar data protection laws, which could divert management's attention and increase our cost of doing business. Likewise, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, such as the California Consumer Privacy Act of 2018, or CCPA, which has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States. Although the CCPA exempts certain data processed in the context of clinical trials, the CCPA, to the extent applicable to our business and operations, may increase our compliance costs and potential liability with respect to the personal information we maintain about California residents. In any event, it is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable information security or privacy laws in light of the lack of applicable precedent and regulations. Federal, state and foreign enforcement bodies have increased their scrutiny of biotechnology companies, which has led to a number of investigations, prosecutions, convictions, fines, penalties and settlements in the industry.

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 have been executive, judicial and congressional challenges to certain aspects 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 of 2017 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 eliminated, 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 eliminated 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. The U.S. Supreme Court is currently reviewing the case, although it is unknown when a decision will be made. Further, although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA.

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 2030 with the exception of a temporary suspension from May 1, 2020 through March 31, 2021 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 used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing the Trump administration's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the U.S. District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic.

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 and Human Capital Resources

As of December 31, 2020, 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.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of stock-based compensation awards in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

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, 2020 and 2019.

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 the Development of Our Product Candidates

If commercialization of AZSTARYS, APADAZ or any of our other product candidates, if approved, are not successful, or we experience significant delays in commercialization, our business will be harmed.

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, 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 AZSTARYS and KP484 worldwide. We cannot guarantee that Commave will be able to successfully develop, manufacture or commercialize AZSTARYS or KP484 or that we will ever receive any future payments under the KP415 License Agreement.

We have also 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, but 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.

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, AZSTARYS under the KP415 License Agreement and generate revenue from any of our other product candidates will depend heavily on their successful development and eventual commercialization. The success of AZSTARYS, APADAZ and any of our other 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 AZSTARYS, APADAZ and any of our other product candidates are outweighed by the benefits;
- successful development of our manufacturing processes for AZSTARYS under the KP415 License Agreement, APADAZ under the APADAZ License Agreement and for any of 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 AZSTARYS, APADAZ and any of our other 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 AZSTARYS, APADAZ and any of our other product candidates and otherwise protecting our rights in our intellectual property portfolio;
- maintaining compliance with regulatory requirements, including cGMPs;
- launching commercial sales of AZSTARYS under the KP415 License Agreement, APADAZ under the APADAZ License Agreement and launching commercial sales of any of our other product candidates, if and when approved, whether alone or in collaboration with Commave or others;
- acceptance of AZSTARYS, APADAZ and any of our other product candidates, if approved, by patients, the medical community and third-party payors;
- competing effectively with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement; and
- maintaining a continued acceptable safety and efficacy profile of the prodrug products following approval.

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

It is possible that none of our product candidates in clinical development 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, KVK could experience an inability to successfully commercialize APADAZ, Corium could experience an inability to successfully commercialize AZSTARYS or any of our other product candidates covered by the KP415 License Agreement, if approved, or we could experience an inability to successfully commercialize any of our other product candidates approved for marketing in the future, if any, which would harm our business.

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. If APADAZ and AZSTARYS are not successfully commercialized under our APADAZ License Agreement or KP415 License Agreement and we do not successfully develop and commercialize any of our other 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 any of our product candidates, or the approved labels are not sufficiently differentiated from other competing products, 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, or the approved label for any approved product may not be sufficiently differentiated from other competing products to support market adoption thereof. On March 2, 2021, we announced that the FDA approved the NDA for AZSTARYS, a once-daily product for the treatment of ADHD in patients ranging from six years and older. 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 AZSTARYS and APADAZ by the FDA, we cannot guarantee that the FDA will approve any of our other product candidates for commercial sale or approve any proposed label we may have for any such product candidate. 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.

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.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, in March 2020 the FDA announced its intention to postpone most foreign and domestic inspections of manufacturing facilities and products, and subsequently, in July 2020, restarted routine surveillance inspections of domestic manufacturing facilities on a risk-based basis. Regulatory authorities outside the United States have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on 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 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 AZSTARYS or KP484, but not both. We utilized the 505(b)(2) NDA pathway for the AZSTARYS NDA which was approved on March 2, 2021. 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.

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.

AZSTARYS, APADAZ and certain of our other 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 products or 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. The FDA has recommended that AZSTARYS be regulated as a "controlled substance" as defined in the CSA. For APADAZ, the DEA has determined it to be a Schedule II drug. We expect that most of our other product candidates, including KP484 and KP879, if approved, will be regulated as “controlled substances” as defined in the CSA and the implementing regulations of the DEA, which establish registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA. These requirements are applicable to us, to our contract manufacturers and to distributors, prescribers and dispensers of our product candidates. The DEA regulates the handling of controlled substances through a closed chain of distribution. This control extends to the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce. A number of states and foreign countries also independently regulate these drugs as controlled substances.

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

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

We expect that most of our 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 AZSTARYS, APADAZ or any of 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 AZSTARYS under the KP415 License Agreement, APADAZ under the APADAZ License Agreement or to commercialize any of 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 AZSTARYS, APADAZ or any of 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 AZSTARYS, APADAZ and any of 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 AZSTARYS, APADAZ or any of our other applicable product candidates.

Risks Related to Our Financial Position and Capital Needs

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. 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 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 recurring negative net operating cash flows. We expect to incur minimal positive net operating cash flows or negative net operating cash flows over the next several years and may never achieve or maintain profitability.

We have had recurring negative net operating cash flows and, as of December 31, 2020, had an accumulated deficit of $258.5 million. For the years ended December 31, 2020 and 2019 net cash used in operations was $1.9 million and of $23.7 million, respectively. We have financed our operations through December 31, 2020 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, the Corium Consulting Agreement and other consulting arrangements.

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, two products, AZSTARYS and 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 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 AZSTARYS and KP484 worldwide. We cannot guarantee that Commave will be able to successfully develop, manufacture or commercialize AZSTARYS, or KP484, if approved, or that we will ever receive any future payments under the KP415 License Agreement. In addition, 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. We may never succeed in commercialization activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

In March 2020, the World Health Organization declared the outbreak of COVID-19 a global pandemic. This outbreak is causing major disruptions to businesses and markets worldwide as the virus spreads. We cannot predict what the long-term effects of this pandemic and the resulting economic disruptions may have on our liquidity and results of operations. The extent of the effect of the COVID-19 pandemic on our liquidity and results of operations will depend on a number future developments, including the duration, spread and intensity of the pandemic, and governmental, regulatory and private sector responses, all of which are uncertain and difficult to predict. The COVID-19 pandemic may make it more difficult for us to enroll patients in any future clinical trials or cause delays in the regulatory approval of our product candidates. A portion of our projected revenue is based upon the achievement of milestones in the KP415 License Agreement associated with regulatory matters that may be impacted by the COVID-19 pandemic. As a result, we cannot predict what, if any, impact that the COVID-19 pandemic may have on our ability to achieve these milestones. If the pandemic continues to be a severe worldwide crisis, it could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

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, AZSTARYS, APADAZ or any of our other 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 Commave will be able to successfully commercialize AZSTARYS or any of the other product candidates subject to the KP415 License Agreement, even if approved, that KVK will be able to successfully commercialize APADAZ or that we will ever receive any payments under the KP415 License Agreement from the commercial sales of AZSTARYS or any future payments under the KP415 License Agreement or payment under the APADAZ License Agreement from commercial sales of APADAZ. 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 those securities or debt may restrict our ability to operate. Any future debt financing and equity financing, if available, may involve agreements that include, covenants limiting and restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, entering into profit-sharing or other arrangements or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

We may need 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.

We expect that our only sources of revenues will be through payments arising from our license agreements with Commave and KVK, or through the Corium Consulting Agreement or other potential consulting arrangements and any other future arrangements related to one of our other product candidates. We cannot guarantee that we will be able to generate sufficient proceeds from the KP415 License Agreement, the APADAZ License Agreement, the Corium Consulting Agreement or other consulting arrangements, or be successful in completing other transactions, that will fully fund our operating expenses. Further, the economic uncertainty surrounding the COVID-19 pandemic may dramatically reduce our ability to secure debt or equity financing necessary to support our operations. 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. 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 commercial revenue, if any, received from commercial sales of AZSTARYS under our KP415 License Agreement, APADAZ under our APADAZ License Agreement, or any of our other product candidates subject to the terms of the KP415 License agreement, or sales of our other product candidates for which we receive marketing approval in the future, which may be affected by market conditions, including obtaining coverage and adequate reimbursement of AZSTARYS, APADAZ, or any of our other product candidates, from third-party payors, including government programs and managed care organizations, and competition within the therapeutic class to which AZSTARYS, APADAZ, or any our other product candidates are assigned;
- the success of our partner, Commave, in commercializing AZSTARYS, or the successful development of other Additional Products or other Licensed Products 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.

We may not be entitled to forgiveness of our recently received Paycheck Protection Program loan, and our application for the Paycheck Protection Program loan could in the future be determined to have been impermissible or could result in damage to our reputation.

On April 23, 2020 we received proceeds of $0.8 million from a loan, or the PPP Loan, under the Paycheck Protection Program, or the PPP, of the recently enacted Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, a portion of which may be forgiven, which we used to retain current employees, maintain payroll and make lease and utility payments. The PPP Loan matures on April 23, 2022 and bears annual interest at a rate of 1.0%. Payments of principal and interest on the PPP Loan were originally deferred for the first six months of the PPP Loan term. Thereafter, we would have been required to pay the lender equal monthly payments of principal and interest.

The CARES Act and the PPP provide a mechanism for forgiveness of up to the full amount borrowed. Under the PPP, we may apply for and be granted forgiveness for all or part of the PPP Loan. The amount of loan proceeds eligible for forgiveness was originally based on a formula that takes into account a number of factors, including the amount of loan proceeds used by us during the eight-week period after the loan origination for certain purposes, including payroll costs, interest on certain mortgage obligations, rent payments on certain leases, and certain qualified utility payments, provided that at least 75% of the loan amount was used for eligible payroll costs. Subject to the other requirements and limitations on loan forgiveness, only loan proceeds spent on payroll and other eligible costs during the covered eight-week period would have qualified for forgiveness.

On June 5, 2020, President Trump signed into law the PPP Flexibility Act of 2020, or the Flexibility Act, which among other things provided the following important changes to the PPP:

- Extended the covered period for loan forgiveness from eight weeks after the date of loan disbursement to 24 weeks after the date of loan disbursement, providing substantially greater flexibility for borrowers to qualify for loan forgiveness. Borrowers who had already received PPP loans retained the option to use an eight-week covered period.

- Lowered the requirements that 75 percent of a borrower's loan proceeds must be used for payroll costs and that 75 percent of the loan forgiveness amount must have been spent on payroll costs during the 24-week loan forgiveness covered period to 60 percent for each of these requirements. If a borrower uses less than 60 percent of the loan amount for payroll costs during the forgiveness covered period, the borrower will continue to be eligible for partial loan forgiveness, subject to at least 60 percent of the loan forgiveness amount having been used for payroll costs.

- Provided a safe harbor from reductions in loan forgiveness based on reductions in full-time equivalent employees for borrowers that are unable to return to the same level of business activity the business was operating at before February 15, 2020, due to compliance with requirements or guidance issued between March 1, 2020 and December 31, 2020 by the Secretary of Health and Human Services, the Director of the Centers for Disease Control and Prevention, or the Occupational Safety and Health Administration, related to worker or customer safety requirements related to COVID–19.

- Provided a safe harbor from reductions in loan forgiveness based on reductions in full-time equivalent employees, to provide protections for borrowers that are both unable to rehire individuals who were employees of the borrower on February 15, 2020, and unable to hire similarly qualified employees for unfilled positions by December 31, 2020.

- Increased to five years the maturity of PPP loans that are approved by the U.S. Small Business Administration, or the SBA, (based on the date SBA assigns a loan number) on or after June 5, 2020.

- Extended the deferral period for borrower payments of principal, interest, and fees on PPP loans to the date that SBA remits the borrower's loan forgiveness amount to the lender (or, if the borrower does not apply for loan forgiveness, 10 months after the end of the borrower's loan forgiveness covered period).

Based on the changes provided by the Flexibility Act we plan to take advantage of (i) the extended covered period for loan forgiveness from eight weeks to 24 weeks, (ii) the lowered requirement that a certain percentage of loan proceeds must be used for payroll costs from 75 percent to 60 percent, (iii) the extended deferral period for payments of principal, interest and fees from six months after loan disbursement to 10 months after the SBA remits the borrower's loan forgiveness amount to the lender and (iv) take advantage of an safe harbor provisions as applicable. We will be required to repay any portion of the outstanding principal that is not forgiven, along with accrued interest, in accordance with the amortization schedule described above. Based on the changes provided by the Flexibility Act we expect that substantially all of the PPP loan will be forgiven, however, we cannot provide any assurance that we will be eligible for loan forgiveness, or that any amount of the PPP Loan will ultimately be forgiven by the SBA. We submitted our application for loan forgiveness of the full amount of the PPP Loan under the applicable SBA guidance and are waiting for a decision on that application.

In order to apply for the PPP Loan, we were required to certify, among other things, that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. We made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital, and believe that we satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan is consistent with the broad objectives of the PPP of the CARES Act. The certification described above does not contain any objective criteria and is subject to interpretation. On April 23, 2020, the SBA issued guidance stating that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. The lack of clarity regarding loan eligibility under the PPP has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. If, despite our good-faith belief that given our company's circumstances we satisfied all eligible requirements for the PPP Loan, we are later determined to have violated any of the laws or governmental regulations that apply to us in connection with the PPP Loan, such as the False Claims Act, or it is otherwise determined that we were ineligible to receive the PPP Loan, we may be subject to penalties, including significant civil, criminal and administrative penalties and could be required to repay the PPP Loan in its entirety. In addition, receipt of a PPP Loan may result in adverse publicity and damage to reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources. Any of these events could have a material adverse effect on our business, results of operations and financial condition.

Our business has been, and may in the future be, adversely affected by the effects of health epidemics, including the recent COVID-19 pandemic, in regions where we or third parties on which we rely have clinical trial sites or other business operations In addition, if COVID-19 continues to be a worldwide pandemic, it could materially affect our operations.

Our business has been, and may continue to be, adversely affected by health epidemics, including the COVID-19 pandemic, in regions where we have significant manufacturing facilities, concentrations of clinical trial sites, or other business operations.

As a result of the COVID-19 outbreak, we have implemented limitations on our operations, including a work-from-home policy, and could face further limitations in our operations in the future. There is a risk that countries or regions may be less effective at containing COVID-19 than others, or it may be more difficult to contain if the outbreak reaches a larger population or broader geography, in which case the risks described herein could be elevated significantly.

In particular, our future clinical trials may be affected by the COVID-19 outbreak or other future health epidemics. Site initiation, patient enrollment, distribution of drug product candidates, study monitoring, and data collection may be delayed due to changes in hospital policies, local regulations, and/or prioritization of hospital resources toward the COVID-19 outbreak or other future health epidemics. If COVID-19 continues to spread or there are similar health epidemics in the future, some patients and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines may impede patient movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be required to delay patient enrollment or unable to obtain patient data as a result.

In addition, third party manufacturing of our product and product candidates and suppliers of the materials used in the production of our product candidates may be impacted by restrictions resulting from the COVID-19 outbreak or other future health epidemics which may disrupt our supply chain or limit our ability to manufacture drug product candidates for our clinical trials.

The ultimate impact of the COVID-19 outbreak or a similar future health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

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 two products approved by the FDA, AZSTARYS, a once-daily product for the treatment of ADHD in patients age six years and older, and 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 that Commave will be able to successfully commercialize AZSTARYS or any of our other product candidates subject to the KP415 License Agreement, if approved, that KVK will be able to successfully commercialize APADAZ, or that we will ever receive any payments under the KP415 License Agreement or the APADAZ License Agreement from commercial sales of AZSTARYS, APADAZ, or any of our other product candidates, if approved. 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 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 AZSTARYS, 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 AZSTARYS, APADAZ, or any of our other 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 AZSTARYS, APADAZ, and any of our other 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 AZSTARYS, APADAZ, or any of our other 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 AZSTARYS, APADAZ or any of our other 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 AZSTARYS, APADAZ, or any of our other product candidates, if approved.

Further, for AZSTARYS, APADAZ and any of our other product candidates, if approved, our suppliers will be subject to regulatory requirements, covering manufacturing, testing, quality control and record keeping relating to AZSTARYS, APADAZ or any of our other 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 AZSTARYS, KP484 or KP879 bulk drug substance. If our current contract manufacturer for AZSTARYS, 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 Commave, to develop, manufacture and commercialize AZSTARYS and KP484 worldwide, and KVK, for the commercialization of APADAZ in the United States. 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 AZSTARYS, APADAZ, or any of our other product candidates, if approved.

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 AZSTARYS 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 AZSTARYS 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.

In addition, 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.

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 any 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 AZSTARYS or APADAZ outside of the United States or any of 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 Commave and KVK, 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 AZSTARYS, APADAZ, or any of our other product candidates 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 AZSTARYS, APADAZ, or any of our other 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;
- AZSTARYS, APADAZ, and any of our other 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 AZSTARYS, APADAZ, or any of our other products covered under the KP415 License Agreement, if approved;
- The Collaborators may not commit sufficient resources to the development, marketing and distribution of AZSTARYS, APADAZ, and any of our other 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 AZSTARYS, APADAZ, or any of our other products covered under the KP415 License Agreement, as applicable, might lead to additional responsibilities for us with respect to AZSTARYS, APADAZ, or any of our other 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 AZSTARYS, APADAZ, or any of our other 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 KP415 License Agreement, the APADAZ License Agreement, and any other licensing or collaboration agreements we may enter into may not lead to commercialization of AZSTARYS, commercialization of APADAZ, or development of KP484, KP879 or any of our other product candidates in the most efficient manner or at all. If Commave or KVK 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 KP415 License Agreement or the APADAZ 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 and Commave may inhibit our ability to enter into future collaborations with third parties.

We are party to a termination agreement with Aquestive Therapeutics, or Aquestive, that may limit the value of any sale, license or commercialization of AZSTARYS, KP484 or KP879. Under this termination agreement, Aquestive has the right to receive a royalty amount equal to 10% of any value generated by AZSTARYS, KP484 or KP879, and any product candidates which contain SDX, including royalty payments on any license of AZSTARYS, KP484 or KP879, the sale of AZSTARYS, KP484 or KP879 to a third party or the commercialization of AZSTARYS, 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 and the regulatory milestone payment we received in the second quarter of 2020.

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.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain trade secret protection or patent protection for our technology, AZSTARYS, APADAZ, or 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, AZSTARYS, APADAZ, or 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 AZSTARYS, APADAZ, and any of 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 KP415 License Agreement, Commave, obtained from us an exclusive, worldwide license to certain patents that cover AZSTARYS and KP484. In addition, as part of the APADAZ License Agreement, KVK obtained from us an exclusive license to certain patents that cover APADAZ.

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, for example, 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 and/or use 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, priority, 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 not be able to acquire patent term extensions of certain patents, domestic or foreign, due to regulatory delays, among others, which may affect the term of enforceability of such patents over time;
- 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 or loss;
- 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, domestic or foreign, to be valid or enforceable or that a competitor’s technology or product would be found by a court, domestic or foreign, to infringe our patents and our patents or patent applications may be challenged by third parties in patent litigation, domestic or foreign, 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 or intervening 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, litigation, 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, priority, 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, domestic or foreign, 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 or nullify 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 Pharmaceuticals, LLC, or 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 our product candidates that are approved for marketing from the products of our competitors. We have registered trademarks for LAT and KemPharm. In addition, we have solicited and applied for trademarks for the KemPharm logo and several potential trade names and logos for future product candidates. 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 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 Products 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 KP415 License Agreement to establish a collaboration for the commercialization of AZSTARYS and any of our other product candidates which are subject to such agreement, and we entered into the APADAZ License Agreement to establish a collaboration for the commercialization of APADAZ, 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 KP415 License Agreement we are entitled to receive 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, as well as, sales milestones based on specified sales targets. 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. Further, 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. We likely will have little control over such third parties, including Commave and KVK, and any of them may fail to devote the necessary resources and attention to sell and market AZSTARYS, APADAZ, or any of our other product candidates, if approved, effectively. Further, we may be liable for conduct of third parties, including Commave and KVK, 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 AZSTARYS, APADAZ, or any of our other product candidates, if approved.

AZSTARYS, APADAZ, or any of our other 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.

AZSTARYS, APADAZ, or any of our other 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 AZSTARYS, APADAZ, or any of our 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 AZSTARYS, APADAZ, or any of our other 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 AZSTARYS and APADAZ are, and we expect that most of our other product candidates likely going to be considered 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 AZSTARYS, APADAZ, or any of our other 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.

AZSTARYS, and, if approved, 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, AZSTARYS and, if approved, 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.

Currently, there are no approved drugs in the United States for the treatment of IH. If approved, KP1077 could face competition from any products for the treatment of IH 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 AZSTARYS, APADAZ, or any of our other product candidates, they may be subject to unfavorable pricing regulations, third-party coverage and reimbursement policies.

The successful commercialization of AZSTARYS, APADAZ, and any of our other product candidates will depend, in part, on the extent to which coverage and adequate reimbursement for AZSTARYS, APADAZ, or any of our other 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, AZSTARYS, APADAZ, or any of our other product candidates 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 AZSTARYS under the KP415 License Agreement, APADAZ under the APADAZ License Agreement, or commercialize any of our other 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 AZSTARYS, APADAZ, or any of our other 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 AZSTARYS under the KP415 License Agreement , APADAZ under the APADAZ License Agreement, or our ability to sell any of any of our other 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 AZSTARYS, APADAZ, or any of our other product candidates 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 AZSTARYS, APADAZ, and any of our other product candidates that may be approved in the future, are commercialized. This includes the risk that our products may be misused. For example, AZSTARYS does, APADAZ does, and we anticipate that any of our 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 AZSTARYS, APADAZ, and any of our other product candidates 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 AZSTARYS, APADAZ, or any of our other product candidates that might be approved in the future.

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 and clinical trial participant 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 AZSTARYS, APADAZ, and any of our other 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 AZSTARYS, APADAZ, and any of our other product candidates internationally, if approved, could affect our business.

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

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

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

AZSTARYS is, APADAZ is, and any of our other product candidates 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 AZSTARYS, APADAZ, or any of our other product candidates when and if any of them are approved.

AZSTARYS is, APADAZ is, and any of our other product candidates 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 AZSTARYS to determine its safety and effectiveness for the claimed indication in pediatric patients. Under the KP415 License Agreement, Commave will be responsible for these regulatory activities going forward, and we cannot guarantee they will be complied with. In addition, 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.

AZSTARYS is, APADAZ is, and if marketing approval of any of our other product candidates 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.

AZSTARYS does, APADAZ does, and if any of our other 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 our products, as well as 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 and their covered subcontractors, 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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, and to report annually certain ownership and investment interests held by physicians and their immediate family members, and, beginning in 2022, will require applicable manufacturers to report information regarding payments and other transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse-midwives; 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 AZSTARYS, 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 AZSTARYS under the KP415 License Agreement or APADAZ under the APADAZ License Agreement and our ability to profitably sell any of our other 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 have been executive, judicial and congressional challenges to certain aspects 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 of 2017 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 eliminated, 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 eliminated the health insurer tax. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended 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. The U.S. Supreme Court is currently reviewing the case, although it is unknown when a decision will be made. Further, although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration 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 2030 with the exception of a temporary suspension from May 1, 2020 through March 31, 2021 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 used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing the Trump administration's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the U.S. District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic.

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.

If our security measures are compromised now, or in the future, or the security, confidentiality, integrity or availability of, our information technology, software, services, communications or data is compromised, limited or fails, this could result in a material adverse impact, including without limitation, a material interruption to our operations, harm to our reputation, significant fines, penalties and liability, breach or a triggering of data protection laws, privacy policies and data protection obligations, loss of customers or sales, or material disruption of our clinical trials or other business activity.

In the ordinary course of our business, we may collect, process and store proprietary, confidential and sensitive information, including personal information (including key-coded data and health information), intellectual property, trade secrets and proprietary business information owned or controlled by ourselves or other parties.

Despite the implementation of security measures, our information technology systems and data, and those of our CROs and other third parties on which we rely, are vulnerable to system failure, interruption, compromise or damage from several sources, such as data corruption; breakdown; malicious human acts; malicious code (such as computer viruses or worms); fraudulent activity; employee misconduct, theft or error; denial-of-service attacks; public health epidemics (such as the COVID-19 pandemic); cyber-attacks by sophisticated nation-state and nation-state supported actors; natural disasters; terrorism; war; and telecommunication and electrical failures. Moreover, our recovery systems (and those of third parties upon whom we rely) are similarly vulnerable. Any of these events could lead to the unauthorized access, disclosure and use of proprietary, confidential, or otherwise non-public information (such as personal information). The techniques used by criminal actors 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. We may be required to expend significant resources, fundamentally change our business activities and practices, or modify our operations, including our clinical trial activities, or information technology in an effort to protect against security breaches and to mitigate, detect and remediate actual and potential vulnerabilities. Due to the nature of some of these threats, we may be unable to anticipate threats, and there is a risk that a threat may remain undetected for a period of time. The costs of maintaining or upgrading our cyber-security systems at the level commercially reasonable to keep up with our expanding operations and prevent against potential attacks are increasing, and despite our best efforts, our network security and data recovery measures and those of our vendors may still not be adequate to protect against such security breaches and disruptions, which could cause harm to our business, financial condition and results of operations.

If we, our service providers, partners, or other relevant third parties have experienced, or in the future experience, any security incident(s) that result in any data loss, deletion or destruction, unauthorized access to, loss of, acquisition or disclosure of, exposure or disclosure of sensitive information, or compromise related to the security, confidentiality, integrity or availability of our (or their) information technology, software, services, communications or data, it may result in a material adverse impact, including without limitation, fines, damages, litigation, enforcement actions, loss of trade secrets, a material disruption of our drug development programs, or other harm to our business. 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. Additionally, applicable data protection laws, privacy policies and data protection obligations (such as contractual obligations) may require us to notify relevant stakeholders of security breaches, including affected individuals, customers and regulators. Such disclosures are costly, and the disclosure or the failure to comply with such requirements, could lead to material adverse impacts, including without limitation, negative publicity, a loss of confidence in our products or operations or breach of contract claims. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable data protection laws, privacy policies or data protection obligations related to information security or security breaches.

Further, failures or significant downtime of our information technology or telecommunication systems or those used by our third-party service providers could cause significant interruptions in our operations and adversely impact the confidentiality, integrity and availability of sensitive or confidential information, including preventing us from conducting clinical trials, tests or research and development activities and preventing us from managing the administrative aspects of our business.

We cannot be sure that our insurance coverage will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or materially adverse impacts arising out of our privacy and cybersecurity practices, processing or security breaches that we may experience, or that such coverage will continue to be available on acceptable terms at all. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of a large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

Failure or perceived failure to comply with existing or future laws, regulations, contracts, self-regulatory schemes, policies, standards and other obligations related to data privacy or security could lead to government enforcement actions (which could include civil or criminal fines or penalties), a disruption of our clinical trials or commercialization of our products, private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such obligations could increase the costs of our products, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

Regulation of data (including personal data)is evolving, as federal, state, and foreign governments continue to adopt new, or modify existing, laws and regulations addressing data privacy and security, and the collection, processing, storage, transfer, and use of data. We and our collaborators may be subject to current, new, or modified federal, state, and foreign data protection laws and regulations (e.g., laws and regulations that address data privacy and security, including, without limitation, personal data such as health data). These new or proposed laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data. Moreover, we are subject to the terms of our privacy and security policies, representations, certifications, standards, publications, contracts and other obligations to third parties related to data privacy, security and processing. These and other requirements could require us or our collaborators to incur additional costs to achieve compliance, limit our competitiveness, necessitate the acceptance of more onerous obligations in our contracts, restrict our ability to use, store, transfer, and process data, impact our or our collaborators' ability to process or use data in order to support the provision of our products, affect our or our partners' ability to offer our products or operate in certain locations, cause regulators to reject, limit, or disrupt our clinical trial activities, result in increased expenses, reduce overall demand for our products and services and make it more difficult to meet expectations of or commitments to customers or collaborators.

In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state information privacy laws (e.g., the California Consumer Privacy Act of 2018, or CCPA), state health information privacy laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission Act), govern the collection, use, disclosure, and protection of health-related and other personal data. These laws and regulations could apply to our operations, the operations of our collaborators or other relevant stakeholders upon whom we depend. In addition, we may obtain health information from third parties (including research institutions from which we may obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to civil and criminal penalties, including if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

The CCPA became effective on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA requires covered entities to provide new disclosures to California residents. The CCPA provides for civil penalties for violations, as well as a private right of action and statutory damages for data breaches that is expected to increase class action data breach litigation. Although there are limited exemptions for clinical trial data, the CCPA's implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. The CCPA may increase our compliance costs and potential liability. It is anticipated that the CCPA will be expanded on January 1, 2023, when the California Privacy Rights Act of 2020 ("CPRA") becomes operative. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive information, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action and establish a new California Privacy Protection Agency to implement and enforce the new law. These laws demonstrate our vulnerability to the evolving regulatory environment related to personal data. As we expand our operations, these and similar laws may increase our compliance costs and potential liability.

Foreign data protection laws, such as, without limitation, the EU's GDPR and member state data protection laws, may also apply to health-related and other personal information that we process, including, without limitation, personal data relating to clinical trial participants. European data protection laws impose strict obligations on the ability to process health-related and other personal information of data subjects in Europe, including, among other things, standards relating to the privacy and security of personal data, which require the adoption of administrative, physical and technical safeguards designed to protect such information. The United Kingdom's vote in favor of exiting the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. Beginning in 2021, the UK will be a "third country" under the GDPR and transfers of European personal information to the U.K. will require an adequacy mechanism to render such transfers compliant under the GDPR. European data protection laws may affect our use, collection, analysis, and transfer (including cross-border transfer) of such personal information. These laws include several requirements relating to transparency related to communications with data subjects regarding the processing of their personal data, obtaining the consent of the individuals to whom the personal data relates, limitations on data processing, establishing a legal basis for processing, notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects, the security and confidentiality of the personal data and various rights that data subjects may exercise.

European data protection laws prohibit the transfer, without an appropriate legal basis, of personal data to countries outside of Europe, such as to the United States, which are not considered by the relevant authorities to provide an adequate level of data protection. A decision by the Court of Justice of the European Union (the "Schrems II" ruling) invalidated the EU-U.S. Privacy Shield Framework, and raised questions about whether the European Commission's Standard Contractual Clauses ("SCCs"), one of the primary alternatives to the Privacy Shield, can lawfully be used for personal information transfers from Europe to the United States or most other countries. Similarly, the Swiss Federal Data Protection and Information Commissioner recently opined that the Swiss-U.S. Privacy Shield is inadequate for transfers of personal data from Switzerland to the U.S. The United Kingdom, whose data protection laws are similar to those of the European Union, may similarly determine that the EU-U.S. Privacy Shield is not a valid mechanism for lawfully transferring personal data from the United Kingdom to the United States. The European Commission recently proposed updates to the SCCs, and additional regulatory guidance has been released that seeks to impose additional obligations on entities that rely on the SCCs. Given that, at present, there are few, if any, alternatives to the EU-U.S. Privacy Shield and the SCCs, any transfers by us or our vendors of personal data from Europe may not comply with European data protection laws, which may increase our exposure to such laws' sanctions for violations of its cross-border transfer restrictions and may prohibit our transfer of European personal data outside of Europe, and may adversely impact our operations, product development and ability to provide our products. Additionally, other countries have passed or are considering passing laws requiring local data residency and/or restricting the international transfer of data.

For example, under the GDPR, regulators may impose substantial fines and penalties for non-compliance. Entities that violate the GDPR can face fines of up to the greater of 20 million Euros or 4% of their worldwide annual turnover (revenue). Additionally, regulators could prohibit our use of personal data subject to the GDPR. The GDPR has increased our responsibility and liability in relation to personal data that we process, requiring us to put in place additional mechanisms to comply with the GDPR and other foreign data protection requirements.

Failure, or perceived failure, to comply with federal, state and foreign data protection laws and regulations, privacy policies, contracts and other data protection obligations could result in government investigations and enforcement actions (which could include civil or criminal penalties, fines, or sanctions), private litigation, a diversion of management's attention, adverse publicity and other negative effects on our operating results and business. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable data protection laws, privacy policies or data protection obligations related to information security or security breaches. Moreover, clinical trial participants or subjects about whom we or our collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights or failed to comply with data protection laws, contracts, privacy notices or other obligations even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Any of these matters could materially adversely affect our business, financial condition, or operational results.

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

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 $176.00 per share (adjusted to give effect to the 1-for-16 reverse stock split), our stock price has ranged from a low of $1.94 to a high of $418.40 through March 10, 2021. 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.

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

The Deerfield Warrant (as defined below) includes exercise price protection provision, 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 at a sale or exercise price per share less than the greater of (i) $93.60 per share, which represents the Deerfield Warrant's exercise price, or (ii) the closing sale price of our common stock 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 1933, as amended, or the Securities Act, of our common stock, the exercise 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 $93.60 per share, provided that this anti-dilution adjustment will not apply to certain specified sales. For example, in January 2021, we entered into the Inducement Letters with certain holders of the Existing Warrants, pursuant to which such holders exercised for cash their Existing Warrants to purchase 6,620,358 shares of our common stock in exchange the Inducement Warrants on substantially the same terms as the Existing Warrants, except as set forth in the following sentence, to purchase up to 7,944,430 shares of our common stock, which was equal to 120% of the number of shares of our common stock issued upon exercise of the Existing Warrants. The purchase price of the Inducement Warrants was $0.125 per share underlying each Inducement Warrant, and the Inducement Warrants have an exercise price of $6.36 per share. The completion of this transaction resulted in the exercise price of the Deerfield Warrant being adjusted downward to $46.25 per share.

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

We may need additional capital 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.

For instance in January 2021, we issued and sold 6,765,463 shares of our common stock, pre-funded warrants to purchase 926,844 shares of our common stock and warrants to purchase 7,692,307 shares of our common stock at an exercise price per share of $6.50 in the Public Offering. Also in January 2021, the underwriter exercised its over-allotment option, in part, for warrants to purchase 754,035 shares of our common stock. Further, in February 2021, the underwriter again exercised its over-allotment option, in part, to purchase 374,035 shares of our common stock.

Also in January 2021, we entered into the Inducement Letters with certain holders of the Existing Warrants, pursuant to which such holders exercised for cash their Existing Warrants to purchase 6,620,358 shares of our common stock in exchange the Inducement Warrants on substantially the same terms as the Existing Warrants, except as set forth in the following sentence, to purchase up to 7,944,430 shares of our common stock, which was equal to 120% of the number of shares of our common stock issued upon exercise of the Existing Warrants. The purchase price of the Inducement Warrants was $0.125 per share underlying each Inducement Warrant, and the Inducement Warrants have an exercise price of $6.36 per share.

Upon closing of the transactions contemplated under the December 2020 Exchange Agreement in January 2021, the holders of our Series B-2 convertible preferred stock are able to convert all or any portion of their shares of Series B-2 convertible preferred stock at any time following the PDUFA Date (as defined in the certificate of designation) at a conversion price equal to $6.4999 price per share.

According to the terms of the shares of Series B-2 convertible preferred stock in no event may any holder thereof convert such holder's shares of Series B-2 convertible preferred stock 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. 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 an equityholder is only able to convert such holder's shares of Series B-2 convertible preferred stock into a limited number of shares due to this conversion limitation, such shares of Series B-2 convertible preferred stock 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.

If the holders of our shares of Series B-2 convertible preferred stock elect to convert such shares 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.

The accounting method for the Deerfield Warrant, our previously 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 previously 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.

Pursuant to the terms of the December 2020 Exchange Agreement, we have filed a registration statement to register for resale the shares of common stock issuable upon conversion of the shares of preferred stock or exercise of the warrants issued under the December 2020 Exchange Agreement. We also filed a registration statement covering the resale of the shares of our common stock issued or issuable upon the exercise of the Inducement Warrants. 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 the Deerfield Warrant 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 AZSTARYS, KP484 or KP879. 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 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, upon the amendment and restatement of the certificate of designation for our Series B-2 convertible preferred stock, the holders of our Series B-2 convertible preferred stock, if any, will receive an amount equal to the greater of (i) $1,000 per share, or (ii) the amount per share each such holder would have been entitled to receive if every share of Series B-2 Preferred Stock had been converted into common stock immediately prior to such sale of the company, in each case, plus any declared but unpaid dividends thereon. 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, or DGCL, our certificate of incorporation or our bylaws, or (iv) any action asserting a claim against us that is governed by the internal affairs doctrine.

In addition, on and effective July 15, 2020, we amended and restated our bylaws, or the Bylaws, pursuant to which: (i) unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) shall be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (A) any derivative action or proceeding brought on behalf of us; (B) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees, to us or our stockholders; (C) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the DGCL our certificate of incorporation or our Bylaws (as each may be amended from time to time); (D) any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our Bylaws (including any right, obligation, or remedy thereunder); (E) any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (F) any action or proceeding asserting a claim against us or any of our directors, officers or other employees, governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants, *provided that* this provision shall not apply to suits brought to enforce a duty or liability created by the Securities Act or the Securities Exchange Act of 1934, as amended, or the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction; (ii) unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act; and (iii) any person or entity holding, owning or otherwise acquiring any interest in any security of us shall be deemed to have notice of and consented to the provisions of the Bylaws.

These 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 or our Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

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, 2020, we had federal net operating loss carryforwards of approximately $226.0 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, 2020, 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.

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.

General Risk Factors

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.

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.

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.

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 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. 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, 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, 2020, 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 addition, we occupy leased laboratory space in Coralville, Iowa and Blacksburg, Virginia and leased office space in Chapel Hill, North Carolina. 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

Our common stock is listed on The Nasdaq Capital Market under the ticker symbol “KMPH”.

Holders of our Common Stock

As of December 31, 2020, there were approximately 134 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.

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 LAT technology. We utilize our proprietary LAT technology to generate improved prodrug versions of drugs approved by the 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 ADHD, SUD and IH. Our co-lead clinical development candidates, AZSTARYS (formerly referred to as KP415) and KP484, are both based on a prodrug of d-MPH but with differing ER effect profiles, and are intended for the treatment of ADHD. Our clinical product candidate for the treatment of SUD is KP879, based on a prodrug of d-MPH. Our preclinical prodrug product candidate for the treatment of IH is KP1077. We have entered into a collaboration and license agreement with Commave for the development, manufacture and commercialization of our product candidates containing SDX and d-MPH. In addition, we have announced our commercial partnership with KVK of APADAZ, an 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.

We expect that our sources of revenues will be through payments arising from our license agreements with Commave and KVK, our consulting agreement with Corium and through other consulting arrangements and any other future arrangements we might enter into related to one of our other product candidates. To date, we have 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, a regulatory milestone payment of $5.0 million following the FDA's acceptance of the AZSTARYS NDA, of which we paid Aquestive $0.5 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. In addition, we have generated revenue under the Corium Consulting Agreement and other consulting arrangements for the performance of consulting services as well as reimbursement of out-of-pocket third-party costs associated with those services.

On March 2, 2021, we announced that the FDA approved the NDA for AZSTARYS, a once-daily product for the treatment of ADHD in patients ranging from six years and older. Corium will lead the commercialization of AZSTARYS per the KP415 License Agreement. Corium expects to make AZSTARYS commercially available in the U.S. as early as the second half of 2021.

We have had recurring negative cash flows from operations and, as of December 31, 2020, had an accumulated deficit of $258.5 million. Our cash flows used in operations for the years ended December 31, 2020 and 2019 were $1.9 million and $23.7 million, respectively.

We expect to continue to incur significant expenses and minimal positive net cash flows from operations or negative net cash flows from operations 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 royalties earned from the sales of AZSTARYS, APADAZ, or any of our other product candidates for which we obtain regulatory approval. 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 AZSTARYS and KP484. 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 either Commave or KVK will be able to successfully commercialize AZSTARYS or any of our product candidates covered under the KP415 License Agreement, or APADAZ, 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.

Recent Financial Developments

In January and February 2021, we undertook a series of transactions to regain our Nasdaq Capital Market listing and improve our balance sheet. These included a reverse stock split, an underwritten public offering, or the Public Offering, a restructuring or our debt and ultimately a payoff of all remaining debt and a transaction in which we induced the holders of some of the warrants we issued in the public offering to exercise those warrants for cash.

Reverse Stock Split and Nasdaq Relisting

Effective May 21, 2020, our common stock had been delisted from The Nasdaq Capital Market and we began listing on the OTC Markets Venture Market under the symbol “KMPH”. In anticipation of the Public Offering, we determined we would need to regain our Nasdaq listing.

In order to relist our common stock on The Nasdaq Capital Market, our common stock was required to satisfy the initial listing standards of the Nasdaq Capital Market, which including among others, that we have stockholders’ equity of at least $5.0 million, a market value of unrestricted publicly held shares of at least $15.0 million, at least 1.0 million unrestricted publicly held shares, at least 300 unrestricted round lot stockholders, at least three market makers and a bid price of at least $4.00 per share, or, collectively, the Nasdaq Listing Requirements. Accordingly, on December 23, 2020, we effectuated a 1-for-16 reverse stock split of our common stock in order to satisfy the bid price component of the Nasdaq Listing Requirements.

On January 7, 2021, our common stock was approved for listing on The Nasdaq Capital Market. Our common stock began trading on The Nasdaq Capital Market on January 8, 2021 under the ticker symbol “KMPH”.

Debt Restructuring

In anticipation of the Public Offering, and to meet the Nasdaq Listing Requirements, we agreed in December 2020 to restructure our outstanding senior secured convertible notes issued in December 2019 and January 2020, or the Senior Secured Notes, in the aggregate principal amount of $60.8 million and the senior secured convertible promissory note held by Deerfield Private Design Fund III, L.P., or Deerfield, in the principal amount of $7.5 million, or the Deerfield Note, and, collectively the Senior Secured Notes, the Facility Notes. The total outstanding principal and accrued interest under the Facility Notes was $69.4 million as of December 31, 2020.

Under the terms of the agreement we entered into with our lenders in connection with this debt restructuring, which we refer to as the December 2020 Exchange Agreement, on January 12, 2021, in connection with the closing of our Public Offering, we:

- exchanged $31.5 million of the outstanding principal and accrued interest on the Facility Notes for (i) 31,476.98412 shares of our Series B-2 convertible preferred stock, and (ii) warrants exercisable for 3,632,019 shares of our common stock, or the Exchange Warrants; and

- made a payment of $30.3 million, or the Debt Payment, in partial repayment of the remaining outstanding principal and accrued interest on the Facility Notes.

Each share of Series B-2 convertible preferred stock issued pursuant to the December 2020 Exchange Agreement has a stated value of $1,000 and is convertible into shares of our common stock at any time following the earlier of March 2, 2021 or our public announcement of the outcome of the FDA’s review of our AZSTARYS NDA at the option of the holder thereof, subject to specified limits, at a conversion price of $6.4999. The shares of Series B-2 convertible preferred stock issued under the December 2020 Exchange Agreement are convertible into an aggregate of 4,842,690 shares of our common stock.

The Exchange Warrants have substantially the same terms and conditions as the warrants sold by us in our January 2021 underwritten offering.

Following the completion of these transactions, the aggregate balance of principal and accrued interest remaining outstanding under the Facility Notes was approximately $7.6 million. With respect to this remaining outstanding balance under the Facility Notes, the December 2020 Exchange Agreement amended the terms of that debt to provide that:

- the maturity date was changed to March 31, 2023, and the debt is prepayable upon specified conditions; and

- interest would accrue at the rate of 6.75% per annum, payable quarterly, would be added to principal until June 30, 2021, and then be payable in cash thereafter.

In connection with the closing of the transactions contemplated under the December 2020 Exchange Agreement, we filed an amended and restated certificate of designation with the Secretary of State of Delaware in order to modify the terms of our authorized, but unissued, shares of Series B-2 convertible preferred stock to reflect those contemplated under the December 2020 Exchange Agreement.

We also filed a registration statement to register for resale under the Securities Act the shares of common stock issuable upon conversion of the shares of Series B-2 convertible preferred stock and exercise of the Exchange Warrants.

Public Offering

On January 8, 2021, we issued and sold 6,765,463 shares of our common stock, pre-funded warrants to purchase 926,844 shares of our common stock and warrants to purchase 7,692,307 shares of our common stock at an exercise price per share of $6.50 in the Public Offering. In addition, we granted the underwriter for the Public Offering an option to purchase, for a period of 45 days, up to an additional 1,153,846 shares of our common stock and/or warrants to purchase up to an additional 1,153,846 shares of our common stock. On January 8, 2021, the underwriter exercised its over-allotment option, in part, for warrants to purchase 754,035 shares of our common stock. On January 12, 2021, we closed the Public Offering. Further, on February 1, 2021, the underwriter again exercised its over-allotment option, in part, to purchase 374,035 shares of our common stock. On February 3, 2021, we closed the underwriter's partial exercise of its over-allotment option.

The aggregate gross proceeds to us from the Public Offering, including from the exercises by the underwriter of its over-allotment option, totaled $52.4 million, before deducting underwriting discounts and commissions and offering expenses payable by us.

December 2020 Exchange Agreement Amendment

On January 12, 2021, in connection with the transactions contemplated by the December 2020 Exchange Agreement, we entered into an Amendment to Senior Secured Convertible Notes and Amendment to Warrant, or the January 2021 Amendment, with Deerfield and Deerfield Special Situations Fund, LP, collectively the Deerfield Holders. The January 2021 Amendment modified certain specified terms of (i) the Facility Notes and (ii) the warrant held be Deerfield, issued on June 2, 2014, or the Deerfield Warrant, to, among other things, exclude the transactions contemplated by the December 2020 Exchange Agreement and issuance of securities pursuant to the Underwriting Agreement from the anti-dilution provisions of the Facility Notes and the Deerfield Warrant.

Warrant Exercise Inducement Letters and Issuance of Warrants

On January 26, 2021, we entered into warrant exercise inducement offer letters, or the Inducement Letters, with certain holders of warrants issued in the Public Offering, or the Existing Warrants, and collectively, the Exercising Holders, pursuant to which such holders exercised for cash their Existing Warrants to purchase 6,620,358 shares of our common stock in exchange for new warrants, or the Inducement Warrants, on substantially the same terms as the Existing Warrants, except as set forth in the following sentence, to purchase up to 7,944,430 shares of our common stock, which was equal to 120% of the number of shares of our common stock issued upon exercise of the Existing Warrants. The purchase price of the Inducement Warrants was $0.125 per share underlying each Inducement Warrant, and the Inducement Warrants have an exercise price of $6.36 per share. We received aggregate gross proceeds of $44.0 million from the exercise of the Existing Warrants by the Exercising Holders and the sale of the Inducement Warrants.

We also filed a registration statement on Form S-3 covering the resale of the shares of our common stock issued or issuable upon the exercise of the Inducement Warrants which was declared effective on February 16, 2021.

Payoff of Facility Agreement Notes and Termination of Facility Agreement

On February 8, 2021, we entered into a payoff letter with the Facility Note holders, pursuant to which we agreed to pay off and thereby terminate the Facility Agreement.

Pursuant to the payoff letter, we paid a total of $8.0 million to the Facility Note holders, representing the principal balance, accrued interest outstanding and a prepayment fee in repayment of our outstanding obligations under the Facility Agreement.

Pursuant to the payoff letter, all outstanding indebtedness and obligations of us owing to the Facility Note holders under the Facility Agreement have been paid in full. The Facility Agreement and the notes thereunder, as well as the security interests in the assets of us securing the Facility Agreement and note obligations, have been terminated.

Third-Party Agreements

KP415 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 AZSTARYS, 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 AZSTARYS 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 AZSTARYS, including FDA approval and specified conditions with respect to the final approval label, and KP484. As a result of the FDA's approval of the AZSTARYS NDA, we have earned a regulatory milestone payment following FDA approval as provided under the KP415 License Agreement, and we are working with Commave to evaluate the related provisions and amounts. 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 AZSTARYS and its final approved label, if any. In May 2020, the FDA accepted our NDA for AZSTARYS. Per the KP415 License Agreement, we received a regulatory milestone payment of $5.0 million following the FDA's acceptance of the AZSTARYS NDA. 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 AZSTARYS 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 AZSTARYS and KP484; provided that Commave shall be the sponsor of any clinical trials conducted by us on behalf of Commave.

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.

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 AZSTARYS and KP484. In early 2019, Shire was acquired by Takeda Pharmaceutical Company, Ltd, or 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 AZSTARYS, KP484 or KP879, and any product candidates containing SDX, including royalty payments on any license of AZSTARYS, KP484 or KP879, the sale of AZSTARYS, KP484 or KP879 to a third party, the commercialization of AZSTARYS, KP484 or KP879 and the portion of any consideration that is attributable to the value of AZSTARYS, 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 and the regulatory milestone payment we received in the second quarter of 2020.

In July 2020, we entered into the Corium Consulting Agreement under which Corium engaged us to guide the product development and regulatory activities for certain current and potential future products in their portfolio, as well as continue supporting preparation for the potential commercial launch of AZSTARYS. Under the Corium Consulting Agreement, we are entitled to receive payments from Corium of up to $15.6 million, $13.6 million of which will be paid in quarterly installments through March 31, 2022. The remaining $2.0 million is conditioned upon the achievement of a specified regulatory milestone related to Corium's product portfolio. Corium also agreed to be responsible for and reimburse us for all development, commercialization and regulatory expenses incurred as part of the performance of the consulting services.

Components of our Results of Operations

Revenue

Our commercial revenue, if any, will be derived from sales of AZSTARYS, APADAZ or any of our 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 Commave and KVK, and through any other future arrangements related to one of our other product candidates. To date, we have 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, a regulatory milestone payment of $5.0 million following the FDA's acceptance of the AZSTARYS NDA, of which we paid Aquestive $0.5 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. In addition, we have generated revenue under the Corium Consulting Agreement and other consulting arrangements for the performance of consulting services as well as reimbursement of out-of-pocket third-party costs associated with those services. We cannot guarantee that either Commave or KVK will be able to successfully commercialize AZSTARYS or our product candidates covered under the KP415 License Agreement, or APADAZ, or that we will ever receive any payments under the KP415 License Agreement from commercial sales of APADAZ or any future payments under the APADAZ 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 generated revenue from the KP415 License Agreement in the form of the non-refundable upfront payment of $10.0 million, a regulatory milestone payment of $5.0 million following the FDA's acceptance of the AZSTARYS NDA, 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 10% of the regulatory milestone, related to the acceptance of the NDA, we received in the second quarter of 2020. In addition, we 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, 2020 and 2019 (in thousands):

	Year Ended December 31,	
	2020	**2019**
Outsourced development costs directly identified to programs:		
AZSTARYS	$ 726	$ 7,831
KP484	5	24
APADAZ	444	3,866
Total outsourced development costs directly identified to programs	1,175	11,721
Research and development costs not directly identified to programs:		
Personnel costs including cash compensation, benefits and stock-based compensation	5,645	5,204
Facilities costs	523	599
Other costs	1,500	1,891
Total research and development costs not directly allocated to programs	7,668	7,694
Total research and development expenses	$ 8,843	$ 19,415

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 AZSTARYS, APADAZ, and any of our other product candidates that may be approved and the development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs required to commercialize AZSTARYS, APADAZ, or any of our other 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 our 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 in 2020 consisted of severance payments and stock-based compensation paid to our former chief business officer who ceased to serve in this role in February 2020. We had no severance expense in 2019.

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. 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, 2020 and 2019 (in thousands):

	Year Ended December 31,		Period-to Period Change
	2020	2019	
Revenue	$ 13,288	$ 12,839	$ 449
Operating expenses:			
Royalty and direct contract acquisition costs	1,305	2,945	(1,640)
Research and development	8,843	19,415	(10,572)
General and administrative	7,921	10,816	(2,895)
Severance expense	828	-	828
Total operating expenses	18,897	33,176	(14,279)
Loss from operations	(5,609)	(20,337)	14,728
Other (expense) income:			
Interest expense related to amortization of debt issuance costs and discount	(2,305)	(1,656)	(649)
Interest expense on principal	(4,785)	(4,858)	73
Fair value adjustment related to derivative and warrant liability	(184)	1,998	(2,182)
Interest and other income, net	89	309	(220)
Total other (expense) income	(7,185)	(4,207)	(2,978)
Loss before income taxes	(12,794)	(24,544)	11,750
Income tax benefit	34	22	12
Net loss	$ (12,760)	$ (24,522)	$ 11,762

Net Loss

Net loss for the year ended December 31, 2020 was $12.8 million, a decrease of $11.8 million compared to net loss for the year ended December 31, 2019 of $24.5 million. The decrease was primarily attributable to a decrease in loss from operations of $14.7 million, partially offset by a change in non-cash fair value adjustment from income of $2.0 million in 2019 to expense of $0.2 million in 2020, related to changes to the derivative and warrant liability, and an increase in net interest expense and other items of $0.8 million.

Revenue

Revenue increased by $0.4 million, from $12.8 million for the year ended December 31, 2019, to $13.3 million for the year ended December 31, 2020. This increase was primarily attributable to an increase in consulting revenue of $5.3 million, primarily related to the Corium Consulting Agreement, and an increase in reimbursement revenue of $0.2 million, partially offset by a decrease in licensing and milestone revenue of $5.0 million, due to the one-time non-refundable upfront payment of $10.0 million received in 2019 compared to, the $5.0 million payment received related to the regulatory milestone in 2020 both pursuant to the KP415 License Agreement.

Royalties and Contract Costs

Royalties and contract costs decreased by $1.6 million, from $2.9 million for the year ended December 31, 2019, to $1.3 million for the year ended December 31, 2020. This decrease was primarily attributable to a decrease in royalties due to Aquestive of $0.5 million related to the upfront and milestone payments we received in 2019 and 2020 discussed above and a decrease in the amortization of capitalized contract costs which were directly attributable to the revenue recognized of $1.1 million.

Research and Development

Research and development expenses decreased by $10.6 million, from $19.4 million for the year ended December 31, 2019, to $8.8 million for the year ended December 31, 2020. This decrease was primarily attributable to a decrease in net third-party research and development costs.

General and Administrative

General and administrative expenses decreased by $2.9 million, from $10.8 million for the year ended December 31, 2019, to $7.9 million for the year ended December 31, 2020. This decrease was primarily attributable to a decrease in professional fees and personnel-related costs.

Severance Expense

Severance expense of $0.8 million was recognized for the year ended December 31, 2020 due to the termination of our chief business officer in February 2020. Severance expense is comprised of $0.4 million of personnel and other related charges and $0.4 million of stock compensation expense related to the acceleration of vesting on certain stock options upon employee termination. We had no severance expense for the year ended December 31, 2019.

Other (Expense) Income

Other expenses increased by $3.0 million, from $4.2 million for the year ended December 31, 2019, to $7.2 million for the year ended December 31, 2020. This period-to-period increase in expense was primarily attributable to a change in non-cash fair value adjustment from income of $2.0 million in 2019 to expense of $0.2 million in 2020 related to our derivative and warrant liability and an increase in net interest expense and other items of $0.8 million.

Comparison for Years Ended December 31, 2019 and 2018

For a discussion and analysis of changes in financial condition and results of operations for the year ended December 31, 2019 as compared to the year ended December 31, 2018, refer to our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on February 28, 2020.

Liquidity and Capital Resources

Sources of Liquidity

Through December 31, 2020, 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 purchase agreements with Lincoln Park Capital LLC, or Lincoln Park, and from revenue received under the KP415 License Agreement, the Corium Consulting Agreement and other consulting arrangements. As of December 31, 2020, we had cash and cash equivalents of $4.2 million and restricted cash of $0.1 million.

In February 2019, we entered into a purchase agreement for an equity line of credit, or the 2019 ELOC 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 2019 ELOC Agreement, and upon execution of the 2019 ELOC Agreement we issued an additional 7,512 shares of our common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the 2019 ELOC Agreement. In February 2020, upon entering into a new purchase agreement for an equity line of credit, or the 2020 ELOC Agreement, with Lincoln Park, we terminated the 2019 ELOC Agreement. As a result, we will not make any future sales under the 2019 ELOC Agreement. Through the date of termination, we sold 212,579 shares of our common stock (exclusive of the 7,512 commitment shares) to Lincoln Park under the 2019 ELOC 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 May 2020, the FDA accepted our NDA for AZSTARYS. Per the KP415 License Agreement, we received a regulatory milestone payment of $5.0 million following the FDA's acceptance of the AZSTARYS NDA. In July 2020, we entered into the Corium Consulting Agreement under which Corium engaged us to guide the product development and regulatory activities for certain current and potential future products in their portfolio, as well as continue supporting preparation for the potential commercial launch of AZSTARYS. Under the Corium Consulting Agreement, we are entitled to receive payments from Corium of up to $15.6 million, $13.6 million of which will be paid in quarterly installments through March 31, 2022. The remaining $2.0 million is conditioned upon the achievement of a specified regulatory milestone related to Corium's product portfolio. Corium also agreed to be responsible for and reimburse us for all development, commercialization and regulatory expenses incurred as part of the performance of the consulting services.

In February 2020, we entered into the 2020 ELOC 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 2020 ELOC Agreement, and upon execution of the 2020 ELOC Agreement we issued an additional 19,289 shares of our common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the 2020 ELOC Agreement. In May 2020, we reached the maximum allowable shares to be issued under the Current Registration Statement of 579,260 shares and therefore we cannot issue additional shares under the 2020 ELOC Agreement. As of December 31, 2020, we have sold 559,971 shares of common stock (exclusive of the 19,289 commitment shares previously issued to Lincoln Park) under the 2020 ELOC Agreement for approximately $2.3 million in gross proceeds.

We have had recurring negative operating cash flows and, as of December 31, 2020, had an accumulated deficit of $258.5 million. We anticipate that we will continue to incur minimal positive net cash flows from operations or negative net cash flows from operations for at least the next several years. We expect that our sources of revenue will be through payments arising from our license agreements with Commave and KVK, or through our Corium Consulting Agreement, and other potential consulting arrangements and any other future arrangements related to one of our other product candidates.

In January 2021, we completed the Public Offering. The aggregate gross proceeds to us from the Public Offering, including from the exercises by the underwriter of its over-allotment option, totaled $52.4 million, before deducting underwriting discounts and commissions and offering expenses payable by us.

In January 2021, we entered into the Inducement Letters. We received aggregate gross proceeds of $44.0 million from the exercise of the Existing Warrants by the Exercising Holders and the sale of the Inducement Warrants.

On April 23, 2020, we received proceeds of $0.8 million from a loan, or the PPP Loan, under the Paycheck Protection Program, or the PPP, of the recently enacted Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, a portion of which may be forgiven, which we used to retain current employees, maintain payroll and make lease and utility payments. The PPP Loan matures on April 23, 2022 and bears annual interest at a rate of 1.0%. Payments of principal and interest on the PPP Loan are deferred for the first 16 months of the PPP Loan term. Thereafter, we could be required to pay the lender equal monthly payments of principal and interest.

The CARES Act and the PPP provide a mechanism for forgiveness of up to the full amount borrowed. Under the PPP, we may apply for and be granted forgiveness for all or part of the PPP Loan. The amount of loan proceeds eligible for forgiveness was originally based on a formula that takes into account a number of factors, including the amount of loan proceeds used by us during the 24-week period after the loan origination for certain purposes, including payroll costs, interest on certain mortgage obligations, rent payments on certain leases, and certain qualified utility payments, provided that at least 60% of the loan amount was used for eligible payroll costs. Subject to the other requirements and limitations on loan forgiveness, only loan proceeds spent on payroll and other eligible costs during the covered 24-week period qualify for forgiveness. We have applied for forgiveness under the provisions of the PPP loan and are awaiting a decision by the SBA.

Convertible Debt

As of December 31, 2020, we had $68.2 million of convertible notes outstanding, consisting of senior secured convertible promissory notes issued, under the Deerfield Facility Agreement with Deerfield. Subsequent to December 31, 2020, we repaid in full the convertible notes and terminated the Deerfield Facility Agreement.

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.

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 37,410 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).

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 16,025 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 120,192 shares of our common stock at an exercise price of $93.60 per share.

2021 Notes

In February 2016, we issued our 5.50% Senior Convertible Notes due 2021, or the 2021 Notes, in aggregate principal amount of $86.3 million. The 2021 Notes were originally issued to Cowen and Company and RBCCM LLC as representatives of the several initial purchasers, who subsequently resold the 2021 Notes to qualified institutional buyers in reliance on the exemption from registration provided by Rule 144A under the Securities Act.

The 2021 Notes were issued pursuant to an indenture, dated as of February 9, 2016, or the indenture, between us 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.

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 the December 2019 Notes and January 2020 Note 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 $48.00 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, 2020, all 9,577 shares of Series A Preferred Stock issued under the October 2018 Exchange Agreement have been converted into an aggregate 199,519 shares of our common stock.

2021 Note Exchange Effected in September 2019

In September 2019, we entered into an Exchange Agreement and Amendment to Facility Agreement, or the September 2019 Exchange Agreement with the Deerfield Lenders. Under the September 2019 Exchange Agreement, we issued an aggregate of 493,742 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) $15.1904 or (ii) the average of the volume-weighted average price of the common stock 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 $15.1904 per share (subject to adjustment to reflect stock splits and similar events). There was an aggregate of 103,749 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) $15.1904 (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 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 1,777,437 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 our 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 we fail 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, 2020, all 1,576 shares of Series B-1 Preferred Stock have been converted into 103,749 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 the December 2019 Notes as senior secured convertible promissory notes under the Deerfield Facility Agreement in the aggregate principal amount of $71,418,011 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 260,876 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 $93.60 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 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, 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 $93.60 per share, provided that this anti-dilution adjustment will not apply to certain specified sales. 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; our liquidation, bankruptcy or other dissolution; 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), 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 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 (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 we 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 $93.60 per share, subject to adjustment on the same basis as the December 2019 Notes.

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 us 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) $9.60, 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 each of the 15 trading days immediately preceding such exchange, (iii) provide that no more than 1,777,437 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 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 our 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) $9.60 (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 each of the 15 trading days immediately preceding such exchange.

As of December 31, 2020, the Deerfield Lenders have converted $17.1 million of principal on the December 2019 Notes into all 1,777,437 shares of common stock issuable under the Deerfield Optional Conversion Feature.

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 the January 2020 Note as a senior secured convertible note in the aggregate principal amount of $3,037,354 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 $273.76 to $93.60 per share, (b) increased the Floor Price (as defined in the December 2019 Notes) from $6.08 to $9.328 per share, and (ii) amended 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). 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 our common stock, assuming a conversion date of January 13, 2020.

Debt Restructuring

In December 2020, we entered into the December 2020 Exchange Agreement, which was amended on December 24, 2020. Pursuant to the December 2020 Exchange Agreement, and (a) we made the Debt Payment as a cash pre-payment of a portion of principal amount of the Senior Secured Notes and the Deerfield Note to the Deerfield Lenders, DSC and Kingdon, or, collectively, the Holders, in an aggregate amount equal to approximately $30.3 million,; and (b) issued 31,476.98412 shares of our Series B-2 Preferred Stock and warrants exercisable for 3,632,019 shares of our common stock, or the Exchange Warrants, in exchange for the cancellation of a portion of the principal amount of the Senior Secured Notes and Deerfield Note owned by the Holders, with such transaction referred to as the Exchange. Immediately following the completion of the Exchange and Debt Payment, the aggregate balance of principal and accrued interest remaining outstanding under the Facility Notes was approximately $7.6 million.

The December 2020 Exchange Agreement amended the Senior Secured Notes to provide that the failure of our common stock to remain listed on an eligible securities market will not constitute a "Major Transaction" unless such failure occurs after March 31, 2023.

The December 2020 Exchange Agreement amended the Deerfield Facility Agreement in order to, among other things, (i) extend the maturity date of the Senior Secured Notes and the Deerfield Note to March 31, 2023, (ii) provide for cash payments of interest on the Loans (as defined in the Deerfield Facility Agreement) for the periods following July 1, 2021, and (iii) provide for specified prepayment terms on the Loans.

The December 2020 Exchange Agreement amended that certain Amended and Restated Investors' Rights Agreement, dated as of February 19, 2015, or the IRA, by and among us, Deerfield and the other parties signatory thereto in order to, among other things, add Deerfield Special Situations Fund, L.P. as a party thereto and to give effect to the issuance of the Exchange Warrants and our registration obligations under the December 2020 Exchange Agreement (as described in more detail below).

The Exercise Warrants are subject to substantially the same terms and conditions as the Existing Warrants, with an exercise price equal to the exercise price per share of the Existing Warrants and will provide that the Holders will be limited from exercising such Exchange Warrants if, as a result of such exercise, 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.

Pursuant to the terms of the December 2020 Exchange Agreement, we also filed a registration statement to register for resale under the Securities Act the shares of common stock issuable upon conversion of the shares of Series B-2 Preferred Stock and exercise of the Exchange Warrants.

In connection with the December 2020 Exchange Agreement, we filed an Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series B-2 Convertible Preferred Stock, or the Amended and Restated 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-2 Preferred Stock.

The shares of Series B-2 Preferred Stock are convertible into an aggregate of 4,842,690 shares of our common stock. Each share of Series B-2 Preferred Stock will have an aggregate stated value of $1,000 and will be convertible into shares of our common stock at a per share price equal to $6.4999 (subject to adjustment to reflect stock splits and similar events).

The Series B-2 Preferred Stock will be convertible at any time on or after the PDUFA Date (as defined in the Amended and Restated Series B-2 Certificate of Designation) at the option of the holders thereof; provided that the holders thereof will be prohibited from converting shares of Series B-2 Preferred Stock into shares 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-2 Preferred Stock will not be redeemable. In the event of our liquidation, dissolution or winding up or our change in control, the holders of Series B-2 Preferred Stock will receive, prior to any distribution or payment on our common stock, an amount equal to the greater of (i) $1,000 per share (in the case of a change in control, transaction consideration with such value), or (ii) the amount (in the case of a change in control, in the form of the transaction consideration) per share each such holder would have been entitled to receive if every share of Series B-2 Preferred Stock had been converted into common stock immediately prior to such event, in each case, plus any declared but unpaid dividends thereon. With respect to rights upon liquidation, the Series B-2 Preferred Stock will rank senior to our common stock, on parity with any Parity Securities (as defined in the Amended and Restated Series B-2 Certificate of Designation) and junior to any Senior Securities (as defined in the Amended and Restated Series B-2 Certificate of Designation) and existing and future indebtedness. Except as otherwise required by law (or with respect to approval of certain actions involving our organizational documents that adversely affect the holders of Series B-2 Preferred Stock and other specified matters regarding the rights, preferences and privileges of the Series B-2 Preferred Stock), the Series B-2 Preferred Stock will not have voting rights. The Series B-2 Preferred Stock will not be subject to any price-based anti-dilution protections and will not provide for any accruing dividends, but will provide that holders of Series B-2 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 Amended and Restated Series B-2 Certificate of Designation also provides for partial liquidated damages in the event that we fail to timely convert shares of Series B-2 Preferred Stock into common stock in accordance with the Amended and Restated Series B-2 Certificate of Designation.

December 2020 Exchange Agreement Amendment

On January 12, 2021, in connection with the transactions contemplated by the December 2020 Exchange Agreement, we entered into an Amendment to Senior Secured Convertible Notes and Amendment to Warrant, or the January 2021 Amendment, with the Deerfield Holders. The January 2021 Amendment modifies certain specified terms of (i) the Facility Notes and (ii) the Deerfield Warrant to, among other things, exclude the transactions contemplated by the December 2020 Exchange Agreement and issuance of securities pursuant to the Underwriting Agreement from the anti-dilution provisions of the Facility Notes and the Deerfield Warrant.

Series B-2 Preferred Stock

On January 11, 2021, as a condition to closing of the transactions contemplated by the December 2020 Exchange Agreement, we filed an Amended and Restated 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-2 Preferred Stock.

Payoff of Facility Agreement Notes and Termination of Facility Agreement

On February 8, 2021, we entered into a payoff letter with the Facility Agreement Note Holders, pursuant to which we agreed to pay off and thereby terminate the Facility Agreement.

Pursuant to the payoff letter, we paid a total of $8.0 million to the Facility Agreement Note Holders, representing the principal balance, accrued interest outstanding and a prepayment fee in repayment of our outstanding obligations under the Facility Agreement.

Pursuant to the payoff letter, all outstanding indebtedness and obligations of us owing to the Facility Agreement Note Holders under the Facility Agreement have been paid in full. The Facility Agreement and the notes thereunder, as well as the security interests in the assets of us securing the Facility Agreement and note obligations, have been terminated. The Facility Agreement Note Holders will retain the warrants previously issued to them.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2020 and 2019 (in thousands):

	Year Ended December 31,		Period-to Period Change
	2020	2019	
Net cash used in operating activities	$ (1,939)	$ (23,737)	$ 21,798
Net cash (used in) provided by investing activities	(33)	3,234	(3,267)
Net cash provided by financing activities	2,739	4,939	(2,200)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 767	$ (15,564)	$ 16,331

Operating Activities

For the year ended December 31, 2020, net cash used in operating activities of $1.9 million consisted of a net loss of $12.8 million, partially offset by $0.4 million in changes in working capital and $10.4 million in adjustments for non-cash items. Net loss was primarily attributable to our spending on research and development programs and operating costs, partially offset by revenue received under the KP415 License Agreement and the Corium Consulting Agreement. The changes in working capital consisted of $0.9 million related to a change in accounts payable and accrued expenses, $0.2 million related to a change in prepaid expenses and other assets and $0.3 million related to operating lease right-of-use assets and other liabilities, partially offset by $0.7 million related to a change in accounts and other receivables and $0.3 million related to operating lease liabilities. The adjustments for non-cash items primarily consisted of stock-based compensation expense of $2.5 million, non-cash interest expense of $4.7 million, amortization of debt issuance costs and debt discount of $2.3 million, loss on sublease and disposal of property and equipment of $0.3 million, a change in the fair value adjustment related to derivative and warrant liabilities of $0.2 million and $0.4 million related to depreciation, amortization and other items.

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.

Investing Activities

For the year ended December 31, 2020, net cash used in investing activities was $33,000, which was attributable to purchases of property and equipment.

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 of $3.3 million, partially offset by purchases of property and equipment of $0.1 million.

Financing Activities

For the year ended December 31, 2020, net cash provided by financing activities was $2.7 million, which was primarily attributable to proceeds from sales of our common stock under the 2020 ELOC of $2.3 million and proceeds from the PPP loan of $0.8 million, partially offset by repayment of principal on finance lease liabilities of $0.2 million and payment of debt issuance and deferred offerings costs of $0.1 million.

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 2019 ELOC 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.

Future Funding Requirements

Based on our current operating forecast, we believe that the proceeds from the Public Offering and inducement warrant transactions, together with our existing cash resources and after giving effect to the Deerfield Debt Payment and the Exchange, will be sufficient to fund our operations at least through Q1 2024. This estimate does not include our projected revenue, a portion of which is based royalties from commercial sales and upon the achievement of milestones in the KP415 License Agreement and the APADAZ License Agreement. Certain of the milestones are associated with regulatory matters that are outside our control.

Potential near-term sources of additional funding include:

- any revenues generated under either the KP415 License Agreement or the APADAZ License Agreement;
- any consulting services revenue or short-term milestone payments generated under the KP415 License Agreement;
- any consulting services revenue or short-term milestone payments generated under the Corium Consulting Agreement; and
- any consulting services revenue generated under other potential consulting arrangements.

We cannot guarantee that we will be able to generate sufficient proceeds from any of these potential sources to fund our operating expenses.

To date, we have generated revenue from the non-refundable upfront payment, regulatory milestone payment, reimbursements of out-of-pocket third-party research and development costs and consulting services under the KP415 License Agreement, consulting services, and associated out-of-pocket third-party costs, under the Corium Consulting Agreement and consulting services under other consulting arrangements. We expect that our only sources of revenues will be through payments arising from the KP415 License Agreement, the APADAZ License Agreement, the Corium Consulting Agreement, or through other potential consulting arrangements and 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 AZSTARYS and KP484, we cannot guarantee that this, or any strategy we adopt in the future, will be successful. For instance, we received a milestone payment of $5.0 million under the KP415 License Agreement due to the FDA's acceptance of the AZSTARYS NDA, and we have earned a regulatory milestone payment for the approval of the AZSTARYS NDA, but we cannot guarantee that we will earn any additional milestone or royalty payments under this agreement in the future. 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.

In March 2020, the World Health Organization declared the outbreak of COVID-19, a novel strain of Coronavirus, a global pandemic. This outbreak is causing major disruptions to businesses and markets worldwide as the virus spreads. We cannot predict what the long-term effects of this pandemic and the resulting economic disruptions may have on our liquidity and results of operations. The extent of the effect of the COVID-19 pandemic on our liquidity and results of operations will depend on a number future developments, including the duration, spread and intensity of the pandemic, and governmental, regulatory and private sector responses, all of which are uncertain and difficult to predict. The COVID-19 pandemic may make it more difficult for us to enroll patients in any future clinical trials or cause delays in the regulatory approval of our product candidates, including causing potential delay of the FDA's review of our AZSTARYS NDA. A portion of our projected revenue is based upon the achievement of milestones in the KP415 License Agreement associated with regulatory matters that may be impacted by the COVID-19 pandemic. As a result, we cannot predict what, if any, impact that the COVID-19 pandemic may have on our ability to achieve these milestones. The economic uncertainty surrounding the COVID-19 pandemic may also dramatically reduce our ability to secure debt or equity financing necessary to support our operations. We are unable to currently estimate the financial effect of the pandemic. If the pandemic continues to be a severe worldwide crisis, it could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

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 the KP415 License Agreement, the APADAZ License Agreement, the Corium Consulting Agreement, and other potential consulting arrangements 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.

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,	
	2020	**2019**
Research and development	$ 937	$ 1,459
General and administrative	1,134	2,951
Severance expense	420	-
Total stock-based compensation	$ 2,491	$ 4,410

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,	
	2020	**2019**
Risk-free interest rate	0.38% - 1.65%	1.75% - 2.61%
Expected term (in years)	5.50 - 10.00	5.50 - 10.00
Expected volatility	89.49% - 93.07%	84.82% - 85.93%
Expected dividend yield	0	0

Fair Value of Financial Instruments

We have a common stock warrant issued to Deerfield, put options embedded within those Deerfield warrants, 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, and put options embedded within the Deerfield Warrants 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 $230,000 and $77,000 at December 31, 2020 and 2019, respectively. The derivative liability for the put options embedded within the Deerfield common stock warrant was $25,000 and $19,000 at December 31, 2020 and 2019, respectively. The derivative liability for the KVK common stock warrant was $49,000 and $24,000 at December 31, 2020 and 2019, respectively. A 10% increase in the enterprise value would result in an increase of $29,000 in the estimated fair value of the Deerfield common stock warrant, an increase of $8,000 in the estimated fair value of the put options embedded within the Deerfield common stock warrant and an increase of $8,000 in the estimated fair value of the KVK common stock warrant at December 31, 2020. 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, 2020, we had federal net operating loss, or NOL, carryforwards of approximately $226.0 million, due to prior period losses, $138.1 million of which, if not utilized, will begin to expire in 2027 and $87.8 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.

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 June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326)—Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which replaces the incurred loss impairment methodology with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. This update applies to all entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. The amendments affect loans, debt securities, trade receivables, net investments in leases, off-balance-sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The adoption of ASU 2016-13 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* ("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. The adoption of ASU 2018-13 did not have a material impact on our financial statements and disclosures.

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40); Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"), which addresses issues identified as a result of the complexities associated with applying U.S. GAAP for certain financial instruments with characteristics of liabilities and equity. This update addresses, among other things, the number of accounting models for convertible debt instruments and convertible preferred stock, targeted improvements to the disclosures for convertible instruments and earnings-per-share ("EPS") guidance and amendments to the guidance for the derivatives scope exception for contracts in an entity's own equity, as well as the related EPS guidance. This update applies to all entities that issue convertible instruments and/or contracts in an entity's own equity. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. FASB specified that an entity should adopt the guidance as of the beginning of its annual fiscal year. We are currently evaluating the impact the adoption of ASU 2020-06 could have 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, 2020. Based on the evaluation of our disclosure controls and procedures as of December 31, 2020, our chief executive officer and our chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal 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 effective as of December 31, 2020, the end of our most recent fiscal year.

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 a smaller reporting company, 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

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, we noted a material change in our internal controls over financial reporting where we entered into an agreement with a third-party financial accounting advisory firm to provide professional services on an as-needed basis. These services could range from technical accounting assistance to staff loan opportunities dependent upon our needs.

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 2021 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, 2020 and 2019, 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, 2020 and 2019, 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.

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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

As described in Note B to the financial statements, the Company's revenues are derived from contracts with customers that may include multiple performance obligations, consideration constrained by regulatory milestones over which the Company may have little or no control, and services that may be delivered over a period of time. Management exercises significant judgement in determining revenue recognition for these customer agreements including:

- Determination of stand-alone selling prices (SSP) for each distinct performance obligation.
- Timing of when revenue is recognized for each distinct performance obligation.
- Estimation of constrained consideration to be included in the transaction price when determining the amount of revenue to recognize.
- Determining the time period over which to recognize revenue.

We identified the Company's revenue recognition related to its collaboration and license contracts and other contracts as a critical audit matter because the identification of accounting performance obligations, determination of the initial transaction price and estimation of SSP for each performance obligation and estimation of the period over which to recognize revenue required significant audit effort and a high degree of auditor judgment and subjectivity to evaluate the evidence obtained.

Our procedures related to the Company's revenue recognition for these customer agreements included the following, among others:

- Evaluated the Company's significant accounting policies related to customer agreements in accordance with the applicable accounting standards.
- Obtained customer agreements and performed the following procedures, among others:
  - Obtained and read contract source documents, including master agreements, statements of work, and other documents that were part of the agreement.
  - Tested management's identification of significant terms for completeness, including the identification of distinct performance obligations and constrained consideration.
  - Tested management's evaluation of the time period over which revenue should be recognized.
- Evaluated management's estimate of SSP related to products and services that are not sold separately for reasonableness and tested the completeness and accuracy of the data used in determining the SSP.

/s/ RSM US LLP

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

Orlando, Florida
March 11, 2021

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

	December 31,	
	2020	**2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 4,213	$ 3,217
Accounts and other receivables	2,579	1,865
Prepaid expenses and other current assets	1,481	1,552
Restricted cash	109	338
Total current assets	8,382	6,972
Property and equipment, net	1,039	1,471
Operating lease right-of-use assets	1,350	1,537
Other long-term assets	438	527
Total assets	$ 11,209	$ 10,507
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 6,647	$ 4,911
Current portion of operating lease liabilities	327	284
Current portion of loans payable	390	-
Other current liabilities	172	236
Total current liabilities	7,536	5,431
Convertible notes, less current portion, net	67,658	77,343
Derivative and warrant liability	304	120
Operating lease liabilities, less current portion	1,587	1,901
Loans payable, less current portion	391	-
Other long-term liabilities	145	168
Total liabilities	77,621	84,963
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, 2020 and 2019	-	-
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, 2020 and 2019	-	-
Series B-2 convertible preferred stock, $0.0001 par value, 27,000 shares authorized, no shares issued or outstanding as of December 31, 2020 and 2019	-	-
Undesignated preferred stock, $0.0001 par value, 9,961,846 shares authorized, no shares issued or outstanding as of December 31, 2020 and 2019	-	-
Common stock, $0.0001 par value, 250,000,000 shares authorized, 4,537,321 shares issued and outstanding as of December 31, 2020; 2,271,882 shares issued and outstanding as of December 31, 2019	0	0
Additional paid-in capital	192,062	171,258
Accumulated deficit	(258,474)	(245,714)
Total stockholders' deficit	(66,412)	(74,456)
Total liabilities and stockholders' deficit	$ 11,209	$ 10,507

See accompanying notes to financial statements

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

	Year Ended December 31,	
	2020	**2019**
Revenue	$ 13,288	$ 12,839
Operating expenses:		
Royalty and direct contract acquisition costs	1,305	2,945
Research and development	8,843	19,415
General and administrative	7,921	10,816
Severance expense	828	-
Total operating expenses	18,897	33,176
Loss from operations	(5,609)	(20,337)
Other (expense) income:		
Interest expense related to amortization of debt issuance costs and discount	(2,305)	(1,656)
Interest expense on principal	(4,785)	(4,858)
Fair value adjustment related to derivative and warrant liability	(184)	1,998
Interest and other income, net	89	309
Total other (expense) income	(7,185)	(4,207)
Loss before income taxes	(12,794)	(24,544)
Income tax benefit	34	22
Net loss	$ (12,760)	$ (24,522)
Net loss per share of common stock:		
Basic and diluted	$ (3.21)	$ (13.23)
Weighted average number of shares of common stock outstanding:		
Basic and diluted	3,980,975	1,853,397

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, 2019	$ -	$ -	$ -	$ -	$ -	$ 154,626	$ (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	-	-	-	-	-	1,200	-	1,200
Issuance of common stock in connection with 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	$ -	$ -	$ -	$ -	$ -	$ 171,258	$ (245,714)	$ (74,456)
Net loss	-	-	-	-	-	-	(12,760)	(12,760)
Stock-based compensation expense	-	-	-	-	-	2,491	-	2,491
Issuance of common stock in connection with equity line of credit	-	-	-	-	-	2,303	-	2,303
Issuance of common stock in connection with Deerfield Optional Conversion Feature	-	-	-	-	-	15,863		15,863
Recognition of deferred offering costs in connection with equity line of credit	-	-	-	-	-	121	-	121
Offering expenses charged to equity	-	-	-	-	-	(153)	-	(153)
Issuance of common stock in exchange for consulting services	-	-	-	-	-	202	-	202
Cash paid in lieu of fractional shares in connection with 16-for-1 reverse stock split	-	-	-	-	-	(23)	-	(23)
Balance as of December 31, 2020	$ -	$ -	$ -	$ -	$ -	$ 192,062	$ (258,474)	$ (66,412)

See accompanying notes to financial statements

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

	Year Ended December 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (12,760)	$ (24,522)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,491	4,410
Non-cash interest expense	4,741	1,417
Amortization of debt issuance costs and debt discount	2,305	1,656
Depreciation and amortization expense	273	304
Fair value adjustment related to derivative and warrant liability	184	(1,998)
Change in estimated deferred offering costs	-	116
Loss on sublease and disposal of property and equipment	251	-
Consulting fees paid in common stock	202	-
Change in assets and liabilities:		
Accounts and other receivables	(714)	(1,725)
Prepaid expenses and other assets	160	544
Operating lease right-of-use assets	128	(1,537)
Accounts payable and accrued expenses	931	(3,789)
Operating lease liabilities	(271)	2,185
Other liabilities	140	(798)
Net cash used in operating activities	(1,939)	(23,737)
Cash flows from investing activities:		
Purchases of property and equipment	(33)	(26)
Maturities of marketable securities	-	3,260
Net cash (used in) provided by investing activities	(33)	3,234
Cash flows from financing activities:		
Proceeds from equity line of credit	2,303	5,446
Proceeds from Payment Protection Program loan	781	-
Payment of offering costs	(84)	-
Repayment of principal on finance lease liabilities	(227)	(207)
Payment of debt issuance costs	(34)	(300)
Net cash provided by financing activities	2,739	4,939
Net increase (decrease) in cash, cash equivalents and restricted cash	767	(15,564)
Cash, cash equivalents and restricted cash, beginning of year	3,555	19,119
Cash, cash equivalents and restricted cash, end of year	$ 4,322	$ 3,555
Supplemental cash flow information:		
Cash paid for interest	$ 78	$ 5,362
2021 Notes principal converted to preferred stock	-	1,537
2021 Notes principal converted to common stock	-	1,463
2019 Notes principal converted to common stock	15,863	1,200
Commitment shares issued in connection with equity line of credit included in deferred offering costs	121	300
Deferred offering costs included in accounts payable and accrued expenses	817	-
Cash paid in lieu of fractional shares in connection with 16-for-1 reverse stock split included in accounts payable and accrued expenses	23	-
Property and equipment financed under a lease agreement	17	-
Property and equipment included in accounts payable and accrued expenses	4	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 AZSTARYS™ (formerly referred to as KP415) and KP484, and the Company's clinical product candidate for the treatment of SUD includes KP879. In addition, the Company has received FDA approval for APADAZ®, an immediate-release combination product containing benzhydrocodone, a prodrug of hydrocodone and acetaminophen. On March 2, 2021, the Company announced that the FDA approved the new drug application ("NDA") for AZSTARYS, a once-daily product for the treatment of ADHD in patients age six years and older.

Reverse Stock Split

On December 23, 2020, the Company completed a one-for-sixteen reverse stock split (the “Reverse Stock Split”), which reduced the number of shares of the Company’s common stock that were issued and outstanding immediately prior to the effectiveness of the Reverse Stock Split. The number of shares of the Company’s authorized common stock was not affected by the Reverse Stock Split and the par value of the Company’s common stock remained unchanged at $0.0001 per share. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who otherwise held fractional shares of the Company’s common stock as a result of the Reverse Stock Split received a cash payment in lieu of such fractional shares. Except where disclosed, all amounts related to number of shares and per share amounts have been retroactively restated in these financial statements.

Liquidity

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 cash and cash equivalents and restricted cash as of December 31, 2020 are not sufficient to fund the Company’s operating expenses and capital expenditure requirements for at least one year from December 31, 2020. However, after taking into account the underwritten public offering, debt restructuring with subsequent payoff and warrant inducement transactions discussed in Note R this concern has been alleviated and the Company's cash and cash equivalents as of the filing date are sufficient to fund the Company's operating expenses and capital expenditure requirements for a least one year from the date these financial statements are issued.

Entry into 2019 ELOC Agreement

In February 2019, the Company entered into a purchase agreement for an equity line of credit (the “2019 ELOC 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 2019 ELOC Agreement, and upon execution of the 2019 ELOC Agreement, the Company issued an additional 7,512 shares of common stock to Lincoln Park as commitment shares in accordance with the closing conditions within the 2019 ELOC Agreement. Concurrently with entering into the 2019 ELOC Agreement, the Company also entered into a registration rights agreement with Lincoln Park (the “2019 ELOC Registration Rights Agreement”) 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 2019 ELOC Agreement pursuant to the Company’s existing shelf registration statement on Form S-3 or a new registration statement. The 2019 ELOC Agreement was terminated in February 2020 in connection with entering into the 2020 ELOC Agreement (discussed below). Prior to the termination of the 2019 ELOC Agreement, the Company sold 212,579 shares of common stock to Lincoln Park (exclusive of the 7,512 commitment shares) under the 2019 ELOC Agreement for gross proceeds of approximately $5.4 million.

Entry into 2020 ELOC Agreement

In February 2020, the Company entered into a purchase agreement for an equity line of credit (the “2020 ELOC Agreement”) with Lincoln Park which provides 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 common stock from time to time over the 12-month term of the 2020 ELOC Agreement, and upon execution of the 2020 ELOC Agreement the Company issued an additional 19,289 shares of common stock to Lincoln Park as commitment shares in accordance with the closing conditions within the 2020 ELOC Agreement. Concurrently with entering into the 2020 ELOC Agreement, the Company also entered into a registration rights agreement with Lincoln Park (the “2020 ELOC Registration Rights Agreement”) 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 2020 ELOC Agreement pursuant to the Company’s existing shelf registration statement on Form S-3 or a new registration statement. In May 2020, the Company reached the maximum allowable shares to be issued under the Current Registration Statement of 579,260 shares (inclusive of the 19,289 commitment shares) as defined in Section 2(f)(i) of the 2020 ELOC Agreement and therefore cannot issue additional shares under the 2020 ELOC Agreement. As of December 31, 2020, the Company has sold 559,971 shares of common stock to Lincoln Park (exclusive of the 19,289 commitment shares) under the 2020 ELOC Agreement for gross proceeds of approximately $2.3 million.

License Agreements

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 AZSTARYS, 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 AZSTARYS 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 AZSTARYS 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.

In May 2020, the FDA accepted the Company's NDA for AZSTARYS. Per the KP415 License Agreement, the Company received a regulatory milestone payment of $5.0 million following the FDA's acceptance of the AZSTARYS NDA.

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 AZSTARYS 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 AZSTARYS 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 AZSTARYS, KP484 or KP879 under the KP415 License 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) if 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.

Consulting Arrangements

From time to time, the Company enters into consulting arrangements with third-parties to provide research and development, manufacturing and/or commercialization services. Such arrangements may require the Company to deliver various rights, services, including research and development services, regulatory services and/or commercialization services. The underlying terms of these arrangements generally provide for consideration to the Company in the form of consulting fees and reimbursements of out-of-pocket third-party research and development, regulatory and commercial costs.

Corium Consulting Agreement

In July 2020, the Company entered into a consultation services arrangement (the "Corium Consulting Agreement") with Corium, Inc. ("Corium") under which Corium engaged the Company to guide the product development and regulatory activities for certain current and potential future products in Corium's portfolio, as well as continue supporting preparation for the potential commercial launch of AZSTARYS (together, "Corium Consulting Services"). Corium is a portfolio company of Gurnet Point Capital and is responsible for leading all commercialization activities for AZSTARYS under the KP415 License Agreement, as discussed above.

Under the Corium Consulting Agreement, the Company is entitled to receive payments from Corium of up to $15.6 million, $13.6 million of which will be paid in quarterly installments through March 31, 2022. The remaining $2.0 million is conditioned upon the achievement of a specified regulatory milestone related to Corium's product portfolio. Corium also agreed to be responsible for and reimburse the Company for all development, commercialization and regulatory expenses incurred as part of the performance of the Corium Consulting Services.

B. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. 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.

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, and accounts receivable, which are concentrated amongst a limited number of customers.

Cash and Cash Equivalents

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

Property and Equipment

The Company records property and equipment at cost less accumulated depreciation and amortization. Costs of renewals and improvements that extend the useful lives of the assets are capitalized. Maintenance and repairs are expensed as incurred. Depreciation is determined on a straight-line basis over the estimated useful lives of the assets, which generally range from 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.

Offering Costs

Offering costs incurred in connection with capital offering arrangements are recorded as deferred offering costs in prepaid expenses and other currents assets on the balance sheet. Once the offering arrangement closes the deferred offering costs are reclassified as a reduction of the related net proceeds of the offering in additional paid-in capital on the balance sheet. If its a continuous offering the deferred offering costs are amortized over the life of the respective offering arrangement using a pro-rata method which matches the costs to the funds raised from the offering. If the continuous offering arrangement terminates prior to all the deferred offering costs being recognized the deferred offering costs are written off and expensed in general and administrative expense on the statement of operations.

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, 2020 or 2019.

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 until the third quarter of 2019.

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, consulting fees 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 AZSTARYS, 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 AZSTARYS and KP484. In May 2020, the FDA accepted the Company's NDA for AZSTARYS. Per the KP415 License Agreement, the Company received a regulatory milestone payment of $5.0 million following the FDA's acceptance of the AZSTARYS NDA. 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 AZSTARYS 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 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 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 at inception. The Company further determined that the transaction price, at inception, 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 AZSTARYS 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 AZSTARYS which was anticipated at the inception date of the KP415 License Agreement. As of December 31, 2020, the Company has recognized all 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 right to first negotiation whereby upon completion of a Phase 1 proof-of-concept study, the Company and Commave may negotiate the economics terms under which that certain Additional Product may be included as a Product 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 AZSTARYS 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 AZSTARYS 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 milestone 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 example, in May 2020, the FDA accepted the Company's NDA for AZSTARYS. Per the KP415 License Agreement, the Company received a regulatory milestone payment of $5.0 million following the FDA's acceptance of the AZSTARYS NDA. Since the FDA accepted the Company's NDA for AZSTARYS the constraint was removed and revenue recognized. The associated revenue was allocated among the two performance obligations identified at contract inception. Since both performance obligations were satisfied as of the end of the second quarter of 2020 the full $5.0 million payment was recognized as revenue during the second quarter of 2020.

For the year ended December 31, 2020, the Company recognized revenue under the KP415 License Agreement of $7.3 million. In accordance with 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, 2020, the Company has recognized all of these incremental costs, $0.8 million of which was recognized in the year ended December 31, 2020 and is recorded in the line item titled royalty and direct contract acquisition costs in the statement of operations. There was $12.8 million of revenue and $1.9 million of associated direct contract acquisition costs recognized for the year ended December 31, 2019 related to the KP415 License Agreement. There was no deferred revenue related to this agreement as of December 31, 2020 or December 31, 2019.

Consulting Arrangements

The Company enters into consulting arrangements with third-parties that fall under the scope of ASC 606. These arrangements may require the Company to deliver various rights, services, including research and development services, regulatory services and/or commercialization support services. The underlying terms of these arrangements generally provide for consideration to the Company in the form of consulting fees and reimbursements of out-of-pocket third-party research and development, regulatory and commercial costs.

Corium Consulting Agreement

The Corium Consulting Agreement is within the scope of ASC 606, as the transaction represents a contract with a customer where the participants function in a customer / vendor relationship and are not exposed equally to the risks and rewards of the activities contemplated under the Corium Consulting Agreement. Using the concepts of ASC 606, the Company identified the performance of consulting services, which includes the reimbursement to the Company of third-party pass-through costs, as its only performance obligation at inception. The Company further determined that the transaction price, at inception, under the agreement was $13.6 million which is the fair value of the consulting services, including the reimbursement of third-party pass-through costs. The Company concluded that the regulatory milestone contains a significant uncertainty associated with a future event. As such, this milestone is constrained at contract inception and is 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 milestone payments. At the end of each reporting period, the Company updates its assessment of whether the milestone is constrained by considering both the likelihood and magnitude of the potential revenue reversal.

The Company determined that the performance of consulting services, including reimbursement of third-party pass-through 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 third-party pass-through 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 of December 31, 2020, the Company has recognized approximately 30% of the consulting services and third-party pass-through costs under the Corium Consulting Agreement.

For the year ended December 31, 2020, the Company recognized revenue under the Corium Consulting Agreement of $3.9 million. There was no revenue recognized for the year ended December 31, 2019 related to the Corium Consulting Agreement. As of December 31, 2020, the Company had deferred revenue related to this agreement of $0.1 million. There was no deferred revenue related to this agreement as of December 31, 2019 as it was not entered into until July 2020.

Other Consulting Arrangements

For the year ended December 31, 2020, the Company recognized revenue under other consulting arrangements of $2.0. There was no revenue recognized from other consulting arrangements for the year ended December 31, 2019. There was no deferred revenue from other from consulting arrangements as of December 31, 2020 or 2019.

Accounts and Other Receivables

Accounts and other receivables consists of receivables under the KP415 License Agreement and Corium Consulting Agreement, as well as receivables related to other consulting arrangements, income tax receivables and other receivables due to the Company. Receivables under the KP415 License Agreement and Corium Consulting Agreement are recorded for amounts due to the Company related to reimbursable third-party costs and performance of consulting services. These receivables, as well as the receivables related to other consulting arrangements, are evaluated to determine if any reserve or allowance should be established at each reporting date. As of December 31, 2020, the Company had receivables related to the Corium Consulting Agreement in the amount of $2.1 million, other consulting arrangements in the amount of $0.4 million and no receivables related to the KP415 License Agreement. As of December 31, 2019, the Company had receivables related to the KP415 License Agreement in the amount of $1.6 million and receivables related to other consulting arrangements of $0.1 million. As of December 31, 2020 and 2019 no reserve or allowance for doubtful accounts 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, 2020 and 2019.

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 2017 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 Accounting Standards Update ("ASU") 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Non-Employee Share-Based Payment Accounting* (“ASU 2018-17”). 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, 2020 and 2019.

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 June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326)—Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which replaces the incurred loss impairment methodology with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. This update applies to all entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. The amendments affect loans, debt securities, trade receivables, net investments in leases, off-balance-sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The adoption of ASU 2016-13 did not have a material impact on the Company's 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* ("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. 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. The adoption of ASU 2018-13 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 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40); Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"), which addresses issues identified as a result of the complexities associated with applying U.S. GAAP for certain financial instruments with characteristics of liabilities and equity. This update addresses, among other things, the number of accounting models for convertible debt instruments and convertible preferred stock, targeted improvements to the disclosures for convertible instruments and earnings-per-share ("EPS") guidance and amendments to the guidance for the derivatives scope exception for contracts in an entity's own equity, as well as the related EPS guidance. This update applies to all entities that issue convertible instruments and/or contracts in an entity's own equity. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. FASB specified that an entity should adopt the guidance as of the beginning of its annual fiscal year. The Company is currently evaluating the impact the adoption of ASU 2020-06 could have 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,	
	2020	2019
Accounts receivable	$ 2,442	$ 1,681
Other receivables	137	184
Total accounts and other receivables	$ 2,579	$ 1,865

D. Prepaid Expenses and Other Current Assets

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

	December 31,	
	2020	2019
Prepaid insurance	$ 453	$ 250
Deferred direct contract acquisition costs	-	805
Prepaid offering costs	825	266
Other prepaid expenses and current assets	203	231
Total prepaid expenses and other current assets	$ 1,481	$ 1,552

E. Property and Equipment

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

	December 31,	
	2020	2019
Laboratory equipment	$ 643	$ 638
Furniture and office equipment	71	119
Computers and hardware	296	303
Leasehold improvements	724	958
Finance lease right-of-use assets	1,031	1,013
Total property and equipment	2,765	3,031
Less: accumulated depreciation and amortization	(1,726)	(1,560)
Property and equipment, net	$ 1,039	$ 1,471

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 $273,000 and $304,000 for the years ended December 31, 2020 and 2019, respectively.

F. Accounts Payable and Accrued Expenses

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

	December 31,	
	2020	2019
Accrued interest	$ 1,158	$ 359
Accrued banking fees	700	700
Accrued severance	53	-
Accrued payroll	1,299	1
Accrued professional fees	1,639	2,364
Accounts payable	1,174	1,140
Other accrued expenses	624	347
Total accounts payable and accrued expenses	$ 6,647	$ 4,911

G. Debt Obligations

As of December 31, 2020 and 2019, the Company had convertible notes outstanding, in the aggregate principal amounts, as follows (in thousands):

	December 31,	
	2020	2019
Deerfield Convertible Note	$ 7,464	$ 6,981
2021 Notes	-	3,000
December 2019 Notes	57,593	70,218
January 2020 Notes	3,186	-
Total outstanding principal on debt obligations	68,243	80,199
Less: debt issuance costs and discounts	(585)	(2,856)
Convertible notes, net	$ 67,658	$ 77,343

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"). After giving effect to the Reverse Stock Split effected in December 2020, the conversion price became $93.60.

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 37,410 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. After giving effect to the Reverse Stock Split effected in December 2020, the reclassified shares became 16,025 shares.

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. After giving effect to the Reverse Stock Split effected in December 2020, the shares issuable upon conversion of the warrant became 120,192 shares of common stock, and the exercise price of the Deerfield Warrant became $93.60 per share, which in January 2021 was further adjusted to $46.25 per share in connection with the Company entering into the Inducement Letters (as defined in Note R) which triggered the anti-dilution provisions of the Deerfield Warrant. 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 O). 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 of 1933, as amended (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. After giving effect to the Reverse Stock Split effected in December 2020, the conversion rate of the 2021 Notes would be approximately 3.6528 shares of the Company's common stock per $1,000 principal amount of the 2021 Notes, which is equal to a conversion price of approximately $273.76 per share.

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.

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 37,410 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). After giving effect to the Reverse Stock Split effected in December 2020, the conversion price of the Series A Preferred Stock would be $48.00 per share and shares of common stock issuable upon conversion of the Series A Preferred Stock would be 199,519 shares of common stock. As of December 31, 2020, all 9,577 shares of Series A Preferred Stock issued under the October 2018 Exchange Agreement have been converted into an aggregate 199,519 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 93,742 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 would 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 would 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 principal securities exchange or trading market on which the common stock is then trading on each of the 15 trading days immediately preceding such exchange. After giving effect to the Reverse Stock Split effected in December 2020, the exchange price of the Optional Exchange Principal Amount would be $15.1904 or the average of the volume-weighted average price of the common stock on the principal securities exchange or trading market on which the common stock is then trading 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). After giving effect to the Reverse Stock Split effected in December 2020, the conversion price of the Series B-1 Preferred Stock would be $15.1904 and the shares of common stock issuable upon conversion of the Series B-1 Preferred Stock would be 103,749 shares of common stock. 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 principal securities exchange or trading market on which the common stock is then trading 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). After giving effect to the Reverse Stock Split effected in December 2020, the conversion price of the Series B-2 Preferred Stock would be $15.1904 or the average of the volume-weighted average price of the common stock on the principal securities exchange or trading market on which the common stock is then trading on each of the 15 trading days immediately preceding such exchange and the shares of stock issuable in exchange of the Optional Exchange Principal Amount or upon conversion of Series B-2 Preferred stock would be 1,777,437 shares of common stock.

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, 2020, all 1,576 shares of Series B-1 Preferred Stock issued under the September 2019 Exchange Agreement have been converted into an aggregate of 103,749 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. After giving effect to the Reverse Stock Split effected in December 2020, the conversion price of the December 2019 Notes would be $273.76 per share and the shares of the Company's common stock issuable upon conversion of the December 2019 Notes would be 260,876 shares of 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 $93.60 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 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, 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 $93.60 per share, provided that this anti-dilution adjustment will not apply to any sales made under (x) the 2020 ELOC, (y) the 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 $9.328 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 $93.60 per share, subject to adjustment on the same basis as the December 2019 Notes.

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 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. After giving effect to the Reverse Stock Split effected in December 2020, the exchange price of the Deerfield Optional Conversion Feature would be $9.60 per share or the average of the volume-weighted average price of the common stock on the principal securities exchange or trading market on which the common stock is then trading on each of the 15 trading days immediately preceding such exchange and the shares of the Company's common stock issued pursuant to the optional exchanges would be 1,777,437 shares of common stock.

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) $9.60 (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 each of the 15 trading days immediately preceding such exchange.

As of December 31, 2020, the Deerfield Lenders have converted $17.1 million of principal under the December 2019 Notes into all 1,777,437 shares of common stock available under the Deerfield Optional Conversion Feature.

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, the Company 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). After giving effect to the Reverse Stock Split effected in December 2020, the Conversion Price became $93.60 per share and the Floor Price became $9.328 per share.

The changes to the 2021 Note, under the January 2020 Exchange Agreement, referred to after as the January 2020 Note, were accounted for as a debt modification, prospectively, the January 2020 Note 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.

December 2020 Exchange Agreement and Amendment to Facility Agreement, Notes and Investors' Rights Agreement

In December 2020, the Company entered into a December 2020 Exchange Agreement and Amendment to Facility Agreement, Notes and Investors' Rights Agreement, as amended (the "December 2020 Exchange Agreement") with the Deerfield Lenders, DSC and Kingdon (collectively, the "Facility Agreement Note Holders"). Under the December 2020 Exchange Agreement, the Company and the Facility Agreement Note Holders have agreed that (a) the Company will make a cash pre-payment of a portion of principal amount of the Deerfield Convertible Note, the December 2019 Notes and the January 2020 Note (collectively, the "Facility Agreement Notes") to the Facility Agreement Note Holders (the "Debt Payment") equal to approximately $30.3 million, plus accrued interest if such payment is made on or after January 1, 2021, and (b) subject to the satisfaction or waiver of certain conditions specified in the December 2020 Exchange Agreement, including the making of the Debt Payment, issue shares of its Series B-2 Preferred Stock and warrants exercisable for shares of its common stock (the "Exchange Warrants"), in exchange for the cancellation of a portion of the principal amount of the Facility Agreement Notes owned by the Facility Agreement Note Holders in an aggregate amount equal to the Debt Payment, plus the Q4 PIK Interest Payment (as defined in the December 2020 Exchange Agreement) (such transaction, the "December 2020 Exchange").

The December 2020 Exchange Agreement amends the Facility Agreement Notes to provide that the failure of the Company's common stock to remain listed on an eligible securities market will not constitute a "Major Transaction" unless such failure occurs after March 31, 2023.

Subject to the satisfaction or waiver of certain conditions specified in the December 2020 Exchange Agreement, including the making of the Debt Payment and the consummation of the exchange, the December 2020 Exchange Agreement will amend that certain Facility Agreement dated as of June 2, 2014, as amended (the "Facility Agreement"), by and among the Company and the Facility Agreement Note Holders in order to, among other things, (i) extend the maturity date of the Facility Agreement Notes to March 31, 2023, (ii) provide for cash payments of interest on the Loans (as defined in the Facility Agreement) for the periods following July 1, 2021, and (iii) provide for specified prepayment terms on the Loans.

The December 2020 Exchange Agreement amends that certain Amended and Restated Investors' Rights Agreement, dated as of February 19, 2015 (the "IRA"), by and among the Company, Deerfield and the other parties signatory thereto in order to, among other things, add Deerfield Special Situations Fund, L.P. as a party thereto and to give effect to the issuance of the Exchange Warrants and the Company's registration obligations under the December 2020 Exchange Agreement (as described in more detail below).

The Exchange Warrants to be issued pursuant to the December 2020 Exchange Agreement will be exercisable for a number of shares of the Company's common stock equal to 75% of the shares of common stock issuable upon conversion of the Series B-2 Preferred Stock issued in the Exchange (without regard for any beneficial ownership limitations included therein). The Exercise Warrants will be subject to substantially the same terms and conditions as the warrants issued to the public in the public offering of the Company's securities contemplated pursuant to a registration statement on Form S-1, file no. 333-250945 (the "Public Offering"), with an exercise price equal to the exercise price per share of the warrants issued in the Public Offering and will provide that the Facility Agreement Note Holders will be limited from exercising such Exchange Warrants if, as a result of such exercise, 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 the Company's common stock then issued and outstanding.

The December 2020 Exchange Agreement contains customary representations, warranties and covenants made by the Company and the Facility Agreement Note Holders party thereto, including a covenant of the Company for the benefit of the Facility Agreement Holders party to the Exchange Agreement to file a registration statement to register for resale under the Securities Act the shares of common stock issuable upon exercise of the Exchange Warrants or conversion of the shares of Series B-2 Preferred Stock issued pursuant to the terms of the December 2020 Exchange Agreement.

The transactions contemplated under the December 2020 Exchange Agreement, including the obligation to pre-pay any portion of the Facility Agreement Notes or to complete the Exchange and the effectiveness of the amendments to the Facility Agreement, the Notes and the IRA, are subject to specified conditions of closing, including certain closing of the Public Offering, the filing of the Restated Series B-2 Certificate of Designation (as defined below) and the approval for listing of the Company's common stock, including the shares issuable upon conversion of the Series B-2 Preferred Stock and exercise of the Exchange Warrants, on the Nasdaq Capital Market.

As a condition to closing of the December 2020 Exchange Agreement, the Company has agreed to file an Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series B-2 Convertible Preferred Stock (the "Restated 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-2 Preferred Stock.

Each share of Series B-2 Preferred Stock will have an aggregate stated value of $1,000 and will be convertible into shares of the Company's common stock at a per share price equal to the price per share to the public of the Company's common stock in the Public Offering (subject to adjustment to reflect stock splits and similar events).

The Series B-2 Preferred Stock will be convertible at any time on or after the PDUFA Date (as defined in the Restated Series B-2 Certificate of Designation) at the option of the holders thereof; provided that the holders thereof will be prohibited from converting shares of Series B-2 Preferred Stock into shares of the Company's 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 the Company's common stock then issued and outstanding. The Series B-2 Preferred Stock will not be redeemable. In the event of the Company's liquidation, dissolution or winding up or a change in control of the Company (each, a "Liquidation Event"), the holders of Series B-2 Preferred Stock will receive, prior to any distribution or payment on our common stock, an amount equal to the greater of (i) $1,000 per share (in the case of a change in control, transaction consideration with such value), or (ii) the amount (in the case of a change in control, in the form of the transaction consideration) per share each such holder would have been entitled to receive if every share of Series B-2 Preferred Stock had been converted into common stock immediately prior to such Liquidation Event, in each case, plus any declared but unpaid dividends thereon. With respect to rights upon liquidation, the Series B-2 Preferred Stock will rank senior to the common stock, on parity with any Parity Securities (as defined in the Restated Series B-2 Certificate of Designation) 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 adversely affect the holders of Series B-2 Preferred Stock and other specified matters regarding the rights, preferences and privileges of the Series B-2 Preferred Stock), the Series B-2 Preferred Stock will not have voting rights. The Series B-2 Preferred Stock will not be subject to any price-based anti-dilution protections and will not provide for any accruing dividends, but provides that holders of Series B-2 Preferred Stock will participate in any dividends on the Company's common stock on an as-converted basis (without giving effect to the limitation on conversion described above). The Restated Series B-2 Certificate of Designation will also provide for partial liquidated damages in the event that the Company fails to timely convert shares of Series B-2 Preferred Stock into common stock in accordance with the Restated Series B-2 Certificate of Designation.

Debt Restructuring

In anticipation of the Public Offering (as defined and discussed in further detail in Note R), and to meet the Nasdaq Listing Requirements, the Company agreed in December 2020 to restructure the December 2019 Notes and the January 2020 Note in the aggregate principal amount of $60.8 million and the Deerfield Note in the principal amount of $7.5 million (collectively the "the Facility Notes"). The total outstanding principal and accrued interest under the Facility Notes was $69.4 million as of December 31, 2020.

Under the terms of the December 2020 Exchange Agreement, the Company, on January 12, 2021, in connection with the closing of the Public Offering:

- Exchanged $31.5 million of the outstanding principal and accrued interest on the Facility Notes for (i) 31,476.98412 shares of Series B-2 Preferred Stock, and (ii) Exchange Warrants exercisable for 3,632,019 shares of the Company's common stock, and
- Made a payment of $30.3 million (the "Debt Payment"), in partial repayment of the remaining outstanding principal and accrued interest of the Facility Notes.

Following the completion of these transactions, the aggregate balance of principal and accrued interest remaining outstanding under the Facility Notes was approximately $7.6 million. With respect to this remaining outstanding balance under the Facility Notes, the December 2020 Exchange Agreement amended the terms of that debt to provide that:

- The maturity date was changed to March 31, 2023, and the debt is prepayable upon specified conditions, and
- Interest would accrue at the rate of 6.75% per annum, payable quarterly, would be added to principal until June 30, 2021, and then be payable in cash thereafter.

Based on the above transactions which occurred after the balance sheet date of December 31, 2020, but prior to the issuance of the financial statement the Company reclassified the entire $68.2 million of convertible notes, and the associated debt issuance costs and discounts, from current to long-term on the balance sheet.

Payoff of Facility Agreement Notes and Termination of Facility Agreement

On February 8, 2021, the Company entered into a payoff letter with the Facility Note holders to pay off and thereby terminate the Deerfield Facility Agreement.

Pursuant to the payoff letter, the Company paid a total of $8.0 million to the Facility Note holders, representing the total principal balance and accrued interest outstanding and a prepayment fee in repayment of our outstanding obligations under the Deerfield Facility Agreement.

For further discussion of the Debt Restructuring and the payoff of the Facility Notes and termination of the Deerfield Facility Agreement refer to Note R.

PPP Loan

On April 23, 2020, the Company received proceeds of $0.8 million from the PPP Loan under the PPP of the recently enacted CARES Act, a portion of which may be forgiven, which the Company used to retain current employees, maintain payroll and make lease and utility payments. The PPP Loan matures on April 23, 2022 and bears annual interest at a rate of 1.0%. Payments of principal and interest on the PPP Loan were originally deferred for the first six months of the PPP Loan term. Thereafter, the Company would have been required to pay the lender equal monthly payments of principal and interest. As of December 31, 2020, $0.4 million of the PPP Loan is recorded on the balance sheet in current portion of loans payable and $0.4 million is recorded in loan payable, less current portion.

The CARES Act and the PPP provide a mechanism for forgiveness of up to the full amount borrowed. Under the PPP, the Company may apply for and be granted forgiveness for all or part of the PPP Loan. The amount of loan proceeds eligible for forgiveness was originally based on a formula that takes into account a number of factors, including the amount of loan proceeds used by the Company during the eight-week period after the loan origination for certain purposes, including payroll costs, interest on certain mortgage obligations, rent payments on certain leases, and certain qualified utility payments, provided that at least 75% of the loan amount was used for eligible payroll costs. Subject to the other requirements and limitations on loan forgiveness, only loan proceeds spent on payroll and other eligible costs during the covered eight-week period would have qualified for forgiveness.

On June 5, 2020, President Trump signed into law the PPP Flexibility Act of 2020 (the “Flexibility Act”), which among other things provided the following important changes to the PPP:

- Extended the covered period for loan forgiveness from eight weeks after the date of loan disbursement to 24 weeks after the date of loan disbursement, providing substantially greater flexibility for borrowers to qualify for loan forgiveness. Borrowers who had already received PPP loans retained the option to use an eight-week covered period.

- Lowered the requirements that 75 percent of a borrower’s loan proceeds must be used for payroll costs and that 75 percent of the loan forgiveness amount must have been spent on payroll costs during the 24-week loan forgiveness covered period to 60 percent for each of these requirements. If a borrower uses less than 60 percent of the loan amount for payroll costs during the forgiveness covered period, the borrower will continue to be eligible for partial loan forgiveness, subject to at least 60 percent of the loan forgiveness amount having been used for payroll costs.

- Provided a safe harbor from reductions in loan forgiveness based on reductions in full-time equivalent employees for borrowers that are unable to return to the same level of business activity the business was operating at before February 15, 2020, due to compliance with requirements or guidance issued between March 1, 2020 and December 31, 2020 by the Secretary of Health and Human Services, the Director of the Centers for Disease Control and Prevention, or the Occupational Safety and Health Administration, related to worker or customer safety requirements related to COVID–19.

- Provided a safe harbor from reductions in loan forgiveness based on reductions in full-time equivalent employees, to provide protections for borrowers that are both unable to rehire individuals who were employees of the borrower on February 15, 2020, and unable to hire similarly qualified employees for unfilled positions by December 31, 2020.

- Increased to five years the maturity of PPP loans that are approved by the U.S. Small Business Administration (the “SBA”) (based on the date SBA assigns a loan number) on or after June 5, 2020.

- Extended the deferral period for borrower payments of principal, interest, and fees on PPP loans to the date that SBA remits the borrower’s loan forgiveness amount to the lender (or, if the borrower does not apply for loan forgiveness, 10 months after the end of the borrower’s loan forgiveness covered period).

Based on the changes provided by the Flexibility Act the Company plans to take advantage of (i) the extended covered period for loan forgiveness from eight weeks to 24 weeks, (ii) the lowered requirement that a certain percentage of loan proceeds must be used for payroll costs from 75 percent to 60 percent, (iii) the extended deferral period for payments of principal, interest and fees from six months after loan disbursement to 10 months after the SBA remits the borrower’s loan forgiveness amount to the lender and (iv) take advantage of an safe harbor provisions as applicable. The Company will be required to repay any portion of the outstanding principal that is not forgiven, along with accrued interest, in accordance with the amortization schedule described above. Based on the changes provided by the Flexibility Act the Company expects that substantially all of the PPP loan will be forgiven, however, the Company cannot provide any assurance that the Company will be eligible for loan forgiveness or that any amount of the PPP Loan will ultimately be forgiven by the SBA.

Letters of Credit

As of December 31, 2020, the Company has one irrevocable letter of credit supporting certain finance lease agreements. This letter of credit is guaranteed by a money market account which is reported as restricted cash on the balance sheet.

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, 2020 and 2019, 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 5 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. In October, 2020, the Company agreed to terminate this sublease in exchange for a termination fee.

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 2021 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 2021.

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.

In March 2020, the Company leased office space in North Carolina under a non-cancelable operating lease. The Company's lease for its North Carolina facilities expires in March 2022.

Finance Lease

The Company leases various laboratory equipment, furniture and office equipment and leasehold improvements that are accounted for as finance leases and that require ongoing payments, including interest expense. The finance leases are financed through various financial institutions and are collateralized by the underlying assets. As of December 31, 2020 and 2019, the interest rates for assets under remaining finance leases range from 7.19% to 14.34%.

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

	Year Ended December 31,	
Lease Cost	**2020**	**2019**
Finance lease cost:		
Amortization of right-of-use assets	$ 124	$ 123
Interest on lease liabilities	23	40
Total finance lease cost	147	163
Operating lease cost	363	473
Short-term lease cost	210	232
Variable lease cost	55	48
Less: sublease income	(106)	(84)
Total lease costs	$ 669	$ 832

Rent expense for non-cancelable operating leases was $0.6 million and $0.7 million for the years ended December 31, 2020 and 2019, respectively.

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

	Year Ended December 31,	
	2020	**2019**
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from finance leases	$ 23	$ 40
Financing cash flows from finance leases	227	207
Operating cash flows from operating leases	447	435
Operating cash flows from short-term leases	210	232
Operating cash flows from variable lease costs	55	48
Right-of-use assets obtained in exchange for lease liabilities:		
Finance leases	$ 17	$ 757
Operating leases	20	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,	
	2020	2019
Finance Leases		
Property and equipment, at cost	$ 1,031	$ 1,013
less: accumulated depreciation and amortization	(523)	(398)
Property and equipment, net	$ 508	$ 615
Other current liabilities	$ 172	$ 236
Other long-term liabilities	22	168
Total finance lease liabilities	$ 194	$ 404
Operating Leases		
Operating lease right-of-use assets	$ 1,350	$ 1,537
Total operating lease right-of-use assets	$ 1,350	$ 1,537
Current portion of operating lease liabilities	$ 327	$ 284
Operating lease liabilities, less current portion	1,587	1,901
Total operating lease liabilities	$ 1,914	$ 2,185
Weighted Average Remaining Lease Term		
Finance leases	1 year	2 years
Operating leases	5 years	6 years
Weighted Average Discount Rate		
Finance leases	8.5%	7.7%
Operating leases	7.5%	7.5%

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

Year Ending December 31,	Finance Leases	Operating Leases
2021	$ 181	$ 460
2022	18	463
2023	6	472
2024	-	484
2025	-	390
Thereafter	-	30
Total lease payments	205	2,299
Less: future interest expense	(11)	(385)
Lease liabilities	$ 194	$ 1,914

I. Supply Arrangement

As of December 31, 2020 and 2019, 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 was recorded under this agreement for the year ended December 31, 2019. The expense under this agreement for the year ended December 31, 2020 was negligible. 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, 2020 and 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, 2020 and 2019. No shares of Series A Preferred Stock or Series B-1 Preferred Stock were outstanding as of December 31, 2020 and 2019. No shares of Series B-2 Preferred Stock were issued or outstanding as of December 31, 2020 and 2019.

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, 2020 all issued shares of Series A Preferred Stock had been converted into shares of common stock. After giving effect to the Reverse Stock Split effected in December 2020, the conversion price of the Series A Preferred Stock would be $48.00 and the shares of common stock issuable upon conversion of the Series A Preferred stock would be 199,519 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 principal securities exchange or trading market on which the common stock is then trading 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). After giving effect to the Reverse Stock Split effected in December 2020, the conversion price of the Series B-1 Preferred Stock would be $15.1904 or the average of the volume-weighted average price of the common stock on the principal securities exchange or trading market on which the common stock is then trading on each of the 15 trading days immediately preceding such exchange and the shares of common stock issuable upon conversion of the Series B-1 Preferred Stock would be 103,749 shares of common stock. 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, 2020 all issued shares of Series B-1 Preferred Stock have been converted into shares of common stock.

As a condition to closing of the December 2020 Exchange Agreement, the Company has agreed to file the Restated 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-2 Preferred Stock. Refer to Note G for further discussion.

K. Common Stock and Warrants

Authorized, Issued, and Outstanding Common Shares

As of December 31, 2020 and 2019, the Company had authorized shares of common stock of 250,000,000 shares. Of the authorized shares, 4,537,321 and 2,271,882 shares of common stock were issued and outstanding as of December 31, 2020 and 2019, respectively.

As of December 31, 2020 and 2019, the Company had reserved authorized shares of common stock for future issuance as follows:

	December 31,	
	2020	**2019**
Conversion of Deerfield Convertible Note	81,101	75,850
Conversion of 2021 Notes	-	10,958
Conversion of January 2020 Note	34,615	-
Conversion of 2019 Notes not subject to the Deerfield Optional Conversion Feature	625,747	199,172
Outstanding awards under equity incentive plans	355,785	324,473
Outstanding common stock warrants	151,442	151,442
In exchange for the Deerfield Optional Conversion Feature*	-	1,652,437
Possible future issuances under the equity line of credit	-	597,065
Possible future issuances under equity incentive plans	47,825	5,325
Total common shares reserved for future issuance	1,296,515	3,016,722

* 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

Common Stock Activity

The following table summarizes common stock activity for the years ended December 31, 2020 and 2019:

	Shares of Common Stock
Balance as of January 1, 2019	1,653,425
Common stock issued under equity line of credit	220,091
Restricted stock vested during the period	6,354
Common stock issued as a result of 2021 Notes principal conversion	93,742
Common stock issued as a result of Series B-1 Preferred Stock conversion	103,749
Common stock issued as a result of Series A Preferred Stock conversion	69,521
Common stock issued as a result of Deerfield Optional Conversion Feature conversion	125,000
Balance as of December 31, 2019	2,271,882
Common stock issued under equity line of credit	579,260
Restricted stock vested during the period	10,247
Common stock issued as compensation to third-parties	23,216
Common stock issued as a result of Deerfield Optional Conversion Feature conversion	1,652,437
Common stock issued as a result of stock option exercise	279
Balance as of December 31, 2020	4,537,321

Warrants

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 J). 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 Company's initial public offering (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. After giving effect to the Reverse Stock Split effected in December 2020, the exercise price of the Deerfield Warrant became $93.60 and the shares of the Company's common stock issuable upon exercise of the Deerfield Warrant became 120,192 shares of common stock. As a result of the Warrant Inducement transaction on January 26, 2021 (refer to Note R) the anti-dilution provisions within this Warrant were triggered and the exercise price was reduced from $93.60 per share to $46.25 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 statements of operations.

The Company determined that the 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 Deerfield Warrant automatically converted into warrants to purchase the Company's common stock. 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 unaudited 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 Stock 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. After giving effect to the Reverse Stock Split effected in December 2020, the exercise price of the KVK Warrant became $36.80 and the shares of common stock issuable upon exercise of the KVK Warrant became 31,250 shares of common stock.

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. As of December 31, 2020 and 2019, a contract asset of $0.4 million is recorded in other long-term assets on the balance sheets related to the KVK Warrant.

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 408,167 as of December 31, 2020. 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, 2021, the common stock reserved for issuance under the 2014 Plan automatically increased by 181,492 shares.

During 2020, the Company granted to certain consultants fully vested restricted stock awards (“RSAs”) under the 2014 Plan. The RSAs were granted as compensation in accordance with each consultants consulting agreement for services performed during 2020. For the year ended December 31, 2020, RSAs were granted for a total of 10,247 shares of common stock.

During 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 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, for the first and second quarters of 2019. For the year ended December 31, 2019, RSAs were granted for a total of 5,104 shares of common stock. In addition, the Company granted to a consultant fully vested RSAs under the 2014 Plan. The RSAs were granted as compensation in accordance with the consultant's consulting agreement for services performed during 2019.

During the year ended December 31, 2020, stock options to acquire 279 shares of common stock were exercised for approximately $2,000 with an intrinsic value of approximately $1,000. During the year ended December 31, 2019 no stock options were exercised.

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,	
	2020	2019
Research and development	$ 937	$ 1,459
General and administrative	1,134	2,951
Severance expense	420	-
Total stock-based compensation expense	$ 2,491	$ 4,410

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, 2020 and 2019, fair value was $5.00 and $22.88 per share, respectively. The assumptions used to estimate fair value are as follows:

	Year Ended December 31,	
	2020	2019
Risk-free interest rate	0.38% - 1.65%	1.75% - 2.61%
Expected term (in years)	5.50 - 10.00	5.50 - 10.00
Expected volatility	89.49% - 93.07%	84.82% - 85.93%
Expected dividend yield	0	0

The activity under the Incentive Stock Plan and the 2014 Plan for the year ended December 31, 2020, is summarized as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Avg Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding balance at January 1, 2020	324,473	$ 100.96	7.63	$ -
Granted	92,869	$ 5.21		
Exercised or released	10,526	$ 0.22		
Canceled or forfeited	50,659	$ 131.61		
Expired	372	$ 85.14		
Outstanding balance at December 31, 2020	355,785	$ 74.60	7.34	$ 543,021
Exercisable at December 31, 2020	191,134	$ 113.12	6.42	$ 103,581
Vested and expected to vest at December 31, 2020	281,368	$ 92.53	6.88	$ 163,506

Information regarding currently outstanding and exercisable options as of December 31, 2020, 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
$2.848 to $80.00	243,875	8.21	97,759	7.69
$80.01 to $160.00	57,494	5.97	38,959	5.44
$160.01 to $240.00	20,864	5.06	20,864	5.06
$240.01 to $320.00	12,616	4.84	12,616	4.84
$320.01 to $327.20	20,936	4.68	20,936	4.68
	355,785	7.33	**191,134**	6.42

The total fair value of stock options vested during the years ended December 31, 2020 and 2019, was $3.7 million and $4.9 million, respectively.

Unvested stock options as of December 31, 2020 and 2019, were as follows:

	Number of Unvested Shares December 31,	
Exercise Price	2020	2019
$2.848 to $80.00	146,116	151,495
$80.01 to $160.00	18,535	31,436
$160.01 to $240.00	-	5,668
$240.01 to $320.00	-	1,260
$320.01 to $327.20	-	-
Total number of unvested stock options	**164,651**	**189,859**

As of December 31, 2020, there was $1.7 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 1.72 years.

There was $0.3 million of stock-based compensation expense related to performance-based awards recognized during the year ended December 31, 2020. There was no stock-based compensation expense related to performance-based awards recognized during the year ended December 31, 2019.

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 $7.3 million and $6.0 million, respectively, as of December 31, 2020 and 2019. The fair value of the December 2019 Notes was $56.2 million and $57.0 million, respectively, as of December 31, 2020 and 2019. The fair value of the January 2020 Note was $3.1 million as of December 31, 2020 and the fair value of the 2021 Notes was $2.4 million as of December 31, 2019. The Deerfield Convertible Note, December 2019 Notes, January 2020 Note and 2021 Notes fall within Level 3 of the fair value hierarchy as their value is based on the credit worthiness of the Company, which is an unobservable input. The Company used a Tsiveriotis-Fernandes model to value the Deerfield Convertible Note and December 2019 Notes as of December 31, 2020 and 2019. The Company also used a Tsiveriotis-Fernandes model to value the January 2020 Note as of December 31, 2020 and the 2021 Notes as of December 31, 2019.

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, 2020 and 2019 (in thousands):

	Balance at December 31, 2020	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Deerfield Warrant liability	$ 230	$ -	$ -	$ 230
Embedded Warrant Put Option	25	-	-	25
Deerfield Note Conversion Feature	-	-	-	-
KVK Warrant liability	49	-	49	-
Total liabilities	$ 304	$ -	$ 49	$ 255

	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

The Company's Deerfield Warrant liability, embedded Warrant Put Option, embedded Deerfield Note Put Option and the fundamental change and the make-whole interest provisions embedded in the 2021 Notes are measured at fair value on a recurring basis. As of December 31, 2020 and December 31, 2019, the Deerfield Warrant liability, embedded Warrant Put Option and the embedded Deerfield Note Put Option are reported on the balance sheets in derivative and warrant liability. The Company used a Monte Carlo simulation to value the Deerfield Warrant liability, embedded Warrant Put Option and the embedded Deerfield Note Put Option as of December 31, 2020 and December 31, 2019. The Company also used a Monte Carlo simulation to value the fundamental change and make-whole interest provisions embedded in the 2021 Notes as of December 31, 2019. 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 and the embedded Deerfield Note Put Option are reflected in the statements of operations for the years ended December 31, 2020 and 2019 as a fair value adjustment related to derivative and warrant liability. In addition, changes in the fair value of the fundamental change and make-whole interest provisions embedded in the 2021 Notes are reflected in the statements of operations for the year ended December 31, 2019 as a fair value adjustment related to derivative and warrant liability.

The derivative liability for the Deerfield Warrant was $230,000 and $77,000 at December 31, 2020 and 2019, respectively. The derivative liability for the embedded Warrant Put Option was $25,000 and $19,000 at December 31, 2020 and 2019, respectively. The derivative liability for the Deerfield Note Conversion Feature had no value at December 31, 2020 or 2019, respectively. A 10% increase in the enterprise value would result in an increase of $29,000 in the estimated fair value of the Deerfield Warrant liability, an increase of $8,000 in the estimated fair value of the embedded Warrant Put Option liability and no change in the estimated fair value of the Deerfield Note Conversion Feature liability. In addition, the Company assumed a weighted-average probability of a liquidity event occurring of approximately 87% with an estimated probability-weighted value of approximately $45.3 million and a weighted-average probability of a fundamental change event occurring of approximately 47% with an estimated probability-weighted value of approximately $200 million, respectively, with estimated timing in each scenario of Q1 2021. The Company also assumed a present value discount rate of approximately 27% in its analysis, which approximates the estimated credit spread of the Company at the date of the latest debt financing event which is most closely related to relative notes.

The Company's KVK Warrant liability is measured at fair value on a recurring basis. As of December 31, 2020 and December 31, 2019, 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, 2020 and 2019 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):

	2020	2019
Balance as of beginning of period	$ 96	$ 1,845
Adjustment to fair value	159	(1,749)
Balance as of end of period	$ 255	$ 96

N. Income Taxes

The Company's financial statements include a total state tax benefit related to research and development credits of $34,000 and $22,000 on a loss before income taxes of approximately $12.8 million and $24.5 million for the years ended December 31, 2020 and 2019, 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	
	2020	**2019**
Federal statutory rate	21.00%	21.00%
Effect of:		
Change in valuation allowance	(22.65)	(28.52)
Return to provision and deferred true-up	0.11	-
Change in rate	0.82	(0.33)
State tax benefit (net of federal)	3.51	3.39
Warrant liability	(0.30)	1.71
State research and development credit	-	0.09
Federal research and development credit	-	1.44
Amortization	-	(0.29)
Stock-based compensation	(2.18)	(1.10)
Other	(0.05)	2.70
Federal income tax provision effective rate	0.26%	0.09%

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

	December 31,	
	2020	**2019**
Deferred tax assets relating to:		
Net operating loss carryforwards	$ 59,050	$ 56,827
Research and development tax carryforward	6,411	6,411
Other deferred tax assets	5,089	4,488
Total gross deferred tax assets	70,550	67,726
Deferred tax liabilities relating to:		
Property and equipment	(18)	-
Other deferred tax liabilities	476	540
Total gross deferred tax liabilities	458	540
Deferred tax assets less liabilities	70,092	67,186
Valuation allowance	(70,092)	(67,186)
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, 2020 (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	56,099	2,271	Indefinite
2019	22,922	352	Indefinite
2020	8,810	-	Indefinite
	$ 225,977	$ 6,411	

The Company also has certain state net operating loss carryforwards totaling $211.3 million, $145.4 million of which, if not utilized, will begin to expire in 2027 and $65.9 million of which have no expiration date. 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.

On March 27, 2020, the CARES Act was enacted into law in response to the COVID-19 pandemic. The Company has evaluated the various income and payroll tax provisions and expects little or no impact to income tax expense.

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 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 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 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,	
	2020	2019
Net loss - basic and diluted	$ (12,760)	$ (24,522)
Weighted average number of shares of common stock - basic and diluted	3,980,975	1,853,397
Net loss per share - basic and diluted	$ (3.21)	$ (13.23)

Diluted net loss per share of common stock is the same as basic net loss per share of common stock for the years ended December 31, 2020 and 2019 because the effects of potentially dilutive items were anti-dilutive for the respective periods. 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,	
	2020	2019
Deerfield Convertible Note	81,101	75,850
2021 Notes	-	10,958
Conversion of January 2020 Note	34,615	-
2019 Notes*	625,747	1,851,609
Awards under equity incentive plans	355,785	324,473
Common stock warrants	151,442	151,442
Total securities excluded from the calculation of weighted average number of shares of common stock outstanding	1,248,690	2,414,332

* Balance as of December 31, 2019 is inclusive of 1,652,437 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. As of December 31, 2020, the Deerfield Optional Conversion Feature has been utilized in full.

P. Severance Expense

In February 2020, the Company eliminated the chief business officer role and Gordon K. Johnson separated from the Company. In connection with his separation, Mr. Johnson is entitled to severance benefits as documented in his Amended and Restated Employment Agreement entered into in June 2015. The severance benefits consist of personnel and other related charges of approximately $0.4 million and stock compensation expense of approximately $0.4 million related to the acceleration of vesting on unvested shares subject to certain stock options. These severance benefits are presented as severance expense in the statements of operations for the year ended December 31, 2020. As of December 31, 2020, the Company had accrued severance expense recorded within accounts payable and accrued expenses in the amount of $0.1 million. As of and for the year ended December 31, 2019, there was no accrued severance or severance expense, 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 $145,000 and $133,000 for the years ended December 31, 2020 and 2019, 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 2020 or 2019.

R. Subsequent Events

Underwriting Agreement

On January 8, 2021, the Company entered into an underwriting agreement (the “Underwriting Agreement”) with Roth Capital Partners, LLC (the “Underwriter” or "Roth"), to issue and sell 6,765,463 shares of common stock of the Company, pre-funded warrants to purchase 926,844 shares of common stock and warrants to purchase 7,692,307 shares of common stock at an exercise price per share of $6.50 in an underwritten public offering (the “Public Offering”) pursuant to a Registration Statement on Form S-1 (File No. 333-250945) and a related prospectus, in each case filed with the Securities and Exchange Commission (the “SEC”). The offering price to the public is $6.50 per share of common stock and accompanying warrant, representing a public offering price of $6.4999 per share of common stock and $0.0001 per related warrant. In addition, the Company granted the Underwriter an option to purchase, for a period of 45 days, up to an additional 1,153,846 shares of the Company’s common stock and/or warrants to purchase up to an additional 1,153,846 shares of the Company’s common stock.

On January 8, 2021, the Underwriter exercised its over-allotment option, in part, for warrants to purchase 754,035 shares of the Company’s common stock. Further on February 1, 2021, the Underwriter again exercised its over-allotment option to purchase 374,035 shares of common stock. On February 3, 2021, we closed the underwriter's partial exercise of its over-allotment option.

On January 12, 2021, the Company closed the Public Offering. The aggregate gross proceeds to the Company from the Public Offering, including over-allotment, totaled approximately $52.4 million, before deducting underwriting discounts and commissions and offering expenses payable by the Company.

Pre-Funded Warrants

On January 12, 2021, pursuant to the terms of the Underwriting Agreement, the Company issued pre-funded warrants to purchase 926,844 shares of the Company’s common stock to specified investors in the Public Offering.

Duration and Exercise Price

Each pre-funded warrant has an initial exercise price per share equal to $0.0001. The pre-funded warrants will be immediately exercisable and will not expire prior to exercise. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting the Company’s common stock.

Exercisability

The pre-funded warrants are exercisable, at the option of each holder, in whole or in part, by delivering to the Company a duly executed exercise notice accompanied by payment in full for the number of shares of common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% of the Company’s outstanding common stock immediately after exercise, except that upon at least 61 days’ prior notice from the holder to the Company, the holder may increase the amount of beneficial ownership of outstanding stock after exercising the holder’s pre-funded warrants up to 9.99% of the number of shares of the Company’s common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants and Delaware law. Purchasers of pre-funded warrants may also elect prior to the issuance of the pre-funded warrants to have the initial exercise limitation set at 9.99% of the Company’s outstanding common stock.

Cashless Exercise

In lieu of making the cash payment otherwise contemplated to be made to the Company upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants.

Rights as a Stockholder

Except as otherwise provided in the pre-funded warrants or by virtue of such holder’s ownership of shares of the Company’s common stock, the holders of the pre-funded warrants do not have the rights or privileges of holders of common stock with respect to the shares of common stock underlying the pre-funded warrants, including any voting rights, until they exercise their pre-funded warrants. The pre-funded warrants provide that holders have the right to participate in distributions or dividends paid on the Company’s common stock.

Fundamental Transaction

In the event of a fundamental transaction, as described in the pre-funded warrants and generally including any reorganization, recapitalization or reclassification of the Company’s common stock, the sale, transfer or other disposition of all or substantially all of the Company’s properties or assets, the Company’s consolidation or merger with or into another person, the acquisition of more than 50% of the Company’s outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by the Company’s outstanding common stock, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction.

As of March 11, 2021, all pre-funded warrants have been exercised for 926,841 shares of common stock and gross proceeds of approximately $72.

Warrants to Purchase Common Stock

On January 12, 2021, pursuant to the terms of the Underwriting Agreement and December 2020 Exchange Agreement (as defined below), the Company issued warrants to purchase 12,078,361 shares of the Company's common stock (collectively, the "Warrants") in the Public Offering and in connection with the transactions contemplated under the December 2020 Exchange Agreement.

Duration and Exercise Price

The Warrants are exercisable from and after the date of their issuance and expire on the fifth anniversary of such date, at an exercise price per share of common stock equal to $6.50 per share. The holder of a Warrant will not be deemed a holder of the underlying common stock until the Warrant is exercised. No fractional shares of common stock will be issued in connection with the exercise of Warrant. Instead, for any such fractional share that would have otherwise been issued upon exercise of a Warrant, the Company will round such fraction up to the next whole share.

Exercisability

The Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to the Company a duly executed exercise notice, provided that payment in full for the number of shares of the Company's common stock purchased upon such exercise is delivered to the Company in accordance with the terms of the Warrants (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Warrant to the extent that the holder and its affiliates and any other person or entities with which such holder would constitute a Section 13(d) "group" would own more than 4.985% of the Company's outstanding common stock immediately after exercise.

Cashless Exercise

If, at the time a holder exercises its Warrants, a registration statement registering the issuance of the shares of common stock underlying such Warrant under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to the Company upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Warrants.

Right as a Stockholder

Except as otherwise provided in the Warrants or by virtue of such holder's ownership of shares of the Company's common stock, the holders of the Warrants do not have the rights or privileges of holders of common stock with respect to the shares of common stock underlying the Warrants, including any voting rights, until they exercise their Warrants. The Warrants provide that holders have the right to participate in distributions or dividends paid on the Company's common stock.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Warrants and generally including any reorganization, recapitalization or reclassification of the Company's common stock, the sale, transfer or other disposition of all or substantially all of the Company's properties or assets, the Company's consolidation or merger with or into another person, the acquisition of more than 50% of the Company's outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by the Company's outstanding common stock, the holders of the Warrants will be entitled to receive upon exercise of the Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Warrants immediately prior to such fundamental transaction. In addition, in the event of a fundamental transaction which is approved by the Company's board of directors, the holders of the warrants have the right to require the Company or a successor entity to redeem the Warrants for cash in the amount of the Black Scholes value of the unexercised portion of the Warrants on the date of the consummation of the fundamental transaction. In the event of a fundamental transaction which is not approved by the Company's board of directors, the holders of the Warrants have the right to require the Company or a successor entity to redeem the Warrants in the amount of the Black Scholes value of the unexercised portion of the Warrants on the date of the consummation of the fundamental transaction payable in the form of consideration paid to the holders of common stock in such fundamental transaction.

As of March 11, 2021, 3,057,395 Warrants have have been exercised for 2,626,418 shares of common stock and gross proceeds of approximately $14.3 million. These amounts are exclusive of the Warrants exercised as part of the Warrant Exercise Inducement transaction discussed below.

Underwriter Warrant

On January 12, 2021, pursuant to the terms of the Underwriting Agreement, the Company issued to the Underwriter a warrant to purchase 806,932 shares of the Company's common stock (the "Underwriter Warrant"). The Underwriter Warrant is subject to substantially the same terms and conditions as the Warrants, provided that the exercise price for the Underwriter Warrant is $8.125 per share. If the Underwriter exercises any additional portion of its over-allotment option, then the Company shall issue the Underwriter an additional Underwriter Warrant exercisable for a number of shares of common stock equal to 5.0% of the number of shares of common stock issued in such over-allotment exercise (including the shares of common stock issuable upon the exercise of any Warrants issued in connection therewith). In connection with the closing of the Underwriter's partial exercise of its over-allotment option, on February 3, 2021, the Underwriter was issued an additional warrant to purchase 18,702 shares of common stock. As of March 11, 2020, no Underwriter Warrants have been exercised.

December 2020 Exchange Agreement Amendment

On January 12, 2021, in connection with the transactions contemplated by the December 2020 Exchange Agreement, the Company entered into an Amendment to Senior Secured Convertible Notes and Amendment to Warrant (the "January 2021 Amendment") with the Deerfield Holders. The January 2021 Amendment modifies certain specified terms of (i) the Facility Notes and (ii) the Deerfield Warrant to, among other things, exclude the transactions contemplated by the December 2020 Exchange Agreement and issuance of securities pursuant to the Underwriting Agreement from the anti-dilution provisions of the Facility Notes and the Deerfield Warrant.

Series B-2 Preferred Stock

Pursuant to the December 2020 Exchange Agreement, on January 12, 2021, the Company issued to the Facility Note Holders an aggregate of 31,476.98412 shares of its Series B-2 Preferred Stock and warrants exercisable for an aggregate of 3,632,019 shares of the Company's common stock (the "Exchange Warrants").

The Series B-2 Preferred Stock is convertible into an aggregate of 4,842,690 shares of the Company's common stock at a conversion price equal to $6.4999.

Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of the Series B-2 Convertible Preferred Stock

On January 11, 2021, as a condition to closing of the transactions contemplated by the December 2020 Exchange Agreement, the Company filed an Amended and Restated 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-2 Preferred Stock.

Immediately following, the closing of the Public Offering, pursuant to the terms of the December 2020 Exchange Agreement, the Company:

- Exchanged approximately $31.5 million (the "Exchange") of the outstanding principal and accrued interest on the Facility Notes for (i) the Series B-2 Preferred Stock and (ii) the Exchange Warrants; and

- made a payment of approximately $30.3 million (the "Debt Payment") in partial repayment of the remaining outstanding principal and accrued interest on the Facility Notes.

Immediately following the completion of the Exchange and Debt Payment, the aggregate balance of principal and accrued interest remaining outstanding under the Facility Notes was approximately $7.6 million.

Upon the closing of the Exchange and related Debt Payment, the amendments to the Facility Agreement, the Notes and the Investors' Rights Agreement, dated as of February 19, 2015, by and among the Company, Deerfield and the other parties signatory thereto, contemplated by the December 2020 Exchange Agreement that were conditional upon, among other things, the closing of the Public Offering, the filing of the Series B-2 Certificate of Designation and/or the approval for listing of the Company's common stock, including the shares issuable upon conversion of the Series B-2 Preferred Stock and exercise of the Exchange Warrants, on the Nasdaq Capital Market, became effective on January 12, 2021.

As of March 11, 2021, all shares of Series B-2 Preferred Stock have have been converted into 4,842,699 shares of common stock.

Listing on the Nasdaq Capital Market

On January 7, 2021, the Company's common stock was approved for listing on The Nasdaq Capital Market. The Company's common stock began trading on The Nasdaq Capital Market on January 8, 2021 under the ticker symbol "KMPH".

Warrant Exercise Inducement Letters and Issuance of Warrants

On January 26, 2021, the Company entered into warrant exercise inducement offer letters ("Inducement Letters") with certain holders of warrants issued in the Public Offering discussed above (the "Existing Warrants") (collectively, the "Exercising Holders") pursuant to which such holders agreed to exercise for cash their Existing Warrants to purchase 6,620,358 shares of the Company's common stock in exchange for the Company's agreement to issue new warrants (the "Inducement Warrants") on substantially the same terms as the Existing Warrants, except as set forth in the following sentence, to purchase up to 7,944,430 shares of the Company's common stock, which is equal to 120% of the number of shares of the Company's common stock issued upon exercise of the Existing Warrants. The purchase price of the Inducement Warrants was $0.125 per share underlying each Inducement Warrant, and the Inducement Warrants have an exercise price of $6.36 per share. The Company received aggregate gross proceeds of approximately $44.0 million from the exercise of the Existing Warrants by the Exercising Holders and the sale of the Inducement Warrants. The Company engaged Roth as its exclusive placement agent in connection with these transactions and paid Roth a fee equal to 6% of gross proceeds from the exercise of the Existing Warrants by the Exercising Holders and the sale of the Inducement Warrants. As a result of this transaction the anti-dilution provisions contained with the Deerfield Warrant were triggered and the exercise price of the Deerfield Warrant was reduced from $93.60 per share to $46.25 per share.

The Company also agreed to file a registration statement covering the resale of the shares of the Company's common stock issued or issuable upon the exercise of the Inducement Warrants no later than 10 calendar days following the date of the Inducement Letters.

Inducement Warrant Terms

Duration and Exercise Price

The Inducement Warrants are exercisable from and after the date of their issuance and expire on the fifth anniversary of such date, at an exercise price per share of common stock equal to $6.36 per share. The holder of an Inducement Warrant will not be deemed a holder of the underlying common stock until the Inducement Warrant is exercised. No fractional shares of common stock will be issued in connection with the exercise of the Inducement Warrants. Instead, for any such fractional share that would have otherwise been issued upon exercise of an Inducement Warrant, the Company will round such fraction up to the next whole share.

Exercisability

The Inducement Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to the Company a duly executed exercise notice, provided that payment in full for the number of shares of the Company's common stock purchased upon such exercise is delivered to the Company in accordance with the terms of the Inducement Warrants (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Inducement Warrant to the extent that the holder and its affiliates and any other person or entities with which such holder would constitute a Section 13(d) "group" would own more than 4.99% (or, upon election by a holder prior to the issuance of its Inducement Warrants, 9.99%) of the Company's outstanding common stock immediately after exercise.

Cashless Exercise

If, at the time a holder exercises its Inducement Warrants, a registration statement registering the issuance of the shares of common stock underlying such Inducement Warrant under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to the Company upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Inducement Warrants.

Right as a Stockholder

Except as otherwise provided in the Inducement Warrants or by virtue of such holder's ownership of shares of the Company's common stock, the holders of the Inducement Warrants do not have the rights or privileges of holders of common stock with respect to the shares of common stock underlying the Inducement Warrants, including any voting rights, until they exercise their Inducement Warrants. The Inducement Warrants provide that holders have the right to participate in distributions or dividends paid on the Company's common stock.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Inducement Warrants and generally including any reorganization, recapitalization or reclassification of the Company's common stock, the sale, transfer or other disposition of all or substantially all of the Company's properties or assets, the Company's consolidation or merger with or into another person, the acquisition of more than 50% of the Company's outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by the Company's outstanding common stock, the holders of the Inducement Warrants will be entitled to receive upon exercise of the Inducement Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Inducement Warrants immediately prior to such fundamental transaction. In addition, in the event of a fundamental transaction which is approved by the Company's board of directors, the holders of the Inducement Warrants have the right to require the Company or a successor entity to redeem the Inducement Warrants for cash in the amount of the Black Scholes value of the unexercised portion of the Inducement Warrants on the date of the consummation of the fundamental transaction. In the event of a fundamental transaction which is not approved by the Company's board of directors, the holders of the Inducement Warrants have the right to require the Company or a successor entity to redeem the Inducement Warrants in the amount of the Black Scholes value of the unexercised portion of the Warrants on the date of the consummation of the fundamental transaction payable in the form of consideration paid to the holders of common stock in such fundamental transaction.

As of March 11, 2021, 1,676,921 Inducement Warrants have have been exercised for 1,676,921 shares of common stock and gross proceeds of approximately $10.7 million.

Payoff of Facility Agreement Notes and Termination of Facility Agreement

On February 8, 2021, the Company entered into a payoff letter with the Facility Agreement Note Holders, pursuant to which the Company agreed to pay off and thereby terminate the Facility Agreement.

Pursuant to the payoff letter, the Company paid a total of $8.0 million to the Facility Agreement Note Holders, representing the principal balance, accrued interest outstanding and a prepayment fee in repayment of the Company's outstanding obligations under the Facility Agreement.

Pursuant to the payoff letter, all outstanding indebtedness and obligations of the Company owing to the Facility Agreement Note Holders under the Facility Agreement have been paid in full. The Facility Agreement and the notes thereunder, as well as the security interests in the assets of the Company securing the Facility Agreement and note obligations, have been terminated. The Facility Agreement Note Holders will retain the warrants previously issued to them by the Company.

FDA Approval of the AZSTARYS NDA

On March 2, 2021, the Company announced that the FDA approved the NDA for AZSTARYS™ (serdexmethylphenidate and dexmethylphenidate capsules, for oral use, CII), a once-daily product for the treatment of ADHD in patients age six years and older. As a result of the FDA's approval of the AZSTARYS NDA, the Company has earned a regulatory milestone payment as provided under the KP415 License Agreement.

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 Amendment of Amended and Restated Certificate of Incorporation of the Company, effective as of December 23, 2020 (incorporated herein by reference to Registrant's Current Report on Form 8-K as filed with the SEC on December 23, 2020).
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	Amended and Restated 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 January 13, 2021).
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 July 17, 2020).
4.1	Reference is made to Exhibits 3.1 , 3.1.1, 3.1.2, 3.1.3 and 3.2 hereof.
4.2*	Specimen stock certificate evidencing shares of Common Stock.
4.3	Form of Series A Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.10 of the Company's Registration Statement on Form S-1 (File No. 333-250945), as amended and filed with the SEC on December 23, 2020)
4.4	Form of Series B Pre-Funded Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.11 of the Company's Registration Statement on Form S-1 (File No. 333-250945), as amended and filed with the SEC on December 23, 2020)
4.5	Form of Common Stock Purchase Warrant and schedule of holders (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on January 13, 2021).
4.6	Series A Common Stock Purchase Warrant for Underwriter (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on January 13, 2021).
4.7	Form of Inducement Warrant (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on January 26, 2021).
4.8*	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	Payoff letter, dated as of February 8, 2021, by and among the Company and the lenders named therein (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on February 9, 2021).
10.3	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).
10.3.1	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).
10.3.2	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).
10.3.3	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).
10.3.4	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)
10.3.5	Amendment to Senior Secured Convertible Notes and Amendment to Warrant, dated as of January 12, 2021, by and among the Company, 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 February 9, 2021)
10.4	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).
10.4.1	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).
10.5	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).
10.6+	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).
10.7#	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).
10.7.1#	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).
10.7.2#	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).
10.7.3#	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).
10.7.4#	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).
10.7.5#	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).
10.7.6#	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)

Exhibit No.	Description
10.8#*	Sixth Amended and Restated Non-Employee Director Compensation Policy.
10.9#	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).
10.10#	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).
10.10.1#	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).
10.11#	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).
10.11.1#	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).
10.12#	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).
10.12.1#	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).
10.13#	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).
10.14	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).
10.14.1	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).
10.14.2	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).
10.14.3	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).
10.15+	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).
10.15.1+	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).
10.16	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).
10.17+	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)
10.18	Form of Inducement Letter (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on January 26, 2021).
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: March 11, 2021

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

Dated: March 11, 2021

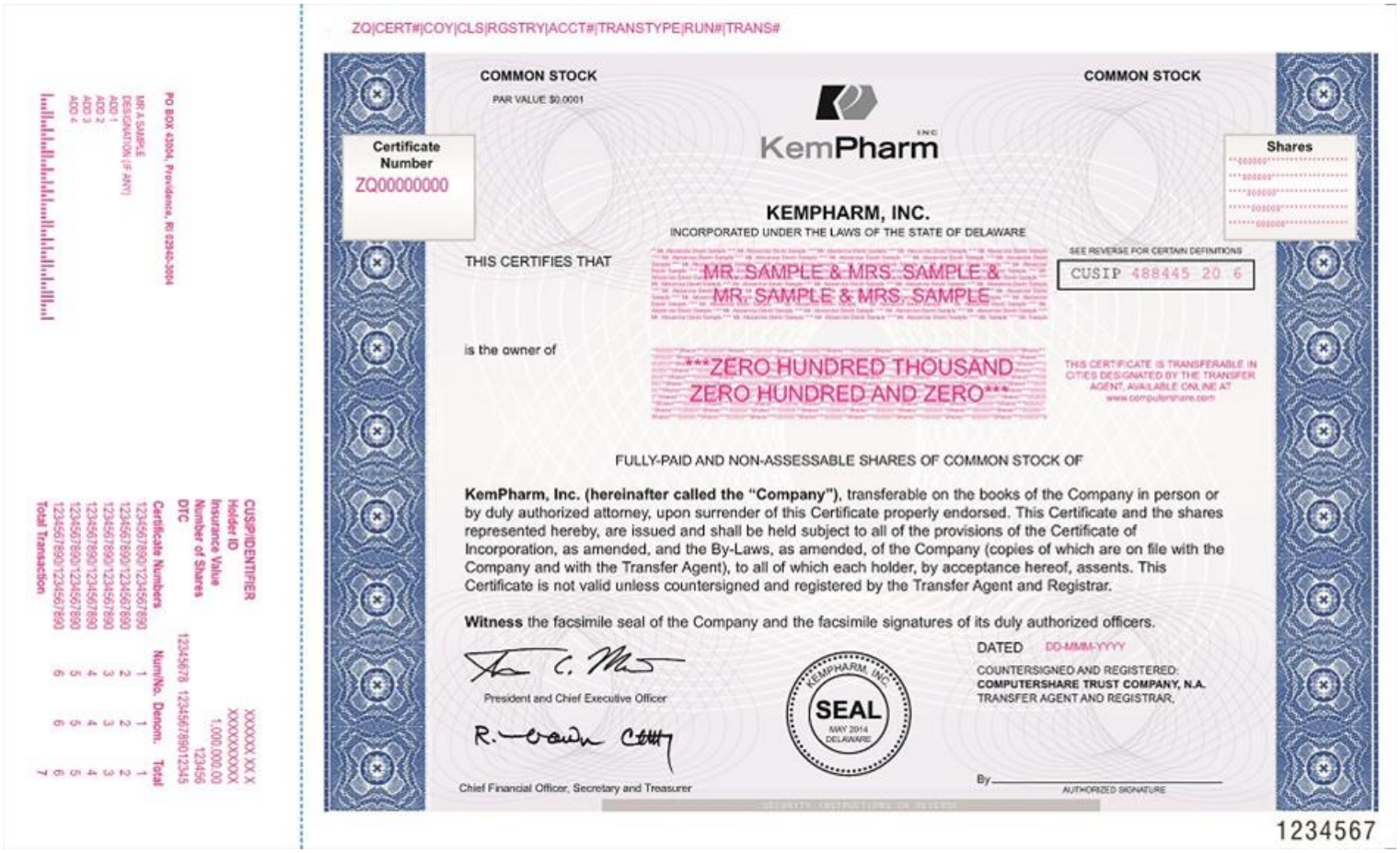
By: /s/ R. LaDuane Clifton
R. LaDuane Clifton, CPA
Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer)

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Travis C. Mickle Travis C. Mickle, Ph.D.	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 11, 2021
/s/ R. LaDuane Clifton R. LaDuane Clifton, CPA	Chief Financial Officer, Secretary and Treasurer (Principal Financial Officer)	March 11, 2021
/s/ Timothy J. Sangiovanni Timothy J. Sangiovanni, CPA	Vice President, Corporate Controller (Principal Accounting Officer)	March 11, 2021
/s/ Matthew R. Plooster Matthew R. Plooster	Director	March 11, 2021
/s/ Richard W. Pascoe Richard W. Pascoe	Director	March 11, 2021
/s/ Joseph B. Saluri Joseph B. Saluri	Director	March 11, 2021
/s/ David S. Tierney David S. Tierney	Director	March 11, 2021



ZQ|CERT#|COY|CLS|RGSTRY|ACCT#|TRANSTYPE|RUN#|TRANS#

PO BOX 43004, Providence, RI 02940-3004

MR A SAMPLE
DESIGNATION (IF ANY)
ADD 1
ADD 2
ADD 3
ADD 4

CUSIP/IDENTIFIER XXXXXX XX X
Holder ID XXXXXXXXXX
Insurance Value 1,000,000.00
Number of Shares DTC 123456

Certificate Numbers	Num/No.	Denom.	Total
1234567890 1234567890	1	1	1
1234567890 1234567890	2	2	2
1234567890 1234567890	3	3	3
1234567890 1234567890	4	4	4
1234567890 1234567890	5	5	5
1234567890 1234567890	6	6	6
Total Transaction			7

COMMON STOCK

PAR VALUE $0.0001

COMMON STOCK

Certificate Number
ZQ00000000

KemPharm INC

Shares

KEMPHARM, INC.

INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE

THIS CERTIFIES THAT

MR. SAMPLE & MRS. SAMPLE &
MR. SAMPLE & MRS. SAMPLE

SEE REVERSE FOR CERTAIN DEFINITIONS

CUSIP 488445 20 6

is the owner of

***ZERO HUNDRED THOUSAND
ZERO HUNDRED AND ZERO***

THIS CERTIFICATE IS TRANSFERABLE IN CITIES DESIGNATED BY THE TRANSFER AGENT, AVAILABLE ON LINE AT www.computershare.com

FULLY-PAID AND NON-ASSESSABLE SHARES OF COMMON STOCK OF

KemPharm, Inc. (hereinafter called the "Company"), transferable on the books of the Company in person or by duly authorized attorney, upon surrender of this Certificate properly endorsed. This Certificate and the shares represented hereby, are issued and shall be held subject to all of the provisions of the Certificate of Incorporation, as amended, and the By-Laws, as amended, of the Company (copies of which are on file with the Company and with the Transfer Agent), to all of which each holder, by acceptance hereof, assents. This Certificate is not valid unless countersigned and registered by the Transfer Agent and Registrar.

Witness the facsimile seal of the Company and the facsimile signatures of its duly authorized officers.

President and Chief Executive Officer

Chief Financial Officer, Secretary and Treasurer

KEMPHARM, INC.
SEAL
MAY 2014
DELAWARE

DATED DD-MMM-YYYY

COUNTERSIGNED AND REGISTERED:
COMPUTERSHARE TRUST COMPANY, N.A.
TRANSFER AGENT AND REGISTRAR,

By _____
AUTHORIZED SIGNATURE

1234567

KEMPHARM, INC.

THE COMPANY WILL FURNISH WITHOUT CHARGE TO EACH SHAREHOLDER WHO SO REQUESTS, A SUMMARY OF THE POWERS, DESIGNATIONS, PREFERENCES AND RELATIVE, PARTICIPATING, OPTIONAL OR OTHER SPECIAL RIGHTS OF EACH CLASS OF STOCK OF THE COMPANY AND THE QUALIFICATIONS, LIMITATIONS OR RESTRICTIONS OF SUCH PREFERENCES AND RIGHTS, AND THE VARIATIONS IN RIGHTS, PREFERENCES AND LIMITATIONS DETERMINED FOR EACH SERIES, WHICH ARE FIXED BY THE CERTIFICATE OF INCORPORATION OF THE COMPANY, AS AMENDED, AND THE RESOLUTIONS OF THE BOARD OF DIRECTORS OF THE COMPANY, AND THE AUTHORITY OF THE BOARD OF DIRECTORS TO DETERMINE VARIATIONS FOR FUTURE SERIES. SUCH REQUEST MAY BE MADE TO THE OFFICE OF THE SECRETARY OF THE COMPANY OR TO THE TRANSFER AGENT. THE BOARD OF DIRECTORS MAY REQUIRE THE OWNER OF A LOST OR DESTROYED STOCK CERTIFICATE, OR HIS LEGAL REPRESENTATIVES, TO GIVE THE COMPANY A BOND TO INDEMNIFY IT AND ITS TRANSFER AGENTS AND REGISTRARS AGAINST ANY CLAIM THAT MAY BE MADE AGAINST THEM ON ACCOUNT OF THE ALLEGED LOSS OR DESTRUCTION OF ANY SUCH CERTIFICATE.

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM	- as tenants in common	UNIF GIFT MIN ACT	- ..... (Cust) Custodian ..... (Minor) under Uniform Gifts to Minors Act ..... (State)
TEN ENT	- as tenants by the entireties		
JT TEN	- as joint tenants with right of survivorship and not as tenants in common	UNIF TRF MIN ACT	- ..... (Cust) Custodian (until age .....) ..... (Minor) under Uniform Transfers to Minors Act ..... (State)

Additional abbreviations may also be used though not in the above list.

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

For value received, _____ hereby sell, assign and transfer unto

_____

(PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS, INCLUDING POSTAL ZIP CODE, OF ASSIGNEE)

_____

_____

_____ Shares

of the common stock represented by the within Certificate, and do hereby irrevocably constitute and appoint

_____ Attorney

to transfer the said stock on the books of the within-named Company with full power of substitution in the premises.

Dated: _____ 20_____

Signature: _____

Signature: _____

Notice: The signature to this assignment must correspond with the name as written upon the face of the certificate, in every particular, without alteration or enlargement, or any change whatever.

Signature(s) Guaranteed: Medallion Guarantee Stamp

THE SIGNATURE(S) SHOULD BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION (Banks, Stockbrokers, Savings and Loan Associations and Credit Unions) WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM, PURSUANT TO S.E.C. RULE 17Ad-15.

SECURITY INSTRUCTIONS

THIS IS WATERMARKED PAPER. DO NOT ACCEPT WITHOUT NOTED WATERMARK. HOLD TO LIGHT TO VERIFY WATERMARK.

The IRS requires that we report the cost basis of certain shares acquired after January 1, 2011. If your shares were covered by the legislation and you have sold or transferred the shares and requested a specific cost basis calculation method, we have processed as requested. If you did not specify a cost basis calculation method, we have defaulted to the first in, first out (FIFO) method. Please visit our website or consult your tax advisor if you need additional information about cost basis.

If you do not keep in contact with us or do not have any activity in your account for the time periods specified by state law, your property could become subject to state unclaimed property laws and transferred to the appropriate state.

15345627

Exhibit 4.8

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 31,480 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). As of March 10, 2021, we had outstanding (i) 28,376,321 shares of common stock, and (ii) no shares of Series B-2 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

Pursuant to our amended and restated certificate of incorporation, our board of directors has the authority, without further action by the stockholders (unless such stockholder action is required by applicable law or stock exchange listing rules), to designate and 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 designations, powers, preferences, privileges and relative participating, optional or special rights and the qualifications, limitations or restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption and liquidation preferences, any or all of which may be greater than the rights of our common stock, 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, without stockholder approval, can issue preferred stock with voting, conversion or other rights that could adversely affect the voting power and other rights of the holders of our common stock. Preferred stock could be issued quickly with terms designed to delay or prevent a change in control of our company or make removal of management more difficult. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of our common stock and may adversely affect the voting power of holders of our common stock and reduce the likelihood that our common stockholders will receive dividend payments and payments upon liquidation.

Our board of directors will fix the designations, voting powers, preferences and rights, as well as the qualifications, limitations or restrictions, of the preferred stock of each series that we offer in the certificate of designation relating to that series.

The Delaware General Corporation Law, the law governing corporations in the state of our incorporation, provides that the holders of preferred stock will have the right to vote separately as a class (or, in some cases, as a series) on an amendment to our certificate of incorporation if the amendment would change the par value or, unless the certificate of incorporation provided otherwise, the number of authorized shares of the class or change the powers, preferences or special rights of the class or series so as to adversely affect the class or series, as the case may be. This right is in addition to any voting rights that may be provided for in the applicable certificate of designation.

As of March 10, 2021, we have designated an aggregate of 42,634 shares of preferred stock, of which 9,578 are designated Series A Preferred Stock, 1,576 are designated Series B-1 Preferred Stock and 31,480 are designated Series B-2 Preferred Stock.

Amended and Restated Series B-2 Certificate of Designation

On January 11, 2021, we filed an Amended and Restated 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-2 Preferred Stock. As of March 10, 2021, we had designated 31,480 shares of preferred stock as Series B-2 Preferred Stock, of which no shares were outstanding.

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 $6.4999 (subject to adjustment to reflect stock splits and similar events).

The Series B-2 Preferred Stock are convertible at any time on or after the PDUFA Date (as defined in the Amended and Restated Series B-2 Certificate of Designation) at the option of the holders thereof; provided that the holders thereof will be prohibited from converting shares of Series B-2 Preferred Stock into shares 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-2 Preferred Stock are not be redeemable. In the event of our liquidation, dissolution or winding up or our change in control, the holders of Series B-2 Preferred Stock will receive, prior to any distribution or payment on our common stock, an amount equal to the greater of (i) $1,000 per share (in the case of a change in control, transaction consideration with such value), or (ii) the amount (in the case of a change in control, in the form of the transaction consideration) per share each such holder would have been entitled to receive if every share of Series B-2 Preferred Stock had been converted into common stock immediately prior to such event, in each case, plus any declared but unpaid dividends thereon. With respect to rights upon liquidation, the Series B-2 Preferred Stock rank senior to our common stock, on parity with any Parity Securities (as defined in the Amended and Restated Series B-2 Certificate of Designation) and junior to any Senior Securities (as defined in the Amended and Restated Series B-2 Certificate of Designation) and existing and future indebtedness. Except as otherwise required by law (or with respect to approval of certain actions involving our organizational documents that adversely affect the holders of Series B-2 Preferred Stock and other specified matters regarding the rights, preferences and privileges of the Series B-2 Preferred Stock), the Series B-2 Preferred Stock do not have voting rights. The Series B-2 Preferred Stock are not be subject to any price-based anti-dilution protections and do not provide for any accruing dividends, but do provide that holders of Series B-2 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 Amended and Restated Series B-2 Certificate of Designation also provides for partial liquidated damages in the event that we fail to timely convert shares of Series B-2 Preferred Stock into common stock in accordance with the Amended and Restated Series B-2 Certificate of Designation.

Outstanding Warrants

As of March 10, 2021, we had outstanding warrants to purchase up to 9,645,193 shares of our common stock at a weighted average exercise price of $7.142 per share and which expire between October 24, 2023 and January 26, 2026. 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 Private Design Fund III, L.P., or Deerfield, as more fully described below under "—Registration Rights."

In June 2014, in connection with our entering into a 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 120,192 shares of our common stock at an exercise price of $93.60 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, 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 on our principal market or exchange 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 certain specified sales and in any offering deemed by the Securities and Exchange Commission, or the SEC, to constitute an "at the market offering" as defined in Rule 415 of the Securities Act of 1933, or the Securities Act, of our common stock, the exercise 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 $93.60 per share. On January 26, 2021, we entered into a Warrant Inducement transaction which triggered these exercise price protection provision and the exercise price of the Deerfield Warrant was reduced from $93.60 per share to $46.25 per share.

In January 2021, and in February 2021 in accordance with the underwriter's partial exercise of their over-allotment option, we issued the Underwritten Warrants and additional substantially similar warrants to purchase shares of our common stock pursuant to an underwriting agreement and the December 2020 Exchange Agreement (as defined below), or, collectively with the Underwritten Warrants and the Warrants, the January 2021 Warrants.

The January 2021 Warrants are exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise). A holder (together with its affiliates) may not exercise any portion of a January 2021 Warrant to the extent that the holder would own more than 4.99% of our outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder of a January 2021 Warrant issued under the underwriting agreement, the holder may increase the amount of beneficial ownership of outstanding stock after exercising the holder's January 2021 Warrant up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the January 2021 Warrant and Delaware law. Purchasers of January 2021 Warrants under the underwriting agreement may have also elected prior to the issuance of the January 2021 Warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock.

If, at the time a holder exercises its January 2021 Warrants, a registration statement registering the issuance of the shares of common stock underlying such January 2021 Warrant under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the January 2021 Warrants.

In the event of a fundamental transaction, as described in the January 2021 Warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, a consolidation or merger of us with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the January 2021 Warrants will be entitled to receive upon exercise of the January 2021 Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the January 2021 Warrants immediately prior to such fundamental transaction. In addition, in the event of a fundamental transaction which is approved by our board of directors, the holders of the January 2021 Warrants have the right to that we or a successor entity to redeem the January 2021 Warrants for cash in the amount of the Black Scholes value of the unexercised portion of the January 2021 Warrants on the date of the consummation of the fundamental transaction. In the event of a fundamental transaction which is not approved by our board of directors, the holders of the January 2021 Warrants have the right to require that we or a successor entity to redeem the January 2021 Warrants in the amount of the Black Scholes value of the unexercised portion of the January 2021 Warrants on the date of the consummation of the fundamental transaction payable in the form of consideration paid to the holders of our common stock in such fundamental transaction.

Registration Rights

Investors' Rights Agreement

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.

Demand Registration Rights

Deerfield has the right to demand that we file a Form S-1 registration statement, as long as the anticipated aggregate offering price, net of underwriting discounts and commissions, would exceed $15.0 million. These registration rights are subject to specified conditions and limitations, including the right of the underwriters, if any, to limit the number of shares included in any such registration under specified circumstances. Upon such a request, we are required to effect the registration as soon as reasonably possible.

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 our 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 has been exercised in full and Rule 144 or another similar exemption under the Securities Act 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 expiration of the Deerfield Warrant.

Anti-Takeover Provisions

Section 203 of the Delaware General Corporation Law

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

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

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

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

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

Certificate of Incorporation and Bylaws

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 our 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 of directors, only be filled by a majority vote of the directors then serving on the board of directors, 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 eliminates 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 bylaws provide that (1) unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) shall be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (A) any derivative action or proceeding brought on behalf of us; (B) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any current or former director, officer or other employee of us, to us or our stockholders; (C) any action or proceeding asserting a claim against us any current or former director, officer or other employee of us, arising out of or pursuant to any provision of the Delaware General Corporation Law, or the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws (as each may be amended from time to time); (D) any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (including any right, obligation, or remedy thereunder); (E) any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (F) any action or proceeding asserting a claim against us or any director, officer or other employee of us, governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants, provided that this provision shall not apply to suits brought to enforce a duty or liability created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; (2) unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act; and (3) any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to the provisions of our amended and restated bylaws.

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."

Exhibit 10.8

KemPharm, Inc.
Sixth Amended and Restated
Non-Employee Director
Compensation Policy

Each member of the board of director (the "***Board***") of KemPharm, Inc. (the "***Company***") who is not also an employee of the Company or any subsidiary of the Company shall be entitled to the following compensation for service on the Board and its committees:

Cash Compensation

Cash compensation shall be paid in the following annual amounts. Payments shall be made in quarterly installments in arrears on the last day of each calendar quarter in which service occurred, and shall be *prorated* as appropriated for a director who does not serve for the full quarter. For the avoidance of doubt, the cash compensation set forth below shall apply for the entire quarter in which this policy is adopted by the Board.

1. Annual Board Service Retainer:

   a. All non-employee directors: $35,000
   b. Chairman of the Board, if not an employee, or lead independent director, if any (in addition to the retainer for all non-employee directors): $15,000

2. Annual Committee Member Service Retainer:

   a. Member of the Audit Committee: $7,500
   b. Member of the Compensation Committee: $5,000
   c. Member of the Nominating and Corporate Governance Committee: $5,000

3. Annual Committee Chair Service Retainer (in addition to Committee Member Service Retainer):

   a. Chairman of the Audit Committee: $15,000
   b. Chairman of the Compensation Committee: $10,000
   c. Chairman of the Nominating and Corporate Governance Committee: $7,500

Equity Compensation

The equity compensation set forth below will be granted under the Company's 2014 Equity Incentive Plan, or, as the case may be, any successor equity incentive plan approved by the stockholders of the Company (the "***Plan***"). All stock options granted under this policy will be nonqualified stock options using the Company's standard form of Nonqualified Stock Option Agreement under the Plan, with an exercise price per share equal to the last reported sale price of the Company's common stock on the NASDAQ Capital Market on the date of grant or, if such grant date is not a trading date, on the last trading date prior to the grant date, and with a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).

Annual Grant: On the date of each annual stockholders meeting of the Company, each director who continues to serve as a non-employee member of the Board following such stockholders meeting will be automatically, and without further action by the Board or the Compensation Committee of the Board, be granted a stock option for 15,000 shares of common stock. The stock options will vest and become exercisable in full on the earlier of (1) the first anniversary of the grant date, (2) the day before the first annual stockholders meeting occurring after the grant date or (3) immediately prior to a "Change in Control" as defined in the Plan, subject in each case to the director's continued service on such vesting date. For the avoidance of doubt, the common stock share number set forth above shall be on a post-reverse stock split basis (giving effect to the reverse stock split adopted by the Company in December 2020).

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements (No. 333-234235, No. 333-252078 and No. 333-252903) on Form S-3 and Registration Statements (No. 333-203703, No. 333-210369, No. 333-216858, No. 333-224062, No. 333-230041, No. 333-236794 and No. 333-252743) on Form S-8 of KemPharm, Inc. of our report dated March 11, 2021 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, 2020.

/s/ RSM US LLP

Orlando, Florida
March 11, 2021

Exhibit 31.1

CERTIFICATIONS

I, Travis C. Mickle, certify that:

1. I have reviewed this Annual Report on Form 10-K of KemPharm, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 11, 2021

/s/ Travis C. Mickle

Name: Travis C. Mickle, Ph.D.
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, R. LaDuane Clifton, certify that:

1. I have reviewed this Annual Report on Form 10-K of KemPharm, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 11, 2021

/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, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Travis C. Mickle, Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 11, 2021

/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, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, R. LaDuane Clifton, Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 11, 2021

/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.