As filed with the Securities and Exchange Commission on January 5, 2021

Registration No. 333-250945

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

Amendment No. 3
to
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

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 Number)**

1180 Celebration Boulevard, Suite 103
Celebration, FL 34747
(321) 939-3416
(Address, including zip code, and telephone number, including area code of registrant's principal executive offices)

Travis C. Mickle, Ph.D.
President, Chief Executive Officer and Chairman of the Board of Directors
KemPharm, Inc.
1180 Celebration Boulevard, Suite 103
Celebration, FL 34747
(321) 939-3416
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Brent B. Siler **Matthew P. Dubofsky** **Cooley LLP** **380 Interlocken Crescent, Suite 900** **Broomfield, CO 80021** **(720) 566-4000**	**R. LaDuane Clifton** **Chief Financial Officer** **KemPharm, Inc.** **1180 Celebration Boulevard, Suite 103** **Celebration, FL 34747** **(321) 939-3416**	**Charles E. Phillips, Esq.** **Ellenoff Grossman & Schole LLP** **1345 Avenue of the Americas** **New York, New York 10105** **(212) 370-1300**

From time to time after the effective date of this Registration Statement
(Approximate date of commencement of proposed sale to the public)

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box: ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum Aggregate offering price(1)	Amount of registration fee
Common stock, $0.0001 par value per share(2)(3)	$57,500,000	$6,273
Warrants to purchase shares of common stock	—	(4)
Common stock issuable upon exercise of warrants(2)(3)	$57,500,000	$6,273
Pre-funded warrants to purchase shares of common stock	(5)	
Shares of common stock issuable upon exercise of the Pre-funded Warrants(3)	(5)	
Underwriter warrants to purchase shares of common stock	—	(4)
Common stock issuable upon exercise of underwriter warrants(2)(3)	$5,750,000	$628
Total	$120,750,000	$13,174(6)

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended, or the Securities Act.
(2) Includes shares subject to the underwriter's over-allotment option.
(3) Pursuant to Rule 416 under the Securities Act, there is also being registered hereby such indeterminate number of additional shares of common stock as may be issued or issuable because of stock splits, stock dividends, stock distributions, and similar transactions.
(4) No fee required pursuant to Rule 457(g).
(5) The proposed maximum aggregate offering price of the common stock will be reduced on a dollar-for-dollar basis based on the offering price of any pre-funded warrants sold in the offering, and the proposed maximum aggregate offering price of the pre-funded warrants to be sold in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any common stock sold in the offering. Accordingly, the proposed maximum aggregate offering price of the common stock and pre-funded warrants (including the common stock issuable upon exercise of the pre-funded warrants), if any, is $57,500,000, including the underwriter's option to purchase additional shares of common stock but excluding the common stock issuable upon exercise of the underwriter options.
(6) The Registrant previously paid $12,860 of the registration fee.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment that specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION
DATED JANUARY 5, 2021

PROSPECTUS

KemPharm INC

4,784,688 Shares of Common Stock
Warrants to Purchase up to 4,784,688 Shares of Common Stock
Pre-Funded Warrants to Purchase Shares of Common stock

We are offering 4,784,688 shares of our common stock and warrants to purchase up to 4,784,688 shares of our common stock. Each share of our common stock is being sold with one warrant to purchase one share of our common stock, at an assumed combined public offering price of $10.45 per share of common stock and accompanying warrant, representing a public offering price of $10.4499 per share of common stock and $0.0001 per related warrant. The warrants are exercisable from and after the date of their issuance and expire on the anniversary of such date, at an exercise price per share of common stock equal to 100% of the combined public offering price per share of common stock and related warrant in this offering. The shares of common stock and warrants will be issued separately.

We are also offering to those purchasers, if any, whose purchase of common stock in this offering would otherwise result in any such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of such purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if such purchaser so chooses, pre-funded warrants in lieu of shares of our common stock that would otherwise result in such purchaser's beneficial ownership exceeding 4.99% (or, at the election of such purchaser, 9.99%) of our outstanding common stock. The purchase price for each pre-funded warrant will equal the per share public offering price for the common stock in this offering less the $0.0001 per share exercise price of each such pre-funded warrant, and the exercise price of each pre-funded warrant will equal $0.0001 per share. Each pre-funded warrant will be exercisable upon issuance and will not expire prior to exercise.

Our common stock is listed on the OTC Markets Venture Market, or the OTCQB, under the symbol "KMPH." On January 4, 2021, the last reported sale price of our common stock as reported on the OTC Markets Venture Market was $10.45 per share. We have applied to list our common stock on The NASDAQ Capital Market under the symbol "KMPH." We will not consummate this offering unless our common stock is approved for listing on The NASDAQ Capital Market. The closing sale price of our common stock as reported on the OTCQB may not be indicative of the market price of our common stock on The NASDAQ Capital Market. There is no established public trading market for the warrants or the pre-funded warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list the warrants or the pre-funded warrants on any national securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the warrants and the pre-funded warrants will be limited.

We are a "smaller reporting company" under applicable Securities and Exchange Commission rules and are subject to reduced public company reporting requirements for this prospectus and future filings.

The combined public offering price per share of our common stock and accompanying warrant will be determined between us, the underwriter and investors based on market conditions at the time of pricing, and may be at a discount to the current market price of our common stock. Therefore, the recent market price used throughout this prospectus may not be indicative of the actual combined public offering price.

Our business and an investment in our common stock involve significant risks. See "Risk Factors" beginning on page 9 of this prospectus.

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

	Per Share and related Warrant(2)	Per Pre-Funded Warrant and related Warrant(2)	Total
Public Offering Price	$	$	$
Underwriting Discounts and Commissions(1)	$	$	$
Proceeds to Us (Before Expenses)	$	$	$

(1) See "Underwriting" for a description of the compensation payable to the underwriter.
(2) The public offering price and underwriting discount corresponds to (x)(i) a public offering price per share of $ and (ii) a public offering price per warrant of $, and (y)(i) a public offering price per pre-funded warrant of $ and (ii) a public offering price per warrant of $.

We have granted the underwriter a 45-day option to purchase up to an additional 717,703 shares of common stock and/or warrants to purchase up to 717,703 shares of common stock, in any combination thereof, from us at the public offering price, less the underwriting discount.

The underwriter expects to deliver the shares, warrants and pre-funded warrants, if any, to purchasers on , 2021.

Roth Capital Partners

The date of this prospectus is , 2021

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We have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we have prepared. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock. Our business, financial condition, results of operations, and prospects may have changed since that date.

For investors outside the United States: We have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of our securities and the distribution of this prospectus outside of the United States.

PROSPECTUS SUMMARY

This summary highlights information contained in greater detail elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider in making your investment decision. You should read the entire prospectus carefully before making an investment in our securities. You should carefully consider, among other things, our consolidated financial statements and related notes and the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in this prospectus. Unless the content otherwise requires, the terms “KemPharm,” “company,” “our,” “us,” and “we” in this prospectus refer to KemPharm, Inc.

Company 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 co-lead clinical development candidates, KP415 and KP484, are both based on a prodrug of d-methylphenidate, or d-MPH, but with differing extended-release, or ER, effect profiles, and are intended for the treatment of ADHD. Our preclinical product candidate for the treatment of SUD is KP879, based on a prodrug of d-MPH. Our preclinical prodrug product candidate for the treatment of IH is KP1077. In addition, we have announced our commercial partnership with KVK Tech, Inc., or KVK, of APADAZ®, an FDA approved immediate-release, or IR, combination product of benzhydrocodone, our prodrug of hydrocodone, and acetaminophen, or APAP, for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. We have entered into a collaboration and license agreement with Commave Therapeutics SA (formerly known as Boston Pharmaceuticals S.A.), an affiliate of Gurnet Point Capital, or Commave, for the development, manufacture and commercialization of our product candidates containing serdexmethylphenidate, or SDX, and d-MPH.

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

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

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

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 continue supporting preparation for the potential commercial launch of KP415. Corium is a portfolio company of Gurnet Point Capital and has been tasked with leading all commercialization activities for KP415 under the KP415 License Agreement.

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.

Reverse Stock Split

In order to list our common stock on The NASDAQ Capital Market in connection with this offering, our common stock will be 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. On December 24, 2020, the last reported sale price of our common stock as reported on the OTCQB was $0.72 per share (without giving effect to the 1-for-16 reverse stock split described herein). 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.

Debt Restructuring

In connection with this offering, we have agreed 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 approximately $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 approximately $7.5 million, or the Deerfield Note. The total outstanding principal and accrued interest under the Senior Secured Notes and the Deerfield Note was approximately $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, upon the closing of this offering, we will:

- subject to specified conditions, exchange approximately $31.5 million of the outstanding principal and accrued interest on the Senior Secured Notes and the Deerfield Note for (i) shares of Series B-2 convertible preferred stock with an equal aggregate stated value, which would be convertible at any time following the earlier of March 2, 2021 or our public announcement of the outcome of the FDA's review of our KP415 NDA at the option of the holders, subject to specified limits, into shares of our common stock at a price per share equal to the offering price per share to the public in this offering, and (ii) warrants exercisable for a number of shares of our common stock equal to 75% of the number of shares issuable upon conversion of the preferred stock on the same terms as the warrants being offered to investors in this offering, or the Exchange Warrants; and
- make a payment of approximately $30.3 million, or the Debt Payment, in partial repayment of the remaining outstanding principal and accrued interest on the Senior Secured Notes and the Deerfield Note.

Following the completion of these transactions, we expect that the aggregate balance of principal and accrued interest remaining outstanding under the Senior Secured Notes and the Deerfield Note would be approximately $7.6 million, based on the amount of accrued interest as of December 31, 2020. With respect to the remaining outstanding balances under the Senior Secured Notes and the Deerfield Note, the December 2020 Exchange Agreement provides that upon closing of this offering we would amend the terms of that debt to provide that:

- the maturity date would be March 31, 2023, and the debt would be prepayable upon specified conditions; and
- interest would accrue at the rate of 6.75% per annum, payable quarterly, which 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 will file 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 have also agreed to file 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. We anticipate that we will file this resale registration statement immediately following the closing of this offering.

The December 2020 Exchange Agreement provides that the debt restructuring described above, or the Debt Restructuring, is conditioned upon the completion of this offering, as well as other agreed upon conditions, and would not otherwise be effected unless such conditions are satisfied.

In connection with the Debt Restructuring, we have agreed to pay a financial advisor a fee in the amount of $2.0 million.

See "Management's Discussion of Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—2021 Note Exchanges," "Management's Discussion of Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Debt Restructuring," "Description of Capital Stock—Amended and Restated Series B-2 Certificate of Designation" and "Description of Capital Stock—Registration Rights" for a more detailed description of the terms of the Senior Secured Notes, the December 2020 Exchange Agreement, our Series B-2 convertible preferred stock and the anticipated Debt Restructuring and other transactions described above.

Selected Risks Affecting Our Business

Investing in our common stock involves risk. You should carefully consider all of the information in this prospectus prior to investing in our common stock. These risks are discussed more fully in the section titled "Risk Factors" beginning on page 9 immediately following this prospectus summary. These risks and uncertainties include, but are not limited to, 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.
- We are early in our development efforts and have only one product which has completed development and obtained regulatory approval by the FDA, APADAZ. All our other active product candidates are in clinical or preclinical development. If commercialization of APADAZ or our product candidates is not successful, or we experience significant delays in commercialization, our business will be harmed.

- 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.
- The auditor's opinion on our audited financial statements for the fiscal year ended December 31, 2019, included in our annual report on Form 10-K, contains an explanatory paragraph relating to our ability to continue as a going concern.
- In connection with preparation of our annual financial statements for the fiscal year ended December 31, 2019, we identified a material weakness in our internal control over financial reporting. Any failure to maintain effective internal control over financial reporting could harm us.
- 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, APADAZ, KP415, KP484 and our other product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology, APADAZ, KP415, KP484 and our other product candidates, if approved, may be impaired.
- 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.
- 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 KVK, for the commercialization of APADAZ in the United States, and Commave, to develop, manufacture and commercialize KP415 and KP484 worldwide. In addition, we may seek collaborations with third parties for the development or commercialization of our other product candidates, or in other territories. If those collaborations are not successful, we may not be able to capitalize on the market potential of APADAZ or KP415, KP484 or other product candidates, if approved.
- 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.

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 prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our securities.

“KemPharm”, the KemPharm logo, “APADAZ,” “LAT” and other trademarks or service marks of KemPharm, Inc. appearing in this prospectus are the property of KemPharm, Inc. This prospectus contains additional trade names, trademarks and service marks of others, which are the property of their respective owners.

Implications of Being a Smaller Reporting Company

We are a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of any fiscal year for so long as either (1) the market value of our shares of common stock held by non-affiliates does not equal or exceed $250.0 million as of the prior June 30th, or (2) our annual revenues did not equal or exceed $100.0 million during such completed fiscal year and the market value of our shares of common stock held by non-affiliates did not equal or exceed $700.0 million as of the prior June 30th. To the extent we take advantage of any reduced disclosure obligations, it may make comparison of our financial statements with other public companies difficult or impossible.

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THE OFFERING

Common Stock Offered by Us	*4,784,688 shares (5, 502, 391 shares if the underwriter exercises the over-allotment option in full).*
Warrants to Purchase Common Stock Offered by Us	Warrants to purchase up to 4,784,688 shares of our common stock, which will be exercisable during the period commencing on the date of their issuance and ending years from such date at an exercise price per share of common stock equal to 100% of the combined public offering price per share of common stock and warrant in this offering. This prospectus also relates to the offering of the shares of our common stock issuable upon exercise of such warrants.
Pre-funded Warrants Offered by Us	We are also offering to those purchasers, if any, whose purchase of common stock in this offering would otherwise result in any such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of such purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if such purchaser so chooses, pre-funded warrants in lieu of shares of our common stock that would otherwise result in such purchaser's beneficial ownership exceeding 4.99% (or, at the election of such purchaser, 9.99%) of our outstanding common stock. Each pre-funded warrant is being sold with one warrant to purchase one share of our common stock, at an assumed combined public offering price of $10.4499 per pre-funded warrant and related warrant, representing a public offering price of $10.4498 per pre-funded warrant and $0.0001 per related warrant. The pre-funded warrants and warrants will be issued separately. The exercise price of each pre-funded warrant will equal $0.0001 per share. Each pre-funded warrant will be exercisable upon issuance and will not expire prior to exercise. For each pre-funded warrant we sell, the number of shares of common stock we are offering will be decreased on a one-for-one basis. This prospectus also relates to the offering of the shares of our common stock issuable upon exercise of the pre-funded warrants.
Option to Purchase Additional Securities	We have granted to the underwriter a 45-day option to purchase up to 717,703 additional shares of common stock and/or warrants at the public offering price, less underwriting discounts and commissions on the same terms as set forth in this prospectus.
Common Stock to be Outstanding Immediately After this Offering	9,316,727 shares (10,034,430 shares if the underwriter exercises the over-allotment option in full), assuming we sell only shares of common stock and no pre-funded warrants and assuming no exercise of the warrants.

Use of Proceeds	We estimate that the net proceeds to us from this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately $46.4 million, assuming an initial public offering price of $10.45 per share and warrant, the last sale price of our common stock as reported on the OTCQB on January 4, 2021. We anticipate that the net proceeds from this offering will be used to make the Debt Payment and the related advisory fee payment and for working capital and general corporate purposes. See “Use of Proceeds” for additional information.
Risk Factors	Investing in our securities involves significant risks. See “Risk Factors” on page 9 of this prospectus.
OTC Markets Venture Market Symbol	“KMPH”
Proposed NASDAQ Capital Market Listing and Symbol	We have applied for our common stock to be listed on The NASDAQ Capital Market under the symbol “KMPH”. The successful listing of our common stock on The NASDAQ Capital Market is a condition of this offering. However, there can be no assurance that NASDAQ will approve our listing application. There is no established public trading market for the warrants or the pre-funded warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list the warrants or the pre-funded warrants on any national securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the warrants and the pre-funded warrants will be limited.

The number of shares of our common stock to be outstanding as shown above is based on 4,532,039 shares outstanding as of September 30, 2020 (adjusted to give effect to the 1-for-16 reverse stock split), and excludes:

- 354,379 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2020, at a weighted average exercise price of $74.86 per share;
- 151,442 shares of our common stock issuable upon exercise of warrants outstanding as of September 30, 2020, at a weighted average exercise price of $81.88 per share and any additional shares of our common stock issuable as a result of any anti-dilution adjustments under these warrants;
- 79,748 shares of our common stock issuable upon conversion of principal and accrued interest underlying the Deerfield Note in the principal amount of approximately $7.3 million and that bears interest at 6.75% per annum previously issued to Deerfield, outstanding as of September 30, 2020, assuming a conversion date of September 30, 2020, and any additional shares of our common stock issuable as a result of any anti-dilution adjustments under the Deerfield Note;
- 50,273 shares of our common stock reserved for future issuance under our 2014 equity incentive plan as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan; and

- 694,344 shares of our common stock issuable upon conversion of principal and accrued interest underlying the approximately $59.7 million aggregate principal amount of our Senior Secured Notes issued in December 2019 and January 2020, assuming a conversion date of September 30, 2020.

Except as otherwise indicated, all information in this prospectus assumes and gives effect to:

- no exercise by the underwriter of its option to purchase additional shares of common stock or warrants to purchase shares of common stock;
- a 1-for-16 reverse stock split effectuated on December 23, 2020;
- no exercise of our outstanding options to purchase our common stock since September 30, 2020;
- no exercise of our outstanding warrants to purchase our common stock since September 30, 2020, including the warrants and pre-funded warrants offered by us in this offering; and
- no conversion of our outstanding convertible promissory notes since September 30, 2020.

RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below. Each of the risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities, and the occurrence of any of these risks might cause you to lose all or part of your investment. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Please also read carefully the section below titled "Special Note Regarding Forward-Looking Statements."

Summary Risk Factors

Investing in our common stock involves a high degree of risk because our business is subject to numerous risks and uncertainties, as fully described below. The principal factors and uncertainties that make investing in our common stock risky include, among others:

- 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.
- We are early in our development efforts and have only one product which has completed development and obtained regulatory approval by the FDA, APADAZ. All our other active product candidates are in clinical or preclinical development. If commercialization of APADAZ or our product candidates is not successful, or we experience significant delays in commercialization, our business will be harmed.
- 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.
- The auditor's opinion on our audited financial statements for the fiscal year ended December 31, 2019, included in our annual report on Form 10-K, contains an explanatory paragraph relating to our ability to continue as a going concern.
- In connection with preparation of our annual financial statements for the fiscal year ended December 31, 2019, we identified a material weakness in our internal control over financial reporting. Any failure to maintain effective internal control over financial reporting could harm us.
- 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, APADAZ, KP415, KP484 and our other product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology, APADAZ, KP415, KP484 and our other product candidates, if approved, may be impaired.
- 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.

- 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 KVK, for the commercialization of APADAZ in the United States, and Commave, to develop, manufacture and commercialize KP415 and KP484 worldwide. In addition, we may seek collaborations with third parties for the development or commercialization of our other product candidates, or in other territories. If those collaborations are not successful, we may not be able to capitalize on the market potential of APADAZ or KP415, KP484 or other product candidates, if approved.
- 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.

Risks Related to Our Financial Position and Capital Needs

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

Based on our current operating plan, our existing resources and projected revenues are expected to be sufficient to fund our operating expense and capital investment requirements past the potential March 2, 2021 date under the Prescription Drug User Fee Act, or PDUFA, for the KP415 New Drug Application, or NDA, and up to the debt maturity date of March 31, 2021. We believe that the proceeds from this offering, together with our existing cash resources and projected revenues and after giving effect to the Debt Payment and the other transactions contemplated under the December 2020 Exchange Agreement, will be sufficient to fund our operations into, but not through, the third quarter of 2022. A portion of our projected revenue is based upon the achievement of milestones in our APADAZ and KP415 license agreements. Certain of the milestones are associated with regulatory matters that are outside our control and we do not have a history of achieving milestones in our license agreements. We do not currently have sufficient funds to finance our continuing operations beyond the short-term or to substantially advance our product candidates further into clinical development. We expect that our only sources of revenues will be through payments arising from our license agreements with KVK and Commave, or through the Corium Consulting Agreement or other potential consulting arrangements and any other future arrangements related to one of our other product candidates. Accordingly, our ability to continue as a going concern will require us to obtain, in the short term, additional financing to fund our operations. In order to substantially advance development of our product candidates, we will need to obtain additional funding in connection with our continuing operations from one or more equity offerings, debt financings, the APADAZ License Agreement, the KP415 License Agreement, the Corium Consulting Agreement, other potential consulting arrangements or other third-party funding, including potential strategic alliances and licensing or collaboration arrangements, and we cannot guarantee that we will be able to generate sufficient proceeds from the APADAZ License Agreement, the KP415 License Agreement, the Corium Consulting Agreement or other consulting arrangements, or be successful in completing other transactions, that will 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. Even if we are able to fund continued development and any of our product candidates, beyond APADAZ, are approved, we expect that we will need to complete a strategic transaction or raise substantial additional funding through public or private debt or equity securities to successfully commercialize any product candidate. Our future capital requirements will depend on many factors, including:

- the progress and results of our preclinical studies, clinical trials, chemistry, manufacturing and controls, or CMC, and other product development and commercialization activities;

- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates;
- the ability to obtain differentiating claims in the labels for our product candidates;
- the number and development requirements of other product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the efforts necessary to institute post-approval regulatory compliance requirements;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of APADAZ under our APADAZ License Agreement, or any product candidate subject to the terms of the KP415 License Agreement or sales of our other product candidates for which we receive marketing approval, which may be affected by market conditions, including obtaining coverage and adequate reimbursement of APADAZ or our product candidates from third-party payors, including government programs and managed care organizations, and competition within the therapeutic class to which APADAZ or our product candidates are assigned;
- our success in developing and commercializing our ADHD product candidates in accordance with the terms of the KP415 License Agreement;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the extent to which we acquire or in-license other product candidates and technologies.

The auditor's opinion on our audited financial statements for the fiscal year ended December 31, 2019 and our unaudited condensed financial statements included in this prospectus each contain an explanatory paragraph relating to our ability to continue as a going concern.

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

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

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

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

If our management is unable to conclude that we have effective internal control over financial reporting, or to certify the effectiveness of such controls, or if additional material weaknesses in our internal controls are identified in the future, we could be subject to regulatory scrutiny and a loss of public confidence, which could have a material adverse effect on our business and our stock price. In addition, if we do not maintain adequate financial and management personnel, processes and controls, we may not be able to manage our business effectively or accurately report our financial performance on a timely basis, which could cause a decline in our common stock price and adversely affect our results of operations and financial condition.

We have incurred significant 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 September 30, 2020, had an accumulated deficit of $253.6 million and negative working capital (current assets less current liabilities) of $62.7 million. Our operating cash flows for the nine months ended September 30, 2020 and 2019, were net cash used in operations of $0.9 million and of $20.6 million, respectively. We have financed our operations through September 30, 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.

In February 2019, we entered into a purchase agreement, or the Prior Purchase Agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park, which provided that, upon the terms and subject to the conditions and limitations set forth therein, we could sell to Lincoln Park up to $15.0 million of shares of our common stock, from time to time over the 36-month term of the Prior Purchase Agreement, and upon execution of the Prior Purchase Agreement we issued 7,512 shares of our common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Prior Purchase Agreement. We terminated the Prior Purchase Agreement in February 2020 in connection with entering into the Current Purchase Agreement (as defined below). We sold 212,579 shares of our common stock (exclusive of the 7,512 commitment shares) to Lincoln Park under the Prior Purchase Agreement for approximately $5.4 million in gross proceeds prior to termination.

In February 2020, we entered into a purchase agreement, or the Current Purchase Agreement, with Lincoln Park, which provides that, upon the terms and subject to the conditions and limitations set forth therein, we may sell to Lincoln Park up to $4.0 million of shares of our common stock, from time-to-time over the 12-month term of the Current Purchase Agreement, and upon execution of the Current Purchase Agreement we issued 19,289 shares of our common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Current Purchase Agreement. Concurrently with entering into the Current Purchase Agreement, the Company also entered into a registration rights agreement with Lincoln Park, or the Current 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 Current Purchase Agreement pursuant to the Company's existing shelf registration statement on Form S-3 or a new registration statement. There are no assurances whether we will utilize all of, or receive all proceeds from, the Current Purchase Agreement. For instance, in May 2020, we reached the maximum allowable shares to be issued under our registration statement on Form S-3, or the Current Registration Statement, of 579,260 shares (inclusive of the 19,289 commitment shares) as defined in Section 2(f)(i) of the Current Purchase Agreement and therefore we cannot issue additional shares under the Current Purchase Agreement. As of September 30, 2020, we sold 559,971 shares of our common stock (exclusive of the 19,289 commitment shares) to Lincoln Park under the Current Purchase Agreement for approximately $2.3 million in gross proceeds.

Our recurring net negative cash flows from operations, net working capital (current assets less current liabilities) deficit and accumulated deficit raise substantial doubt about our ability to continue as a going concern. The perception of our inability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials. We are in various stages of development of our product candidates, and we have only completed development of, and received regulatory approval for, one product, APADAZ. We expect to continue to incur significant expenses and operating losses over the next several years and our net losses may fluctuate significantly from quarter to quarter and year to year as we:

- continue our ongoing preclinical studies, clinical trials and our product development activities for our pipeline of product candidates;
- seek regulatory approvals for product candidates that successfully complete clinical trials;
- continue research and preclinical development and initiate clinical trials of our product candidates;
- seek to discover and develop additional product candidates either internally or in partnership with other pharmaceutical companies;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio;
- incur additional legal, accounting and other expenses in operating as a public company; and
- add operational systems and personnel, if needed, to support any future commercialization efforts.

To become and remain profitable, we must succeed in developing and eventually commercializing prodrugs that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials and obtaining regulatory approval of our product candidates, and manufacturing, marketing and selling, whether ourselves or through a license with a third party, any of our product candidates for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We are in various stages of these activities for our product candidates and we cannot guarantee that any strategy we adopt will be successful. For instance, in October 2018, we entered into the APADAZ License Agreement with KVK pursuant to which we granted an exclusive license to KVK to commercialize APADAZ in the United States. We cannot guarantee that KVK will be able to successfully commercialize APADAZ or that we will ever receive any payments under the APADAZ License Agreement from commercial sales of APADAZ. In addition, in September 2019, we entered into the KP415 License Agreement with Commave pursuant to which we granted an exclusive, worldwide license to Commave to develop, manufacture and commercialize KP415 and KP484 worldwide. Even if approved, we cannot guarantee that Commave will be able to successfully develop, manufacture or commercialize KP415 or KP484 or that we will ever receive any future payments under the KP415 License Agreement. We may never succeed in commercialization activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

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, including causing potential delay of the FDA's review of our KP415 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. 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, APADAZ or our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of prodrug products. We cannot guarantee that KVK will be able to successfully commercialize APADAZ, that Commave will be able to successfully commercialize any product candidates subject to the KP415 License Agreement, even if approved, or that we will ever receive any payments under the APADAZ License Agreement from commercial sales of APADAZ or any future payments under the KP415 License Agreement. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or debt securities, the terms of these securities or this debt may restrict our ability to operate. We previously entered into a $60 million multi-tranche credit facility, or the Deerfield Facility Agreement, with Deerfield. The Deerfield Facility Agreement includes, and any future debt financing and equity financing, if available, may involve agreements that include, covenants limiting and restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, entering into profit-sharing or other arrangements or declaring dividends. The Deerfield Facility Agreement also includes high yield discount obligation protections that went into effect in June 2019. Going forward, if at any interest payment date our outstanding indebtedness under the Deerfield Facility Agreement would qualify as an “applicable high yield discount obligation” under the Internal Revenue Code of 1986, as amended, or the Code, then we are obligated to prepay in cash on each such date the amount necessary to avoid such classification. Under the terms of the Deerfield Facility Agreement periodic interest is paid-in-kind and added to principal, we are required to make payments of all paid-in-kind interest and principal upon maturity. In this regard, if holders of the notes do not convert their notes prior to the maturity date, we will be required to repay the principal amount of all then outstanding notes plus any paid-in-kind, accrued and unpaid interest. We may also be required to repurchase the notes for cash upon the occurrence of a change of control or certain other fundamental changes involving us. If our capital resources are insufficient to satisfy our debt service obligations, we will be required to seek to sell additional equity or debt or to obtain debt financing. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

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

We have a significant amount of indebtedness. As of September 30, 2020, we had $67.1 million of outstanding borrowings under the Deerfield Facility Agreement. Amounts outstanding under the Deerfield Facility Agreement bear interest at a rate of 6.75% per annum, and all outstanding principal and accrued interest for our outstanding borrowings under the Deerfield Facility Agreement are due and payable on March 31, 2021. While we have entered into the December 2020 Exchange Agreement in hopes of restructuring some portion of this debt, we cannot guarantee that the transactions contemplated under the December 2020 Exchange Agreement will be consummated. Our obligations under the Deerfield Facility Agreement are secured by substantially all of our assets. We could in the future incur additional indebtedness beyond our borrowings under our Deerfield Facility Agreement.

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

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

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

We may 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, that we will ultimately apply for forgiveness, or that any amount of the PPP Loan will ultimately be forgiven by the SBA.

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.

Even if we are relisted on NASDAQ, we may be unable to issue securities under our shelf registration statement, which may have an adverse effect on our liquidity.

We have filed our Current Registration Statement with the U.S. Securities and Exchange Commission, or the SEC, but will not eligible to effect additional offerings under our Current Registration Statement unless we are relisted on NASDAQ. Even if we are able to relist our common stock on the NASDAQ Capital Market in connection with this offering, we may be unable to issue securities under the Current Registration Statement. Based on the market value of our outstanding common stock held by non-affiliates as of March 31, 2020, the date we filed amendment No. 1 to our Current Registration Statement, we must rely on Instruction I.B.6. of Form S-3 to sell securities under our Current Registration Statement, which imposes a limitation on the maximum amount of securities that we may sell pursuant to the registration statements on Form S-3 during any twelve-month period. At the time we sell securities pursuant to the Current Registration Statement, the amount of securities to be sold plus the amount of any securities we have sold during the prior twelve months in reliance on Instruction I.B.6. may not exceed one-third of the aggregate market value of our outstanding common stock held by non-affiliates as of a day during the 60 days immediately preceding such sale, as computed in accordance with Instruction I.B.6. Based on this calculation, as of March 31, 2020, the amount of securities we are able to sell under the Current Registration Statement was approximately \$6.8 million, of which we (i) have filed a prospectus supplement to register approximately \$2.7 million for sales under the Current Purchase Agreement; and (ii) have previously sold an aggregate of \$4.1 million of shares of common stock in prior offerings on Form S-3 in the previous 12 months. Accordingly, we expect that we will be unable to sell additional securities beyond those amounts on the Current Registration Statement in the near term even if we regain our listing with NASDAQ, unless and until the market value of our outstanding common stock held by non-affiliates increases significantly. In addition, under the terms of the Current Purchase Agreement, stockholder approval may be required to access a portion of the amounts available under the Current Purchase Agreement. For instance, in May 2020, we 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 Current Purchase Agreement and therefore we cannot issue additional shares under the Current Purchase Agreement. If we cannot sell securities on Form S-3, we may be required to utilize more costly and time-consuming means of accessing the capital markets, which could materially adversely affect our liquidity and cash position.

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

We commenced active operations in 2006, and our operations to date have been largely focused on raising capital, identifying potential product candidates, broadening our expertise in the development of our prodrugs, undertaking preclinical studies and conducting clinical trials. To date, we have only one product approved by the FDA, APADAZ for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. We have not yet demonstrated an ability to manufacture a prodrug on a commercial scale, or arrange for a third party to do so, or conduct sales and marketing activities necessary for successful commercialization. Further, we cannot guarantee that KVK will be able to successfully commercialize APADAZ, that Commave will be able to successfully commercialize any product candidates subject to the KP415 License Agreement, if approved, or that we will ever receive any payments under the APADAZ License Agreement or the KP415 License Agreement from commercial sales of

APADAZ or any other approved product candidates, if any. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

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

Risks Related to the Development of Our Product Candidates

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

A key element of our strategy is to use our proprietary LAT technology to build a pipeline of prodrugs and progress product candidates based on these prodrugs through clinical development for the treatment of a variety of diseases and conditions. The scientific discoveries that form the basis for our efforts to discover and develop prodrugs are relatively new. As our scientific efforts are primarily focused on discovering novel prodrugs with new molecular structures, the evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. Although our research and development efforts to date have resulted in a pipeline of prodrug product candidates, we may not be able to develop those product candidates into prodrugs that are bioequivalent, safe and effective and that have commercially significant improvements over already approved drugs. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, for reasons including being shown to have harmful side effects, a lack of efficacy, or other characteristics that indicate that they are unlikely to be prodrugs that will receive marketing approval and achieve market acceptance. For instance, in June 2016, we received a Complete Response Letter, or CRL, from the FDA for the APADAZ NDA. Following a Formal Dispute Resolution Request, or FDRR, process and detailed discussions with the FDA, we responded to the CRL by submitting an amended NDA for APADAZ. In February 2018, we announced that the FDA approved the NDA for APADAZ. If APADAZ is not successfully commercialized under our APADAZ License Agreement and we do not successfully develop and commercialize our product candidates based upon our proprietary LAT technology, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

If we are not able to obtain required regulatory approvals for our product candidates, 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. In February 2018, we announced that the FDA approved the NDA for APADAZ for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Even with the regulatory approval of APADAZ by the FDA, we cannot guarantee that the FDA will approve any of our other product candidates for commercial sale or approve any proposed label we may have for any such product candidate. For example, our NDA submission for KP415 may encounter review difficulties and may ultimately receive a Complete Response Letter for any deficiencies in nonclinical, clinical or manufacturing of KP415 or, even if approved, the approved label for KP415 may not sufficiently differentiate KP415 from competing, generic products which are already broadly available. If our development efforts for our product candidates, including regulatory approval, are not successful for their planned indications or are delayed, or if adequate demand for our product candidates that are approved for marketing, if any, is not generated, our business will be harmed.

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

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

We have only limited experience in filing the applications necessary to gain regulatory approvals and have relied, and expect to continue to rely, on consultants and third-party contract research organizations, or CROs, with expertise in this area to assist us in this process. Securing FDA approval requires the submission of extensive non-clinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA for each therapeutic indication to establish a product candidate’s safety and efficacy for each indication and manufacturing quality. Additionally, we cannot guarantee that regulators will agree with our assessment of the results of the clinical trials we have conducted or that any future trials will be successful. For example, in May 2016, the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the FDA voted 16 to 4 for the approval of APADAZ, but voted 18 to two against inclusion of abuse-deterrent labeling for APADAZ. Additionally, in June 2016, we received a CRL from the FDA for the APADAZ NDA. Following a FDRR process and detailed discussions with the FDA, we responded to the CRL we received in June 2016 by submitting an amended NDA for APADAZ for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. In February 2018, we announced that the FDA approved the NDA for APADAZ.

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

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

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, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt 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.

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

We are early in our development efforts and have only one product that has completed development and been approved by the FDA, APADAZ. All of our other active product candidates are in clinical or preclinical development. We currently generate no commercial revenue from the sale of any prodrugs and we may never be able to successfully commercialize a prodrug product. For instance, while we have entered into the APADAZ License Agreement with KVK pursuant to which we granted an exclusive license to KVK to commercialize

APADAZ in the United States, we cannot guarantee that KVK will be able to successfully commercialize APADAZ or that we will ever receive any payments under the APADAZ License Agreement from commercial sales of APADAZ. In addition, we entered into the KP415 License Agreement with Commave pursuant to which we granted an exclusive, worldwide license to Commave to develop, manufacture and commercialize KP415 and KP484 worldwide. We cannot guarantee that Commave will be able to successfully develop, manufacture or commercialize KP415 or KP484 or that we will ever receive any future payments under the KP415 License Agreement. We have invested substantially all our efforts and financial resources in the development of our proprietary LAT technology, the identification of potential product candidates and the development of our product candidates. Our ability to generate revenue from APADAZ under the APADAZ License Agreement and generate revenue from our product candidates will depend heavily on their successful development and eventual commercialization. The success of APADAZ and our product candidates will depend on several factors, including:

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

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

Although APADAZ obtained regulatory approval in February 2018, it is possible that none of our other existing product candidates or any of our future product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or KVK could experience an inability to successfully commercialize APADAZ or we could experience an inability to successfully commercialize our product candidates approved for marketing in the future, if any, which would harm our business.

If we, subject to the approval of Commave, or Commave themselves, attempt to rely on Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act and the FDA does not conclude that our product candidates are sufficiently bioequivalent, or have comparable bioavailability, to approved drugs, or if the FDA does not allow us or Commave to pursue the 505(b)(2) NDA pathway as anticipated, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and the FDA may not ultimately approve our product candidates.

A key element of our strategy is to seek FDA approval for most of our product candidates under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, otherwise known as the 505(b)(2) NDA pathway with any NDA submitted thereunder a 505(b)(2) NDA, where possible. The 505(b)(2) NDA pathway permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Such reliance is typically predicated on a showing of bioequivalence or comparable bioavailability to an approved drug.

If the FDA does not allow us to pursue the 505(b)(2) NDA pathway as anticipated, or if we cannot demonstrate bioequivalence or comparable bioavailability of our product candidates to approved products, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. Moreover, even if the FDA does allow us to pursue the 505(b)(2) NDA pathway, depending on the product candidate, we may still need to conduct additional clinical trials, including clinical trials to assess product safety or efficacy. For instance, subject to Commave approval, we currently plan on relying on the 505(b)(2) pathway for any NDA submitted for KP484 and relied on the 505(b)(2) pathway for the KP415 NDA submitted in March 2020. However, we do not anticipate that the 505(b)(2) pathway will be available for every product candidate. For instance, it is possible we will only be permitted to utilize the 505(b)(2) NDA pathway for either KP415 or KP484, but not both. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates, and complications and risks associated with our product candidates, would likely substantially increase.

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

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

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

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

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

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

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

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

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

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

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

The risk of failure for our product candidates is high. It is impossible to predict when or if any of our current product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Interpretation of results from early, usually smaller, studies that suggest positive trends in some subjects, requires caution. Results from later stages of clinical trials enrolling more subjects may fail to show the desired safety and efficacy results or otherwise fail to be consistent with the results of earlier trials of the same product candidates. Later clinical trial results may not replicate earlier clinical trials for a variety of reasons, including differences in trial design, different trial endpoints, or lack of trial endpoints in exploratory studies, subject population, number of subjects, subject selection criteria, trial duration, drug dosage and formulation and lack of statistical power in the earlier studies. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. For instance, in June 2016, the FDA issued a CRL for the APADAZ NDA. In its CRL, the FDA advised us that it did not believe our proposed labeling included in the application accurately conveyed the outcome of our abuse-deterrent studies of APADAZ. Following a FDRR process and detailed discussions with the FDA, we responded to the CRL we received in June 2016 by submitting an amended NDA for APADAZ. In February 2018, we announced that the FDA approved the NDA for APADAZ for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Despite this, the final approved product labeling for APADAZ concluded that the overall results of the clinical program did not demonstrate abuse-deterrence by current measurement standards.

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

- regulators or IRBs may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site or amend clinical trial protocols as needed;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and CROs;
- clinical trials of our product candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance in cases where that is required, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon prodrug development programs;

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

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

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

Our prodrug development costs may also increase if we experience delays in testing or obtaining marketing approvals. Additionally, if we do not successfully develop any product candidates subject to the KP415 License Agreement, we may not be eligible to receive any future payments under the KP415 License Agreement. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates.

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

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

Our decision to seek approval of our product candidates under the 505(b)(2) NDA pathway, if available, may increase the risk that patent infringement suits are filed against us, which would delay the FDA's approval of such product candidates.

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

We may not be successful in our efforts to develop a prodrug-based product that might allow us to seek a rare pediatric disease priority review voucher.

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

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

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

The FDA has indicated that opioid analgesic drugs formulated with the active ingredients hydrocodone, fentanyl, hydromorphone, methadone, morphine, oxycodone, oxymorphone and others will be required to have a REMS to ensure that the benefits of the drugs continue to outweigh the risks. In September 2018, the FDA approved the

Opioid Analgesic REMS for extended-release, long-acting, or ER/LA, and IR opioids as one strategy among multiple national and state efforts to reduce the risk of abuse, misuse, addiction, overdose and deaths due to prescription opioid analgesics. The Opioid Analgesic REMS affects more than 60 companies that manufacture these products. Under this REMS, companies are required to make training available to all healthcare providers who are involved in the management of patients with pain, including nurses and pharmacists. To meet this requirement, drug companies with approved opioid analgesics will provide unrestricted grants to accredited continuing education providers for the development of education courses for healthcare providers based on the FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain. The REMS program also requires companies to make available FDA-approved patient education materials on the safe use of these drugs. The companies must perform periodic assessments of the implementation of the REMS and the success of the program in meeting its goals. The FDA will review these assessments and may require additional elements to achieve the goals of the program. Independent audits must also be conducted of the educational efforts.

APADAZ is subject to this REMS, and we anticipate that any opioid product candidates we may choose to develop in the future, if approved by the FDA, are likely to also be subject to a REMS requirement. There may be increased cost, administrative burden and potential liability associated with the marketing and sale of these types of product candidates subject to a REMS requirement, which could increase the costs to us and reduce the commercial benefits to us from the sale of these product candidates. In October 2018, we entered into the APADAZ License Agreement with KVK pursuant to which we granted an exclusive license to KVK to commercialize APADAZ in the United States. As part of this agreement KVK has assumed most regulatory and commercialization costs, including this REMS requirement.

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

Before we can commercialize any of our product candidates, if approved, the DEA will need to determine the controlled substance schedule, taking into account the recommendation of the FDA. This may be a lengthy process that could delay our marketing of a product candidate and could potentially diminish any regulatory exclusivity periods for which we may be eligible. For APADAZ, the DEA has completed its process for determining the controlled substance schedule and determined it to be a Schedule II drug. We expect that most of our product candidates, including KP415, KP484 and KP879, if approved, will be regulated as "controlled substances" as defined in the Controlled Substances Act, or the CSA, and the implementing regulations of the DEA, which establish registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA. These requirements are applicable to us, to our contract manufacturers and to distributors, prescribers and dispensers of our product candidates. The DEA regulates the handling of controlled substances through a closed chain of distribution. This control extends to the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce. A number of states and foreign countries also independently regulate these drugs as controlled substances.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

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

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

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

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

We contract with third parties for the manufacture of our partnered product and product candidates that utilize benzhydrocodone and SDX as the API used in our clinical trials and with a sole source supplier for the manufacture of bulk quantities of benzhydrocodone and SDX used in the partnered product and product candidates that utilize these moieties as the API and we expect to continue to do so. This reliance on third-party manufacturers increases the risk that we will not have sufficient quantities of benzhydrocodone and SDX, or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities. We procure the bulk drug substances for KP415, KP484, APADAZ and KP879 from sole-source, third-party manufacturers and the partnered product and product candidates that utilize these moieties as the API used in our clinical trials from other third parties. We anticipate we will continue to do so for the foreseeable future. We also expect to continue to rely on third parties as we proceed with preclinical and clinical testing of our product candidates, as well as for commercial manufacture of APADAZ or our product candidates should they receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of benzhydrocodone, SDX, other bulk drug substances or our partnered product or product candidates, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our ability to timely conduct our clinical trials or our other development or commercialization efforts.

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

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

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

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

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

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

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

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

There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for KP415, KP484 or KP879 bulk drug substance. If our current contract manufacturer for KP415, KP484 or KP879 bulk drug substance cannot perform as agreed, we may be required to replace such manufacturer and we may incur added costs and delays in identifying and qualifying any such replacement.

We have entered into collaborations with KVK, for the commercialization of APADAZ in the United States, and Commave, to develop, manufacture and commercialize KP415 and KP484 worldwide. In addition, we may seek collaborations with third parties for the development or commercialization of our other product candidates, or in other territories. If those collaborations are not successful, we may not be able to capitalize on the market potential of APADAZ or KP415, KP484 or other product candidates, if approved.

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

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

We may also seek additional third-party collaborators for the commercialization of APADAZ outside of the United States or for the development or commercialization of our other product candidates, which are not subject to the KP415 License Agreement, or those that are subject to the KP415 License Agreement but the option is not exercised by Commave. In such cases, our likely collaborators would include large and mid-size pharmaceutical companies, regional, national and international pharmaceutical companies and biotechnology companies. If we do enter into any such collaboration arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of APADAZ outside of the United States or our other product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

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

- The Collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;

- The Collaborators may not perform their obligations as expected;
- The Collaborators may not pursue commercialization of APADAZ the products covered under the KP415 License Agreement, if approved, or may elect not to continue or renew commercialization programs based on post-approval clinical trial results, changes in the Collaborator’s strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- The Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with APADAZ or the products covered under the KP415 License Agreement, as applicable, if the Collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- APADAZ and the products covered under the KP415 License Agreement may be viewed by the Collaborators as competitive with their own product candidates or products, which may cause the Collaborators to cease to devote resources to the commercialization of APADAZ or the products covered under the KP415 License Agreement, if approved;
- The Collaborators may not commit sufficient resources to the development, marketing and distribution of APADAZ and the products covered under the KP415 License Agreement, as applicable;
- disagreements with the Collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development or commercialization, might cause delays or termination of the development or commercialization of APADAZ or the products covered under the KP415 License Agreement, as applicable, might lead to additional responsibilities for us with respect to APADAZ or the products covered under the KP415 License Agreement, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- The Collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- The Collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- the license agreements may be terminated by the Collaborators under specified circumstances and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of APADAZ or the products covered under the KP415 License Agreement.

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

The APADAZ License Agreement, KP415 License Agreement and any other licensing or collaboration agreements we may enter into may not lead to commercialization of APADAZ or development or commercialization of KP415, KP484 or of our other product candidates in the most efficient manner or at all. If KVK, Commave or a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

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

Our prodrug development programs and the potential commercialization of our product candidates, if approved, will require substantial additional capital. For our product candidates, which are not subject to the terms of the APADAZ License Agreement or KP415 License Agreement, we may need to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

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

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

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

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

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

Provisions in the Deerfield Facility Agreement may inhibit our ability to enter into specified transactions, including any joint venture, partnership or any other profit-sharing arrangement.

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

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain trade secret protection or patent protection for our technology, APADAZ, KP415, KP484 and our other product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology, APADAZ, KP415, KP484 and our other product candidates, if approved, may be impaired.

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

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

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

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

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

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

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

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

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

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

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

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

The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For instance, the Leahy-Smith Act established the inter partes review and post grant review procedures that has lowered the burden of proof for invalidity challenges to issued patents and limited the ability to amend patent claims in response to such challenges. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our owned and licensed patents and/or patent applications.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Many of our employees were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees do not use the proprietary information, show-how or know-how of others in their work for us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. For example, in March 2012, we settled litigation regarding similar matters with Shire 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 APADAZ and any of our product candidates that are approved for marketing from the products of our competitors. We have registered trademarks for APADAZ, LAT and KemPharm. In addition, we have solicited and applied for trademarks for the KemPharm Logo and several potential tradenames and logos for KP415. For our other product candidates, we have not yet solicited trademarks and have not yet begun the process of applying to register trademarks. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. If our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

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

In addition to seeking patent and trademark protection for APADAZ and our product candidates, we also rely on trade secrets, including unpatented show-how, know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets.

Monitoring unauthorized uses and disclosures of our intellectual property, including our trade secrets, is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

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

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

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

Risks Related to the Commercialization of Our Partnered Product and Product Candidates

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

We have only a limited sales and marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product candidate for which we may obtain marketing approval in the United States, we will need to enter into collaborations with one or more parties or establish our own sales and marketing organization. While we entered into the APADAZ License Agreement to establish a collaboration for the commercialization of APADAZ and we entered into the KP415 License Agreement to establish a collaboration for the commercialization of any product candidates subject to such agreement, we may not choose to enter into a collaboration for any future approved product. Should we decide to establish our own sales, marketing and distribution capabilities, we would encounter a number of risks. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- our inability to access government and commercial health plan formularies or secure preferred coverage and adequate reimbursement levels;
- the inability of sales personnel to obtain access to physicians or achieve adequate numbers of physicians to prescribe any future prodrug products;

- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- liability for personnel, including sales personnel, failing to comply with applicable legal requirements; and
- costs associated with maintaining compliance with the FDA's marketing and promotional requirements, including ongoing training and monitoring, as well as unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

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

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

- the efficacy and potential advantages compared to alternative treatments, including less expensive generic treatments;
- the ability to obtain differentiating claims in the labels for most of our product candidates;
- our ability to offer our prodrug products for sale at competitive prices;
- the clinical indications for which our product candidates are approved;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- different regulatory requirements for maintaining approval of drugs in foreign countries;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- reduced protection for contractual and intellectual property rights in some countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in North America;
- tighter restrictions on privacy and the collection and use of patient data; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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

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

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

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

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

- differing regulatory requirements in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market with low or lower prices rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;

- potential liability under the 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.

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

APADAZ is, and any product candidate for which we obtain marketing approval could be, subject to a comprehensive regulatory scheme, which includes the regulation of manufacturing processes, post-approval clinical data, labeling, advertising, marketing, distribution and promotional activities for such product, by the FDA and other regulatory authorities. For example, we are required to conduct pediatric studies related to APADAZ to determine its safety and effectiveness for the claimed indication in pediatric patients. Under the APADAZ License Agreement, KVK will be responsible for these regulatory activities going forward, and we cannot guarantee they will be complied with. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, payment of substantial annual product and establishment fees, labeling requirements, promotional, marketing and advertising requirements, requirements related to further development, packaging, storage and distribution requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. If there are any modifications to the drug, including changes in indications, labeling, manufacturing processes or facilities, or new safety issues arise, a new or supplemental NDA, a post-implementation notification or other reporting may be required or requested depending on the change, which may require additional data or additional preclinical studies and clinical trials.

APADAZ is, and if marketing approval of a product candidate is granted may be, subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a REMS, which could involve requirements for, among other things, a medication guide, special training for prescribers and dispensers, and patient registries. For example, in September 2018, the FDA approved the Opioid Analgesic REMS for ER/LA and IR opioids as one strategy among multiple national and state efforts to reduce the risk of abuse, misuse, addiction, overdose, and deaths due to prescription opioid analgesics. APADAZ is subject to this REMS, and we anticipate that any of our other opioid product candidates that we may choose to develop in the future, if approved by the FDA, are likely to also be subject to a REMS requirement.

APADAZ does, and if any of our product candidates receive marketing approval they may, have a label that limits their approved uses, including more limited subject populations, than we request, and regulatory authorities may require that contraindications, warnings or precautions be included in the product labeling, including a boxed warning, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, which could limit sales of the product. For instance, we expect that at least some of our product candidates would likely be required to carry boxed warnings, including warnings regarding tampering, lethality if our oral tablets or capsules are prepared for injection and hepatotoxicity.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. APADAZ is subject to a post-marketing requirement for four deferred pediatric assessments that must be completed pursuant to the FDA's February 2018 approval letter. The FDA closely regulates the post-approval marketing and promotion of products to ensure products are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our prodrug products, if any, for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug and Cosmetic Act relating to the promotion of prescription drugs may lead to a number of actions and penalties, including warning letters, cyber letters, or untitled letters, adverse publicity, the requirement for dear-health-care-provider letters or other corrective information, fines and other monetary penalties, civil or criminal prosecution, including False Claims Act liability, restrictions on our operations and other operating requirements through consent decrees or corporate integrity agreements, debarment, exclusion from participation in federal health care programs and refusal of government contracts or future orders under existing contracts, among other consequences.

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

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

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

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

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

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

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

- the 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 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 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 healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Open Payments program, created under Section 6002 of the Affordable Care Act, or the ACA, and its implementing regulations, which imposes new annual reporting requirements for specified manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, to annually report certain payments and transfers of value provided to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, and to report annually certain ownership and investment interests held by physicians and their immediate family members; and
- comparable state and foreign laws, which may be broader in scope than the analogous federal laws and may differ from each other in significant ways.

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

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws, or that our compliance systems are inadequate to detect and report such conduct or to report accurate pricing information to the government. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, corporate integrity agreements or similar agreements to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, which could significantly harm our business. If any of the physicians or other healthcare providers or entities with whom we currently, or expect to, do business, including future collaborators, is found not to be in compliance with applicable laws, they and we may be subject to significant penalties and potential exclusion from participation in healthcare programs as a result of their non-compliance.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of our product candidates and increase the cost to commercialize APADAZ and any of our product candidates that may be approved in the future and affect the prices thereof.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect the ability to profitably sell APADAZ under the APADAZ License Agreement and our ability to profitably sell any product candidates for which we obtain marketing approval.

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

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

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded drugs and generic drugs, respectively;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;
- establishment of a new and distinct methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices (generally as negotiated between the Medicare Part D plan and the pharmacy) of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations and extension of the inflation percentage applicable to existing branded drugs to new formulations for purposes of computing the inflation penalty component of Medicaid rebates;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- the new requirements under the federal Open Payments program and its implementing regulations;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There remain judicial and congressional challenges to numerous provisions of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA, and we expect there will be additional challenges and amendments in the future. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provision of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act includes a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which occurred on November 10, 2020. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013, and, due to subsequent legislative amendments, including the BBA, will stay in effect through 2029 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In addition, it is possible that additional governmental action is taken to address the COVID-19 pandemic that may impact commercialization of our product and product candidates. The CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare rate reduction sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. In addition, on April 18, 2020, CMS announced that Qualified Health Plan issuers under the ACA may suspend activities related to the collection and reporting of quality data that would have otherwise been reported between May and June 2020 given the challenges healthcare providers are facing responding to the COVID-19 virus.

Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and, has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. These new laws may result in additional reductions in Medicare and other healthcare funding, which could negatively impact customers for our product candidates, if approved, and, accordingly, our financial operations.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may, among other things, result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our prodrug product candidates.

Legislative and regulatory proposals and enacted statutes have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. For instance, the Drug Supply Chain Security Act imposes obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing.

Among the requirements of this new legislation, manufacturers are required to provide specified information regarding the drug products they produce to individuals and entities to which product ownership is transferred, label drug products with a product identifier and keep specified records regarding the drug products. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers are also required to verify that purchasers of products are appropriately licensed. Further, under this legislation, manufacturers have drug product investigation, quarantine, disposition and FDA and trading-partner notification responsibilities related to counterfeit, diverted, stolen and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

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

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

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

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

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

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

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

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

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

Failure to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions (which could include civil or criminal fines or penalties), private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs of our products and services, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

Regulation of data processing 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 data security, including, without limitation, 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. 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 or services, affect our or our partners' ability to offer our products and services 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), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. 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 by requiring covered companies to provide new disclosures to California consumers (broadly defined as all California residents) and provide such consumers new ways to opt-out of certain sales of personal information. 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. Many similar privacy laws have been proposed at the federal level and in other states.

Foreign data protection laws, including, without limitation, the EU's GDPR that took effect in May 2018, and member state data protection legislation, may also apply to health-related and other personal information that we process, including, without limitation, personal data relating to clinical trial participants in the EU and the United Kingdom. These laws impose strict obligations on the ability to process health-related and other personal information of data subjects in the EU and the United Kingdom, 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. These 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 requirements 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.

The GDPR prohibits the transfer, without an appropriate legal basis, of personal data to countries outside of the European Economic Area, or EEA, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, uncertainty about compliance with EU data protection laws remains and such mechanisms may not be available or applicable with respect to the personal data processing activities necessary to research, develop, and market our products and services. For example, ongoing legal challenges in Europe to the mechanisms allowing companies to transfer personal data from the EEA to the United States could result in further limitations on the ability to transfer personal data across borders, particularly if governments are unable or unwilling to reach new or maintain existing agreements that support cross-border data transfers, such as the EU-U.S. and Swiss-U.S. Privacy Shield frameworks. Additionally, other countries have passed or are considering passing laws requiring local data residency and/or restricting the international transfer of data.

Under the GDPR, regulators may impose substantial fines and penalties for non-compliance. Companies that violate the GDPR can face fines of up to the greater of 20 million Euros or 4% of their worldwide annual turnover (revenue). 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 ensure compliance with the GDPR and other EU and international data protection rules.

Failure to comply with U.S. and foreign data protection laws and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties, fines, or sanctions), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients 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 or applicable privacy notices 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

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

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

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

Our stock price has been, and is likely to continue to be, volatile. Since shares of our common stock were sold in our initial public offering in April 2015 at a price of $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 January 4, 2021 (adjusted to give effect to the 1-for-16 reverse stock split). 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, biotechnology and pharmaceutical companies 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 significant portion of our outstanding warrants and convertible securities are entitled to certain anti-dilution protections which, if triggered, may cause substantial dilution to your investment.

Our outstanding senior secured convertible promissory notes and the Deerfield Warrant (as defined below) each include conversion or exercise, as applicable, price protection provision, pursuant to which the conversion or exercise, as applicable, price of each note or the Deerfield Warrant will be adjusted downward on a broad-based weighted-average basis if we issue or sell any shares of common stock, convertible securities, warrants or options at a sale or exercise price per share less than the greater of (i) $93.60 per share, which represents the Deerfield Warrant's exercise price and the conversion price of our outstanding senior secured convertible promissory notes, or (ii) the closing sale price of our common stock 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 and conversion price of our outstanding senior secured convertible promissory notes will be adjusted downward pursuant to this anti-dilution adjustment only if such sales are made at a price less than $93.60 per share, provided that this anti-dilution adjustment will not apply to certain specified sales.

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

We expect that we will need significant additional capital in the short term to continue as a going concern and in the future to fund our planned future operations, including to complete potential clinical trials for our product candidates. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time.

The holders of our senior secured convertible promissory notes may convert all or any portion of the outstanding principal and any accrued but unpaid interest on such notes into shares of our common stock at a conversion price of $93.60 per share.

Upon closing of the transactions contemplated under the December 2020 Exchange Agreement, the holders of our Series B-2 convertible preferred stock will be 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 the price per share to the public of our common stock in this offering.

According to the terms of our outstanding senior secured convertible promissory notes and the shares of Series B-2 convertible preferred stock to be outstanding upon closing of the transactions contemplated under the December 2020 Exchange Agreement in no event may any holder thereof convert such holder’s note or 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, provided that this limitation is 19.985% of our issued and outstanding common stock for any holder of our senior secured convertible promissory note who owned more than 4.985% of our issued and outstanding common stock at the time the issuance of such note. This conversion limitation may not be waived and any purported conversion that is inconsistent with this conversion limitation will be null and void. This conversion limitation will not apply to any conversion made immediately prior to a change of control transaction. If an equityholder is only able to convert such holder’s senior secured convertible promissory note or shares of Series B-2 convertible preferred stock into a limited number of shares due to this conversion limitation, such note or 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 senior secured convertible promissory notes or shares of Series B-2 convertible preferred stock elect to convert such notes or 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 outstanding senior secured convertible promissory notes and the warrant we issued to KVK under the APADAZ License Agreement could have a material effect on our reported financial results.

The Deerfield Warrant, our outstanding senior secured convertible promissory notes and the warrant we issued to KVK under the APADAZ License Agreement contain embedded derivatives, which require mark-to-market accounting treatment and could result in a gain or loss on a quarterly basis with regards to the mark-to-market value of that feature. Such accounting treatment could have a material impact on, and could potentially result in significant volatility in, our quarterly results of operations.

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

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

Deerfield has the right, subject to some conditions, to require us to file one or more registration statements covering its shares of our common stock, including shares issued or issuable upon conversion or exercise of its senior secured convertible promissory note issued in June 2014 and the Deerfield Warrant, as applicable, or to include such shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. For instance, pursuant to the terms of the December 2020 Exchange Agreement, we have agreed to file 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 to be issued under the December 2020 Exchange Agreement in connection with this offering. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

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

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

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

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

In addition, the provisions of our termination agreement with Aquestive and our outstanding senior secured convertible promissory notes, the Deerfield Warrant and Deerfield Facility Agreement, may delay or prevent a change in control of our company. For example, if we enter into a merger, an asset sale or any other change of control transaction, then Aquestive will be entitled to a royalty equal to 10% of the price being paid to us and our stockholders in such transaction which is attributable to the value of KP415, KP484 or KP879. Pursuant to the Deerfield Facility Agreement, we may not enter into any major transaction without the prior approval of a majority of the holders of our outstanding senior secured convertible promissory notes, including a merger, asset sale or change of control transaction, and pursuant to the terms of such notes, each holder thereof has the option to demand repayment of all outstanding principal, and any unpaid interest accrued thereon, of such note immediately prior to consummation of such event. Further, under the Deerfield Warrant, Deerfield has the right to demand that we redeem the Deerfield Warrant for a cash amount equal to the Black-Scholes value of a portion of the warrant upon the occurrence of specified events, including a merger, an asset sale or any other change of control transaction. A takeover of us may trigger the requirement that we repurchase our outstanding senior secured convertible promissory notes and the Deerfield Warrant, which could make it more costly for a potential acquirer to engage in a business combination transaction with us.

Finally, in the event of a sale of the company, upon the amendment and restatement of the certificate of designation for our Series B-2 convertible preferred stock, which we plan to effect in connection with this offering in accordance with the terms of the December 2020 Exchange Agreement, 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.

Exclusive forum provisions in our certificate of incorporation and bylaws 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 September 30, 2020, we had federal net operating loss carryforwards of approximately $223.3 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 U.S. Internal Revenue Service, or the IRS, 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.

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

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

Risks Related to this Offering

Our management might apply the net proceeds from this offering in ways with which you do not agree and in ways that may impair the value of your investment.

We currently intend to use the net proceeds from this offering to make the Debt Payment and the related advisory fee payment and for working capital and general corporate purposes. Our management has broad discretion as to the use of these proceeds and you will be relying on the judgment of our management regarding the application of these proceeds. We might apply these proceeds in ways with which you do not agree, or in ways that do not yield a favorable return. If our management applies these proceeds in a manner that does not yield a significant return, if any, on our investment of these net proceeds, it could compromise our ability to pursue our growth strategy and adversely affect the market price of our common stock.

If you purchase our common stock and warrants in this offering, you will incur immediate and substantial dilution in the book value of your investment. You will experience further dilution if we issue additional equity securities in future fundraising transactions.

Since we expect that the public offering price per share of our common stock and the accompanying warrant in this offering will be substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution with respect to the net tangible book value of the common stock you purchase in this offering. Based on an assumed public offering price of $10.45 per share and accompanying warrant, which represents the closing price of our common stock on the OTCQB on January 4, 2021, and our net tangible book value as of September 30, 2020, if you purchase shares of common stock and warrants in this offering, you will suffer immediate and substantial dilution of $9.02 per share with respect to the net tangible book value of the common stock. See the section entitled “Dilution” for a more detailed discussion of the dilution you will incur if you purchase securities in this offering.

In addition, we have a significant amount of convertible debt, stock options and warrants outstanding. To the extent that outstanding convertible notes, stock options or warrants, including the warrants offered hereby, have been or may be exercised or other shares issued, investors purchasing our common stock and accompanying warrants in this offering may experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders, result in downward pressure on the price of our common stock and a decline in the value of the warrants offered in this offering.

There is no public market for the warrants and pre-funded warrants to purchase shares of our common stock being offered in this offering.

There is no established public trading market for the warrants and pre-funded warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the warrants or pre-funded warrants on any national securities exchange or other nationally recognized trading system, including The NASDAQ Capital Market. Without an active market, the liquidity of the warrants will be limited.

Holders of our warrants and pre-funded warrants will have no rights as a common stockholder until they acquire our common stock.

Until you acquire shares of our common stock upon exercise of the warrants or pre-funded warrants, you will have no rights with respect to shares of our common stock issuable upon exercise of such warrants. Upon exercise of your warrants or pre-funded warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

The warrants are speculative in nature.

The warrants offered hereby merely represent the right to acquire shares of common stock at a fixed price. Specifically, commencing on the date of issuance, holders of the warrants may acquire the common stock issuable upon exercise of such warrants at an exercise price of $ per share. Moreover, following this offering, the market value of the warrants is uncertain and there can be no assurance that the market value of the warrants will equal or exceed their public offering price. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants and consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

Our failure to meet the continued listing requirements of The NASDAQ Capital Market could result in a delisting of our common stock.

We have conditioned the closing of this offering on the acceptance of our common stock to be listed on The NASDAQ Capital Market. If accepted for listing on The NASDAQ Capital Market, we are required to meet certain listing requirements to maintain the listing of our common stock on The NASDAQ Capital Market.

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

For instance, in May 2020, we were delisted from The NASDAQ Capital Market for failure to satisfy certain continued listing requirements thereof. Even if we are successful in relisting our shares of common stock on The NASDAQ Capital Market, there can be no assurance that we will be successful in maintaining the listing of our common stock on The NASDAQ Capital Market. If we are again delisted from The NASDAQ Capital Market, this could impair the liquidity and market price of our common stock. In addition, the delisting of our common stock again from a national exchange could have a material adverse effect on our access to capital markets, and any limitation on market liquidity or reduction in the price of our common stock as a result of that delisting could adversely affect our ability to raise capital on terms acceptable to us, or at all.

We do not intend to list the warrants or pre-funded warrants on The NASDAQ Capital Market, any other national securities exchange or any other nationally recognized trading system.

General Risk Factors

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.

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

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. For our fiscal year ended December 31, 2019, we performed system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K, as required by Section 404 of the Sarbanes-Oxley Act. We will be required to perform this evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting on an annual basis. This requires that we incur substantial additional professional fees and internal costs and that we expend significant management efforts on an annual basis. We have and will be required to test our internal controls within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements.

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

For example, management identified a control deficiency as of December 31, 2019 regarding our ineffective controls over non-routine transactions that constituted a material weakness. For more information regarding the material weakness refer to our risk factor titled "In connection with preparation of our annual financial statements for the fiscal year ended December 31, 2019, we identified a material weakness in our internal control over financial reporting. Any failure to maintain effective internal control over financial reporting could harm us" and Item 9A of our annual report on Form 10-K, filed with the SEC on February 28, 2020. We are still considering the full extent of the procedures to implement in order to remediate this material weakness. We can give no assurances that any additional material weakness will not arise in the future due to our failure to implement and maintain adequate internal controls over financial reporting. In addition, even if we are successful in strengthening our controls and procedures to resolve this material weakness, those controls and procedures may not be adequate to prevent or identify irregularities or ensure the fair presentation of our financial statements included in our periodic reports filed with the SEC.

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

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

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. These are based on our management's current beliefs, expectations and assumptions about future events, conditions and results and on information currently available to us. Discussions containing these forward-looking statements may be found, among other places, in the sections of this prospectus entitled "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations".

Any statements in this prospectus about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. Within the meaning of Section 27A of the Securities Act, and Section 21E of the Exchange Act, these forward-looking statements include statements regarding:

- 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;
- the expected timing of our clinical trials for our product candidates and the availability of data and result of those trials;
- our expectations regarding federal, state and foreign regulatory requirements;
- the potential therapeutic benefits and effectiveness of our product and product candidates;
- the size and characteristics of the markets that may be addressed by our product 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 product and product candidates;
- our expectations as to future financial performance, expense levels and liquidity sources; and
- the timing of commercializing our product and product candidates.

In some cases, you can identify forward-looking statements by the words "may," "might," "can," "will," "to be," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "likely," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future, although not all forward-looking statements contain these words. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements.

You should refer to the "Risk Factors" section contained in this prospectus and any related free writing prospectus for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Given these risks, uncertainties and other factors, many of which are beyond our control, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate, and you should not place undue reliance on these forward-looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to revise any forward-looking statements to reflect events or developments occurring after the date of this prospectus, even if new information becomes available in the future.

You should read this prospectus and the documents that we have filed as exhibits to the registration statement on Form S-1, of which this prospectus is a part, that we have filed with the SEC with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect.

MARKET AND INDUSTRY DATA

This prospectus contain 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 prospectus are reliable and are based on reasonable assumptions, these data involve 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 prospectus.

USE OF PROCEEDS

We estimate that the net proceeds we will receive from this offering will be approximately $46.4 million ($53.5 million if the underwriter exercises its over-allotment option in full), based on the assumed public offering price of $10.45 per share and accompanying warrant, the last reported sale price of our common stock on the OTCQB on January 4, 2021, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the warrants are exercised in full, the estimated net proceeds will increase to $96.4 million (or $103.5 million if underwriter exercises its over-allotment option in full).

A $1.00 increase (decrease) in the assumed public offering price of $10.45 per share and accompanying warrant, would increase (decrease) the net proceeds that we receive from this offering by $4.5 million, assuming that the number of shares of common stock, warrants and pre-funded warrants offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase or decrease of 100,000 in the number of shares of common stock (or common stock underlying pre-funded warrants) and accompanying warrants offered by us, as set forth on the cover page of this prospectus, would increase or decrease net proceeds to us from this offering approximately by $1.0 million, assuming no change in the assumed public offering price per share of common stock and accompanying warrant and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use $30.3 million of the net proceeds of this offering to make the Debt Payment and $2.0 million to make the related advisory payment. We intend to use the remainder of the net proceeds for working capital and general corporate purposes. See "Management's Discussion and Analysis of Financial Condition and Result of Operations—Liquidity and Capital Resources—Debt Restructuring" for additional information regarding the Debt Payment.

We may also use a portion of the net proceeds to invest in or acquire businesses or technologies that we believe are complementary to our own, although we have no current plans, commitments or agreements with respect to any acquisitions as of the date of this prospectus. Pending these uses, we expect to invest the net proceeds in short-term, interest-bearing obligations, certificates of deposit or direct or guaranteed obligations of the United States.

MARKET FOR OUR COMMON STOCK AND DIVIDEND POLICY

Market Information

Our common stock is quoted on the OTCQB under the symbol "KMPH." Quotations on the OTCQB reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions. On January 4, 2021, the last reported sale price of our common stock on the OTCQB was $10.45 per share.

We have applied to have our common stock listed on The NASDAQ Capital Market under the symbol "KMPH" contingent on the completion of this offering. The last reported sale price of our common stock on the OTCQB may not be indicative of the market price of our common stock on The NASDAQ Capital Market if our common stock is approved for listing thereon.

As of December 31, 2020, there were approximately 134 holders of record of our common stock.

Dividend Policy

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

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of September 30, 2020, on:

- an actual basis; and
- a pro forma basis to give effect to (1) the sale and issuance of 4,784,688 shares of our common stock and warrants to purchase up to 4,784,688 shares of our common stock offered by us in this offering, based on the assumed public offering price of $10.45 per share and accompanying warrant, the last reported sale price of our common stock on the OTCQB on January 4, 2021, assuming no sale of pre-funded warrants in this offering, no exercise of the warrants being offered in this offering, that no value is attributed to such warrants and that such warrants are classified as and accounted for as equity, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, and (2) the Debt Restructuring, including the use of a portion of the net proceeds from this offering to make the Debt Payment and the related advisory payment. The advisory payment related to the Debt Restructuring is capitalized and will be amortized over the life of the debt remaining after the restructuring. The advisory payment is recorded as an offset to the remaining debt principal amount in the line item entitled Convertible notes, less current portion, net in the table below.

You should read this table together with the sections of this prospectus titled "Description of Capital Stock" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited consolidated financial statements and related notes in this prospectus.

	As of September 30, 2020	
	Actual	Pro Forma(1)
	(in thousands, except share and per share data)	
Cash and cash equivalents	$ 5,267	$ 19,388
Current portion of convertible notes	$65,920	$ —
Convertible notes, less current portion, net	—	5,509
Derivative and warrant liability	184	184
Stockholders' (deficit) equity:		
Preferred stock:		
Series A convertible preferred stock, $0.0001 par value, 9,578 shares authorized, 9,577 shares issued and no shares outstanding, actual and pro forma	—	—
Series B-1 convertible preferred stock, $0.0001 par value, 1,576 shares authorized, 1,576 shares issued and no shares outstanding, actual and pro forma	—	—
Series B-2 convertible preferred stock, $0.0001 par value, 27,000 shares authorized, no shares issued or outstanding actual; 31,477 shares authorized, issued and outstanding, pro forma	—	0
Undesignated preferred stock, $0.0001 par value, 9,961,846 shares authorized, no shares issued or outstanding, actual; 9,957,369 shares authorized, no shares issued or outstanding, pro forma	—	—

	As of September 30, 2020	
	Actual	Pro Forma(1)
	(in thousands, except share and per share data)	
Common stock, $0.0001 par value, 250,000,000 shares authorized, 4,523,039 shares issued and outstanding, actual; 9,316,727 shares issued and outstanding, pro forma	0	1
Additional paid-in capital	191,291	268,049
Accumulated deficit	(253,618)	(254,689)
Total stockholders' (deficit) equity	(62,327)	13,361
Total capitalization	$ 3,777	$ 19,054

(1) The pro forma information is illustrative only, and our capitalization following the completion of this offering will depend on the actual public offering price of our securities and other final terms of the offering. Each $1.00 increase or decrease in the assumed public offering price of $10.45 per share and accompanying warrant, the last reported sale price of our common stock on the OTCQB on January 4, 2021, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, would increase or decrease our pro forma amount of each of cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by $4.5 million, assuming that the number of shares, warrants and pre-funded warrants offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase or decrease of 100,000 in the number of shares of our common stock (or shares of our common stock underlying pre-funded warrants) and accompanying warrants offered by us, as set forth on the cover page of this prospectus, would increase or decrease our pro forma amount of each of cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by $1.0 million, assuming no change in the assumed public offering price per share of common stock and accompanying warrant and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of our common stock to be outstanding as shown above is based on 4,532,039 shares outstanding as of September 30, 2020 (adjusted to give effect to the 1-for-16 reverse stock split described herein), and excludes:

- 354,379 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2020, at a weighted average exercise price of $4.86 per share;
- 151,442 shares of our common stock issuable upon exercise of warrants outstanding as of September 30, 2020, at a weighted average exercise price of $81.88 per share and any additional shares of our common stock issuable as a result of any anti-dilution adjustments under these warrants;
- 79,748 shares of our common stock issuable upon conversion of principal and accrued interest underlying the Deerfield Note outstanding as of September 30, 2020, assuming a conversion date of September 30, 2020, and any additional shares of our common stock issuable as a result of any anti-dilution adjustments under the Deerfield Note;
- 50,273 shares of our common stock reserved for future issuance under our 2014 equity incentive plan as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan; and
- 649,344 shares of our common stock issuable upon conversion of principal and accrued interest underlying the approximately $59.7 million aggregate principal amount of our Senior Secured Notes, assuming a conversion date of September 30, 2020.

DILUTION

The sale of our common stock, warrants to purchase common stock and pre-funded warrants pursuant to this prospectus will have a dilutive impact on our stockholders.

Our net tangible book deficit as of September 30, 2020 was $(62.3) million, or $(13.75) per share. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of September 30, 2020. Dilution with respect to net tangible book value per share represents the difference between the amount per share and accompanying warrant paid by purchasers in this offering and the pro forma net tangible book value per share of our common stock immediately after this offering.

After giving effect to (1) the sale of 4,784,688 shares of our common stock and warrants to purchase up to 4,784,688 shares of our common stock in this offering, at an assumed sale price of $10.45 per share and accompanying warrant, the last reported sale price of our common stock on the OTCQB Market on January 4, 2021, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and (2) the Debt Restructuring, including the use of a portion of the net proceeds from this offering to make the Debt Payment and the related advisory payment, our pro forma net tangible book value as of September 30, 2020 would have been $13.4 million, or $1.43 per share. This represents an immediate increase in net tangible book value of $15.18 per share to existing stockholders and an immediate dilution of $9.02 per share to new investors purchasing shares of our common stock and accompanying warrants in this offering.

The following table illustrates this calculation on a per share basis.

Assumed public offering price per share		$10.45
Net tangible book deficit per share as of September 30, 2020	$(13.75)	
Increase in net tangible book value per share attributable to this offering and the Debt Restructuring	15.18	
Pro forma net tangible book value per share after the offering		1.43
Dilution per share to new investors participating in the offering		$ 9.02

If the underwriter exercises its option to purchase additional shares in full, our as-adjusted net tangible book value as of September 30, 2020 would be $20.4 million, or $2.03 per share, representing an increase in the net tangible book value to existing stockholders of $15.78 per share and immediate dilution of $8.42 per share to new investors purchasing shares of our common stock in this offering.

The number of shares of our common stock to be outstanding as shown above is based on 4,532,039 shares outstanding as of September 30, 2020, and excludes as of that date:

- 354,379 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2020, at a weighted average exercise price of $74.86 per share;
- 151,442 shares of our common stock issuable upon exercise of warrants outstanding as of September 30, 2020 at a weighted average exercise price of $81.88 per share and any additional shares of our common stock issuable as a result of any anti-dilution adjustments under these warrants;
- 79,748 shares of our common stock issuable upon conversion of principal and accrued interest underlying the Deerfield Note, outstanding as of September 30, 2020, assuming a conversion date of September 30, 2020, and any additional shares of our common stock issuable as a result of any anti-dilution adjustments under the Deerfield Note;

- 50,273 shares of our common stock reserved for future issuance under our 2014 equity incentive plan as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan; and
- 649,344 shares of our common stock issuable upon conversion of principal and accrued interest underlying the $59.7 million aggregate principal amount of our Senior Secured Notes, assuming a conversion date of September 30, 2020.

To the extent that options or warrants (including the warrants and pre-funded warrants to be issued in this offering) outstanding as of September 30, 2020 have been or may be exercised or converted or other shares are issued, investors purchasing our securities in this offering may experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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, 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 preclinical 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. 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 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.

We expect that our only source of revenues will be through payments arising from our license agreements with KVK and Commave, 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 KP415 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. In May 2020, the FDA accepted our NDA for KP415.

We have had recurring negative cash flows from operations and, as of September 30, 2020, had an accumulated deficit of $253.6 million and a net working capital (current assets less current liabilities) deficit of $62.7 million. Our cash flows from operations for the nine months ended September 30, 2020 and 2019 were $0.9 million and $20.6 million of net cash used in operations, 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 sales of APADAZ or any other product candidates for which we obtain regulatory approval. In October 2018, we entered into the APADAZ License Agreement with KVK, pursuant to which we granted an exclusive license to KVK to commercialize APADAZ in the United States, and in September 2019, we entered into the KP415 License Agreement, pursuant to which we granted an exclusive, worldwide license to Commave to develop, manufacture and commercialize our product candidates containing SDX and d-MPH, including KP415 and KP484. We cannot guarantee that KVK or Commave will be able to successfully commercialize APADAZ or our product candidates covered under the KP415 License Agreement, or that we will ever receive any payments under the APADAZ License Agreement from commercial sales of APADAZ or any future payments under the KP415 License Agreement. We also do not know when, if ever, any other product candidate will be commercially available. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or debt, the terms of these securities may restrict our ability to operate. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

Our recurring negative cash flows from operations, net working capital (current assets less current liabilities) deficit and stockholders' deficit raise substantial doubt about our ability to continue as a going concern. We expect that our only sources of revenues will be through payments arising from our license agreements with KVK and Commave, and through the Corium Consulting Agreement and other potential consulting arrangements and any other future arrangements related to one of our other product candidates. Accordingly, our ability to continue as a going concern will require us to obtain additional financing to fund our operations. The perception of our inability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or debt, the terms of these securities may restrict our ability to operate. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

Third-Party Agreements

APADAZ License Agreement

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

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

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

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

KP415 License Agreement

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

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

Pursuant to the KP415 License Agreement, Commave paid us an upfront payment of $10.0 million and agreed to pay up to $63.0 million in milestone payments upon the occurrence of specified regulatory milestones related to the KP415 and KP484. In addition, Commave agreed to make additional payments upon the achievement of specified U.S. sales milestones of up to $420.0 million in the aggregate, depending, among other things, on timing of approval for a new drug applicable for KP415 and its final approved label, if any. In May 2020, the FDA accepted our NDA for KP415. Per the KP415 License Agreement, we received a regulatory milestone payment of $5.0 million following the FDA's acceptance of the KP415 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 KP415 and KP484. Subject to the oversight of the joint steering committee, we otherwise retain all responsibility for the conduct of all regulatory activities required to obtain new drug application approval of KP415 and KP484; provided that Commave shall be the sponsor of any clinical trials conducted by us on behalf of Commave.

JMI Agreement

In November 2009, we entered into a supply agreement, or the Supply Agreement, with Johnson Matthey, Inc., or JMI, whereby JMI has agreed to supply us with all the benzhydrocodone necessary for clinical trials and commercial sale for a price equal to JMI's manufacturing cost and to provide process optimization and development services for benzhydrocodone. In exchange, we issued shares of our common stock to JMI, provided that the commercial supply arrangement for benzhydrocodone would be exclusive to JMI in the United States and agreed to pay JMI royalties on the net sales of any products that utilize benzhydrocodone as the active pharmaceutical ingredient, or API. The percentage royalty rate ranges from the high teens at low volumes to the mid-single digits at higher volumes. Our FDA-approved drug, APADAZ, contains benzhydrocodone.

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

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

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

Other Third-Party Agreements

Under our March 2012 asset purchase agreement with Shire, Shire had a right of first refusal to acquire, license or commercialize KP415 and KP484. In early 2019, Shire was acquired by Takeda 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 KP415, KP484 or KP879, and any product candidates containing SDX, including royalty payments on any license of KP415, KP484 or KP879, the sale of KP415, KP484 or KP879 to a third party, the commercialization of KP415, KP484 or KP879 and the portion of any consideration that is attributable to the value of KP415, KP484 or KP879 and paid to us or our stockholders in a change of control transaction. In connection with the KP415 License Agreement, we paid Aquestive a royalty equal to 10% of the upfront license payment we received in the third quarter of 2019 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 KP415. 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 APADAZ or any other product candidates for which we obtain regulatory approval. We expect that our only source of revenues will be through payments arising from our license agreements with KVK and Commave, and through any other future arrangements related to one of our other product candidates. To date, we have only generated revenue from the KP415 License Agreement in the form of the non-refundable upfront payment of $10.0 million, of which we paid Aquestive $1.0 million as a royalty payment, reimbursement of out-of-pocket third-party research and development costs and payments related to the performance of consulting services. We cannot guarantee that KVK or Commave will be able to successfully commercialize APADAZ or our product candidates covered under the KP415 License Agreement, or that we will ever receive any payments under the APADAZ License Agreement from commercial sales of APADAZ or any future payments under the KP415 License Agreement. We also do not know when, if ever, any other product candidate will be commercially available.

Royalties and Contract Costs

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

Operating Expenses

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

Research and Development Expense

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

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

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

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

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

General and Administrative Expense

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

We expect that our general and administrative expense will fluctuate as we continue to operate as a public reporting company and continue to develop our product candidates. We believe that these fluctuations will likely include costs related to the hiring of additional personnel and fees for outside consultants, lawyers and accountants. We also expect to continue to incur costs to comply with corporate governance, internal controls, investor relations, disclosure and similar requirements applicable to public reporting companies.

Severance Expense

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

Other (Expense) Income

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

Income Tax Benefit

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

Results of Operations

Comparison of the three months ended September 30, 2020 and 2019 (in thousands):

	Three months ended September 30, 2020	Three months ended September 30, 2019	Period-to-Period Change
Revenue	$ 1,925	$11,463	$ (9,538)
Operating expenses:			
Royalty and direct contract acquisition costs	—	1,000	(1,000)
Research and development	1,709	3,616	(1,907)
General and administrative	1,429	3,613	(2,184)
Total operating expenses	3,138	8,229	(5,091)
(Loss) income from operations	(1,213)	3,234	(4,447)
Other (expense) income:			
Interest expense related to amortization of debt issuance costs and discount	(578)	(371)	(207)
Interest expense on principal	(1,163)	(1,208)	45
Fair value adjustment related to derivative and warrant liability	(137)	1,351	(1,488)
Interest and other income, net	48	60	(12)
Total other expenses	(1,830)	(168)	(1,662)
(Loss) income before income taxes	(3,043)	3,066	(6,109)
Income tax benefit (expense)	34	(3)	37
Net (loss) income	$(3,009)	$ 3,063	$ (6,072)

Net (Loss) Income

Net loss for the three months ended September 30, 2020 was $3.0 million, compared to net income for the three months ended September 30, 2019 of $3.1 million. The change was primarily attributable to a change in (loss) income from operations of $4.4 million, a change in the fair value adjustment related to derivative and warrant liability of $1.5 million and an increase in net interest expense and other items of $0.2 million.

Revenue

Revenue for the three months ended September 30, 2020 was $1.9 million, a decrease of $9.5 million compared to revenue for the three months ended September 30, 2019 of $11.5 million. The decrease was primarily attributable to an upfront payment on the KP415 License Agreement of $10.0 million in 2019, which did not recur in 2020, combined with a decrease in reimbursements revenue of $1.2 million, partially offset by an increase in consulting fees revenue of $1.7 million period over period.

Royalty and Direct Contract Acquisition Costs

Royalties and direct contract acquisition costs for the three months ended September 30, 2020 was $0, a decrease of $1.0 million compared to royalty and direct contract acquisition costs for the three months ended September 30, 2019 of $1.0 million. The decrease was attributable to a royalty payment of $1.0 million paid to Aquestive in 2019 related to the upfront payment on the KP415 License Agreement which did not recur in 2020. We had no royalties and direct contract acquisition costs for the three months ended September 30, 2020.

Research and Development

The following table summarizes our research and development costs for the three months ended September 30, 2020 and September 30, 2019 (in thousands):

	Three Months Ended September 30,	
	2020	**2019**
Outsourced development costs directly identified to programs:		
KP415	$ 62	$ 1,559
KP484	1	2
APADAZ	86	97
Total outsourced development costs directly identified to programs	149	1,658
Research and development costs not directly identified to programs:		
Personnel costs including cash compensation, benefits and stock-based compensation	1,082	1,309
Facilities costs	127	162
Other costs	351	487
Total research and development costs not directly allocated to programs	1,560	1,958
Total research and development expenses	$ 1,709	$ 3,616

Research and development expenses decreased by $1.9 million, from $3.6 million for the three months ended September 30, 2019, to $1.7 million for the three months ended September 30, 2020. This decrease was primarily attributable to a decrease in net third-party research and development costs, personnel-related costs and other miscellaneous research and development expenses.

General and Administrative

General and administrative expenses decreased by $2.2 million, from $3.6 million for the three months ended September 30, 2019, to $1.4 million for the three months ended September 30, 2020. This decrease was primarily attributable to a decrease in personnel-related costs, professional fees and other miscellaneous general and administrative costs.

Other (Expense) Income

Other expenses increased by $1.7 million, from $0.2 million for the three months ended September 30, 2019, to $1.8 million for the three months ended September 30, 2020. This period-to-period increase in expense was primarily attributable to a change in the fair value adjustment related to derivative and warrant liability of $1.5 million and an increase in net interest expense and other items of $0.2 million.

Comparison of the nine months ended September 30, 2020 and 2019 (in thousands):

	Nine months ended September 30,		Period-to-Period Change
	2020	2019	
Revenue	$10,922	$ 11,463	$ (541)
Operating expenses:			
Royalty and direct contract acquisition costs	1,305	1,000	305
Research and development	5,789	16,950	(11,161)
General and administrative	5,393	9,440	(4,047)
Severance expense	830	—	830
Total operating expenses	13,317	27,390	(14,073)
Loss from operations	(2,395)	(15,927)	13,532
Other (expense) income:			
Interest expense related to amortization of debt issuance costs and discount	(1,723)	(981)	(742)
Interest expense on principal	(3,620)	(3,669)	49
Fair value adjustment related to derivative and warrant liability	(65)	1,783	(1,848)
Interest and other (expense) income, net	(135)	295	(430)
Total other expenses	(5,543)	(2,572)	(2,971)
Loss before income taxes	(7,938)	(18,499)	10,561
Income tax benefit	34	14	20
Net loss	$ (7,904)	$(18,485)	$ 10,581

Net Loss

Net loss for the nine months ended September 30, 2020 was $7.9 million, a decrease of $10.6 million compared to a net loss for the nine months ended September 30, 2019 of $18.5 million. The decrease was primarily attributable to a decrease in loss from operations of $13.5 million, partially offset by a change in fair value adjustment related to derivative and warrant liability of $1.8 million and an increase in net interest expense and other items of $1.1 million.

Revenue

Revenue for the nine months ended September 30, 2020 was $10.9 million, a decrease of $0.5 million compared to revenue for the nine months ended September 30, 2019 of $11.5 million. The decrease was primarily attributable to an upfront payment on the KP415 License Agreement of $10.0 million in 2019, which did not recur in 2020, combined with a decrease in reimbursements revenue of $0.3 million period over period, partially offset by a one-time regulatory milestone payment under the KP415 License Agreement of $5.0 million received in 2020 following the FDA's acceptance of the KP415 NDA, combined with an increase in consulting fees revenue of $4.8 million period over period.

Royalty and Direct Contract Acquisition Costs

Royalties and direct contract acquisition costs for the nine months ended September 30, 2020 was $1.3 million, an increase of $0.3 million compared to royalty and direct contract acquisition costs for the nine months ended September 30, 2019 of $1.0 million. The increase was primarily attributable to a royalty payment of $0.5 million paid to Aquestive in 2020 related to the one-time regulatory milestone payment under the KP415 License Agreement, combined with the amortization of $0.8 million of costs directly attributable to the revenue recognized under the KP415 License Agreement, partially offset by $1.0 million paid to Aquestive in 2019 related to the upfront payment on the KP415 License Agreement which did not recur in 2020.

Research and Development

The following table summarizes our research and development costs for the nine months ended September 30, 2020 and September 30, 2019 (in thousands):

	Nine Months Ended September 30,	
	2020	**2019**
Outsourced development costs directly identified to programs:		
KP415	$ 466	$ 7,166
KP484	4	14
APADAZ	117	3,820
Total outsourced development costs directly identified to programs	587	11,000
Research and development costs not directly identified to programs:		
Personnel costs including cash compensation, benefits and stock-based compensation	3,672	4,042
Facilities costs	384	459
Other costs	1,146	1,449
Total research and development costs not directly allocated to programs	5,202	5,950
Total research and development expenses	$ 5,789	$16,950

Research and development expenses decreased by $11.2 million, from $17.0 million for the nine months ended September 30, 2019, to $5.8 million for the nine months ended September 30, 2020. This decrease was primarily attributable to a decrease in net third-party research and development costs, personnel-related costs and other miscellaneous research and development expenses.

General and Administrative

General and administrative expenses decreased by $4.0 million, from $9.4 million for the nine months ended September 30, 2019, to $5.4 million for the nine months ended September 30, 2020. This decrease was primarily attributable to a decrease in personnel-related costs, professional fees and other miscellaneous general and administrative costs.

Severance Expense

Severance expense of $0.8 million was recognized for the nine months ended September 30, 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 in the nine months ended September 30, 2019.

Other (Expense) Income

Other expenses increased by $3.0 million, from $2.6 million for the nine months ended September 30, 2019, to $5.5 million for the nine months ended September 30, 2020. This period-to-period increase in expense was primarily attributable to a change in fair value adjustment related to derivative and warrant liability of $1.8 million and an increase in net interest expense and other items of $1.1 million.

Results of Operations

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

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

Net Loss

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

Revenue

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

Royalties and Contract Costs

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

Research and Development

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

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

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

General and Administrative

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

Severance Expense

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

Other (Expense) Income

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

Liquidity and Capital Resources

Sources of Liquidity

Through September 30, 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, and from revenue received under the KP415 License Agreement, the Corium Consulting Agreement and other consulting arrangements. As of September 30, 2020, we had cash and cash equivalents of $5.3 million and restricted cash of $0.2 million.

We filed a registration statement on Form S-3 covering the sale from time to time of up to $150.0 million of our common stock, preferred stock, debt and/or warrants, which was declared effective by the Securities and Exchange Commission, or SEC, on October 17, 2016, or the Prior Registration Statement. In October 2019, we filed a registration statement on Form S-3 covering the sale from time to time of up to $80.0 million of our common stock, preferred stock, and debt and/or warrants, which was declared effective by the SEC on April 10, 2020, or the Current Registration Statement. Effective April 10, 2020, we ceased making any sales under the Prior Registration Statement.

Based on the market value of our outstanding common stock held by non-affiliates as of March 31, 2020, the date we filed amendment No. 1 to the Current Registration Statement, in order to issue securities under the Current Registration Statement we must rely on Instruction I.B.6. of Form S-3, which requires that we be listed on a national securities exchange and imposes a limitation on the maximum amount of securities that we may sell pursuant to the Current Registration Statement during any twelve-month period. Thus, even if we are relisted on NASDAQ, at the time we sell securities pursuant to the Current Registration Statement, the amount of securities to be sold plus the amount of any securities we have sold during the prior twelve months in reliance on Instruction I.B.6. may not exceed one-third of the aggregate market value of our outstanding common stock held by non-affiliates as of a day during the 60 days immediately preceding such sale, as computed in accordance with Instruction I.B.6. Based on this calculation, the amount of securities we are able to sell under the Current Registration Statement, as of March 31, 2020, was approximately $6.8 million, of which we (i) have filed a prospectus supplement to register approximately $2.7 million for sales under the Current Purchase Agreement; and (ii) have previously sold an aggregate of $4.1 million of shares of common stock in prior offerings on Form S-3 in the previous 12 months. Accordingly, we expect that we will be unable to sell additional securities beyond those amounts pursuant to our Current Registration Statement in the near term even if we regain our listing with NASDAQ, unless and until the market value of our outstanding common stock held by non-affiliates increases significantly. In addition, under the terms of the Current Purchase Agreement, stockholder approval may be required to access a portion of the amounts available under the Current Purchase Agreement.

In February 2019, we entered into the Prior Purchase Agreement with Lincoln Park, which provided that, upon the terms and subject to the conditions and limitations set forth therein, we may sell to Lincoln Park up to $15.0 million of shares of our common stock, from time to time over the 36-month term of the Prior Purchase

Agreement, and upon execution of the Prior Purchase Agreement we issued an additional 7,512 shares of our common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Prior Purchase Agreement. Concurrently with entering into the Prior Purchase Agreement, we also entered into a registration rights agreement with Lincoln Park, pursuant to which we agreed to register the sale of the shares of our common stock that have been and may be issued to Lincoln Park under the Prior Purchase Agreement pursuant to our existing shelf registration statement on Form S-3 or a new registration statement. In February 2020, upon entering into the Current Purchase Agreement with Lincoln Park, we terminated the Prior Purchase Agreement and we filed a prospectus supplement to the Prior Registration Statement to terminate this offering in its entirety. As a result, we will not make any future sales under the Prior Purchase Agreement. Through the date of termination we sold 212,579 shares of our common stock (exclusive of the 7,512 commitment shares) to Lincoln Park under the Prior Purchase Agreement for approximately $5.4 million in gross proceeds.

In September 2019, we entered into the KP415 License Agreement with Commave and Commave paid us a non-refundable upfront payment of $10.0 million. In May 2020, the FDA accepted our NDA for KP415. Per the KP415 License Agreement, we received a regulatory milestone payment of $5.0 million following the FDA's acceptance of the KP415 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 KP415. 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 Current Purchase Agreement with Lincoln Park, which provided that, upon the terms and subject to the conditions and limitations set forth therein, we may sell to Lincoln Park up to $4.0 million of shares of our common stock, from time to time over the 12-month term of the Current Purchase Agreement, and upon execution of the Current Purchase 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 Current Purchase Agreement. Concurrently with entering into the Current Purchase Agreement, we also entered into a registration rights agreement with Lincoln Park, pursuant to which we agreed to register the sale of the shares of our common stock that have been and may be issued to Lincoln Park under the Current Purchase Agreement pursuant to our existing shelf registration statement on Form S-3 or a new registration statement. In May 2020, we 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 Current Purchase Agreement and therefore we cannot issue additional shares under the Current Purchase Agreement. As of September 30, 2020, we have sold 559,971 shares of common stock (exclusive of the 19,289 commitment shares previously issued to Lincoln Park) under the Current Purchase Agreement for approximately $2.3 million in gross proceeds.

We have had recurring negative operating cash flows and, as of September 30, 2020, had an accumulated deficit of $253.6 million and a net working capital (current assets less current liabilities) deficit of $62.7 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. Our recurring negative operating cash flows, net working capital (current assets less current liabilities) deficit and stockholders' deficit raise substantial doubt about our ability to continue as a going concern. We expect that our only sources of revenue will be through payments arising from our license agreements with KVK and Commave, or through our Corium Consulting Agreement and other potential consulting arrangements and any other future arrangements related to one of our other product candidates. Accordingly, our ability to continue as a going concern may require us to obtain additional financing to fund our operations. The perception of our inability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or debt, the terms of these securities may restrict our ability to operate. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

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 KP415 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.

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, that we will ultimately apply for forgiveness, or that any amount of the PPP Loan will ultimately be forgiven by the SBA.

Convertible Debt

As of September 30, 2020, we had $67.1 million of convertible notes outstanding, consisting of senior secured convertible promissory notes issued, under the Deerfield Facility Agreement with Deerfield, (i) in June 2014, or the Deerfield Convertible Note (as described below), in the principal amount of $7.3 million, (ii) in December 2019, or the December 2019 Notes (as described below), in the aggregate principal amount of $56.6 million and (iii) in January 2020, or the January 2020 Note (as described below), in the principal amount of $3.1 million.

Deerfield Facility Agreement

In June 2014, we entered into the Deerfield Facility Agreement as a $60.0 million multi-tranche credit facility with Deerfield. At the time we entered into the Deerfield Facility Agreement, we borrowed the first tranche, which consisted of a $15.0 million term note and the $10.0 million convertible note, or the Deerfield Convertible Note. We used approximately $18.6 million of the net proceeds from the offering of the 2021 Notes to repay in full the $15.0 million original principal amount on the term note issued under the Deerfield Facility Agreement plus all accrued but unpaid interest on the term note, a make whole interest payment on the term note and a prepayment premium on the term note. Deerfield is no longer obligated to provide us any additional disbursements under the Deerfield Facility Agreement.

The Deerfield Convertible Note originally bore interest at 9.75% per annum, but was subsequently reduced to 6.75%. Interest accrued on the outstanding balance under the Deerfield Convertible Note was due quarterly in arrears. We originally had to repay one-third of the outstanding principal amount of the Deerfield Convertible Note on the fourth and fifth anniversaries of the Deerfield Facility Agreement (June 2018 and June 2019). In June 2018, Deerfield agreed to convert the $3,333,333 of the principal amount then due, plus $168,288 of accrued interest, into 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). We are also obligated to repay principal in the amount of $6,980,824 plus any capitalized interest to date on March 31, 2021. Prepayment of the outstanding balance is not allowed without written consent of Deerfield.

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

Pursuant to the Deerfield Facility Agreement, we may not enter into specified transactions, including a debt financing in the aggregate value of $750,000 or more, other than permitted indebtedness under the Deerfield Facility Agreement, a merger, an asset sale or any other change of control transaction or any joint venture, partnership or other profit-sharing arrangement, without the prior approval of the Required Lenders (as defined in the Deerfield Facility Agreement). Additionally, if we were to enter into a major transaction, including a merger, consolidation, sale of substantially all of our assets or other change of control transaction, Deerfield would have the ability to demand that prior to consummation of such transaction we repay all outstanding principal and accrued interest of the Deerfield Convertible Note. Deerfield has the right to demand that we redeem the Deerfield Warrant for a cash amount equal to the Black-Scholes value of a portion of the warrant upon the occurrence of specified events, including a merger, an asset sale or any other change of control transaction.

The Deerfield Facility Agreement also includes high yield discount obligation protections that went into effect in June 2019. Going forward, if at any interest payment date our outstanding indebtedness under the Deerfield Facility Agreement would qualify as an “applicable high yield discount obligation” under the Code, then we are obligated to prepay in cash on each such date the amount necessary to avoid such classification.

2021 Notes

In February 2016, we issued 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.

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 approximately 3.6528 shares of our common stock per $1,000 principal amount of the 2021 Notes, subject to adjustment under the indenture, which was equal to an initial conversion price of approximately $273.76 per share of our common stock.

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

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

As described in more detail below, in multiple exchanges occurring in October 2018, December 2019 and January 2020, all outstanding 2021 Notes were exchanged by the holders thereof for either shares of our common stock or 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 September 30, 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 September 30, 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 September 30, 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. Under the December 2020 Exchange Agreement, the Deerfield Lenders, DSC and Kingdon, or, collectively, the Holders, and we have agreed that (a) upon closing of this offering, we will make 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 Holders in an aggregate amount 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 our Series B-2 Preferred Stock and warrants exercisable for 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 in an aggregate amount equal to the Debt Payment, plus the Q4 PIK Interest Payment (as defined in the December 2020 Exchange Agreement), with such transaction referred to as the Exchange. Upon payment of the Debt Payment and completion of the Exchange, we anticipate that the aggregate principal amount of the outstanding indebtedness held by the Holders under the Deerfield Facility Agreement will be approximately $7.6 million.

The December 2020 Exchange Agreement amends 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.

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 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 amends 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 Exchange Warrants to be issued pursuant to the December 2020 Exchange Agreement will be exercisable for a number of shares of our 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 offered to investors in this offering, with an exercise price equal to the exercise price per share of the warrants issued in this offering 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.

The December 2020 Exchange Agreement contains customary representations, warranties and covenants made by us and the Holders party thereto, including a covenant by us for the benefit of the 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 Senior Secured Notes or the Deerfield Note or to complete the Exchange and the effectiveness of certain amendments to the Deerfield Facility Agreement, the Senior Secured Notes and the IRA, are subject to specified conditions of closing, including the closing of this offering, the filing of an amended and restated certificate of designation for the Series B-2 Preferred Stock and the approval for listing of our 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 under the December 2020 Exchange Agreement, we have agreed to file 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.

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 the price per share to the public of our common stock in this 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 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 will 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.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2020 and 2019 (in thousands):

	Nine months ended September 30,	
	2020	2019
Net cash used in operating activities	$ (880)	$ (20,639)
Net cash (used in) provided by investing activities	(7)	3,239
Net cash provided by financing activities	2,785	5,289
Net increase (decrease) in cash, cash equivalents and restricted cash	$1,898	$ (12,111)

Operating Activities

For the nine months ended September 30, 2020, net cash used in operating activities of $0.9 million consisted of a net loss of $7.9 million and $1.1 million in changes in working capital, partially offset by $8.1 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 $1.3 million related to a change in accounts payable and accrued expenses, $0.3 million related to a change in accounts and other receivables and $0.2 million related to operating lease liabilities, partially offset by $0.5 million related to a change in prepaid expenses and other assets and $0.2 million related to operating lease right-of-use assets and other liabilities. The adjustments for non-cash items primarily consisted of stock-based compensation expense of $2.0 million, non-cash interest expense of $3.6 million, amortization of debt issuance costs and debt discount of $1.7 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 $0.1 million and $0.5 million related to depreciation, amortization and other items.

For the nine months ended September 30, 2019, net cash used in operating activities of $20.6 million consisted of a net loss of $18.5 million and $6.2 million in changes in working capital; partially offset by $4.1 million in adjustments for non-cash items. The changes in working capital consisted of $1.5 million related to a change in accounts and other receivables, $6.1 million related to a change in accounts payable and accrued expenses, $1.6 million related to operating lease right-of-use assets and $0.8 million related to a change in other liabilities; partially offset by $1.4 million related to a change in prepaid expenses and other assets and $2.3 million related to operating lease liabilities. The adjustments for non-cash items primarily consisted of stock-based compensation expense of $3.7 million, non-cash interest expense of $1.0 million, amortization of debt issuance costs and debt discount of $1.0 million and $0.2 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 $1.8 million.

Investing Activities

For the nine months ended September 30, 2020, net cash used in investing activities was $7,000, which was attributable to purchases of property and equipment.

For the nine months ended September 30, 2019, net cash provided by investing activities was $3.2 million, which was primarily attributable to maturities of marketable securities.

Financing Activities

For the nine months ended September 30, 2020, net cash provided by financing activities was $2.8 million, which was primarily attributable to proceeds from sales of our common stock under the Current Purchase Agreement 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 nine months ended September 30, 2019, net cash provided by financing activities was $5.3 million, which was primarily attributable to proceeds from sales of our common stock under the Prior Purchase Agreement of $5.4 million; partially offset by repayment of principal on finance lease liabilities of $0.2 million.

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

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

Operating Activities

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

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

Investing Activities

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

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

Financing Activities

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

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

Future Funding Requirements

We anticipate that we will need substantial additional funding in connection with our continuing operations. Based upon our current operating plan, revenue projections and existing cash resources as of September 30, 2020, we believe our cash resources will be sufficient to fund operating expense and capital investment requirements past the potential March 2, 2021 PDUFA date for the KP415 NDA and up to the debt maturity date of March 31, 2021. We believe that the proceeds from this offering, together with our existing cash resources and projected revenues and after giving effect to the Deerfield Debt Payment and the Exchange, will be sufficient to fund our operations into, but not through, the third quarter of 2022. A portion of our projected revenue is based upon the achievement of milestones in our APADAZ and KP415 license agreements. Certain of the milestones are associated with regulatory matters that are outside our control and we do not have a history of achieving milestones in our license agreements.

Potential near-term sources of additional funding include:

- any revenues generated under 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, and, as of

September 30, 2020, we have a net working capital (current assets less current liabilities) deficit of $62.7 million. We expect that our only sources of revenues will be through payments arising from our license agreements with KVK and Commave, 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 KP415 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 KP415 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 KP415 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.

Our audited condensed financial statements for the fiscal year ended December 31, 2019 and our unaudited condensed financial statements for the quarter ended September 30, 2020, each include an explanatory paragraph stating that our recurring losses, negative operating cash flows, net working capital (current assets less current liabilities) deficit and stockholders' deficit raise substantial doubt about our ability to continue as a going concern. We expect that our only sources of revenues will be through payments arising from our license agreements with KVK and Commave, the Corium Consulting Agreement or through other potential consulting arrangements and any other future arrangements related to one of our other product candidates. Accordingly, our ability to continue as a going concern will require us to obtain additional financing to fund our operations. The perception of our inability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or debt, the terms of these securities may restrict our ability to operate. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

We have based our estimates of our cash needs and cash runway on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect and we cannot guarantee that we will be able to generate sufficient proceeds from our license agreements with KVK and Commave, 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 Judgments and Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, as well as the reported revenues and expenses during the reported periods. We evaluate these estimates and 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 prospectus, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements and understanding and evaluating our reported financial results.

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,		Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2020	2019	2020	2019
Research and development	$ 1,459	$ 1,608	$ 157	$ 400	$ 748	$ 1,196
General and administrative	2,951	3,651	228	657	866	2,468
Severance expense	—	1,236	—	—	420	—
Total stock-based compensation	$ 4,410	$ 6,495	$ 385	$ 1,057	$ 2,034	$ 3,664

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,		Nine months ended September 30,	
	2019	2018	2020	2019
Risk-free interest rate	1.75% - 2.61%	2.43% - 2.91%	0.38% - 1.65%	2.33% - 2.61%
Expected term (in years)	5.50 - 10.00	5.50 - 6.79	5.50 - 10.00	5.50 - 7.00
Expected volatility	84.82% - 85.93%	83.10% - 85.05%	89.49% - 92.67%	84.82% - 85.93%
Expected dividend yield	0%	0%	0%	0%

Based upon the stock price of $6.08 per share, which was the last sale price of our common stock reported on The NASDAQ Stock Market as of December 31, 2019 (adjusted to give effect to the 1-for-16 reverse stock split), outstanding options to purchase shares of our common stock as of December 31, 2019 had no intrinsic value; and there was also no aggregate intrinsic value of outstanding options to purchase shares of our common stock as of December 31, 2018.

Based upon the stock price of $9.032 per share, which was the last sale price of our common stock reported on OTCQB as of September 30, 2020, the aggregate intrinsic value of outstanding options to purchase shares of our common stock as of September 30, 2020, was $289,000, of which $27,000 related to vested options and $262,000 related to unvested options, and there was no aggregate intrinsic value of outstanding options to purchase shares of our common stock as of September 30, 2019.

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

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

Fair Value of Financial Instruments

We have a common stock warrant issued to Deerfield, put options embedded within those Deerfield warrants, fundamental change and make-whole interest provisions embedded within the 2021 Notes, a conversion feature within the Deerfield Convertible Note and the Senior Secured Notes and common stock warrants issued to KVK that meet the definition of derivative financial instruments and are accounted for as derivatives. The fair value of the common stock warrant issued to Deerfield, put options embedded within the Deerfield Warrants, fundamental change and make-whole interest provisions embedded within the 2021 Notes and the conversion feature within the Deerfield Convertible Note and the Senior Secured Notes 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 $134,000 and $192,000 at September 30, 2020 and 2019, respectively. The derivative liability for the put options embedded within the Deerfield common stock warrant was $19,000 and $77,000 at September 30, 2020 and 2019, respectively. The conversion feature within the Deerfield Convertible Note had no value at September 30, 2020 and 2019. The derivative liability for the KVK common stock warrant was $31,000 and $66,000 at September 30, 2020 and 2019, respectively. The derivative liability for the fundamental change and make-whole interest provisions embedded within the 2021 Notes had no value at either September 30, 2019. A 10% increase in the enterprise value would result in an increase of $19,000 in the estimated fair value of the Deerfield common stock warrant, no change in the estimated fair value of the put options embedded within the Deerfield common stock warrant, no change in the estimated fair value of the conversion feature within the Deerfield Convertible Note and an increase of $5,000 in the estimated fair value of the KVK common stock warrant at September 30, 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 September 30, 2020, we had federal net operating loss, or NOL, carryforwards of approximately $223.3 million, due to prior period losses, $138.1 million of which, if not utilized, will begin to expire in 2027. As of December 31, 2019, we had federal NOL carryforwards of approximately $138.1 million with expiration dates from 2027 to 2037 and $78.9 million with no expiration. We also had research and development credit carryforwards of $3.8 million with expiration dates ranging from 2027 to 2037 and $2.6 million with no expiration.

In accordance with Section 382 of the Code, a change in equity ownership of greater than 50% within a three-year period results in an annual limitation on a company's ability to utilize its NOL carryforwards created during the tax periods prior to the change in ownership. We performed a Section 382 ownership change analysis in 2017 and determined that we experienced an ownership change in 2010, which resulted in a portion of our net operating loss carryforwards being subject to an annual limitation under Section 382 through 2012. No other ownership changes or limitations on our historical net operating loss carryforwards were noted through the year ended December 31, 2017. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, including as a result of the conversion of our outstanding convertible debt or as a result of future changes in our stock ownership. If we determine that an ownership change has occurred and our ability to use our historical net operating loss carryforwards is materially limited, it would harm our future operating results by increasing our future tax obligations.

Emerging Growth Company Status

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we were subject to the same new or revised accounting standards as other public companies that were not emerging growth companies during the periods in which we qualified as an emerging growth company. On January 1, 2021, we no longer qualified as an emerging growth company.

Recent Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in our audited and unaudited financial statements appearing at the end of this prospectus.

BUSINESS

Company 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, KP415 and KP484, are both based on a prodrug of d-MPH, but with ER effect profiles, and are intended for the treatment of ADHD. Our preclinical product candidate for the treatment of SUD is KP879, based on a prodrug of d-MPH. Our preclinical prodrug product candidate for the treatment of IH is KP1077. In addition, we have announced our commercial partnership with KVK of APADAZ®, an FDA 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 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.

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

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

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

In July 2020, we entered into the Corium Consulting Agreement with 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 continue supporting preparation for the potential commercial launch of KP415. Corium is a portfolio company of Gurnet Point Capital and has been tasked with leading all commercialization activities for KP415 under the KP415 License Agreement.

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.

Our Strategy

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

- ***Leverage our proprietary LAT technology to improve the attributes of widely-prescribed, FDA-approved drugs.*** We plan to employ our proprietary LAT technology to discover and develop prodrugs that can improve one or more of the attributes of FDA-approved drugs that are widely-prescribed. We intend to discover and develop prodrugs of FDA-approved drugs in multiple therapeutic areas.
- ***Advance the development of our pipeline product candidates.*** We plan, together with Commave, to advance the development of our co-lead product candidates, KP415 and KP484, for the treatment of ADHD. We plan to initiate a pivotal efficacy trial for KP484 in 2021. We have submitted an NDA for KP415 with a potential PDUFA date of March 2, 2021. In addition, we are developing KP879, our prodrug of d-methylphenidate, for the treatment of SUD, and our prodrug product candidate KP1077 for the treatment of IH.
- ***Continue to build a global intellectual property portfolio.*** We intend to vigorously pursue composition-of-matter patent protection for our prodrugs in markets covering a majority of the global commercial opportunity.
- ***Commercialize APADAZ.*** We announced that in November 2019, APADAZ and its authorized generic (AG-APADAZ) became available nationally. To date KVK's commercialization strategy has targeted outreach to pharmacy benefit managers, managed care organizations and integrated delivery networks for the exclusive utilization of APADAZ as an alternative to currently available hydrocodone/acetaminophen products. We may also license the international commercial rights to APADAZ to one or more collaborators.

Our Proprietary LAT Technology

We employ our proprietary LAT technology to create prodrugs that are new molecules by chemically attaching one or more molecules, referred to as ligands, to an FDA-approved parent drug. We typically use ligands that have been demonstrated to be safe in toxicological studies or have been granted Generally Recognized as Safe, or GRAS, status by the FDA. When the prodrug is administered, human metabolic processes, such as those in the gastrointestinal, or GI, tract, separate the ligand from the prodrug and release the parent drug, which can then exert its therapeutic effect. We select ligands that, when combined with the parent drug, create prodrugs believed to have improved drug attributes while maintaining efficacy potentially equivalent to the parent drug.

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

- ***Improved drug properties.*** We seek to discover and develop prodrugs that are new molecules with potentially improved attributes over FDA-approved drugs, such as enhanced bioavailability, extended duration of action, increased safety and reduced susceptibility to abuse.
- ***Composition-of-matter patent protection.*** Our prodrugs are new molecules and thus may be eligible for patent protection as novel compositions of matter, provided that all other applicable requirements are met. We seek patent protection not only for our product candidates, but also for related compounds with the intention of creating potential heightened barriers to market entry.
- ***Eligibility for 505(b)(2) NDA pathway.*** Our proprietary LAT technology allows us to discover and develop prodrugs that may be eligible to use the 505(b)(2) NDA pathway. Under that regulatory pathway, if we are able to provide an adequate bridge between our product candidates and appropriate FDA-approved drugs, we will then be able to reference the FDA's previous findings of safety and effectiveness of the approved drugs in our 505(b)(2) NDA submissions. This may allow us to avoid the significant time and expense of conducting large clinical trials and potentially eliminate the need for some preclinical activities.

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

The ADHD market is relatively well served by a number of methylphenidate and amphetamine stimulant products. However, we believe there is a significant need for longer duration products. While many of the currently marketed methylphenidate products provide good symptom control for up to 12 hours post-dose, there is increasing attention to addressing late afternoon/early evening behavioral deficits, while maintaining early symptom control.

A study published in a peer-reviewed journal characterized the frequency and severity of ADHD symptoms throughout the day in children and adolescents treated with stable doses of stimulant medications. Results of that particular study indicated that the time from awakening to arriving at school can comprise up to 20% of waking hours per day (2-3 hours), and therefore such symptoms can cause significant distress for both children and caregivers. As a result, we believe there is a need to develop a methylphenidate product that provides early-morning control of symptoms.

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

Our Product Candidates and Approved Products

We have employed our proprietary LAT technology to create a portfolio of product candidates and approved products that we believe will offer significant improvements over FDA-approved and widely-prescribed drugs.
A selection of our product candidates and approved products are summarized in the table below:

Selected KemPharm Partnered and Optioned Assets

Parent Drug (Effect Profile) (Indication)	Product Candidate / Product (Status)	Development Status	Key Milestone
Methylphenidate (ER) (ADHD)	KP415 (Partnered)	Clinical	Potential PDUFA Date - March 2021
Methylphenidate (ER) (ADHD)	KP484 (Partnered)	Clinical	Initiation of Pivotal Efficacy Trial - 2021
Methylphenidate (ER)* (SUD)	KP879 (Optioned)	Preclinical	IND Acceptance - 2021
Undisclosed (IH)	KP1077	Preclinical	Pre-IND Meeting - 1H 2021
Hydrocodone/APAP (IR) (Pain)	APADAZ (Partnered)	FDA Approved	Tracking Payor Contracts and TRx's - 2020

* This product candidate is subject to an option in favor of Commave under the terms of the KP415 License Agreement, but is not currently licensed to Commave, thereunder.

Subject to Commave's approval, we intend to seek approval of both KP415 and KP484 under the 505(b)(2) NDA pathway, which will allow us to rely on the FDA's previous findings of safety and effectiveness for one or more approved products. We have submitted a NDA for KP415 with a potential PDUFA date of March 2, 2021. We anticipate initiating additional pharmacokinetic, or PK, and pivotal efficacy trials for KP484 in 2021, subject to Commave's approval.

KP415 and KP484

Overview

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

Subject to Commave's approval, we intend to seek approval of both KP415 and KP484 under the 505(b)(2) NDA pathway, which will allow us to rely on the FDA's previous findings of safety and effectiveness for one or more approved products. We have submitted a NDA for KP415 with a potential PDUFA date of March 2, 2021. We anticipate initiating additional PK and pivotal efficacy trials for KP484 in 2021, subject to Commave's approval.

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

Under the terms of the KP415 License Agreement, we granted Commave an exclusive, worldwide license to commercialize and develop the Licensed Product Candidates; provided that such license shall apply to an Additional Product Candidates only if Commave exercises its option under the KP415 License Agreement related thereto. If Commave exercises its option related to any Additional Product Candidate under the KP415 License Agreement, the parties are obligated to negotiate in good faith regarding the economic terms of such Additional Product Candidate.

We also granted to Commave a right of first refusal to acquire, license or commercialize any Additional Product Candidate, with such right of first refusal expiring upon the acceptance of a new drug application for such Additional Product Candidate. In addition, we granted Commave a right of first negotiation and a right of first refusal, subject to specified exceptions, for any assignment of our rights under the KP415 License Agreement.

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

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

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

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

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

Under our March 2012 termination agreement with Aquestive, Aquestive has the right to receive a royalty amount equal to 10% of any value generated by KP415, KP484 or KP879, and any product candidates which contain SDX, including royalty payments on any license of KP415, KP484 or KP879, the sale of KP415, KP484 or KP879 to a third party, the commercialization of KP415, KP484 or KP879 and the portion of any consideration that is attributable to the value of KP415, KP484 or KP879 and paid to us or our stockholders in a change of control transaction. In connection with the KP415 License Agreement, we paid Aquestive a royalty equal to 10% of the upfront license payment we received in the third quarter of 2019 and the regulatory milestone payment we received in the second quarter of 2020.

Market Opportunity

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

Key Features of KP415

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

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

- ***Reduced abuse potential.*** In order to evaluate the potential for reduced abuse of SDX, our prodrug of d-methylphenidate and major component of KP415, we conducted preclinical and clinical studies to compare the exposure to d-methylphenidate following oral, intranasal and intravenous, or IV, administration of the prodrug as compared to oral, intranasal and IV administration of d-methylphenidate hydrochloride. We observed significantly lower concentrations of d-methylphenidate following oral, intranasal and IV administration of the prodrug compared to oral, intranasal and IV administered d-methylphenidate hydrochloride. Consistent with this lower exposure, in human abuse potential studies, we also observed significantly lower abuse-related pharmacodynamic effects compared to d-methylphenidate comparators. Our prodrug of d-methylphenidate incorporates our proprietary LAT technology and, based on our preclinical and clinical studies, we believe it may have lower abuse potential compared to d-methylphenidate.
- ***Once-daily dosing.*** PK data from our preclinical studies suggest that the time to maximum plasma concentration of d-methylphenidate after oral administration of KP415 is approximately three times longer than that after oral administration of currently marketed IR d-methylphenidate. We believe our PK studies in human subjects also demonstrate that KP415 affords d-methylphenidate concentrations that are consistent with a once-daily, extended-duration product.
- ***Amenable to patient-friendly formulations.*** Our preclinical and clinical data show that KP415 could ultimately be used in a variety of patient-friendly dosage forms such as oral thin film and orally dissolving tablets as a means of increasing patient convenience and dosage compliance by regularly and consistently taking the medication as indicated.
- ***Composition-of-matter patent protection.*** We have a U.S. composition-of-matter patent that will expire, after utilizing all appropriate patent term adjustments but excluding possible term extensions, in 2032 that generally covers at least one component of KP415. Our patent strategy is focused primarily on key geographic markets, and we have composition-of-matter patents in multiple countries, including in Canada, China, Europe, Malaysia, Mexico, Indonesia, Israel, Japan, New Zealand, Philippines, Russia, Singapore, South Africa, South Korea and Vietnam, and additional patent filings pending in the United States and foreign jurisdictions. In addition, subject to further discussions with the FDA, we believe additional patent protection may be eligible for new chemical entity, or NCE, exclusivity status, which could allow for five years of U.S. market exclusivity following the FDA's approval of an NDA for KP415.
- ***No generic equivalent product.*** KP415 contains a prodrug that was given a new chemical name, serdexmethylphenidate, by the U.S. Adopted Names Council, or USAN, which means that there may be no generic equivalent product for KP415 in most states, making drug-equivalent substitution potentially difficult at the pharmacy.

Key Features of KP484

Based on our preclinical and clinical data, we believe KP484, if approved by the FDA, may have valuable product features and may provide significant benefits to patients, physicians, and society when compared to other FDA-approved and widely-prescribed methylphenidate products:

- ***Super-extended release.*** We believe that this KP484 may provide sustained, consistent effectiveness through the day and into the evening hours.
- ***Reduced abuse potential.*** The preclinical and clinical studies of SDX, the prodrug of d-methylphenidate, discussed above in the KP415 "Reduced Abuse Potential" subsection are being used by us for the abuse potential evaluation of the KP484 product candidate. Accordingly, we believe

serdexmethylphenidate may have attributes that disincentivize certain forms of abuse, as observed in these preclinical and clinical studies.

- ***Once-daily dosing.*** PK data from our clinical studies suggest that under fasted conditions, the time to maximum plasma concentration of d-methylphenidate after oral administration of KP484 is potentially five to seven times longer compared to oral administration of currently marketed IR d-methylphenidate. We believe this extended-duration attribute of KP484 may allow for convenient, once-daily dosing.
- ***Amenable to patient-friendly formulations.*** Our preclinical and clinical data shows that KP484 could ultimately be used in a variety of patient-friendly dosage forms such as oral thin film and orally dissolving tablets as a means of increasing patient convenience and dosage compliance by regularly and consistently taking the medications as indicated.
- ***Composition-of-matter patent protection.*** KP484 is generally protected by a U.S. composition-of-matter patent that will expire, after utilizing all appropriate patent term adjustments but excluding possible term extensions, in 2032. Our patent strategy is focused primarily on key geographic markets, and we have composition-of-matter patents generally protecting the major component of KP484 in New Zealand, South Africa and select other countries.
- ***No generic equivalent product.*** KP484 contains a prodrug that was given a new chemical name, serdexmethylphenidate, by the USAN, which means that there may be no generic equivalent product for KP484 in most states, making drug-equivalent substitution potentially difficult at the pharmacy.

KP879

KP879, a prodrug of d-methylphenidate using our proprietary LAT technology, is our product candidate for the treatment of SUD including, for example, abuse or misuse of cocaine, methamphetamine and prescription stimulants. Currently there are no approved drugs in the United States for SUD. We filed an IND with the FDA for KP879 in December 2020.

KP1077

KP1077 is our prodrug product candidate for the treatment of IH, an underserved, orphan disease indication. Currently there are no approved drugs in the United States for IH.

APADAZ

Overview

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

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

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

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

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

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

Market Opportunity

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

Key Product Features of APADAZ

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

- ***Composition-of-matter patent protection.*** APADAZ is protected by a U.S. composition-of-matter patent on benzhydrocodone, the prodrug of hydrocodone contained in APADAZ, that will expire, after utilizing all appropriate patent term adjustments but excluding possible patent term extensions, in 2031. Our patent strategy is focused primarily on key geographic markets and benzhydrocodone has received granted, issued or allowed patent status in multiple foreign jurisdictions and patent applications covering benzhydrocodone were pending in other foreign jurisdictions.
- ***No generic equivalent product.*** Benzhydrocodone, the APADAZ active pharmaceutical ingredient, or API, is a prodrug with a new chemical name given by the USAN, benzhydrocodone. APADAZ has a lower prescribed milligram strength of benzhydrocodone than the therapeutic equivalent amount of hydrocodone bitartrate used in existing IR hydrocodone/APAP combination products. The difference in chemical structure and prescription strength means that there is no generic equivalent product for APADAZ in most states (outside of the authorized generic AG-APADAZ), making substitution difficult at the pharmacy.

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

Our Intellectual Property

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

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

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

In 2013, the United States Patent and Trademark Office, or the USPTO, issued a composition-of-matter patent covering benzhydrocodone, which will expire, after utilizing all appropriate patent term adjustments but excluding possible patent term extensions, no earlier than 2030. Further, there are granted or recently allowed compositions-of-matter patents covering benzhydrocodone in Australia, Canada, Chile, China, Mexico, South Africa, and South Korea. In addition, three U.S. patent applications covering benzhydrocodone-related compositions-of-matter were pending as of December 31, 2019, and patent applications covering benzhydrocodone were pending as of December 31, 2019, in Brazil, EPC, Israel, Thailand, New Zealand, South Korea, and Vietnam.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. To help protect our LAT technology, as well as any proprietary know-how and show-how beyond that which is patentable, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we generally require our employees, consultants and advisors to enter into confidentiality agreements prohibiting the disclosure of confidential information and, in some cases, requiring disclosure and assignment to us of the ideas, developments, discoveries, inventions and improvements important to our business.

Commercialization

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

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

With the exception of APADAZ, commercialization activities for our product candidates in active development have not yet begun, other than pre-commercial activities by Corium for potential commercial launch of KP415 if approved by the FDA. Because many of our product candidates may have large potential market opportunities, and may require significant marketing resources, we may conclude that the most appropriate approach to their commercialization, if they receive regulatory approval, will involve forming a commercial collaboration or strategic relationship similar to those we have entered into with KVK and Commave, or consummating some type of strategic transaction, with a larger pharmaceutical or other marketing organization. Alternatively, we may conclude that building our own focused sales and marketing organization will be most appropriate, perhaps as part of a co-promotional arrangement, or some other form of collaboration. As we get closer to potential approval of our product candidates which are not currently subject to the APADAZ License Agreement or KP415 License Agreement, we will work to identify and implement the commercialization strategies that we conclude are the most desirable with regard to the specific product candidates.

Research and Development

Historically, we have devoted a significant amount of resources to develop our product candidates. For the years ended December 31, 2019 and 2018 and the nine-month periods ended September 30, 2020 and 2019, we recorded $19.4 million, $41.8 million, $5.8 million and $17.0 million, respectively, in research and development expenses. We plan to devote a significant portion of our capital towards research and development for the foreseeable future as we continue our efforts to further advance the development of our product candidates and commercialize APADAZ and our product candidates, if approved, subject to the availability of additional funding. However, as part of the KP415 License Agreement, Commave agreed to be responsible for and reimburse us for all of development, commercialization and regulatory expenses for the Licensed Product Candidates, as defined in the KP415 License Agreement, subject to certain limitations as set forth in the KP415 License Agreement.

Competition

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

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

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

Currently, there are no approved drugs in the United States for the treatment of IH. If approved, KP1077 will face potential 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.

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 JMI, a third-party manufacturer, to produce the bulk quantities of benzhydrocodone required to manufacture APADAZ under a supply agreement. We have contracted with another third-party manufacturer to supply KP415 and KP484 to be used in our non-clinical, clinical and formulation development programs necessary to support an NDA filing. We plan to continue to rely on these manufacturers to manufacture commercial quantities of APADAZ, and subject to Commave's approval, KP415 and KP484, respectively, for sale in the United States, if and when we receive approval by the FDA. We expect to contract with third-party manufacturers for the manufacture of all API supply needs outside the United States if and when we receive approval by regulatory authorities outside the United States.

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

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

Supply Agreement with Johnson Matthey

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

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

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

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

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

Asset Purchase Agreement with Shire

In March 2012, as a result of a litigation settlement, we and our chief executive officer, Travis C. Mickle, Ph. D., entered into an asset purchase agreement with Shire pursuant to which we sold assets and intellectual property to Shire for proceeds of $5.1 million. Pursuant to this agreement, we also granted Shire a right of first refusal to acquire, license or commercialize KP415 and KP484. In January 2019, Shire was acquired by Takeda to whom this right of first refusal was transferred at that time. Takeda did not exercise this right of first refusal as part of the KP415 License Agreement.

Third-Party Reimbursement

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

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

Within the Medicare program, as self-administered drugs, our product and product candidates would be reimbursed under the expanded prescription drug benefit known as Medicare Part D. This program is a voluntary Medicare benefit administered by private plans that operate under contracts with the federal government. These plans develop formularies that determine which products are covered and what co-pay will apply to covered drugs. The plans have considerable discretion in establishing formularies and tiered co-pay structures, negotiating rebates with manufacturers and placing prior authorization and other restrictions on the utilization of specific products, subject to review by the Centers for Medicare & Medicaid Services, or CMS, for discriminatory practices. These Part D plans negotiate discounts with drug manufacturers, which are passed on, in whole or in part, to each of the plan's enrollees through reduced premiums. Historically, Part D beneficiaries have been exposed to significant out-of-pocket costs after they surpass an annual coverage limit and until they reach a catastrophic coverage threshold. However, changes made by recent legislation will reduce this patient coverage gap, known as the "donut hole", by transitioning patient responsibility in that coverage range from 100% in 2010 to only 25% currently. To help achieve this reduction, pharmaceutical manufacturers are required to provide quarterly discounts of 50%, and 70% commencing January 1, 2019. In 2020, drug manufacturers will be responsible for a larger share of total drug costs due to an increase to the catastrophic threshold. Such increase will also result in a higher out-of-pocket threshold paid by Part D beneficiaries.

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

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

Government Regulation

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

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

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

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

The testing and approval process requires substantial time, effort and financial resources. Preclinical studies include laboratory evaluation of drug substance chemistry, pharmacology, toxicity and drug product formulation, as well as animal studies to assess potential safety and efficacy. Prior to commencing the first human clinical trial with a product candidate, we must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Additional non-clinical studies may be required even after the IND is submitted.

The IND becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the conduct of the clinical trial by imposing a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development, as well as amendments to previously submitted clinical trials. Further, an independent IRB for each study site proposing to conduct the clinical trial must review and approve the plan for any clinical trial, its informed consent form and other communications to study subjects before the clinical trial commences at that site. The IRB must continue to oversee the clinical trial while it is being conducted, including any changes to the study plans. Regulatory authorities, an IRB or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk, the clinical trial is not being conducted in accordance with the FDA's or the IRB's requirements, if the drug has been associated with unexpected serious harm to subjects, or based on evolving business objectives or competitive climate. Some studies also include a data safety monitoring board, which receives special access to unblinded data during the clinical trial and may advise us to halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

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

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

In the case of a 505(b)(2) NDA, some of the above-described studies and preclinical studies may not be required or may be abbreviated. Bridging studies may be needed, however, to demonstrate the relevance of the studies that were previously conducted by other sponsors to the drug that is the subject of the NDA.

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

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

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

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

505(b)(2) Approval Process

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

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

Orange Book Listing

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

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

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

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

Exclusivity

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

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

NDA Submission and Review by the FDA

Assuming successful completion of the required clinical and preclinical testing, among other items, the results of product development, including chemistry, manufacture and controls, non-clinical studies and clinical trials are submitted to the FDA, along with proposed labeling, as part of an NDA. The submission of an NDA requires payment of a substantial application user fee to the FDA. These user fees must be filed at the time of the first submission of the application, even if the application is being submitted on a rolling basis. Fee waivers or reductions are available in some circumstances.

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

The FDA may refer drugs which present difficult questions of safety, purity or potency to an advisory committee. An advisory committee is a panel that typically includes clinicians and other experts who review, evaluate and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

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

Once the FDA receives an application, it has 60 days to review the NDA to determine if it is substantially complete to permit a substantive review, before it accepts the application for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. The timeline for the FDA to complete its review of a NDA may differ based on whether the application is a standard review or priority review application. The FDA may give a priority review designation to drugs that are intended to treat serious conditions and provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions. Under the goals and policies agreed to by the FDA under 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 CRL or approval letter. A CRL indicates that the review cycle of the application is complete, and the application is not ready for approval. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing, or other information or analyses in order for the FDA to reconsider the application. The FDA has the goal of reviewing 90% of application resubmissions in either two or six months of the resubmission date, depending on the kind of resubmission (Class 1 or Class 2). Even with the submission of additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

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

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed or may include contraindications, warnings or precautions in the product labeling, including a boxed warning. If the FDA requires a boxed warning, we would also be subject to specified promotional restrictions, such as the prohibition of reminder advertisements. The FDA also may not approve the inclusion of labeling claims necessary for successful marketing. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require Phase 4 post-marketing studies to monitor the effect of approved products and may limit further marketing of the product based on the results of these post-marketing studies.

Post-approval Requirements

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

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

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

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

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

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

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

Risk Evaluation and Mitigation Strategy

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

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

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

DEA Regulation

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

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

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

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

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

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

The DEA typically inspects a facility to review its security measures prior to issuing a registration and on a periodic basis. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA, for example distribution reports for Schedule I and II controlled substances, Schedule III substances that are narcotics, and other designated substances. Reports must also be made for thefts or losses of any controlled substance, and to obtain authorization to destroy any controlled substance. In addition, special permits and notification requirements apply to imports and exports of narcotic drugs. To enforce these requirements, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in administrative, civil or criminal enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate administrative proceedings to revoke those registrations. In some circumstances, violations could result in criminal proceedings.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Distributions of any Schedule I or II controlled substance or Schedule III narcotic must also be accompanied by special order forms, with copies provided to the DEA. Because APADAZ and most of our current product candidates may be regulated as Schedule II controlled substances, they may be subject to the DEA's production and procurement quota scheme. The DEA establishes annually an aggregate quota for how much of a controlled substance may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. The limited aggregate amount of stimulants that the DEA allows to be produced in the United States each year is allocated among individual companies, which must submit applications annually to the DEA for individual production and procurement quotas. We and our contract manufacturers must receive an annual quota from the DEA in order to produce or procure any Schedule I or Schedule II substances for use in manufacturing of our product candidates. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Our, or our contract manufacturers', quota of an active ingredient may not be sufficient to meet commercial demand or complete clinical trials. Any delay, limitation or refusal by the DEA in establishing our, or our contract manufacturers', quota for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position and results of operations.

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

Other Healthcare Regulations

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

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for, or purchasing, leasing, ordering, or arranging for the purchase, lease or order of, any good, facility, item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Additionally, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, amended the intent requirement of the federal Anti-Kickback Statute, and some other healthcare criminal fraud statutes, so that a person or entity no longer needs to have actual knowledge of the federal Anti-Kickback Statute, or the specific intent to violate it, to have violated those statutes. The ACA also provided that a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the False Claims Act.

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

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

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

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

Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in significant civil monetary penalties.

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

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

Depending on the circumstances, failure to comply with these laws can result in significant penalties, including criminal, civil and/or administrative penalties, damages, fines, disgorgement, debarment from government contracts, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, exclusion from government programs, refusal to allow us to enter into supply contracts, including government contracts, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our business.

Healthcare Reform Measures

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

For example, in March 2010, the ACA was passed. The ACA has substantially changed health care financing by both governmental and private insurers, and significantly affected the U.S. pharmaceutical industry. The ACA, among other things, subjected manufacturers to new annual fees and taxes for specified branded prescription drugs, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, expanded health care fraud and abuse laws, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, imposed an inflation penalty on new formulations of drugs, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, expanded the 340B program which caps the price at which manufacturers can sell covered outpatient pharmaceuticals to specified hospitals, clinics and community health centers, and provided incentives to programs that increase the federal government's comparative effectiveness research. There remain judicial and congressional challenges to certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by ACA. Concurrently, Congress has considered legislation to repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, including the BBA, will remain in effect through 2029 unless additional Congressional action is taken. In addition, in January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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

The Foreign Corrupt Practices Act

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

Foreign Regulation

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

Employees

As of September 30, 2020, we employed 21 full-time employees. We have never had a work stoppage, and none of our employees are represented by a labor organization or under any collective bargaining arrangements. We consider our employee relations to be good.

Segments and Geographic Information

We view our operations and manage our business as one operating segment. See our financial statements for a discussion of revenues, operating loss, net loss and total assets. All of our assets were held in the United States for the years ended December 31, 2019 and 2018 and for the nine-month periods ended September 30, 2020 and September 30, 2019.

MANAGEMENT

Directors and Executive Officers

The following table sets forth information concerning our directors and executive officers, including their ages as of September 30, 2020:

Name	Age	Position(s)
Executive Officers:		
Travis C. Mickle, Ph.D.	47	President, Chief Executive Officer and Chairman of the Board
Sven Guenther, Ph.D.	48	Executive Vice President, Research and Development
R. LaDuane Clifton, CPA	48	Chief Financial Officer, Secretary and Treasurer
Non-Employee Directors:		
Richard W. Pascoe(1)(3)	56	Director
Matthew R. Plooster(1)(2)	39	Director
Joseph B. Saluri(2)(3)	54	Director
David S. Tierney(1)(2)(3)	57	Director

(1) Member of the compensation committee.
(2) Member of the nominating and corporate governance committee.
(3) Member of the audit committee.

Executive Officers

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

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

Mr. Clifton has served as our chief financial officer since June 2015 and as our secretary and treasurer since February 2016. Previously, Mr. Clifton served as our vice president of finance and corporate controller from April 2015 to June 2015. Prior to joining our company, Mr. Clifton served in a variety of positions with The LGL Group, Inc., a publicly held producer of industrial and commercial products and services, from August 2009 to February 2015, including chief financial officer, secretary and treasurer from December 2012 to February 2015, chief accounting officer and secretary from March 2010 to December 2012, and corporate controller from August 2009 to March 2010. From August 2008 to August 2009, Mr. Clifton served as the chief financial officer of a21, Inc., a publicly held holding company with businesses in stock photography and the online retail and manufacture of framed art, and as its corporate controller from March 2007 to August 2008. Mr. Clifton served in a variety of finance and medical cost analysis roles with Aetna, Inc., a publicly held provider of healthcare benefits, from August 1991 to August 2004. Mr. Clifton was an auditor with KPMG, LLP from August 2004 to March 2007. Mr. Clifton received his B.B.A. and M.B.A. degrees from the University of North Florida and is a certified public accountant in the state of Florida.

Non-Employee Directors

Mr. Pascoe, has served as a director of our company since January 2014 and our lead independent director since November 2014. Since January 2019, Mr. Pascoe has served as the chairman of the board of directors and chief executive officer of Histogen Inc, a biologics company. From March 2013 to January 2019, Mr. Pascoe was the chief executive officer and director of Apricus Biosciences. From August 2008 to March 2013, Mr. Pascoe was the president and chief executive officer and a director of Pernix Sleep, Inc. (formerly known as Somaxon Pharmaceuticals, Inc.), a specialty pharmaceutical company. Prior to Pernix, from 2005 to 2008, Mr. Pascoe worked for ARIAD Pharmaceuticals, Inc., a specialty pharmaceutical company, where he was most recently senior vice president and chief operating officer. Mr. Pascoe also serves as a director of Seelos Therapeutics, Inc, a specialty pharmaceutical company. Mr. Pascoe received his B.S. degree from the United States Military Academy at West Point. Our Board believes that Mr. Pascoe's experience as a pharmaceutical company executive provides him with the qualifications and skills to serve as a director of our company.

Mr. Plooster has served as a director of our company since March 2011. Mr. Plooster co-founded Bridgepoint Investment Banking, a division of Bridgepoint Holdings, LLC, where he has served as a managing director since March 2012. Previously, Mr. Plooster worked as an investment banker from 2004 to 2012 at various firms including, Morgan Stanley and Deutsche Bank. Mr. Plooster received his Certificate in Business Excellence from Columbia Business School and his B.A. degree from the University of Chicago. Our Board believes that Mr. Plooster's experience as an investor in and transaction experience with healthcare companies, as well as other board of director's experience, provides him with the qualifications and skills to serve as a director of our company.

Mr. Saluri has served as a director of our company since January 2014. Since August 2018, Mr. Saluri has served as chairman of the board and chief executive officer of BlueAllele, LLC, a start-up biotechnology company. Mr. Saluri previously served as executive vice president and general counsel for, Calyxt, Inc. from June 2017 to March 2018. Prior to his employment with Calyxt, Inc., Mr. Saluri served as vice president and general counsel for Stine Seed Company and its affiliates from July 1999 to March 2017. Prior to his employment with Stine, Mr. Saluri practiced as an attorney and solicitor at law with Nicholas Critelli Associates, PC, in Des Moines, Iowa and London, England from June 1993 to June 1999. Mr. Saluri served as a director of Newlink Genetics Corporation, a public biopharmaceutical company from May 2010 to July 2017. Mr. Saluri received his J.D. degree from Drake University Law School and his B.S.B.A. degree from Drake University. Our Board believes that Mr. Saluri's extensive legal background and experience in corporate management, finance and investor relations provides him with the qualifications and skills to serve as a director of our company.

Dr. Tierney has served as a director of our company since March 2015. Since February 2020, Dr. Tierney has served as chief executive officer of Pharma Two B, Ltd., a privately held company developing innovative therapeutics based on previously approved drugs for Parkinson's disease. From September 2019 until January 2020, Dr. Tierney served as President & CEO of BiopharmX (BPMX:NYSEAMERICAN) a dermatology drug development company. From March 2014 until March 2018 Dr. Tierney was President & CEO of Icon Bioscience, a private ophthalmology company which was merged into Psivida, Inc to form Eyepoint Pharmaceuticals. From January 2013 until March 2014, Dr. Tierney was a venture partner at Signet Healthcare Partners, a New York City based life science private equity fund. Dr. Tierney served as President & COO and as a member of the board of directors of Oceana Therapeutics, Inc., a private specialty pharmaceutical company, from its organization in 2008 through its sale to Salix Pharmaceuticals, Ltd. in December 2011. Dr. Tierney served as the president and chief executive officer and as a member of the board of directors of Valera Pharmaceuticals, Inc., a specialty pharmaceutical company, between August 2000 and April 2007, when Valera completed a merger with lndevus Pharmaceuticals, Inc. From January 2000 to August 2000, Dr. Tierney served as president of Biovail Technologies, a division of Biovail Corporation, a Canadian drug delivery company. From March 1997 to January 2000, Dr. Tierney was senior vice president of drug development at Roberts Pharmaceutical Corporation and from December 1989 to March 1997, Dr. Tierney was employed by Elan Corporation, a pharmaceutical company, in a variety of management positions. Dr. Tierney is also a director of Catalyst Pharmaceuticals, Inc (CPRX:NASDAQ), BiopharmX (BPMX:NYSEAMERICAN) and Bimeda, Inc a private global veterinary pharmaceutical company. Dr. Tierney received his medical degree from the Royal

College of Surgeons in Dublin, Ireland and was subsequently trained in internal medicine. Our Board believes that Dr. Tierney's experience as a pharmaceutical company executive provides him with the qualifications and skills to serve as a director of our company.

Classified Board

Our Board currently consists of five members. Our Board is divided into three classes. Each class consists, as nearly as possible, of one-third of the total number of directors, and each class has a three-year term. Vacancies on the Board may be filled only by persons elected by a majority of the remaining directors. A director elected by the Board to fill a vacancy in a class, including vacancies created by an increase in the number of directors, shall serve for the remainder of the full term of that class and until the director's successor is duly elected and qualified. Our directors are divided among the three classes as follows:

- The terms of Mr. Plooster and Mr. Saluri will expire at the annual meeting of stockholders to be held in 2021;
- The term of Dr. Mickle will expire at the annual meeting of stockholders to be held in 2022; and
- The terms of Mr. Pasco and Dr. Tierney will expire at the annual meeting of stockholders to be held in 2023.

We expect that additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Director Independence

As required under the NASDAQ listing standards, a majority of the members of our Board must qualify as "independent," as affirmatively determined by the Board. Our Board consults with our counsel to ensure that the Board's determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of NASDAQ, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and the Company, its senior management and its independent registered public accounting firm, the Board has affirmatively determined that the following four directors are independent directors within the meaning of the applicable NASDAQ listing standards: Messrs. Pascoe, Plooster, Saluri, and Tierney.

In making this determination, the Board found that none of these directors had a material or other disqualifying relationship with us. The Board considered the current and prior relationships that each non-employee director has with us and all other facts and circumstances our Board deemed relevant in determining their independence. Dr. Mickle, our president and chief executive officer, is not an independent director by virtue of his employment with the Company.

Lead Independent Director

The Board appointed Mr. Pascoe as our lead independent director to help reinforce the independence of the Board as a whole. The position of lead independent director has been structured to serve as an effective balance to a combined chief executive officer and board chair. As the lead independent director, Mr. Pascoe presides over meetings of our independent directors when needed, serves as a liaison between our chairman and the independent directors and performs additional duties as our Board may otherwise determine or delegate from time to time. As a result, we believe that the lead independent director can help ensure the effective independent functioning of the Board in its oversight responsibilities. In addition, we believe that the lead independent director is better positioned to build a consensus among directors and to serve as a conduit between the other independent directors and the board chair, for example, by facilitating the inclusion on meeting agendas of matters of concern to the independent directors. In light of Dr. Mickle's extensive history with and knowledge of the Company, and because the Board's lead independent director is empowered to play a significant role in the Board's leadership and in reinforcing the independence of the Board, the Company believes that it is advantageous for the Company to combine the positions of chief executive officer and board chair.

Board Committees

The Board has established an audit committee, a compensation committee and a nominating and corporate governance committee. Our board of directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by the Board.

Audit Committee

The Audit Committee reviews our internal accounting procedures and consults with and reviews the services provided by our independent registered public accounting firm. Our Audit Committee consists of three directors, Richard W. Pascoe, Joseph B. Saluri and David S. Tierney. Our Board has determined that each of Messrs. Pascoe, Saluri and Tierney are independent directors under NASDAQ listing rules and under Rule 10A-3 under the Exchange Act. Mr. Pascoe is the chairman of the Audit Committee and our Board has determined that Mr. Pascoe is an "audit committee financial expert" as defined by SEC rules and regulations and based on a qualitative assessment of Mr. Pascoe's level of knowledge and experience based on a number of factors including his previous business experience as described above. The principal duties and responsibilities of the Audit Committee include:

- appointing and retaining an independent registered public accounting firm to audit our financial statements, overseeing the independent registered public accounting firm's work and determining the independent registered public accounting firm's compensation;
- approving in advance all audit services and non-audit services to be provided to us by our independent registered public accounting firm;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls, auditing or compliance matters, as well as for the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;
- reviewing and discussing with management and our independent registered public accounting firm the results of the annual audit and the independent registered public accounting firm's review of our quarterly financial statements; and
- conferring with management and our independent registered public accounting firm about the scope, adequacy and effectiveness of our internal accounting control and our financial reporting.

The Audit Committee met five times during 2020. Our Board has adopted a written audit committee charter that is available to our stockholders at www.kempharm.com.

Compensation Committee

The Compensation Committee is composed of three directors, Richard W. Pascoe, Matthew R. Plooster and David S. Tierney. All members of our Compensation Committee are independent (as independence is currently defined in the relevant rules of the NASDAQ listing standards) and each is a non-employee member of our Board as defined in Rule 16b-3 under the Exchange Act. Mr. Plooster is the chairman of the Compensation Committee. Our Board has determined that the composition of the Compensation Committee satisfies the applicable independence requirements under, and the functioning of our Compensation Committee, complies with the applicable requirements of the NASDAQ listing rules and SEC rules and regulations.

The principal duties and responsibilities of the Compensation Committee include:

- establishing and approving, or, if it deems appropriate, recommend to the Board, performance goals and objectives relevant to the compensation of our chief executive officer, evaluating the performance of our chief executive officer in light of those goals and objectives and setting, or recommending to the full Board for approval, the compensation of our chief executive officer's compensation, including incentive-based and equity-based compensation, based on that evaluation;
- setting the compensation of our other executive officers, based in part on recommendations of the chief executive officer;
- exercising administrative authority under our stock plans, as well as stock appreciation rights plans, pension and profit-sharing plans, incentive plans, stock bonus plans, stock purchase plans, bonus plans, deferred compensation plans, or any other similar programs which may be adopted from time to time;
- establishing policies and making recommendations to our Board regarding director compensation;
- reviewing and discussing with management the compensation discussion and analysis that we may be required from time to time to include in SEC filings; and
- preparing a compensation committee report on executive compensation as may be required from time to time to be included in our annual proxy statements or annual reports on Form 10-K filed with the SEC.

The Compensation Committee met two times during 2020. Our Board has adopted a written compensation committee charter that is available to our stockholders at www.kempharm.com.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee is composed of three directors, Matthew R. Plooster, Joseph B. Saluri and David S. Tierney. Mr. Saluri is the chairman of the Nominating and Corporate Governance Committee. All members of the Nominating and Corporate Governance Committee are independent (as independence is currently defined in the relevant rules of the NASDAQ listing standards).

The principal duties and responsibilities of the Nominating and Corporate Governance Committee include:

- identifying, reviewing and evaluating candidates to serve as our directors (consistent with criteria approved by the Board);
- reviewing and evaluating incumbent directors;
- recommending to the Board for selection candidates for election to the Board;
- making recommendations to the Board regarding the membership of the committees of the Board;
- assessing the performance of the Board; and
- overseeing and reviewing the Company's corporate governance functions on behalf of the Board.

The Nominating and Corporate Governance Committee met two times during 2020. The Board has adopted a written Nominating and Corporate Governance Committee charter that is available to our stockholders at www.kempharm.com.

Code of Conduct

We have adopted the KemPharm, Inc. Code of Business Conduct and Ethics, or the Code of Conduct, that applies to all officers, directors and employees. The Code of Conduct is available on our website at www.kempharm.com. If we make any substantive amendments to the Code of Conduct or grant any waiver from a provision of the Code of Conduct to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website.

Non-Employee Director Compensation

The following table sets forth information regarding compensation earned for service on our Board during 2020 by our non-employee directors. Dr. Mickle, our president and chief executive officer, was also a director during 2020 but did not receive any additional compensation for his service as a director. Dr. Mickle's compensation as an executive officer is set forth above under "Executive Compensation—Summary Compensation Table."

Name	Fees Earned or Paid in Cash ($)	Option Awards(1) ($)	Total ($)
Richard W. Pascoe	42,188(2)	5,899	48,087
Matthew R. Plooster	33,750(3)	5,899	39,649
Joseph B. Saluri	33,750(4)	5,899	39,649
David S. Tierney	32,813(5)	5,899	38,712

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

(2) Represents stipends awarded for Mr. Pascoe's service on our Board, as our lead independent director, as a member of our Compensation Committee and as the chairman of our Audit Committee during 2020.

(3) Represents stipends awarded for Mr. Plooster's service on our Board, as the chairman of our Compensation Committee and as a member of our Nominating and Corporate Governance Committee during 2020.

(4) Represents stipends awarded for Mr. Saluri's service on our Board, as a member of our Audit Committee and as the chairman of our Nominating and Corporate Governance Committee during 2020.

(5) Represents stipends awarded for Mr. Tierney's service on our Board, as a member of our Compensation Committee, as a member of our Nominating and Corporate Governance Committee and as a member of our Audit Committee during 2020.

The table below shows the aggregate number of option awards outstanding for each of our non-employee directors as of December 31, 2020:

Name	Aggregate Option Awards Outstanding (#)
Richard W. Pascoe	7,020(1)
Matthew R. Plooster	7,312(2)
Joseph B. Saluri	7,020(1)
David S. Tierney	7,020(1)

(1) As of December 31, 2020, 5,145 shares underlying these options were vested. The remaining 1,875 shares underlying these options will vest on the earlier of (i) June 19, 2021 or (ii) one day prior to the date of the 2021 annual meeting of stockholders.

(2) As of December 31, 2020, 5,437 shares underlying these options were vested. The remaining 1,875 shares underlying these options will vest on the earlier of (i) June 19, 2021 or (ii) one day prior to the date of the 2021 annual meeting of stockholders.

EXECUTIVE COMPENSATION

Our chief executive officer and two of our other most highly compensated executive officers for the year ended December 31, 2020 are listed below:

- Travis C. Mickle, Ph.D., our president, chief executive officer and chairman of the board;
- Sven Guenther, Ph.D., our executive vice president, research and development; and
- R. LaDuane Clifton, CPA, our chief financial officer, secretary and treasurer:

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

Summary Compensation Table

The following table presents the compensation awarded to, earned by or paid to each of our named executive officers for the years ended December 31, 2020 and 2019, as applicable.

Name and Principal Position	Year	Salary ($)	Bonus $	Option Awards ($)(1)	All Other Compensation ($)(2)	Total ($)
Travis C. Mickle, Ph.D.	2020	530,450	—	134,381	11,400	676,231
President, chief executive officer and chairman of the board	2019	527,875	—	825,807	6,492	1,360,174
Sven Guenther, Ph.D.	2020	374,792	10,000	51,193	13,061	449,046
Executive vice president, research and development	2019	363,875	—	311,906	11,950	687,731
R. LaDuane Clifton, CPA	2020	350,200	—	51,193	4,894	406,287
Chief financial officer, secretary and treasurer	2019	348,500	—	311,906	4,081	664,487

(1) The amounts reflect the full grant date fair value for awards granted during 2020 and 2019, respectively. The grant date fair value was computed in accordance with ASC Topic 718, Compensation—Stock Compensation. Unlike the calculations contained in our financial statements, this calculation does not give effect to any estimate of forfeitures related to service-based vesting, but assumes that the executive will perform the requisite service for the award to vest in full. The assumptions we used in valuing options are described in Note L to our audited financial statements included in this prospectus.

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

Narrative to Summary Compensation Table

We review compensation at least annually for all employees, including our executives. In setting executive base salaries and bonuses and granting equity incentive awards, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders, and a long-term commitment to our company. We do not target a specific competitive position or a specific mix of compensation among base salary, bonus or long-term incentives. The Compensation Committee has historically determined our executives' compensation. Our Compensation Committee typically reviews and discusses management's proposed compensation with the chief executive officer for all executives other than the chief executive officer. Based on those discussions and its discretion, our Compensation Committee, without members of management present, discusses and ultimately approves the compensation of our executive officers.

Annual Base Salary

Our named executive officers' base salaries are reviewed periodically by our Compensation Committee, and adjustments may be made upon the approval of the Compensation Committee.

Effective March 1, 2019, our Compensation Committee approved an increase in Dr. Mickle's, Dr. Guenther's and Mr. Clifton annual base salaries to $530,450, $365,650, and $350,200 respectively.

Effective March 1, 2020, our Compensation Committee approved an increase in Dr. Guenther's annual base salary to $376,620.

Annual Bonus and Non-Equity Incentive Plan Awards

Our Board and Compensation Committee may make cash bonus and non-equity incentive plan awards in their discretion. In May 2020, we awarded Dr. Guenther a cash bonus of $10,000 in connection with his product development efforts.

In February 2020, our Compensation Committee determined that no cash awards would be paid to our executive officers for their services in 2019. The Compensation Committee has yet to make any determinations regarding the payment of cash awards to our executive officers for their services in 2020. If the Compensation Committee approves any cash awards to be paid to our executive officers, we will report these awards pursuant to a Current Report on Form 8-K.

Long-Term Incentives

Our 2014 equity incentive plan, or the 2014 Plan, authorizes us to make grants to eligible recipients of non-qualified stock options, incentive stock options and other stock-based awards. All of our awards under this plan have been in the form of stock options.

We typically grant stock options at the start of employment to each executive and our other employees. Through December 31, 2020, we have not maintained a policy of granting additional equity on an annual basis, but we have retained discretion to provide additional targeted grants in appropriate circumstances.

We award stock options to employees who are not officers of the Company on the date the single person non-officer stock award subcommittee of the Compensation Committee approves the grant. If employees are officers of the Company we award stock options on the date the Compensation Committee approves the grant. We set the option exercise price as the last reported sale price of our common stock on The NASDAQ Stock Market on the date of grant.

In February 2019, we granted Dr. Mickle an option to purchase 26,250 shares of our common stock. The shares subject to this option will vest in equal annual installments over a period of four years. The exercise price of this option is $42.56 per share, which equaled the closing sale price per share of our common stock as reported on The NASDAQ Stock Market on the date of grant. In November 2019, we granted Dr. Mickle an option to purchase 2,250 shares of our common stock. The shares subject to this option will vest in full and become immediately exercisable upon the achievement of specified product development milestones. The exercise price of this option is $8.2576 per share, which equaled the closing sale price per share of our common stock as reported on The NASDAQ Stock Market on the date of grant. In February 2020, we granted Dr. Mickle an option to purchase 26,250 shares of our common stock. The shares subject to this option will vest in full and become immediately exercisable upon the achievement of specified product development milestones. The exercise price of this option is $5.984 per share, which equaled the closing sale price per share of our common stock as reported on The NASDAQ Stock Market on the date of grant. All shares underlying these options will vest in full and become immediately exercisable upon a change of control of the Company or if the Dr. Mickle is terminated without cause or resigns for good reason (each as defined in Dr. Mickle's employment agreement, discussed under "Employment Arrangements and Potential Payments upon Termination of Employment" herein). With respect to equity awards that vest based on the attainment of performance goals, the performance goals will be deemed to have met as of the date of termination.

In February 2019, we granted Dr. Guenther an option to purchase 10,000 shares of our common stock. The shares subject to this option will vest in equal annual installments over a period of four years. The exercise price of this option is $42.56 per share, which equaled the closing sale price per share of our common stock as reported on The NASDAQ Stock Market on the date of grant. In November 2019, we granted Dr. Guenther an option to purchase 3,500 shares of our common stock. The shares subject to this option will vest in full and become immediately exercisable upon the achievement of specified product development milestones. The exercise price of this option is $8.2576 per share, which equaled the closing sale price per share of our common stock as reported on The NASDAQ Stock Market on the date of grant. In February 2020, we granted Dr. Guenther an option to purchase 10,000 shares of our common stock. The shares subject to this option will vest in full and become immediately exercisable upon the achievement of specified product development milestones. The exercise price of this option is $5.984 per share, which equaled the closing sale price per share of our common stock as reported on The NASDAQ Stock Market on the date of grant. All shares underlying these options will vest in full and become immediately exercisable upon a change of control of the Company or if the Dr. Guenther is terminated without cause or resigns for good reason (each as defined in Dr. Guenther's employment agreement, discussed under "Employment Arrangements and Potential Payments upon Termination of Employment" herein). With respect to equity awards that vest based on the attainment of performance goals, the performance goals will be deemed to have met as of the date of termination.

In February 2019, we granted Mr. Clifton an option to purchase 10,000 shares of our common stock. The shares subject to these options will vest in equal annual installments over a period of four years. The exercise price of these options are $42.56 per share, which equaled the closing sale price per share of our common stock as reported on The NASDAQ Stock Market on the date of grant. In November 2019, we granted Mr. Clifton an option to purchase 2,250 shares of our common stock. The shares subject to this option will vest in full and become immediately exercisable upon the achievement of specified product development milestones. The exercise price of this option is $8.2576 per share, which equaled the closing sale price per share of our common stock as reported on The NASDAQ Stock Market on the date of grant. In February 2020, we granted Mr. Clifton an option to purchase 10,000 shares of our common stock. The shares subject to this option will vest in full and become immediately exercisable upon the achievement of specified product development milestones. The exercise price of this option is $5.984 per share, which equaled the closing sale price per share of our common stock as reported on The NASDAQ Stock Market on the date of grant. All shares underlying these options will vest in full and become immediately exercisable upon a change of control of the Company or if the Mr. Clifton is terminated without cause or resigns for good reason (each as defined in Mr. Clifton's employment agreement, discussed under "Employment Arrangements and Potential Payments upon Termination of Employment" herein). With respect to equity awards that vest based on the attainment of performance goals, the performance goals will be deemed to have met as of the date of termination.

Other Compensation

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

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

Employment Arrangements and Potential Payments upon Termination of Employment

In May 2014, we entered into an employment agreement with Dr. Mickle, under which Dr. Mickle serves as our president and chief executive officer. Under this agreement, upon the execution of a release of claims, Dr. Mickle is eligible to receive severance benefits in specified circumstances.

In the event that we terminate Dr. Mickle without cause or he resigns for good reason, Dr. Mickle will be entitled to receive (a) an amount equal to 18 months of his annual base salary, less applicable deductions, payable in accordance with our normal payroll schedule, (b) a pro rata bonus award payable on the first regularly scheduled pay day following the 60th day after his termination, (c) 18 months of continued health coverage and (d) full vesting of his outstanding equity awards, except that if such termination occurs within 60 days before, upon or within one year following a sale that constitutes a "change in control event" as defined in Section 409A of the Code, then in lieu of the payments described in clause (a) Dr. Mickle will be entitled to receive a lump sum payment equal to one and one-half his annual salary plus his target annual bonus on the first regularly scheduled pay day following the 60th day after his termination. In the event that we terminate Dr. Mickle with cause, Dr. Mickle resigns without good reason, or his employment is terminated due to mutual agreement, death or disability, then Dr. Mickle will not be entitled to receive severance benefits. Under the terms of Dr. Mickle's employment agreement, if we enter into any change of control, all then unvested shares subject to outstanding options shall become fully vested and immediately exercisable immediately prior to such change in control.

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

- "cause" means (a) executive is convicted of, or pleads nolo contendere to, a crime constituting a misdemeanor involving dishonesty or moral turpitude or any crime constituting a felony, (b) executive neglects, refuses or fails to perform executive's material duties, (c) executive commits a material act of dishonesty or otherwise engages in or is guilty of gross negligence or willful misconduct in the performance of executive's duties or (d) executive materially breaches the provisions of any written non-competition, non-disclosure or non-solicitation agreement, or any other agreement with us provided, however, that executive shall have 15 days following a notice of termination specifying a condition under clause (b), (c) or (d) constituting cause to cure such condition; and

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

In April 2016, we entered into an amended and restated employment agreement with Dr. Guenther, under which Dr. Guenther serves as our executive vice president, research and development. Under this agreement, upon the execution of a release of claims, Dr. Guenther is eligible to receive severance benefits in specified circumstances.

In the event that we terminate Dr. Guenther without cause or he resigns for good reason, Dr. Guenther will be entitled to receive (a) an amount equal to 12 months of his annual base salary, less applicable deductions, payable in accordance with our normal payroll schedule, (b) a pro rata bonus award payable on the first regularly scheduled pay day following the 60th day after his termination, (c) 12 months of continued health coverage and (d) full vesting of his outstanding equity awards, except that if such termination occurs within 60 days before, upon or within one year following a sale that constitutes a "change in control event" as defined in Section 409A of the Code then in lieu of the payment described in clause (a) Dr. Guenther will be entitled to a lump sum payment equal to his annual base salary on the first regularly scheduled pay day following the 60th day after his termination. In the event that we terminate Dr. Guenther with cause, Dr. Guenther resigns without good reason, or the employment is terminated due to mutual agreement, death or disability, then Dr. Guenther will not be entitled to receive severance benefits. Under the terms of Dr. Guenther's employment agreement, if we enter into any change of control, all then unvested shares subject to outstanding options shall become fully vested and immediately exercisable immediately prior to such change in control.

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

- "cause" means (a) executive performed an act or acts of willful and material malfeasance or misconduct with respect to the performance of his duties and responsibilities as an employee and executive officer or under the agreement that results in material harm to us that remains uncorrected for 15 days after receipt of written notice, (b) executive's continued failure to devote his full business time and attention and his best efforts to the faithful performance of his material duties and responsibilities (other than a failure resulting from disability) that remains uncorrected for 15 days after receipt of written notice, (c) executive's material breach of any material provision of the agreement that remains uncorrected for 15 days after receipt of written notice, (d) executive commits an act of fraud, embezzlement, misappropriation, or personal dishonesty against us (which, if proven, would constitute a felony) or (e) the conviction of, or plea of nolo contendere by, executive to a crime constituting a felony; and
- "good reason" means (a) material diminution by us of executive's authority, duties or responsibilities, the duration of which is greater than 15 days and which is not the result of his acts or omissions which constitute cause (b) a material change in the geographic location at which executive must principally perform services under the agreement, (c) a material diminution in his base salary which is not the result of his acts or omissions which constitute cause or (d) any action or inaction that constitutes a material breach by us of the agreement, including our failure to pay any amounts due to executive or our failure to obtain from a successor the express assumption of the agreement.

In June 2015, we entered into an amended and restated employment agreement with Mr. Clifton under which he serves as our chief financial officer. Under this agreement, Mr. Clifton is eligible to receive severance benefits in specified circumstances.

In the event that we terminate Mr. Clifton without cause or he resigns for good reason, Mr. Clifton will be entitled to receive (a) an amount equal to 12 months of his annual base salary, less applicable deductions, payable in accordance with our normal payroll schedule, (b) a pro rata bonus award payable on the first regularly scheduled pay day immediately after his termination, (c) 12 months of continued health coverage and (d) full vesting of his outstanding equity awards, except that if such termination occurs upon or within one year following a sale that constitutes a "change in control event" as defined in Section 409A of the Code then in lieu of the payment described in clause (a) Mr. Clifton will be entitled to a lump sum payment equal to his annual base salary on the first regularly scheduled pay day immediately following the effective date of his termination. In the event that we terminate Mr. Clifton with cause, Mr. Clifton resigns without good reason, or the employment is terminated due to mutual agreement, death or disability, then Mr. Clifton will not be entitled to receive severance benefits. Under the terms of Mr. Clifton's amended and restated employment agreement, as amended, if we enter into any change of control, all then unvested shares subject to outstanding options shall become fully vested and immediately exercisable immediately prior to such change in control.

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

- "cause" means (a) executive performed an act or acts of willful and material malfeasance or misconduct with respect to the performance of his duties and responsibilities as an employee and executive officer or under the agreement that results in material harm to us that remains uncorrected for 15 days after receipt of written notice, (b) executive's continued failure to devote his full business time and attention and his best efforts to the faithful performance of his material duties and responsibilities (other than a failure resulting from disability) that remains uncorrected for 15 days after receipt of written notice, (c) executive's material breach of any material provision of the agreement that remains uncorrected for 15 days after receipt of written notice, (d) executive commits an act of fraud, embezzlement, misappropriation, or personal dishonesty against us (which, if proven, would constitute a felony) or (e) the conviction of, or plea of nolo contendere by, executive to a crime constituting a felony; and

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

Outstanding Equity Awards at End of 2020

The following table provides information about outstanding stock options held by each of our named executive officers at December 31, 2020. All of these options were granted under our stock incentive plan, or the 2007 Plan, or our 2014 Plan.

	Option Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Travis C. Mickle, Ph.D.	3,333	—	$ 93.60	8/17/2022
	1,666	—	$ 93.60	7/30/2024
	13,750	—	$ 327.20	9/4/2025
	9,375	—	$ 201.92	2/10/2026
	10,546	3,516(1)(2)	$ 56.80	1/26/2027
	7,031	7,031(1)(3)	$ 88.00	1/24/2028
	6,562	19,688(1)(4)	$ 42.56	2/5/2029
	2,250	—	$ 8.2576	11/24/2029
	—	26,250(1)(5)	$ 5.984	2/4/2030
Sven Guenther, Ph.D.	1,250	—	$ 93.60	7/9/2024
	3,125	—	$ 327.20	9/3/2025
	3,125	—	$ 201.92	2/10/2026
	3,515	1,172(1)(2)	$ 56.80	1/26/2027
	2,343	2,344(1)(3)	$ 88.00	1/24/2028
	2,500	7,500(1)(4)	$ 42.56	2/5/2029
	3,500	—	$ 8.2576	11/24/2029
	—	10,000(1)(5)	$ 5.984	2/4/2030
R. LaDuane Clifton, CPA	1,333	—	$ 176.00	4/1/2025
	2,812	—	$ 292.64	6/25/2025
	937	—	$ 327.20	9/3/2025
	3,125	—	$ 201.92	2/10/2026
	3,515	1,172(1)(2)	$ 56.80	1/26/2027
	2,343	2,344(1)(3)	$ 88.00	1/24/2028
	2,500	7,500(1)(4)	$ 42.56	2/5/2029
	2,250	—	$ 8.2576	11/24/2029
	—	10,000(1)(5)	$ 5.984	2/4/2030

(1) All shares underlying these option grants will vest in full and become immediately exercisable (i) in the event that the option holder is terminated by us without cause or resigns for good reason or (ii) immediately prior to any change in control of KemPharm.

(2) The shares underlying this option will vest in equal annual installments over a period of four years beginning on January 27, 2018 through January 27, 2021.

(3) The shares underlying this option will vest in equal annual installments over a period of four years beginning on January 25, 2019 through January 25, 2022.
(4) The shares underlying this option will vest in equal annual installments over a period of four years beginning on February 6, 2020 through February 6, 2023.
(5) The shares subject to this option will vest in full and become immediately exercisable upon the achievement of specified product development milestones.

Pension Benefits

Our named executive officers did not participate in, or otherwise receive any benefits under, any pension or retirement plan sponsored by us during 2020 or 2019.

Nonqualified Deferred Compensation

Our named executive officers did not participate in, or otherwise receive any benefits under, any nonqualified deferred compensation plan sponsored by us during 2020 or 2019.

Equity Incentive Plans

2014 Equity Incentive Plan

Our Board adopted and our stockholders have approved our 2014 Plan. The 2014 Plan became effective on April 15, 2015. As of September 30, 2020, options exercisable for 341,784 shares of our common stock have been granted and 16,110 shares of our common stock have been issued under our 2014 Plan. Our 2014 Plan provides for the grant of incentive stock options within the meaning of Section 422 of the Code to our employees and our parent and subsidiary corporations' employees, and for the grant of non-statutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of stock compensation to our employees, including officers, consultants and directors. Our 2014 Plan also provides for the grant of performance cash awards to our employees, consultants and directors.

Authorized Shares

The maximum number of shares of our common stock that may be issued under our 2014 Plan as of September 30, 2020 was 408,167 shares. The number of shares of our common stock reserved for issuance under our 2014 Plan will automatically increase on January 1 of each year, for a period of ten years, from January 1, 2016 continuing through January 1, 2024, by 4.0% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares as may be determined by our Board. On January 1, 2020, the maximum number of shares of our common stock reserved for issuance under our 2014 Plan was increased by 90,876 shares as a result of this automatic increase. The maximum number of shares that may be issued pursuant to the exercise of incentive stock options under the 2014 Plan is 408,167. The aggregate maximum number of shares subject to awards granted during a single fiscal year to any non-employee director, taken together with any cash fees paid to such non-employee director during the fiscal year, cannot exceed $500,000 in total value, calculating the value of any such awards based on the grant date fair value of such awards for financial reporting purposes and excluding the value of any dividend equivalent payments paid pursuant to any award granted in a previous fiscal year.

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

Administration

Our Board, or a duly authorized committee thereof, has the authority to administer our 2014 Plan. Our Board has delegated its authority to administer our 2014 Plan to our Compensation Committee under the terms of the Compensation Committee's charter. Our Board, or a duly authorized committee thereof, may also delegate to one or more of our officers the authority to (a) designate employees other than officers to receive specified stock awards and (b) determine the number of shares of our common stock to be subject to such stock awards. Our Compensation Committee has delegated this authority to our chief executive officer, Travis C. Mickle, but not for himself and not for our executive officers. Subject to the terms of our 2014 Plan, the administrator has the authority to determine the terms of awards, including recipients, the exercise price or strike price of stock awards, if any, the number of shares subject to each stock award, the fair market value of a share of our common stock, the vesting schedule applicable to the awards, together with any vesting acceleration, the form of consideration, if any, payable upon exercise or settlement of the stock award and the terms and conditions of the award agreements for use under our 2014 Plan.

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

Certain Limits

No participant may be granted stock awards covering more than 212,500 shares of our common stock under our 2014 Plan during any calendar year pursuant to stock options, stock appreciation rights and other stock awards whose value is determined by reference to an increase over an exercise price or strike price of at least 100% of the fair market value of our common stock on the date of grant. Additionally, no participant may be granted in a calendar year a performance stock award covering more than 212,500 shares of our common stock or a performance cash award having a maximum value in excess of $5,000,000 under our 2014 Plan.

Performance Awards

Our 2014 Plan permits the grant of performance-based stock and cash awards. Our Compensation Committee can structure such awards so that the stock or cash will be issued or paid pursuant to such award only following the achievement of specified pre-established performance goals during a designated performance period.

Corporate Transactions

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

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

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

Change in Control

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

Plan Amendment or Termination

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

2007 Plan

Our 2007 Plan was adopted by our Board and approved by our stockholders in June 2007. Awards outstanding under our 2007 Plan prior to completion of our initial public offering continue to be governed by their existing terms under the 2007 Plan. No further awards will be made under the 2007 Plan.

As of September 30 2020, options to purchase 12,595 shares of our common stock were outstanding under the 2007 Plan.

Administration

Our Board or the Compensation Committee of our Board act as the administrator of the 2007 Plan. The administrator has the complete discretion to make all decisions relating to the plan and outstanding awards.

Eligibility

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

Types of Awards

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

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

Terms of Awards

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

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

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

Change in Control

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

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

Changes in Capitalization

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

Amendment and Termination

Our Board may at any time amend the 2007 Plan. However, our Board must obtain approval of our stockholders or any amendment requiring such approval under federal tax or federal securities laws. In addition, our Board may not alter or impair any award previously granted under the 2007 Plan without the consent of the holder of such award. The 2007 Plan will terminate ten years after the earliest of the date the 2007 Plan was adopted by our Board, the date our stockholder approved the 2007 Plan or a date determined by our Board.

401(k) Plan

We maintain a tax-qualified retirement plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees are able to defer eligible compensation subject to applicable annual Code limits. Currently, we match 100% of each eligible employee's contributions up to 4% of total eligible compensation. In June 2019, we temporarily suspended this match as a cash conservation measure, and reinstated this match in September 2019. Employees' pre-tax contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. Employees are immediately and fully vested in their contributions, and our matching contribution is also immediately and fully vested when made. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan.

Limitations on Liability and Indemnification Matters

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

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

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

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

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

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with the terms of our insider trading policy.

CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS

The following is a description of each transaction since January 1, 2018 in which we have been a participant in which the amount involved exceeded or will exceed $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or any members of their immediate family, had or will have a direct or indirect material interest, other than compensation arrangements which are described under “Executive Compensation.”

Employment Relationship with Christal M.M. Mickle

Christal M.M. Mickle currently serves as our vice president of operations and product development and is a co-founder of our company. Ms. Mickle was an immediate family member of Travis C. Mickle, Ph.D., our chief executive officer and a member of our Board, for 2020, 2019 and 2018. The following table presents the compensation awarded to, earned by or paid to Ms. Mickle by us for the years ended December 31, 2020, 2019 and 2018.

Year	Salary ($)	Option Awards ($)(1)	Bonus $(2)	All Other Compensation ($)(3)	Total ($)
2020	322,004	19,197	10,000	11,796	362,997
2019	312,625	119,191	—	9,236	441,052
2018	302,233	122,356	—	12,775	437,364

(1) The amounts reflect the full grant date fair value for awards granted during 2020, 2019 and 2018, respectively. The grant date fair value was computed in accordance with ASC Topic 718, Compensation—Stock Compensation. Unlike the calculations contained in our financial statements, this calculation does not give effect to any estimate of forfeitures related to service-based vesting, but assumes that the executive will perform the requisite service for the award to vest in full. The assumptions we used in valuing options are described in Note L to our audited financial statements included herein.

(2) In May 2020, we awarded Ms. Mickle a cash bonus of $10,000 in connection with her support for our product development efforts. We did not pay any cash bonuses to Ms. Mickle in 2019 or 2018.

(3) Amounts shown relate to company contributions to the 401(k) plan and payments for dependent care we paid for on behalf of Ms. Mickle.

Effective March 1, 2018, Ms. Mickle’s annual base salary was increased to $305,000.

Effective March 1, 2019, Ms. Mickle’s annual base salary was increased to $314,150.

Effective March 1, 2020, Ms. Mickle’s annual base salary was increased to $323,575.

In January 2018, we granted Ms. Mickle an option to purchase 1,875 shares of our common stock. The shares subject to this option will vest in equal annual installments over a period of four years. The exercise price of this option is $88.00 per share, which equaled the closing sale price per share of our common stock as reported on The NASDAQ Stock Market on the date of grant. In February 2019, we granted Ms. Mickle an option to purchase 3,750 shares of our common stock. The shares subject to this option will vest in equal annual installments over a period of four years. The exercise price of this option is $42.56 per share, which equaled the closing sale price per share of our common stock as reported on The NASDAQ Stock Market on the date of grant. In November 2019, we granted Ms. Mickle an option to purchase 2,250 shares of our common stock. The shares subject to this option will vest in full and become immediately exercisable upon the achievement of specified product development milestones. The exercise price of this option is $8.2576 per share, which equaled the closing sale price per share of our common stock as reported on The NASDAQ Stock Market on the date of grant. In February 2020, we granted Ms. Mickle an option to purchase 3,750 shares of our common stock. The shares subject to this option will vest in full and become immediately exercisable upon the achievement of specified product development milestones. The exercise price of this option is $5.984 per share, which equaled the closing sale price per share of our common stock as reported on The NASDAQ Stock Market on the date of grant. All shares underlying these options will vest in full and become immediately exercisable upon a change of control of the Company or if the Ms. Mickle is terminated without cause or resigns for good reason (each as defined in Ms. Mickle's employment agreement, discussed below). With respect to equity awards that vest based on the attainment of performance goals, the performance goals will be deemed to have met as of the date of termination.

In May 2014, we entered into an employment agreement with Ms. Mickle, under which Ms. Mickle serves as our vice president of operations and product development. Under this agreement, upon the execution of a release of claims, Ms. Mickle is eligible to receive severance benefits in specified circumstances.

In the event that we terminate Ms. Mickle without cause or she resigns for good reason, Ms. Mickle will be entitled to receive (i) an amount equal to 12 months of her annual base salary, less applicable deductions, payable in accordance with our normal payroll schedule, (ii) a pro rata bonus award payable on the first regularly scheduled pay day immediately after her termination, (iii) 12 months of continued health coverage and (iv) full vesting of her outstanding equity awards; provided, however, if such termination occurs upon or within one year following a sale that constitutes a "change in control event" as defined in Section 409A of the Code, then in lieu of the payment described in clause (a) Ms. Mickle will be entitled to a lump sum payment equal to her annual base salary on the first regularly scheduled pay day immediately following the effective date of her termination. In the event that we terminate Ms. Mickle with cause, Ms. Mickle resigns without good reason, or the employment is terminated due to mutual agreement, death or disability, then Ms. Mickle will not be entitled to receive severance benefits. Under the terms of Ms. Mickle's employment agreement, if we enter into any change of control, all then unvested shares subject to outstanding options shall become fully vested and immediately exercisable immediately prior to such change in control.

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

- "cause" means (a) executive performed an act or acts of willful and material malfeasance or misconduct with respect to the performance of his duties and responsibilities as an employee and executive officer or under the agreement that results in material harm to us that remains uncorrected for 15 days after receipt of written notice, (b) executive's continued failure to devote his full business time and attention and his best efforts to the faithful performance of his material duties and responsibilities (other than a failure resulting from disability) that remains uncorrected for 15 days after receipt of written notice, (c) executive's material breach of any material provision of the agreement that remains uncorrected for 15 days after receipt of written notice, (d) executive commits an act of fraud, embezzlement, misappropriation, or personal dishonesty against us (which, if proven, would constitute a felony) or (e) the conviction of, or plea of nolo contendere by, executive to a crime constituting a felony; and

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

Public Offering of Common Stock

In October 2018, we entered into an underwriting agreement with RBC Capital Markets, LLC, to issue and sell 520,833 shares of common stock of the Company in an underwritten public offering pursuant to a Registration Statement on Form S-3 (File No. 333-213926) and a related prospectus and prospectus supplement, in each case filed with the SEC. The offering price to the public was $48.00 per share of common stock in this offering.

The table below sets forth the number of shares of our common stock purchased by and the aggregate purchase price for the shares of common stock for each purchaser that was then a director, executive officer or 5% stockholder, and their affiliates in this offering:

Name of Purchaser	Shares of Common Stock	Aggregate Purchase Price ($)
Delaware Street Capital L.L.C.	125,000	6,000,000
Deerfield Management Company, L.P(1)	72,916	3,499,998
Alyeska Investment Group, L.P	62,500	3,000,000

(1) As of the date of this offering, Deerfield Management Company, L.P., together with its affiliates, was a 5% stockholder.

Exchange Agreements

October 2018 Exchange

In October 2018, we entered into an the October 2018 Exchange Agreement with the Deerfield Lenders, which at the time were beneficial owners of more than 5% of our common stock. 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 Preferred Stock. All 9,577 shares of such Series A Preferred Stock have been converted into 199,519 shares of common stock.

We also agreed to pay the Deerfield Lenders an amount of $95,105 in cash, which represented the amount of accrued and unpaid interest on the exchanged 2021 Notes. The October 2018 Exchange Agreement contains customary representations, warranties and covenants made by us and the Deerfield Holders. The October 2018 Exchange Agreement required us to reimburse the Deerfield Holders for up to $25,000 of expenses relating to the exchange.

December 2019 Exchange

In December 2019, we entered into the December 2019 Exchange Agreement with DSC, which is a beneficial owner of more than 5% of our common stock. Under the December 2019 Exchange Agreement, we issued Senior Secured Notes in the aggregate principal amount of $71,418,011.21, in exchange for the cancellation of an aggregate of $71,418,011.21 principal amount and accrued interest on the 2021 Notes. In this exchange, we issued a Senior Secured Note to DSC in the aggregate principal amount of $8,336,969, or the DSC Note, in exchange for the cancellation of an aggregate of $8,336,969 principal amount and accrued interest of the 2021 Notes owned by DSC. Upon entering into the December 2019 Exchange Agreement, we agreed to pay DSC an interest payment of $86,969 which represents 50% of the accrued interest, as of December 18, 2019, on the 2021 Notes owned by DSC. The remainder of such interest owed to DSC was included in the principal amount of the DSC Note.

In January 2020, we entered into the December 2019 Note Amendment with the holders of the Senior Secured Notes, including DSC, that, among other things, amended the Senior Secured Notes to (i) reduce the Conversion Price (as defined in the Senior Secured Notes) from $273.76 to $93.60 per share and (ii) increased the Floor Price (as defined in the Senior Secured Notes) from $6.08 to $9.328 per share.

December 2020 Exchange

In December 2020, we entered into the December 2020 Exchange Agreement with the Holders, including DSC, which is a beneficial owner of more than 5% of our common stock. Under the December 2020 Exchange

Agreement, we have agreed to, in connection with the closing of this offering, (i) make a cash repayment of $3,903,651 on the outstanding principal of the Senior Secured Note held by DSC, and (ii) exchange $4,052,733 of the outstanding principal and accrued interest on the Senior Secured Note held by DSC for shares of Series B-2 convertible preferred stock and Exchange Warrants exercisable for shares of our common stock on the terms and conditions of the December 2020 Exchange Agreement. Following, the transactions contemplated under the December 2020 Exchange Agreement, we anticipate that the outstanding principal and accrued interest on the Senior Secured Note held by DSC will equal $979,166.

Please see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Convertible Debt-2021 Note Exchanges” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Debt Restructuring” for further discussion of these exchanges of the 2021 Notes and the Debt Restructuring.

Investors’ Rights Agreement

We have entered into an investors’ rights agreement with some of our stockholders, including Deerfield, which was then a 5% stockholder. The investors’ rights agreement, among other things, grants these stockholders specified registration rights with respect to shares of our common stock, including shares of common stock issued or issuable upon conversion or reclassification of the shares of our redeemable convertible preferred stock, convertible notes and warrants held by them. The provisions of this agreement, other than those relating to registration rights, terminated upon completion of our initial public offering, which terminated on the two-year anniversary of our initial public offering as to all stockholders party to such agreement, other than Deerfield.

Indemnification Agreements

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

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

Policy on Related-Person Transactions

In connection with our initial public offering in April 2015, we adopted a related person transaction policy in writing that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds $120,000. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.
Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on

terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our Code of Conduct, our employees and directors will have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances including, but not limited to:

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

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

PRINCIPAL STOCKHOLDERS

The following table sets forth the beneficial ownership of our common stock as of November 30, 2020 for:

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

The percentage ownership information shown in the table is based upon 4,536,699 shares of common stock outstanding as of November 30, 2020.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to (i) the conversion of outstanding convertible notes, assuming a conversion date of January 29, 2021, and (ii) the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before January 29, 2021. These shares are deemed to be outstanding and beneficially owned by the person holding those convertible notes, options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for persons listed in the table is c/o KemPharm, Inc., 1180 Celebration Boulevard, Suite 103, Celebration, FL 34747.

Name of Beneficial Owner	Number of Shares Beneficially Owned before the Offering	Percentage of Shares Beneficially Owned before the Offering	Percentage of Shares Beneficially Owned after the Offering(1)
Principal Stockholders:			
Delaware Street Capital Master Fund, L.P.(2)	351,969	7.6%	3.7%
Named Executive Officers and Directors:			
Travis C. Mickle, Ph.D.(3)	220,980	4.8	2.4
Sven Guenther, Ph.D.(4)	24,442	*	*
R. LaDuane Clifton, CPA(5)	24,284	*	*
Richard W. Pascoe(6)	6,930	*	*
Matthew R. Plooster(7)	7,038	*	*
Joseph B. Saluri(8)	6,451	*	*
David S. Tierney(9)	6,980	*	*
All current directors and executive officers as a group (7) persons)(10)	297,105	6.4%	3.1%

* Represents beneficial ownership of less than 1%.

(1) Assumes the issuance of 4,784,688 shares of our common stock, warrants to purchase up to 4,784,688 shares of our common stock and no pre-funded warrants in this offering and no exercise by the underwriter of its option to purchase additional shares and does not give effect to the Exchange or Debt Payment. See the sections of this prospectus titled "Underwriting" and "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Debt Restructuring."

(2) Consists of 255,994 shares of common stock and 95,975 shares issuable upon the conversion of convertible promissory notes through January 29, 2021 held by Delaware Street Capital Master Fund, L.P. (the "Fund"). In accordance with the terms of the convertible promissory notes, the holder thereof may not convert or exercise this convertible promissory note if such conversion or exercise would result in such holder and its affiliates and any other person or entities with which such holder would constitute a Section 13(d) "group" beneficially owning more than 9.985% of the then issued and outstanding shares of our common stock. This conversion limitation may not be waived and any purported conversion that is inconsistent with this conversion limitation is null and void. The shares held by the Fund are indirectly beneficially owned by (a) DSC Advisors, L.P. ("DSCA"), as investment manager of the Fund, (b) DSC Managers, L.L.C., as general partner of the Fund, (c) DSC Advisors, L.L.C. ("DSCA LLC"), as general partner of DSCA, and (d) Andrew G. Bluhm, the principal of DSCA LLC. The principal business address of Delaware Street Capital Master Fund, L.P. is 900 North Michigan, Suite 1600, Chicago, IL 60611.

(3) Consists of (a) 118,007 shares of common stock held directly by Dr. Mickle, (b) 9,824 shares of common stock held by the Travis C. Mickle 2015 Dynasty Trust dated 7/21/2015, for which Ms. Christal M.M. Mickle ("Ms. Mickle") serves as trustee, (c) 15,242 shares of common stock held by the Christal M.M. Mickle 2015 Gift Trust dated 7/21/2015, for which Dr. Mickle serves as trustee, (d) 1,341 shares of common stock held by the TCM Family Trust u/d/p April 30, 2009, for which Dr. Mickle and Ms. Mickle serve as co-trustees, (e) 7,701 shares of common stock held by the Mickle Family Trust u/d/p April 30, 2009, for which Dr. Mickle and Ms. Mickle serve as co-trustees, (f) 6,287 shares of common stock held jointly by Dr. Mickle and Ms. Mickle, (g) 1,034 shares of common stock held by Mickle Investments LLC, for which Dr. Mickle and Ms. Mickle serve as members and (h) 61,544 shares of common stock underlying options held by Dr. Mickle that are exercisable within 60 days of November 30, 2020.

(4) Consists of (a) 2,740 shares of common stock held directly by Dr. Guenther and (b) 21,702 shares of common stock underlying options that are exercisable within 60 days of November 30, 2020.

(5) Consists of (a) 3,125 shares of common stock held directly by Mr. Clifton and (b) 21,159 shares of common stock underlying options that are exercisable within 60 days of November 30, 2020.

(6) Consists of (a) 1,785 shares of common stock held directly by Mr. Pascoe and (b) 5,145 shares of common stock underlying options that are exercisable within 60 days of November 30, 2020.

(7) Consists of (a) 1,532 shares of common stock held directly by Mr. Plooster, (b) 69 shares of common stock held by TD Ameritrade Clearing Inc. Custodian FBO Matthew Ryan Plooster Roth IRA, for which Mr. Plooster serves as trustee, (c) 5,437 shares of common stock underlying options held by Mr. Plooster that are exercisable within 60 days of November 30, 2020.

(8) Consists of (a) 1,306 shares of common stock held directly by Mr. Saluri and (b) 5,145 shares of common stock underlying options that are exercisable within 60 days of November 30, 2020.

(9) Consists of (a) 1,835 shares of common stock held directly by Mr. Tierney and (b) 5,145 shares of common stock underlying options that are exercisable within 60 days of November 30, 2020.

(10) Consists of (a) 171,828 shares of common stock and (b) 125,277 shares of common stock underlying options that are exercisable within 60 days of November 30, 2020.

DESCRIPTION OF CAPITAL STOCK

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

General

Under our amended and restated certificate of incorporation we are authorized to issue up to 250,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share, of which 9,578 are designated Series A preferred stock, or the Series A Preferred Stock, 1,576 are designated Series B-1 preferred stock, or the Series B-1 Preferred Stock, and 27,000 are designated Series B-2 Preferred Stock, or the Series B-2 Preferred Stock, with the Series B-1 Preferred Stock and Series B-2 Preferred Stock referred to herein, collectively, as the Series B Preferred Stock. Our board of directors may establish the rights and preferences of the preferred stock from time to time. As of September 30, 2020, we had outstanding (i) 4,532,039 shares of common stock, and (ii) no shares of preferred stock.

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 our 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 our 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.

Pre-Funded Warrants Offered in this Offering

The following summary of certain terms and provisions of the pre-funded warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the pre-funded warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of pre-funded warrant for a complete description of the terms and conditions of the pre-funded warrants.

Duration and Exercise Price

Each pre-funded warrant offered hereby will have 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 our common stock.

Exercisability

The pre-funded warrants will be 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 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 outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, 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 our 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 in this offering may also elect prior to the issuance of the pre-funded warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock.

Cashless Exercise

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 pre-funded warrants.

Transferability

Subject to applicable laws, a pre-funded warrant may be transferred at the option of the holder upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the pre-funded warrants. Rather, the number of shares of common stock to be issued will be rounded to the nearest whole number.

Trading Market

There is no established public trading market for the pre-funded warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list the pre-funded warrants on any national securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants will be limited.

Right as a Stockholder

Except as otherwise provided in the pre-funded warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the pre-funded warrants do not have the rights or privileges of holders of our 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 will provide that holders have the right to participate in distributions or dividends paid on our 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 our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger 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 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.

Warrants Offered in this Offering

The following summary of certain terms and provisions of the warrants to purchase common stock that are being offered hereby (not including the Representative’s Warrants, as described in the section of this prospectus titled “Underwriting”) is not complete and is subject to, and qualified in its entirety by, the provisions of the warrants, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of warrant for a complete description of the terms and conditions of the warrants. The warrants will be issued in certificated form.

Duration and Exercise Price

The warrants are exercisable from and after the date of their issuance and expire on the   anniversary of such date, at an exercise price per share of common stock equal to 100% of the combined public offering price per share of common stock and accompanying warrant in this offering. The holder of a warrant will not be deemed a holder of our 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, we will round such fraction down 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 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 as discussed below). A holder (together with its affiliates) may not exercise any portion of the warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days’ prior notice from the holder to us, the holder may increase the amount of beneficial ownership of outstanding stock after exercising the holder’s warrants 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 warrants and Delaware law. Purchasers of warrants in this offering may also elect prior to the issuance of the warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock.

Cashless Exercise

If, at the time a holder exercises its warrants, a registration statement registering the issuance of the shares of common stock underlying the warrants 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 warrants.

Transferability

Subject to applicable laws, a warrant may be transferred at the option of the holder upon surrender of the warrant to us together with the appropriate instruments of transfer.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of warrant. Rather, the number of shares of common stock to be issued will be rounded to the nearest whole number.

Trading Market

There is no established public trading market for the warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list the warrants on any national securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the warrants will be limited.

Right as a Stockholder

Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the warrants do not have the rights or privileges of holders of our common stock with respect to the shares of common stock underlying the warrants, including any voting rights, until they exercise their warrants. The warrants will provide that holders have the right to participate in distributions or dividends paid on our 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 our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger 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 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.

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 under this prospectus and applicable prospectus supplements in the certificate of designation relating to that series. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of any certificate of designation that describes the terms of the series of preferred stock we are offering before the issuance of that series of preferred stock. This description will include:

- the title and stated value;
- the number of shares we are offering;
- the liquidation preference per share;
- the purchase price per share;
- the dividend rate per share, dividend period and payment dates and method of calculation for dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- our right, if any, to defer payment of dividends and the maximum length of any such deferral period;
- the procedures for any auction and remarketing, if any;
- the provisions for a sinking fund, if any;
- the provisions for redemption or repurchase, if applicable, and any restrictions on our ability to exercise those redemption or repurchase rights;
- any listing of the preferred stock on any securities exchange or market;
- whether the preferred stock will be convertible into our common stock or other securities of ours, including depositary shares and warrants, and, if applicable, the conversion period, the conversion price, or how it will be calculated, and under what circumstances it may be adjusted;
- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange period, the exchange price, or how it will be calculated, and under what circumstances it may be adjusted;
- voting rights, if any, of the preferred stock;
- preemption rights, if any;
- restrictions on transfer, sale or other assignment, if any;
- whether interests in the preferred stock will be represented by depositary shares;
- a discussion of any material or special United States federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs;
- any limitations on issuances of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock being issued as to dividend rights and rights if we liquidate, dissolve or wind up our affairs; and
- any other specific terms, rights, preferences, privileges, qualifications or restrictions of the preferred stock.

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 September 30, 2020, we have designated an aggregate of 38,154 shares of preferred stock, of which 9,578 are designated Series A Preferred Stock, 1,576 are designated Series B-1 Preferred Stock and 27,000 are designated Series B-2 Preferred Stock.

Series A Preferred Stock

In October 2018, we filed a Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, or the Series A Certificate of Designation, with the Secretary of State of the State Delaware, setting forth the preferences, rights and limitations of the Series A Preferred Stock. Our board of directors designated 9,578 shares of preferred stock Series A Preferred Stock, of which none were outstanding as of September 30, 2020.

Each share of Series A Preferred Stock has an aggregate stated value of $1,000 and is convertible into shares of our common stock at a per share price equal to $48.00 (subject to adjustment to reflect stock splits and similar events). The Series A Preferred Stock is convertible at any time at the option of the holders thereof, provided that the holders of Series A Preferred Stock are prohibited from converting shares of Series A Preferred Stock into shares of our common stock if, as a result of such conversion, such holders (together with certain affiliates and "group" members) would beneficially own more than 4.985% of the total number of shares of our common stock then issued and outstanding. The Series A Preferred Stock is not redeemable. In the event of our liquidation, dissolution or winding up, the holders of our Series A Preferred Stock will receive an amount equal to $0.0001 per share, plus any declared but unpaid dividends, and thereafter will share ratably in any distribution of our assets with the holders of our common stock and the holders of Series B Preferred Stock, on an as-converted basis. With respect to rights upon liquidation, the Series A Preferred Stock ranks senior to our common stock, is pari passu with the Series B Preferred Stock and junior to existing and future indebtedness. Except as otherwise required by law (or with respect to approval of certain actions involving our organizational documents that materially and adversely affect the holders of Series A Preferred Stock), the Series A Preferred Stock does not have voting rights. The Series A Preferred Stock is not subject to any price-based anti-dilution protections and does not provide for any accruing dividends, but provides that holders of Series A Preferred Stock will participate in any dividends on our common stock on an as-converted basis (without giving effect to the limitation on conversion described above). The Series A Certificate of Designation also provides for partial liquidated damages in the event that we fail to timely convert shares of Series A Preferred Stock into shares of our common stock in accordance with the Series A Certificate of Designation.

Series B Preferred Stock

In September 2019, we filed a Certificate of Designation of Preferences, Rights and Limitations of Series B-1 Convertible Preferred Stock, or the Series B-1 Certificate of Designation, and a Certificate of Designation of Preferences, Rights and Limitations of Series B-2 Convertible Preferred Stock, or the Series B-2 Certificate of Designation, with the Secretary of State of the State Delaware, setting forth the preferences, rights and limitations of the Series B-1 Preferred Stock and the Series B-2 Preferred Stock, respectively. Our board of directors designated 1,576 shares of Series B-1 Preferred Stock and 27,000 shares of Series B-2 Preferred Stock, of which no shares of Series B-1 Preferred Stock or Series B-2 Preferred Stock were outstanding as of September 30, 2020.

Each share of Series B-1 Preferred Stock has an aggregate stated value of $1,000 and is convertible into shares of our common stock at a per share price equal to $15.1904 (subject to adjustment to reflect stock splits and similar events). Each share of Series B-2 Preferred Stock has an aggregate stated value of $1,000 and is convertible into shares of our common stock at a per share price equal to the greater of (i) $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 our principal market or exchange on each of the 15 trading days immediately preceding such exchange.

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

Amended and Restated Series B-2 Certificate of Designation

As a condition to closing under the December 2020 Exchange Agreement, we have agreed to file 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.

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 the price per share to the public of our common stock in this 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 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 will 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.

Convertible Notes

In June 2014, we issued to Deerfield the Deerfield Note in the principal amount of $10.0 million. As of September 30, 2020, the outstanding principal amount of the Deerfield Note was approximately $7.3 million. In December 2019 and January 2020, we issued Senior Secured Notes to Deerfield, Deerfield Special Situations Fund, L.P., Delaware Street Capital Master Fund, L.P. and M. Kingdon Offshore Master Fund, LP in the aggregate principal amount of $74.5 million. We refer to the Deerfield Note and the Senior Secured Notes together as the Convertible Notes. The Convertible Notes bear interest at 6.75% per annum. The Convertible Notes are convertible into shares of our common stock at an initial conversion price of $93.60 per share, subject to adjustment in accordance with the terms of the Convertible Notes. The conversion price of the Convertible Notes will be adjusted downward if we issue or sell any shares of our common stock, convertible securities, warrants or options at a sale or exercise price per share less than the greater of the conversion price of the Convertible Notes or the closing sale price of our common stock 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. If we effect an “at the market offering” as defined in Rule 415 of the Securities Act of our common stock, the conversion price of the Convertible Notes will be adjusted downward pursuant to this anti-dilution adjustment only if such sales are made at a price less than $93.60 per share, provided that this anti-dilution adjustment will not apply to certain specified sales. Notwithstanding anything to the contrary in the Convertible Notes, the anti-dilution adjustment of the Convertible Notes shall not result in the conversion price of the Convertible Notes being less than $9.328 per share. The Convertible Notes are convertible at any time at the option of the holders thereof, provided that each holder is prohibited from converting the Convertible Notes into shares of our common stock if, as a result of such conversion, such holder (together with certain affiliates and “group” members of such holder) would beneficially own more than 4.985% of the total number of shares of our common stock then issued and outstanding. However, the Convertible Note issued to Delaware Street Capital Master Fund, L.P., due to the fact Delaware Street Capital Master Fund, L.P. was a beneficial owner of more than 4.985% of the total number of shares of our common stock then issued and outstanding, has a beneficial ownership cap equal to 19.985% of the total number of shares of our common stock then issued and outstanding. Pursuant to the Convertible Notes, the holders thereof have the option to demand repayment of all outstanding principal, and any unpaid interest accrued thereon, in connection with a Major Transaction (as defined in the Convertible Notes), which shall include, among others, any acquisition or other change of control of us; a liquidation, bankruptcy or other dissolution of us; or if at any time after March 31, 2021, shares of our common stock are not listed on an Eligible Market (as defined in the Convertible Notes) provided, that upon closing of the Exchange, this date will be extended to March 31, 2023. The Convertible Notes are subject to specified events of default, the occurrence of which would entitle the holders thereof to immediately demand repayment of all outstanding principal and accrued interest on the Convertible Notes. Such events of default include, among others, failure to make any payment under the Convertible Notes when due, failure to observe or perform any covenant under the Facility Agreement (as defined in the Convertible Notes) or the other transaction documents related thereto (subject to a standard cure period), our failure to be able to pay debts as they come due, the commencement of bankruptcy or insolvency proceedings against us, a material judgement levied against us and a material default by us under the Warrant or the Notes (each as defined in the Facility Agreement).

The foregoing information is qualified entirely by reference to the applicable provisions of the terms of the Facility Agreement and the Convertible Notes, which are each incorporated by reference and included as exhibits to the registration statement of which this prospectus is a part.

Outstanding Warrants

As of September 30, 2020, we had outstanding warrants to purchase up to 151,442 shares of our common stock at a weighted average exercise price of $81.88 per share and which expire between October 24, 2023 and June 2, 2024. The warrants include a net exercise provision and contain provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of each warrant in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations. We have also granted registration rights to Deerfield, as more fully described below under "—Registration Rights."

In June 2014, in connection with our entering into the Facility Agreement, we issued to Deerfield a warrant, or the Deerfield Warrant, to purchase 14,423,076 shares of Series D redeemable convertible preferred stock at an exercise price of $0.78 per share, which is exercisable until June 2, 2024. Upon completion of our initial public offering, the Deerfield Warrant automatically converted into a warrant to purchase 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, including in this offering, at a sale or exercise price per share less than the greater of the Deerfield Warrant's exercise price or the closing sale price of our common stock 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 any offering deemed by the SEC to constitute an "at the market offering" as defined in Rule 415 of the Securities Act of our common stock, the conversion price of the Deerfield Warrant will be adjusted downward pursuant to this anti-dilution adjustment only if such sales are made at a price less than $93.60 per share, provided that this anti-dilution adjustment will not apply to certain specified sales.

The foregoing information is qualified entirely by reference to the applicable provisions of the terms of the warrants, which are each incorporated by reference and included as exhibits to the registration statement of which this prospectus is a part.

Registration Rights

December 2020 Exchange Agreement

Pursuant to the terms of the December 2020 Exchange Agreement, we have agreed to, for the benefit of the noteholders party thereto, 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. We anticipate that we will file this resale registration statement immediately following the closing of this offering. We will pay all expenses related to the registration of these securities.

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. The following information is qualified entirely by reference to the applicable provisions of the investors' rights agreement, which is incorporated by reference as an exhibit into the registration statement of which this prospectus is a part.

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. Deerfield has waived these rights as they may apply to the filing of the registration statement of which this prospectus is a part.

Registration on Form S-3

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

Expenses of Registration

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

Termination of Registration Rights

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

Anti-Takeover 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.

Listing

Our common stock is listed on the OTCQB under the trading symbol "KMPH." We have applied to have our common stock listed, contingent upon completion of this offering, on The NASDAQ Capital Market under the trading symbol "KMPH."

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.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a general discussion of the material U.S. federal income tax considerations of the purchase, ownership and disposition of shares of our common stock issued pursuant to this offering, or the shares, the purchase, exercise, disposition and lapse of warrants to purchase shares of our common stock pursuant to this offering, or the purchase warrants, the ownership and disposition of shares of our common stock issuable upon exercise of the purchase warrants, or the warrant shares, and the purchase, ownership and disposition of pre-funded warrants to purchase shares of our common stock issued pursuant to this offering, or the pre-funded warrants. The shares, the purchase warrants, the warrant shares and the pre-funded warrants are collectively referred to herein as our securities. All prospective holders of our securities should consult their tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our securities.

This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating to the purchase, ownership and disposition of our securities. This discussion is based on current provisions of the Code, existing U.S. Treasury Regulations promulgated thereunder, published administrative pronouncements and rulings of the IRS and judicial decisions, all as in effect as of the date of this prospectus supplement. These authorities are subject to change and to differing interpretation, possibly with retroactive effect. Any change or differing interpretation could alter the tax consequences to holders described in this discussion. There can be no assurance that a court or the IRS will not challenge one or more of the tax consequences described herein, and we have not obtained, nor do we intend to obtain, a ruling with respect to the U.S. federal income tax consequences to a holder of the purchase, ownership or disposition of our securities.

We assume in this discussion that a holder holds our securities as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular holder in light of that holder's individual circumstances, nor does it address the special tax accounting rules under Section 451(b) of the Code, any alternative minimum, Medicare contribution, estate or gift tax consequences, or any aspects of U.S. state, local or non-U.S. taxes or any other U.S. federal tax laws. This discussion also does not address consequences relevant to holders subject to special tax rules, such as holders that own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below), corporations that accumulate earnings to avoid U.S. federal income tax, tax-exempt organizations, governmental organizations, banks, financial institutions, investment funds, insurance companies, brokers, dealers or traders in securities, commodities or currencies, regulated investment companies or real estate investment trusts, persons that have a "functional currency" other than the U.S. dollar, tax- qualified retirement plans, holders who hold or receive our securities pursuant to the exercise of employee stock options or otherwise as compensation, holders holding our securities as part of a hedge, straddle or other risk reduction strategy, conversion transaction or other integrated investment, holders deemed to sell our securities under the constructive sale provisions of the Code, passive foreign investment companies and certain former U.S. citizens or long-term residents.

In addition, this discussion does not address the tax treatment of partnerships (or entities or arrangements that are treated as partnerships or disregarded entities for U.S. federal income tax purposes) or persons that hold our securities through such partnerships. If a partnership, including any entity or arrangement treated as a partnership for U.S. federal income tax purposes, holds our securities, the U.S. federal income tax treatment of a partner in such partnership will generally depend upon the status of the partner and the activities of the partnership. Such partners and partnerships should consult their tax advisors regarding the tax consequences of the purchase, ownership and disposition of our securities.

Treatment of Pre-Funded Warrants

Although it is not entirely free from doubt, we believe a pre-funded warrant should be treated as a share for U.S. federal income tax purposes and a holder of pre-funded warrants should generally be taxed in the same manner as a holder of shares, as described below. Accordingly, no gain or loss should be recognized upon the exercise of a pre-funded warrant and, upon exercise, the holding period of a pre-funded warrant should carry over to the share received. Similarly, the tax basis of the pre-funded warrant should carry over to the share received upon exercise, increased by the exercise price of $0.0001 per share. However, our characterization is not binding on the IRS, and the IRS may treat the pre-funded warrants as warrants to acquire our shares. If so, the amount and character of your gain with respect to an investment in our pre-funded warrants could change. Accordingly, each holder should consult his, her or its own tax advisor regarding the risks associated with the acquisition of pre-funded warrants pursuant to this offering (including potential alternative characterizations). The balance of this discussion generally assumes that the characterization described above is respected for U.S. federal income tax purposes.

Allocation of Purchase Price

Each purchaser of shares or pre-funded warrants must allocate its purchase price for such shares or pre-funded warrants between each share or pre-funded warrant, as applicable and the associated purchase warrant based on the respective relative fair market values of each at the time of issuance. This allocation of the purchase price will establish the holder's initial tax basis for U.S. federal income tax purposes for each share, pre-funded warrant and purchase warrant. A holder's allocation of the purchase price among the shares, pre-funded warrants and purchase warrants is not binding on the IRS or the courts, and no assurance can be given that the IRS or the courts will agree with a holder's allocation. Each holder should consult its own tax advisor regarding the allocation of the purchase price among the shares, pre-funded warrants and purchase warrants.

Tax Considerations Applicable to U.S. Holders

Definition of U.S. Holder

In general, a "U.S. holder" means a beneficial owner of our securities (other than a partnership or an entity or arrangement treated as a partnership for U.S. federal income tax purposes) that is, for U.S. federal income tax purposes:

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

Distributions on the Shares or the Warrant Shares

As described in the section entitled "Dividend Policy," we do not anticipate declaring or paying any future distributions. However, if we do make distributions on the shares or the warrant shares, such distributions will constitute dividends to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles, and will be includible in your income as ordinary income when received. However, with respect to dividends received by individuals, such dividends are generally taxed at the lower applicable long-term capital gains rates, provided certain holding period and other requirements are satisfied. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the U.S. holder's investment, up to such U.S. holder's adjusted tax basis in the shares or the warrant shares, as applicable. Any remaining excess will be treated as capital gain from the sale or exchange of such shares or warrant shares, subject to the tax treatment described below in "—Sale or Other Taxable Disposition of the Shares, Purchase Warrants or Warrant Shares."

Sale or Other Taxable Disposition of the Shares, Purchase Warrants or Warrant Shares

Upon the sale, exchange or other taxable disposition of the shares, purchase warrants (other than by exercise) or warrant shares, a U.S. holder will generally recognize capital gain or loss equal to the difference between the amount of cash and the fair market value of any property received upon the sale, exchange or other taxable disposition and such U.S. holder's adjusted tax basis in the shares, purchase warrants or warrant shares. This capital gain or loss will be long-term capital gain or loss if the U.S. holder's holding period in such shares, purchase warrants or warrant shares is more than one year at the time of the sale, exchange or other taxable disposition. Long-term capital gains recognized by certain non-corporate U.S. holders, including individuals, generally will be subject to reduced rates of U.S. federal income tax. The deductibility of capital losses is subject to certain limitations.

Exercise of Purchase Warrants

A U.S. holder generally will not recognize gain or loss on the exercise of a purchase warrant and the related receipt of warrant shares. A U.S. holder's initial tax basis in a warrant share will be equal to the sum of (a) such U.S. holder's tax basis in the purchase warrant plus (b) the exercise price paid by such U.S. holder on the exercise of such purchase warrant. A U.S. holder's holding period in a warrant share received on the exercise of a purchase warrant generally should begin on the day after the date that such purchase warrant is exercised by such U.S. holder.

In certain circumstances, the purchase warrants may be exercised on a cashless basis. The U.S. federal income tax treatment of an exercise of a warrant on a cashless basis is not clear, and could differ from the consequences described above. It is possible that a cashless exercise could be a taxable event. U.S. holders are urged to consult their tax advisors as to the consequences of an exercise of a purchase warrant on a cashless basis, including with respect to their holding period and tax basis in the warrant share.

Lapse of Purchase Warrants

Upon the lapse or expiration of a purchase warrant, a U.S. holder will recognize a loss in an amount equal to such U.S. holder's tax basis in the purchase warrant. Any such loss generally will be a capital loss and will be long-term capital loss if the purchase warrant is held for more than one year. Deductions for capital losses are subject to limitations. Because the term of the purchase warrants purchased in this offering is more than one year, the U.S. holder's capital loss will be treated as a long-term capital loss. The deductibility of capital losses is subject to certain limitations.

Certain Adjustments to the Purchase Warrants

The terms of each purchase warrant provide for an adjustment to the number of warrant shares for which the purchase warrant may be exercised or to the exercise price of the purchase warrant in certain events, and a distribution upon exercise that corresponds to distributions, if any, made on the warrant shares after issuance of the purchase warrants and prior to exercise. An adjustment to the exercise price of a purchase warrant may be treated as a constructive distribution to a U.S. holder of the purchase warrants depending on the circumstances of such adjustment if, and to the extent that, such adjustment has the effect of increasing such U.S. holder's proportionate interest in our "earnings and profits" or assets, depending on the circumstances of such adjustment. In addition, the failure to provide for such an adjustment (or to adequately adjust) may also result in a deemed distribution to U.S. holders of the purchase warrants or shares. Any such constructive distribution may be taxable whether or not there is an actual distribution of cash or other property. However, adjustments to the exercise price of purchase warrants made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holders thereof generally should not be considered to result in a constructive distribution. Generally, such deemed distributions will be taxable in the same manner as an actual distribution as described above under "—Distributions on the Shares or the Warrant Shares," except that it is unclear whether such deemed distributions would be eligible for the reduced tax rate applicable to certain dividends paid to non-corporate holders or the dividend-received deduction applicable to certain dividends paid to corporate holders. Generally, a U.S. holder's tax basis in the underlying stock will be increased to the extent any such constructive distribution is treated as a dividend. Proposed U.S. Treasury Regulations address the amount of, timing of, and withholding obligations in respect to, constructive distributions made to holders of convertible securities such as the purchase warrants. These proposed regulations are effective for constructive distributions made on or after the date of finalization, but may generally be relied upon as to certain matters for constructive distributions that occur prior to such date. U.S. holders should consult their own tax advisors regarding the application of such regulations and other tax considerations relating to the possibility of constructive distributions.

Contingent Payments on the Purchase Warrants

The purchase warrants entitle a holder to receive payments upon the occurrence of certain contingencies, including a distribution on the shares or a failure of the company to deliver warrant shares upon exercise of a purchase warrant. The tax treatment of such payments, if made, is subject to substantial uncertainty, but may result in ordinary income to a U.S. holder and, in the case of distributions, would likely not be eligible for the lower tax rate applicable to certain dividends paid to non-corporate U.S. holders of shares and warrant shares as described above in "—Distributions on the Shares or the Warrant Shares." U.S. holders should consult their own tax advisors as to the appropriate tax treatment of any such contingent payments that may be made to them in respect of the purchase warrants.

Backup Withholding and Information Reporting

A U.S. holder may be subject to information reporting and backup withholding when such holder receives payments on our securities (including constructive dividends) or receives proceeds from the sale or other taxable disposition of our securities. Certain U.S. holders are exempt from backup withholding, including C corporations and certain tax-exempt organizations. A U.S. holder will be subject to backup withholding if such holder is not otherwise exempt and such holder:

- fails to furnish the holder's taxpayer identification number, which for an individual is ordinarily his or her social security number;
- furnishes an incorrect taxpayer identification number;
- is notified by the IRS that the holder previously failed to properly report payments of interest or dividends; or
- fails to certify under penalties of perjury that the holder has furnished a correct taxpayer identification number and that the IRS has not notified the holder that the holder is subject to backup withholding.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a U.S. holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS. U.S. holders should consult their tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption.

Tax Considerations Applicable to Non-U.S. Holders

Definition of non-U.S. Holder

For purposes of this discussion, a "non-U.S. holder" is a beneficial owner of our securities that is neither a U.S. holder nor a partnership or an entity or arrangement treated as a partnership for U.S. federal income tax purposes.

Exercise of Purchase Warrants

A non-U.S. holder generally will not recognize gain or loss on the exercise of a purchase warrant and the related receipt of warrant shares. See "—Tax Considerations Applicable to U.S. Holders—Exercise of Purchase

Warrants." However, if a cashless exercise of purchase warrants results in a taxable exchange, as described in "—Tax Considerations Applicable to U.S. Holders—Exercise of Purchase Warrants," the rules described below under "Gain on Sale, Exchange or Other Taxable Disposition of Our Securities" would apply.

Lapse of Purchase Warrants

If a non-U.S. holder allows a purchase warrant to expire unexercised, such non-U.S. holder will recognize a capital loss in an amount equal to such holder's tax basis in the purchase warrant. See "—Tax Considerations Applicable to U.S. Holders—Lapse of Warrants" above.

Certain Adjustments to the Purchase Warrants

See the discussion of the rules applicable to constructive distributions on a purchase warrant under the heading "—Tax Considerations Applicable to U.S. Holders—Certain Adjustments to the Purchase Warrants" above. If an adjustment to the number of warrant shares that will be issued on the exercise of the Warrants, or an adjustment to the exercise price of the purchase warrants, results in a constructive distribution, as described in "—Tax Considerations Applicable to U.S. Holders—Certain Adjustments to the Purchase Warrants," the rules described below under "—Distributions on the Shares or the Warrant Shares" would apply. U.S. federal income tax required to be withheld on any portion of such constructive distribution that is treated as a dividend (as described below under "— Distributions on the Shares or the Warrant Shares") may be withheld from warrant shares, sales proceeds subsequently paid or credited, or other amounts payable or distributable to a non-U.S. holder.

Contingent Payments on the Purchase Warrants

As described above under the heading "—Tax Considerations Applicable to U.S. Holders—Contingent Payments on the Purchase Warrants," in certain circumstances, a holder of purchase warrants may receive payments upon the occurrence of certain contingencies. The tax treatment of such payments, if made, is subject to substantial uncertainty. Non-U.S. holders should consult their own tax advisors as to the appropriate U.S. federal income tax treatment of any such contingent payments that may be made to them in respect of the purchase warrants and the potential for any such payments being subject to a U.S. dividend or other withholding tax. Any U.S. federal income tax required to be withheld on any portion of such contingent payment may be withheld from warrant shares, sales proceeds subsequently paid or credited, or other amounts payable or distributable to a non-U.S. holder.

Distributions on the Shares or the Warrant Shares

If we make distributions on the shares or the warrant shares such distributions will constitute dividends to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such non-U.S. holder's adjusted tax basis in the shares or the warrant shares, as applicable. Any remaining excess will be treated as capital gain from the sale or exchange of such shares or warrant shares, subject to the tax treatment described below in "—Gain on Sale, Exchange or Other Taxable Disposition of Our Securities."

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

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

To claim a reduction or exemption from withholding, a non-U.S. holder generally will be required to provide (a) a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E (or successor form) and satisfy applicable certification and other requirements to claim the benefit of an applicable income tax treaty between the United States and such non-U.S. holder's country of residence, or (b) a properly executed IRS Form W-8ECI stating that dividends are not subject to withholding because they are effectively connected with such non-U.S. holder's conduct of a trade or business within the United States. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

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

Distributions will also be subject to the discussion below under the headings "—Backup Withholding and Information Reporting" and "—Foreign Accounts."

Gain on Sale, Exchange or Other Taxable Disposition of Our Securities

Subject to the discussion below under the headings "—Backup Withholding and Information Reporting" and "—Foreign Accounts," in general, a non-U.S. holder will not be subject to any U.S. federal income tax on any gain realized upon such non-U.S. holder's sale, exchange or other taxable disposition of our securities unless:

- the gain is effectively connected with a U.S. trade or business of the non-U.S. holder and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed base maintained in the United States by such non-U.S. holder, in which case the non-U.S. holder generally will be taxed at the U.S. federal income tax rates applicable to U.S. persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "—Distributions on the Shares or the Warrant Shares" also may apply;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% U.S. federal income tax (or such lower rate as may be specified by an applicable income tax treaty) on the net gain derived from the disposition, which may be offset by U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States); or
- we are, or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation" in which case such non-U.S. holder generally will be taxed on its net gain derived from the disposition as effectively connected income taxable at the U.S. federal income tax rates applicable to U.S. persons (as defined in the Code); however, the branch profits tax described above will not apply to a non-U.S. holder that is a foreign corporation. Generally, a corporation is a U.S. real property holding corporation if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. Even if we are or become a U.S. real property holding corporation, provided that our common stock is regularly traded,

as defined by applicable U.S. Treasury Regulations, on an established securities market, the shares and the warrant shares will be treated as a U.S. real property interest only with respect to a non-U.S. holder that holds more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held the shares or warrant shares, as applicable. There can be no assurance that our common stock will continue to qualify as regularly traded on an established securities market. Disposition by a non-U.S. holder of purchase warrants (that are not expected to be regularly traded on an established securities market) may also be eligible for an exemption from withholding even if we are treated as a U.S. real property holding corporation, if on the date such purchase warrants were acquired by such non-U.S. holder such holdings had a fair market value no greater than the fair market value on that date of 5% of our regularly-traded common stock, provided that, if a non-U.S. holder holding our not-regularly-traded purchase warrants subsequently acquires additional purchase warrants, then such interests would be aggregated and valued as of the date of the subsequent acquisition to apply this 5% limitation.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our securities paid to such non-U.S. holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders will have to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to any distributions on our securities. A non-U.S. holder generally will not be subject to U.S. backup withholding with respect to payments of distributions on our securities if it certifies its non-U.S. status by providing a valid IRS Form W-8BEN or IRS Form W-8BEN-E (or successor form) or IRS Form W-8ECI, or otherwise establishes an exemption; provided we do not have actual knowledge or reason to know such non-U.S. holder is a U.S. person, as defined in the Code. Dividends paid to non-U.S. holders subject to the U.S. withholding tax, as described above in "—Distributions on the Shares or the Warrant Shares" generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our securities by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them.

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

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

Foreign Accounts

The Code generally imposes a U.S. federal withholding tax of 30% on dividends and, subject to the discussion below regarding proposed regulations issued by the U.S. Treasury Department, the gross proceeds of a disposition of our securities paid to a "foreign financial institution" (as defined in the Code), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding accounts held by certain "specific United States persons" or "United States owned foreign entities" (each as defined in the Code), or otherwise qualifies for an exemption from these rules. A U.S. federal withholding tax of 30% also applies to dividends and, subject to the discussion below regarding proposed regulations issued by the U.S. Treasury Department, will apply to the gross proceeds of a disposition of our securities paid to a "non-financial foreign entity" (as defined in the Code), unless such entity provides the withholding agent with either a certification that it does not have any "substantial United States owners" (as defined in the Code), provides information regarding each substantial United States owners of the entity, or otherwise qualifies for an exemption from these rules. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph.

The withholding provisions described above currently apply to dividends paid on our securities. The U.S. Treasury Department released proposed regulations which, if finalized in their present form, would eliminate the U.S. federal withholding tax of 30% applicable to the gross proceeds of a sale or other disposition of our securities. In its preamble to such proposed regulations, the U.S. Treasury Department stated that taxpayers may generally rely on the proposed regulations until final regulations are issued.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISOR REGARDING THE PARTICULAR U.S. FEDERAL, STATE AND LOCAL AND NON-U.S. TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR SECURITIES, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

UNDERWRITING

We have entered into an underwriting agreement, dated , 2021, with Roth Capital Partners, LLC, acting as the representative of the several underwriters named below (Roth or the representative), with respect to the shares of common stock, pre-funded warrants and warrants subject to this offering. Subject to certain conditions, we have agreed to sell to the underwriters, and the underwriters have severally agreed to purchase, the number of shares of common stock, pre-funded warrants, and warrants provided opposite their respective names.

Underwriter	Number of Shares	Number of Pre-Funded Warrants	Number of Warrants
Roth Capital Partners, LLC			
Total			

The underwriters are offering the shares of common stock, pre-funded warrants, and warrants subject to their acceptance of the shares of common stock, pre-funded warrants, and warrants from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock, pre-funded warrants, and warrants offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock, pre-funded warrants, and warrants if any such securities are taken. However, the underwriters are not required to take or pay for the securities covered by the underwriters' over-allotment option described below.

Over-Allotment Option

We have granted the underwriters an option, exercisable for 45 days from the date of this prospectus, to purchase up to an aggregate of additional shares of common stock at a purchase price of $ per share and/or additional warrants to purchase up to shares of common stock at a purchase price of $ per warrant, in any combination thereof, to cover over-allotments, if any, of the securities offered by this prospectus. If the underwriters exercise this option, each underwriter will be obligated, subject to certain conditions, to purchase the number of additional shares and/or warrants, proportionate to that underwriter's initial purchase commitment as indicated in the table above for which the option has been exercised.

Discount, Commissions and Expenses

The underwriters have advised us that they propose to offer the shares of common stock, the pre-funded warrants and the warrants to the public at the combined public offering prices set forth on the cover page of this prospectus and to certain dealers at those prices less a concession not in excess of $ per share and $ per related warrant. After this offering, the combined public offering prices and concession to dealers may be changed by the underwriters. No such change will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus. The shares of common stock, pre-funded warrants, and warrants are offered by the underwriters as stated herein, subject to receipt and acceptance by them and subject to their right to reject any order in whole or in part. The underwriters have informed us that they do not intend to confirm sales to any accounts over which they exercise discretionary authority.

The following table shows the underwriting discount payable to the underwriters by us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' over-allotment option to purchase additional shares of common stock and warrants.

	Per Share and Related Warrant	Per Pre-Funded Warrant and Related Warrant	Total Without Exercise of Over-Allotment Option	Total With Exercise of Over-Allotment Option
Public offering price	$	$	$	$
Underwriting discount (6.0%)	$	$	$	$

We have agreed to reimburse the underwriters for certain out-of-pocket expenses, including the fees and disbursements of their counsel, up to an aggregate of $50,000. We estimate that the total expenses payable by us in connection with this offering, other than the underwriting discount referred to above, will be approximately $560,000.

Representative's Warrants

We will issue to Roth or its designees warrants to purchase an aggregate number of shares of our common stock equal to 5.0% of the number of shares of common stock issued in this offering (including the shares of common stock issuable upon the exercise of the pre-funded warrants and the warrants), at an exercise price per share equal to % of the public offering price (the "Representative's Warrants"). The Representative's Warrants will be exercisable, in whole or in part, upon issuance and will expire on the fifth anniversary of the commencement of sales in this offering in accordance with FINRA Rule 5110(g)(8)(A).

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and liabilities arising from breaches of representations and warranties contained in the underwriting agreement, or to contribute to payments that the underwriters may be required to make in respect of those liabilities.

Lock-Up Agreements

We and each of our officers and directors have agreed, subject to certain exceptions, for a period of 90 days after the date of this prospectus, not to offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of, directly or indirectly any shares of common stock or any securities convertible into or exchangeable for our common stock either owned as of the date of the underwriting agreement or thereafter acquired without the prior written consent of the representative. The representative may, in its sole discretion and at any time or from time to time before the termination of the lock-up period, without notice, release all or any portion of the securities subject to lock-up agreements.

Price Stabilization, Short Positions and Penalty Bids

In connection with the offering the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions and penalty bids in accordance with Regulation M under the Exchange Act:

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
- Over-allotment involves sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase, which creates a short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any covered short position by either exercising their over-allotment option and/or purchasing shares in the open market.
- Syndicate covering transactions involve purchases of shares of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. If the underwriters sell more shares than could be covered by

the over-allotment option, a naked short position, the position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.

- Penalty bids permit a syndicate representative to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, over-allotment transactions, syndicate covering transactions and penalty bids, to the extent applicable, may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of our securities may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor the underwriters make any representations that the underwriters will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

NASDAQ Listing

Our shares of common stock are quoted on the OTCQB under the symbol “KMPH.” We have applied to list our common stock on The NASDAQ Capital Market under the symbol “KMPH.” We will not consummate this offering unless our common stock is approved for listing on The NASDAQ Capital Market. There is no established public trading market for the warrants or the pre-funded warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list the warrants or the pre-funded warrants on any national securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the warrants and the pre-funded warrants will be limited.

Electronic Distribution

This preliminary prospectus in electronic format may be made available on websites or through other online services maintained by the underwriters, or by their affiliates. Other than this preliminary prospectus in electronic format, the information on any underwriter’s website and any information contained in any other website maintained by such underwriter is not part of this preliminary prospectus or the registration statement of which this preliminary prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

Other

The underwriters and/or their affiliates may in the future provide various investment banking and other financial services for us for which services they may in the future receive customary fees. In the course of their businesses, the underwriters and their affiliates may actively trade our securities or loans for their own account or for the accounts of customers, and, accordingly, the underwriters and their affiliates may at any time hold long or short positions in such securities or loans. Except for services provided in connection with this offering, no underwriter has provided any investment banking or other financial services to us during the 180-day period preceding the date of this prospectus and we do not expect to retain any underwriter to perform any investment banking or other financial services for at least 90 days after the date of this prospectus.

LEGAL MATTERS

The validity of the common stock offered by this prospectus will be passed upon by Cooley LLP, Broomfield, Colorado. Ellenoff Grossman & Schole LLP, New York, New York, is acting as counsel for the underwriter in connection with this offering.

EXPERTS

The financial statements of KemPharm, Inc. as of December 31, 2019 and 2018 and for each of the years in the two-year period ended December 31, 2019 have been audited by RSM US LLP, an independent registered public accounting firm, as stated in their report thereon which report expresses an unqualified opinion and includes an explanatory paragraph relating to going concern uncertainty, and included in this prospectus and registration statement in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

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

We file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains a website that contains reports, proxy statements and other information regarding issuers that file electronically with the SEC, including KemPharm. The address of the SEC website is www.sec.gov.

We maintain a website at www.kempharm.com. Information contained in or accessible through our website does not constitute a part of this prospectus.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

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

Emphasis of Matter Regarding Going Concern Uncertainty

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

Basis of Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ RSM US LLP

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

Orlando, Florida
February 28, 2020, except for the Reverse Stock Split paragraph of Note A as to which the date is December 27, 2020

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

	As of December 31, 2019	As of December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 3,217	$ 18,409
Marketable securities	—	3,260
Accounts and other receivables	1,865	140
Prepaid expenses and other current assets	1,552	1,912
Total current assets	6,634	23,721
Property and equipment, net	1,471	1,753
Operating lease right-of-use assets	1,537	—
Restricted cash	338	710
Other long-term assets	527	562
Total assets	$ 10,507	$ 26,746
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,911	$ 8,342
Current portion of convertible notes	—	3,333
Current portion of capital lease obligation	—	214
Current portion of operating lease liabilities	284	—
Other current liabilities	236	115
Total current liabilities	5,431	12,004
Convertible notes, less current portion, net	77,343	78,105
Derivative and warrant liability	120	2,118
Capital lease obligation, less current portion	—	396
Operating lease liabilities, less current portion	1,901	—
Other long-term liabilities	168	689
Total liabilities	84,963	93,312
Commitments and contingencies (Note H)		
Stockholders' deficit:		
Preferred stock:		
Series A convertible preferred stock, $0.0001 par value, 9,578 shares authorized, 9,577 shares issued and no shares outstanding as of December 31, 2019; 9,577 shares issued and 3,337 shares outstanding as of December 31, 2018	—	—
Series B-1 convertible preferred stock, $0.0001 par value, 1,576 shares authorized, 1,576 shares issued and no shares outstanding as of December 31, 2019; no shares authorized, issued or outstanding as of December 31, 2018	—	—
Series B-2 convertible preferred stock, $0.0001 par value, 27,000 shares authorized, no shares issued or outstanding as of December 31, 2019; no shares authorized, issued or outstanding as of December 31, 2018	—	—
Undesignated preferred stock, $0.0001 par value, 9,961,846 shares authorized, no shares issued or outstanding as of December 31, 2019; 9,990,422 shares authorized, no shares issued or outstanding as of December 31, 2018	—	—
Common stock, $0.0001 par value, 250,000,000 shares authorized, 2,271,833 shares issued and outstanding as of December 31, 2019; 1,653,376 shares issued and outstanding as of December 31, 2018	—	—
Additional paid-in capital	171,258	154,626
Accumulated deficit	(245,714)	(221,192)
Total stockholders' deficit	(74,456)	(66,566)
Total liabilities and stockholders' deficit	$ 10,507	$ 26,746

See accompanying notes to financial statements

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

	Year Ended December 31, 2019	2018
Revenue	$ 12,839	$ —
Operating expenses:		
Royalty and direct contract acquisition costs	2,945	—
Research and development	19,415	41,759
General and administrative	10,816	12,508
Severance expense	—	1,636
Total operating expenses	33,176	55,903
Loss from operations	(20,337)	(55,903)
Other (expense) income:		
Gain on extinguishment of debt	—	2
Interest expense related to amortization of debt issuance costs and discount	(1,656)	(1,618)
Interest expense on principal	(4,858)	(5,469)
Fair value adjustment related to derivative and warrant liability	1,998	5,976
Interest and other income, net	309	420
Total other (expense) income	(4,207)	(689)
Loss before income taxes	(24,544)	(56,592)
Income tax benefit	22	126
Net loss	$ (24,522)	$ (56,466)
Net loss per share of common stock:		
Basic and diluted	$ (13.23)	$ (50.39)
Weighted average number of shares of common stock outstanding:		
Basic and diluted	1,853,348	1,120,626

See accompanying notes to financial statements

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

	Preferred Stock							
	Series A Convertible Preferred Stock	Series B-1 Convertible Preferred Stock	Series B-2 Convertible Preferred Stock	Undesignated Preferred Stock	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance as of January 1, 2018	$ —	$ —	$ —	$ —	$ —	$ 107,210	$ (164,726)	$ (57,516)
Net loss	—	—	—	—	—	—	(56,466)	(56,466)
Stock-based compensation expense	—	—	—	—	—	6,495	—	6,495
Issuance of common stock in connection with ATM, net of commissions	—	—	—	—	—	4,828	—	4,828
Offering expenses charged to equity	—	—	—	—	—	(554)	—	(554)
Conversion of principal and interest on Deerfield Convertible Note	—	—	—	—	—	3,502	—	3,502
Exercise of stock options	—	—	—	—	—	68	—	68
Issuance of common stock in connection with underwritten public offering, net of commissions	—	—	—	—	—	23,500	—	23,500
Conversion of principal on 2021 Notes	—	—	—	—	—	9,577	—	9,577
Balance as of December 31, 2018	$ —	$ —	$ —	$ —	$ —	$ 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
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)

See accompanying notes to financial statements

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

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

See accompanying notes to financial statements

KEMPHARM, INC.
NOTES TO FINANCIAL STATEMENTS

A. Description of Business and Basis of Presentation

Organization

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

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 will receive 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.

Going Concern

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

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

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

After the Company files this Annual Report on Form 10-K for the fiscal year ended December 31, 2019 (the "Annual Report"), in order to issue securities under the Current Registration Statement or the Replacement Registration Statement, once effective, it must rely on Instruction I.B.6. of Form S-3, which imposes a limitation on the maximum amount of securities that the Company may sell pursuant to the registration statements during any twelve-month period. At the time it sells securities pursuant to the applicable registration statement, the amount of securities to be sold plus the amount of any securities it has sold during the prior twelve months in reliance on Instruction I.B.6. may not exceed one-third of the aggregate market value of its outstanding common stock held by non-affiliates as of a day during the 60 days immediately preceding such sale, as computed in accordance with Instruction I.B.6. As of filing this Annual Report, based on this calculation, the amount of securities the Company is able to sell under a registration statement on Form S-3 is approximately $10.9 million, of which the Company (i) has filed a prospectus supplement to register approximately $4.0 million for sales under the Purchase Agreement (as defined below); and (ii) has previously sold an aggregate of $5.7 million of shares of common stock in prior offering on Form S-3 in the previous 12 months. Based on this calculation, the Company expects it will be unable to sell additional securities beyond those amounts pursuant to the Current Registration Statement or the Replacement Registration Statement, once effective, in the near term, unless and until the market value of its outstanding common stock held by non-affiliates increases significantly. In addition, under the terms of the Purchase Agreement, stockholder approval may be required to access a portion of the amounts available under the Purchase Agreement. As of December 31, 2019, the Company has sold 212,579 shares of common stock registered under the Current Registration Statement for approximately $5.4 million in gross proceeds under the Prior Purchase Agreement.

Entry into First ATM Agreement

In October 2016, the Company entered into a Common Stock Sales Agreement (the "First ATM Agreement") with Cowen and Company, LLC ("Cowen"). The First ATM Agreement was terminated in September 2018. Prior to termination of the First ATM Agreement, the Company sold an aggregate of 47,638 shares of common stock under the First ATM Agreement resulting in gross proceeds to the Company of $4.9 million. The Company paid Cowen a commission of up to three percent (3.0%) of the gross sales proceeds for such sales of common stock. Pursuant to the terms of the First ATM Agreement, specified obligations of the parties, including the Company's indemnification obligations to Cowen, survive the termination of the First ATM Agreement.

Entry into Second ATM Agreement

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

Underwritten Public Offering

In October 2018, the Company entered into an underwriting agreement (the "Underwriting Agreement") with RBCCM, pursuant to which, on October 10, 2018, the Company sold 520,833 shares of common stock of the Company in an underwritten public offering pursuant to the Company's registration statement on Form S-3, filed with the SEC on October 17, 2016, and a related prospectus and prospectus supplement, filed with the SEC on October 17, 2016 and October 5, 2018, respectively. The offering price to the public was $48.00 per share. The Company's net proceeds from the offering were approximately $23.1 million, after deducting underwriting discounts and commissions and estimated offering expenses.

Entry into Prior Purchase Agreement

In February 2019, the Company entered into a purchase agreement (the "Prior Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") which provided that, upon the terms and subject to the conditions and limitations set forth therein, the Company previously could sell to Lincoln Park up to $15.0 million of shares of common stock from time to time over the 36-month term of the Prior Purchase Agreement, and upon execution of the Prior Purchase Agreement the Company issued an additional 7,512 shares of common stock to Lincoln Park as commitment shares in accordance with the closing conditions within the Prior Purchase Agreement. Concurrently with entering into the Prior Purchase Agreement, the Company also entered into a registration rights agreement with Lincoln Park pursuant to which the Company agreed to register the sale of the shares of common stock that have been and may be issued to Lincoln Park under the Prior Purchase Agreement pursuant to the Company's existing shelf registration statement on Form S-3 or a new registration statement. As of December 31, 2019, the Company has sold 212,579 shares of common stock to Lincoln Park under the Prior Purchase Agreement for approximately $5.4 million in gross proceeds. In February 2020, and in connection with entering into the Purchase Agreement (see discussion below), the Company terminated the Prior Purchase Agreement.

Entry into APADAZ License Agreement

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

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

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

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

Entry into KP415 License Agreement

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

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

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

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

Entry into Purchase Agreement

In February 2020, the Company entered into a purchase agreement with Lincoln Park (the "Purchase Agreement"), which provided that, upon the terms and subject to the conditions and limitations set forth therein, the Company may sell to Lincoln Park up to $4.0 million of shares of its common stock, from time to time over the 12-month term of the Purchase Agreement, and upon execution of the Purchase Agreement the Company issued an additional 19,289 shares of its common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Purchase Agreement. Concurrently with entering into the Purchase Agreement, the Company also entered into a registration rights agreement with Lincoln Park, pursuant to which the Company agreed to register the sale of the shares of its common stock that have been and may be issued to Lincoln Park under the Purchase Agreement pursuant to the Company's existing shelf registration statement on Form S-3 or a new registration statement.

B. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("GAAP") requires the Company to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

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

Reclassifications

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

Concentration of Credit Risk

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

Cash and Cash Equivalents

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

Marketable Securities and Long-term Investments

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

Property and Equipment

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

Debt Issuance Costs

Debt issuance costs incurred in connection with financing arrangements are recorded as a reduction of the related debt on the balance sheet and amortized over the life of the respective financing arrangement using the effective interest method.

Supply Arrangements

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

Impairment of Long-Lived Assets

Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets may not be recoverable. When such events occur, the Company compares the carrying amounts of the assets to their undiscounted expected future cash flows. If the undiscounted cash flows are insufficient to recover the carrying values, an impairment loss is recorded for the difference between the carrying values and fair values of the asset. No such impairment occurred for the years ended December 31, 2019 or 2018.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, based on the Company's principal or, in absence of a principal, most advantageous market for the specific asset or liability.

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

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

Revenue Recognition

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

Arrangements with Multiple-Performance Obligations

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

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

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

Licensing Agreements

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

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

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

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

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

KP415 License Agreement

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

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

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

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

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

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

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

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

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

Accounts and Other Receivables

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

Research and Development

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

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

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

Patent Costs

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

Income Taxes

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

Uncertain tax positions are recognized only when the Company believes it is more likely than not that the tax position will be upheld on examination by the taxing authorities based on the merits of the position. The Company recognizes interest and penalties, if any, related to unrecognized income tax uncertainties in income tax expense. The Company did not have any accrued interest or penalties associated with uncertain tax positions as of December 31, 2019 and 2018.

The Company files income tax returns in the United States for federal and various state jurisdictions. With few exceptions, the Company is no longer subject to U.S. federal and state and local income tax examinations for years prior to 2014, although carryforward attributes that were generated prior to 2014 may still be adjusted upon examination by the Internal Revenue Service if used in a future period. No income tax returns are currently under examination by taxing authorities.

Stock-Based Compensation

The Company measures and recognizes compensation expense for all stock-based payment awards made to employees, officers and directors based on the estimated fair values of the awards as of the grant date. The Company records the value of the portion of the award that is ultimately expected to vest as expense over the requisite service period. The Company also accounts for equity instruments issued to non-employees using a fair value approach under Accounting Standards Codification (“ASC”) subtopic 505-50, inclusive of the modifications made by ASU 2018-07. The Company values equity instruments and stock options granted using the Black-Scholes option pricing model.

Basic and Diluted Net Loss per Share of Common Stock

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

Segment and Geographic Information

Operating segments are defined as components of an enterprise (business activity from which it earns revenue and incurs expenses) for which discrete financial information is available and regularly reviewed by the chief operating decision maker (“CODM”) in deciding how to allocate resources and in assessing performance. The Company’s CODM is its Chief Executive Officer. The Company views its operations and manages its business as a single operating and reporting segment. All assets of the Company were held in the United States as of December 31, 2019 and 2018.

Application of New or Revised Accounting Standards—Adopted

From time to time, the Financial Accounting Standards Board (the “FASB”) or other standard-setting bodies issue accounting standards that are adopted by the Company as of the specified effective date.

In April 2012, President Obama signed the Jump-Start Our Business Startups Act (the “JOBS Act”) into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an emerging growth company. As an emerging growth company, the Company could have elected to adopt new or revised accounting standards when they become effective for non-public companies, which typically is later than public companies must adopt the standards. The Company has irrevocably elected not to take advantage of the extended transition period afforded by the JOBS Act and, as a result, will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

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

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

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

Application of New or Revised Accounting Standards—Not Yet Adopted

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

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C. Accounts and Other Receivables

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

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

D. Prepaid Expenses and Other Current Assets

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

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

E. Property and Equipment

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

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

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

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

Depreciation and amortization expense, including amounts pertaining to assets held under finance leases, was approximately $304,000 and $324,000 for the years ended December 31, 2019 and 2018, respectively.

F. Accounts Payable and Accrued Expenses

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

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

G. Debt Obligations

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

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

Deerfield Facility Agreement

In June 2014, the Company entered into a $60 million multi-tranche credit facility (the "Deerfield Facility Agreement") with Deerfield Private Design Fund III, LP ("Deerfield"). At the time the Company entered into the Deerfield Facility Agreement, the Company borrowed the first tranche, which consisted of a term loan of $15 million (the "Term Note") and a senior secured loan of $10 million (the "Deerfield Convertible Note"). Deerfield is no longer obligated to provide the Company any additional disbursements under the Deerfield Facility Agreement. Deerfield may convert any portion of the outstanding principal and any accrued but unpaid interest on the Deerfield Convertible Note into shares of the Company's common stock at an initial conversion price of $5.85 per share (the "Deerfield Note Put Option"). After giving effect to the Reverse Stock Split effected in December 2020, the conversion price of the Deerfield Note Put Option became $93.60 per share.

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 number of shares of the Company’s common stock 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 exercise price of the Deerfield Warrant became $93.60 per share, and the warrant became exercisable into 120,192 shares of the Company’s common stock. This warrant qualifies as a participating security under ASC Topic 260, Earnings per Share, and is treated as such in the net loss per share calculation (Note J). If a Major Transaction occurs (as defined in the Deerfield Facility Agreement) Deerfield may require the Company to redeem the Deerfield Warrant for a cash amount equal to the Black-Scholes value of the portion of the Deerfield Warrant to be redeemed (the “Warrant Put Option”).

The Company recorded the fair value of the shares of Series D Preferred to debt issuance costs on the date of issuance. The Company also recorded the fair value of the Deerfield Warrant and the embedded Warrant Put Option to debt discount on the date of issuance. The debt issuance costs and debt discount are amortized over the term of the related debt and the expense is recorded as interest expense related to amortization of debt issuance costs and discount in the statements of operations.

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

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

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

In February 2016, the Company issued $86.3 million aggregate principal amount of its 5.50% Senior Convertible Notes due 2021 (the "2021 Notes") to Cowen and RBC Capital Markets, LLC, as representatives of the several initial purchasers (the "Initial Purchasers"), who subsequently resold the 2021 Notes to qualified institutional buyers (the "Note Offering") in reliance on the exemption from registration provided by Rule 144A under the Securities Act.

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

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

The 2021 Notes were not redeemable prior to the maturity date, and no sinking fund was provided for the 2021 Notes. The 2021 Notes were convertible at an initial conversion rate of 58.4454 shares of the Company's common stock per $1,000 principal amount of the 2021 Notes, subject to adjustment under the Indenture, which is equal to an initial conversion price of approximately $17.11 per share of common stock. 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 of common stock.

If the Company underwent a "fundamental change" (as defined in the Indenture), holders could have required that the Company repurchase for cash all or any portion of their 2021 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2021 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. As December 31, 2019, the Company is bifurcating the fundamental change and make-whole interest payment provisions as embedded derivatives and marking them to fair value each reporting period (Note M).

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

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

Facility Agreement Waiver and Fifth Amendment to Senior Secured Convertible Note

In June 2018, the Company entered into the Facility Agreement Waiver and Fifth Amendment (the "Fifth Amendment") to the Deerfield Convertible Note with Deerfield. The Fifth Amendment, among other things, provided that (i) $3,333,333 of the principal amount, plus $168,288 of accrued interest, of the Deerfield Convertible Note issued pursuant to the terms of the Deerfield Facility Agreement was converted into 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). As of December 31, 2019, all 9,577 shares of Series A Preferred Stock issued under the October 2018 Exchange Agreement have been converted into an aggregate 199,519 shares of the Company's 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 per share and the aggregate shares of common stock issuance upon conversion of the Series A Preferred Stock would be 199,519 shares of 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 will be effected at an exchange price of $1,000 per share. If the Deerfield Lenders choose to exchange any portion of the Optional Exchange Principal Amount for shares of common stock, such exchange will be effected at an exchange price equal to the greater of (i) $0.9494, or (ii) the average of the volume-weighted average price of the common stock on the 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 per share and the common stock issuable upon conversion of the then outstanding Series B-1 Preferred Stock would be an aggregate of 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 per share or 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 and the common stock issuable in exchange for the Optional Exchange Principal Amount or upon conversion of the 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, 2019, 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.

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

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

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

2021 Note Exchange Effected in December 2019

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

The December 2019 Notes bear interest at 6.75% per annum. The December 2019 Notes are convertible into shares of the Company's common stock at an initial conversion price of $17.11 per share (which represents the conversion price of the 2021 Notes), subject to adjustment in accordance with the terms of the December 2019 Notes. As of the date of issuance, the December 2019 Notes were convertible, by their terms, into an aggregate of 4,174,051 shares of the Company's common stock. The Company subsequently amended the December 2019 Notes to provide that such notes shall be convertible into shares of the Company's common stock at a conversion price of $5.85 per share (which represents the conversion price of the Deerfield Convertible Note). After giving effect to the Reverse Stock Split effected in December 2020, the conversion price of the December 2019 Notes became $273.76 per share and the aggregate shares which the December 2019 Notes were convertible became 260,876. The conversion price of the December 2019 Notes will be adjusted downward if the Company issues or sells any shares of common stock, convertible securities, warrants or options at a sale or exercise price per share less than the greater of the December 2019 Notes' conversion price or the closing sale price of the Company's common stock as reported on the NASDAQ Stock Market on the last trading date immediately prior to such issuance, or, in the case of a firm commitment underwritten offering, on the date of execution of the underwriting agreement between the Company and the underwriters for such offering. However, if the Company effects an "at the market offering" as defined in Rule 415 of the Securities Act or 1933, as amended (the "Securities Act"), of its common stock, the conversion price of the December 2019 Notes will be adjusted downward pursuant to this anti-dilution adjustment only if such sales are made at a price less than $5.85 per share, provided that this anti-dilution adjustment will not apply to any sales made under (x) the Purchase Agreement, (y) the Second ATM

Agreement, or (z) the September 2019 Exchange Agreement (as amended). Notwithstanding anything in the contrary in the December 2019 Notes, the anti-dilution adjustment of such notes shall not result in the conversion price of the December 2019 Notes being less than $0.583 per share. The December 2019 Notes are convertible at any time at the option of the holders thereof, provided that a holder of a December 2019 Note is prohibited from converting such note into shares of the Company's common stock if, as a result of such conversion, such holder (together with certain affiliates and "group" members) would beneficially own more than 4.985% of the total number of shares of common stock then issued and outstanding. However, the December 2019 Note issued to DSC, due to the fact DSC was a beneficial owner of more than 4.985% of the total number of shares of the Company's common stock then issued and outstanding, has a beneficial ownership cap equal to 19.985% of the total number of shares of the Company's common stock then issued and outstanding. Pursuant to the December 2019 Notes, the December 2019 Holders have the option to demand repayment of all outstanding principal, and any unpaid interest accrued thereon, in connection with a Major Transaction (as defined in the December 2019 Notes), which shall include, among others, any acquisition or other change of control of the Company; a liquidation, bankruptcy or other dissolution of the Company; or if at any time after March 31, 2021, shares of the Company's common stock are not listed on an Eligible Market (as defined in the December 2019 Notes). The December 2019 Notes are subject to specified events of default, the occurrence of which would entitle the December 2019 Holders to immediately demand repayment of all outstanding principal and accrued interest on the December 2019 Notes. Such events of default include, among others, failure to make any payment under the December 2019 Notes when due, failure to observe or perform any covenant under the Deerfield Facility Agreement (as defined below) or the other transaction documents related thereto (subject to a standard cure period), the failure of the Company to be able to pay debts as they come due, the commencement of bankruptcy or insolvency proceedings against the Company, a material judgement levied against the Company and a material default by the Company under the Deerfield Warrant, the December 2019 Notes or the Deerfield Convertible Note.

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

The December 2019 Exchange Agreement also amends and restates the Deerfield Convertible Note to conform the definitions of "Eligible Market" and "Major Transactions" to the definition in the December 2019 Notes, to remove provisions that were only applicable prior to the Company's initial public offering and to make certain other changes to conform to the December 2019 Notes. The conversion price for the Deerfield Convertible Note remains $5.85 per share, subject to adjustment on the same basis as the existing senior secured convertible notes, but subject to a floor price of $0.583. After giving effect to the Reverse Stock Split effected in December 2020, the conversion price of the Deerfield Convertible Note became $93.60 per share and the floor price became $9.328.

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

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

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

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

As of December 31, 2019, the Deerfield Lenders have converted $1.2 million of principal under the December 2019 Notes into 125,000 shares of common stock.

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

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

2021 Note Exchange Effected in January 2020

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

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

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

Convertible Notes

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

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

Line of Credit

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

H. Commitments and Contingencies

Legal Matters

From time to time, the Company is involved in various legal proceedings arising in the normal course of business. For some matters, a liability is not probable, or the amount cannot be reasonably estimated and, therefore, an accrual has not been made. However, for such matters when it is probable that the Company has incurred a liability and can reasonably estimate the amount, the Company accrues and discloses such estimates. As of December 31, 2019 and 2018, no accruals have been made related to commitments and contingencies.

Lease Agreements

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

Florida

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

Iowa

The Company leases office and laboratory facilities in Iowa under a non-cancelable operating lease. The Company's lease for its Iowa facilities expires in September 2020 and includes a renewal option that could extend the lease for successive one-year terms upon expiration.

Virginia

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

North Carolina

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

Capital Lease

The Company leases various laboratory equipment, furniture and office equipment and leasehold improvements that are accounted for as capital leases and that require ongoing payments, including interest expense. The capital leases are financed through various financial institutions and are collateralized by the underlying assets. As of December 31, 2019 and 2018, the interest rates for assets under remaining capital leases range from 7.19% to 9.57%.

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

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

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

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

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

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

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

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

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

I. Supply Arrangement

As of December 31, 2019 and 2018, the Company has one manufacturing arrangement that involves potential future expenditures related to research and development.

In November 2009, the Company entered into a supply agreement (the “Supply Agreement”) with Johnson Matthey Inc. (“JMI”) whereby JMI has agreed to supply the Company with all of the benzhydrocodone necessary for clinical trials and commercial sale for a price equal to JMI’s manufacturing cost and to provide process optimization and development services for benzhydrocodone. The Company's FDA-approved drug, APADAZ, contains benzhydrocodone. Expense of $3.2 million and $3.6 million was recorded under this agreement for the year ended December 31, 2019, respectively. The Company must purchase all of its U.S. benzhydrocodone needs from JMI and JMI cannot supply benzhydrocodone to other companies. The term of the Supply Agreement extends as long as the Company holds a valid and enforceable patent for benzhydrocodone or until the tenth anniversary of a commercial launch of a FDA-approved drug incorporating benzhydrocodone, whichever date is later. Upon the expiration of such term, the agreement will automatically renew for a period of two years unless either party provides 12 months prior notice of its intent not to renew. Under the agreement, JMI will receive a tiered-based royalty share on the net sales on the commercial sale of a FDA-approved drug incorporating benzhydrocodone. No reliable estimate of the future payments can be made at this time.

J. Preferred Stock and Warrants

Authorized, Issued, and Outstanding Preferred Stock

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

In October 2018, the Company entered into the October 2018 Exchange Agreement. Under the October 2018 Exchange Agreement the Company issued to the Holders 9,577 shares of Series A Preferred Stock. Each share of Series A Preferred Stock has an aggregate stated value of $1,000 and is convertible into shares of common stock at a price equal to $3.00 per share (subject to adjustment to reflect stock splits and similar events). Immediately following the exchange under the October 2018 Exchange Agreement, there were an aggregate of 3,192,333 shares of common stock issuable upon conversion of the Series A Preferred Stock (without giving effect to the limitation on conversion described below), and as of December 31, 2019 all issued shares of Series A Preferred Stock had been converted into shares of common stock. 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 the aggregate shares of common stock issuable upon conversion of the Series A Preferred Stock would be 199,519 shares.

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 per share and the aggregate shares of common stock issuable upon conversion of the Series B-1 Preferred Stock would be 103,749 shares. The Series B Preferred Stock is convertible at any time at the option of the Holders; provided that the Holders are prohibited from converting shares of Series B Preferred Stock into shares of common stock if, as a result of such conversion, such Holders (together with certain affiliates and "group" members of such Holders) would beneficially own more than 4.985% of the total number of shares of common stock then issued and outstanding. The Series B Preferred Stock is not redeemable. In the event of the Company's liquidation, dissolution or winding up, the Holders will receive an amount equal to $0.0001 per share, plus any declared but unpaid dividends, and thereafter will share ratably in any distribution of the Company's assets with holders of common stock and with the holders of any shares of any other class or series of capital stock of the Company entitled to share in such remaining assets of the Company (including Series A Preferred Stock on an as-converted basis. With respect to rights upon liquidation, the Series B Preferred Stock ranks senior to the common stock, on parity with the Series A Preferred Stock, if any is then outstanding, and junior to existing and future indebtedness. Except as otherwise required by law (or with respect to approval of certain actions involving the Company's organizational documents that materially and adversely affect the holders of Series B Preferred Stock), the Series B Preferred Stock does not have voting rights. The Series B Preferred Stock is not subject to any price-based anti-dilution protections and does not provide for any accruing dividends, but provides that holders of Series B Preferred Stock will participate in any dividends on the common stock on an as-converted basis (without giving effect to the limitation on conversion described above). The Series B-1 Certificate of Designation and the Series B-2 Certificate of Designation also provide for partial liquidated damages in the event that the Company fails to timely convert shares of Series B-1 Preferred Stock or Series B-2 Preferred Stock, respectively, into Common Stock in accordance with the applicable Certificate of Designation. As of December 31, 2019, 1,576 shares of Series B-1 Preferred Stock have been converted into 103,749 shares of common stock.

K. Common Stock and Warrants

Authorized, Issued, and Outstanding Common Shares

As of December 31, 2019 and 2018, the Company had authorized shares of common stock of 250,000,000 shares. Of the authorized shares, 2,271,833 and 1,653,376 shares of common stock were issued and outstanding as of December 31, 2019 and 2018, respectively.

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

	December 31,	
	2019	2018
Conversion of Deerfield Convertible Note	75,850	72,975
Conversion of 2021 Notes	10,958	280,072
Conversion of 2019 Notes not subject to the Deerfield Optional Conversion Feature	199,172	—
Outstanding awards under equity incentive plans	324,473	231,493
Outstanding common stock warrants	151,442	157,957
Conversion of Series A Preferred Stock	—	69,521
In exchange for the Deerfield Optional Conversion Feature*	1,652,437	—
Possible future issuances under the Prior Purchase Agreement	597,065	—
Possible future issuances under equity incentive plans	5,325	40,557
Total common shares reserved for future issuance	3,016,722	852,575

Common Stock Activity

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

	Shares of Common Stock
Balance as of January 1, 2018	916,021
Common stock sold under First ATM Agreement	47,638
Common stock issued as a result of Deerfield Convertible Note principal and interest conversion	37,410
Common stock options exercised	1,476
Common stock sold under underwritten public offering	520,833
Common stock issued as a result of Series A Preferred Stock conversion	129,998
Balance as of December 31, 2018	1,653,376
Common stock issued under the Prior Purchase Agreement	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	2,271,833

In September 2018, the Company terminated the First ATM Agreement with Cowen. Prior to termination of the First ATM Agreement, the Company sold an aggregate of 47,638 shares of common stock under the First ATM Agreement resulting in gross proceeds to the Company of $4.9 million. As of December 31, 2019, the Company has not sold any shares of common stock under the Second ATM Agreement. Refer to Note A for a further discussion of the First and Second ATM Agreements.

In October 2018, the Company entered into an underwriting agreement with RBCCM pursuant to which the Company issued and sold 520,833 shares of common stock of the Company in an underwritten public offering pursuant to the Company's registration statement on Form S-3. Refer to Note A for a further discussion of the underwritten public offering.

Also in October 2018, the Company entered into the October 2018 Exchange Agreement pursuant to which the Company issued to the Holders 9,577 shares of Series A Preferred Stock. As of December 31, 2019, 9,577 shares of Series A Preferred Stock have been converted into 199,519 shares of common stock. Refer to Note G for a further discussion of the October 2018 Exchange Agreement.

On September 3, 2019, the Company entered into the September 2019 Exchange Agreement pursuant to which the Company issued to the Holders 93,742 shares of common stock and 1,576 shares of Series B-1 Preferred Stock. As of December 31, 2019, 1,576 shares of Series B-1 Preferred Stock have been converted into 103,749 shares of common stock. Refer to Note G for a further discussion of the September 2019 Exchange Agreement.

Warrants

During 2013, the Company issued $3.8 million of convertible notes and the warrants (the "2013 Warrants") to purchase 1,079,453 shares of equity securities in a future financing meeting specified requirements (a "Qualified

Financing”). The 2013 Warrants allow the holders to purchase shares of the same class and series of equity securities issued in the Qualified Financing for an exercise price equal to the per share price paid by the purchasers of such equity securities in the Qualified Financing. When the Company entered into the Deerfield Facility Agreement, the 2013 Warrants became warrants to purchase 1,079,453 shares of Series D Preferred. Upon completion of the IPO, the 2013 Warrants automatically converted into warrants to purchase 143,466 shares of the Company’s common stock at an exercise price of $5.85 per share. The 2013 Warrants expired on June 2, 2019. After giving effect to the Reverse Stock Split effected in December 2020, the exercise price of the 2013 Warrants would be $93.60 per share and the aggregate shares of common stock issuable upon conversion of the 2013 Warrants would be 8,966 shares.

On June 2, 2014, pursuant to the terms of the Deerfield Facility Agreement, the Company issued the Deerfield Warrant to purchase 14,423,076 shares of Series D Preferred (Note G). The Company recorded the fair value of the Deerfield Warrant as a debt discount and a warrant liability. The Deerfield Warrant, if unexercised, expires on the earlier of June 2, 2024, or upon a liquidation event. Upon completion of the IPO, the Deerfield Warrant automatically converted into a warrant to purchase 1,923,077 shares of the Company’s common stock at an exercise price of $5.85 per share. The Company is amortizing the debt discount over the term of the Deerfield Convertible Note and the expense is recorded as interest expense related to amortization of debt issuance costs and discount in the condensed statements of operations. After giving effect to the Reverse Stock Split effected in December 2020, the exercise price of the Deerfield Warrant became $93.60 per share and the aggregate shares of common stock issuable upon exercise of the Deerfield Warrants became 120,192 shares.

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

In connection with a Collaboration and License Agreement (the “APADAZ License Agreement”) with KVK Tech, Inc. (“KVK”), in October 2018, the Company issued to KVK a warrant to purchase up to 500,000 shares of common stock of the Company at an exercise price of $2.30 per share, which reflected the closing price of the Company’s common stock on the NASDAQ 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 per share and the aggregate shares of common stock issuable upon exercise of the KVK Warrant became 31,250 shares.

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

L. Stock-Based Compensation

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

In November 2014, the Board of Directors of the Company ("the Board"), and in April 2015, the Company's stockholders, approved the Company's 2014 Equity Incentive Plan (the "2014 Plan"), which became effective in April 2015. The 2014 Plan provides for the grant of stock options, other forms of equity compensation, and performance cash awards. The maximum number of shares of common stock that may be issued under the 2014 Plan is 317,291 as of December 31, 2019. The number of shares of common stock reserved for issuance under the 2014 Plan will automatically increase on January 1 of each year, beginning on January 1, 2016, and ending on and including January 1, 2024, by 4% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Board. Pursuant to the terms of the 2014 Plan, on January 1, 2020, the common stock reserved for issuance under the 2014 Plan automatically increased by 90,876 shares.

During the second quarter of 2019, the Company granted to each non-employee member of the Company's board of directors (each a "non-employee Director") two separate fully vested restricted stock awards ("RSAs") under the 2014 Plan. The RSAs were granted in lieu of the quarterly cash compensation payable under the Company's Third Amended and Restated Non-Employee Director Compensation Policy to each non-employee Director for service as a member of the Company's board of directors, and applicable committees thereof, in the first and second quarters of 2019. For the first and second quarter of 2019, RSAs were granted for a total of 2,650 and 2,454 shares of common stock, respectively.

In addition, the Company granted to a consultant fully vested RSAs under the 2014 Plan. The RSAs were granted as part of the monthly compensation package to the consultant for services performed. As of December 31, 2019, RSAs were granted for a total of 1,250 shares of common stock for this purpose.

During the year ended December 31, 2019 no stock options were exercised. During the year ended December 31, 2018, stock options to acquire 1,476 shares of common stock were exercised for approximately $68,000 with an intrinsic value of approximately $69,000.

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

	Year ended December 31,	
	2019	2018
Research and development	$1,459	$1,608
General and administrative	2,951	3,651
Severance expense	—	1,236
Total stock-based compensation expense	$4,410	$6,495

Stock Option Awards

The Company estimates the fair value of stock options using the Black-Scholes option-pricing model, which requires the use of subjective assumptions, including the expected term of the option, the expected stock price volatility, expected dividend yield and the risk-free interest rate for the expected term of the option. The expected term represents the period of time the stock options are expected to be outstanding. Due to the lack of sufficient historical exercise data to provide a reasonable basis upon which to otherwise estimate the expected term of the stock options, the Company uses the simplified method to estimate the expected term for its “plain vanilla” stock options. Under the simplified method, the expected term of an option is presumed to be the mid-point between the vesting date and the end of the contractual term. Some options, for example those that have exercise prices in excess of the fair value of the underlying stock, are not considered “plain vanilla” stock options. For these options, the Company uses an expected term equal to the contractual term of the option. Expected volatility for options granted prior to the second anniversary of the IPO is based on a blend of historical volatilities for publicly traded stock of comparable companies and the Company over the estimated expected term of the stock options. For options granted after the second anniversary of the IPO, expected volatility is based on the Company’s historical volatility over the estimated expected term of the stock options. The Company assumes no dividend yield because dividends are not expected to be paid in the near future, which is consistent with the Company’s history of not paying dividends.

The Company recognizes compensation expense related to stock-based payment transactions upon satisfaction of the requisite service or vesting requirements. Forfeitures are estimated at the time of grant and revised based on actual forfeitures, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Using the Black-Scholes option-pricing model, the weighted-average fair value of awards granted during the years ended December 31, 2019 and 2018, fair value was $1.43 and $4.05 per share, respectively. After giving effect to the Reverse Stock Split effected in December 2020, the fair values became $22.88 and $64.80 per share, respectively. The assumptions used to estimate fair value are as follows:

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

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

	Number of Options	Weighted Average Exercise Price	Weighted Avg Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding balance at January 1, 2019	231,477	$149.62	7.48	$ —
Granted	143,223	$ 29.30		
Exercised or released	(6,354)	$ —		
Canceled or forfeited	(42,209)	$140.81		
Expired	(1,664)	$ 76.80		
Outstanding balance at December 31, 2019	324,473	$100.96	7.63	$ —
Exercisable at December 31, 2019	134,614	$172.84	6.04	$ —
Vested and expected to vest at December 31, 2019	281,356	$114.56	7.30	$ —

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

	Options Outstanding		Options Exercisable	
Exercise Price	Number of Shares	Weighted Avg Remaining Contractual Term	Number of Shares	Weighted Avg Remaining Contractual Term
$8.2576 to $80.00	181,415	8.72	29,920	7.19
$80.01 to $160.00	68,914	6.74	37,478	5.62
$160.01 to $240.00	29,489	5.94	23,821	5.90
$240.01 to $320.00	23,719	5.70	22,459	5.67
$320.01 to $327.20	20,936	5.68	20,936	5.68
	324,473	7.63	**134,614**	6.04

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

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

	Number of Unvested Shares December 31,	
Exercise Price	2019	2018
$8.2576 to $80.00	151,495	39,646
$80.01 to $160.00	31,436	51,165
$160.01 to $240.00	5,668	11,659
$240.01 to $320.00	1,260	8,740
$320.01 to $327.20	—	5,432
Total number of unvested stock options	**189,859**	**116,642**

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

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

M. Fair Value of Financial Instruments

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

The fair value of the Deerfield Convertible Note was $6.0 million and $6.2 million, respectively, as of December 31, 2019 and 2018. The fair value of the 2021 Notes was $2.4 million and $51.2 million, respectively, as of December 31, 2019 and 2018. The fair value of the December 2019 Notes was $57.0 million as of December 31, 2019. The Deerfield Convertible Note, 2021 Notes and December 2019 Notes fall within Level 3 of the fair value hierarchy as their value is based on the credit worthiness of the Company, which is an unobservable input. The Company used a Tsiveriotis-Fernandes model to value the Deerfield Convertible Note, 2021 Notes and December 2019 Notes as of December 31, 2019 and 2018.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company evaluates its financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level in which to classify them for each reporting period. This determination requires significant judgments to be made. The following table summarizes the conclusions reached regarding fair value measurements as of December 31, 2019 and 2018 (in thousands):

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

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

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

The Company's KVK Warrant liability is measured at fair value on a recurring basis. As of December 31, 2019 and December 31, 2018, the KVK Warrant liability is reported on the balance sheets in derivative and warrant liability. The Company estimates the fair value of the KVK Warrant using a probability-weighted Black-Scholes option-pricing model, which requires the use of subjective assumptions, including the expected term of the warrant, the expected stock price volatility, expected dividend yield and the risk-free interest rate for the expected term of the warrant. The expected term represents the period of time the warrant is expected to be outstanding. For the KVK Warrant, the Company used an expected term equal to the contractual term of the warrant. Expected volatility is based on the Company's historical volatility since the IPO. The Company assumes no dividend yield because dividends are not expected to be paid in the near future, which is consistent with the Company's history of not paying dividends. Changes in the fair value of the KVK Warrant liability are reflected in the statements of operations for the years ended December 31, 2019 and 2018 as a fair value adjustment related to derivative and warrant liability.

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

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

N. Income Taxes

The Company's financial statements include a total state tax benefit related to research and development credits of $22,000 and $126,000 on a loss before income taxes of approximately $24.2 million and $56.6 million for the years ended December 31, 2019 and 2018, respectively. A reconciliation of the difference between the benefit for income taxes and income taxes at the statutory U.S. federal income tax rate is as follows (shown as a percentage):

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

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

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

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. Based upon the level of historical taxable income and projections for future taxable income over the periods in which the deferred tax assets are deductible, management believes it is more likely than not that the Company will not realize the benefits of these deductible differences in the future.

The Company had the following federal net operating loss carryforward and research activities credits as of December 31, 2019 (in thousands):

Year Incurred	Net Operating Loss CF	Research Activities Cr.	Expiration
2007	$ 454	$ 30	2027
2008	1,178	65	2028
2009	3,060	176	2029
2010	3,423	149	2030
2011	9,929	176	2031
2012	—	170	2032
2013	4,353	133	2033
2014	15,897	894	2034
2015	23,496	598	2035
2016	41,580	745	2036
2017	34,776	652	2037
2018	56,155	2,272	Indefinite
2019	22,784	352	Indefinite
	$217,085	$ 6,412	

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

ASC 740-10, *Accounting for Uncertainty in Income Taxes*, uses the term “more likely than not” to evaluate whether or not a tax position will be sustained upon examination. The Company has not identified any tax positions that do not meet the more likely than not threshold.

O. Net Loss Per Share

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

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

	Year Ended December 31,	
	2019	2018
Net loss—basic and diluted	$ (24,522)	$ (56,466)
Weighted average number of shares of common stock—basic and diluted	1,853,348	1,120,626
Net loss per share—basic and diluted	$ (13.23)	$ (50.39)

Diluted net loss per share of common stock is the same as basic net loss per share of common stock for all periods presented because the effects of potentially dilutive items were anti-dilutive given the Company’s net loss. The following securities, presented on a common stock equivalent basis, have been excluded from the calculation of weighted average number of shares of common stock outstanding because their effect is anti-dilutive:

	December 31,	
	2019	2018
Deerfield Convertible Note	75,850	72,975
2021 Notes	10,958	280,072
2019 Notes*	1,851,609	—
Awards under equity incentive plans	324,473	231,493
Common stock warrants	151,442	157,957
Series A Convertible Preferred Stock	—	69,521
Total securities excluded from the calculation of weighted average number of shares of common stock outstanding	2,414,332	812,018

* Inclusive of 1,652,437 of shares of Common Stock issuable (i) in exchange of the Deerfield Optional Conversion Feature, or (ii) upon conversion of the Series B-2 Preferred Stock issuable in exchange of the Deerfield Optional Conversion Feature.

P. Severance Expense

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

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

Q. Employee Benefit Plan

The Company has a 401(k) retirement plan (the “401(k) Plan”) that covers substantially all employees. The Company may provide a discretionary match with a maximum amount of 4% of the participant’s compensation, which vests immediately. The Company made matching contributions under the 401(k) Plan of $133,000 and $212,000 for the years ended December 31, 2019 and 2018, respectively.

The Company has a discretionary profit sharing plan (the “Profit Sharing Plan”) that covers all employees. Employees become eligible participants in the Profit Sharing Plan once they have provided three years of service to the Company. The Company made no contributions to the Profit Sharing Plan in 2019 or 2018.

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

	September 30, 2020 (unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 5,267	$ 3,217
Accounts and other receivables	2,202	1,865
Prepaid expenses and other current assets	675	1,552
Total current assets	8,144	6,634
Property and equipment, net	1,079	1,471
Operating lease right-of-use assets	1,357	1,537
Restricted cash	186	338
Other long-term assets	438	527
Total assets	$ 11,204	$ 10,507
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,347	$ 4,911
Current portion of convertible notes	65,920	—
Current portion of operating lease liabilities	318	284
Other current liabilities	213	236
Total current liabilities	70,798	5,431
Convertible notes, less current portion, net	—	77,343
Derivative and warrant liability	184	120
Operating lease liabilities, less current portion	1,673	1,901
Loans payable	781	—
Other long-term liabilities	95	168
Total liabilities	73,531	84,963
Commitments and contingencies (Note D)		
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 September 30, 2020 (unaudited) and December 31, 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 September 30, 2020 (unaudited) and December 31, 2019	—	—
Series B-2 convertible preferred stock, $0.0001 par value, 27,000 shares authorized, no shares issued or outstanding as of September 30, 2020 (unaudited) and December 31, 2019	—	—
Undesignated preferred stock, $0.0001 par value, 9,961,846 shares authorized, no shares issued or outstanding as of September 30, 2020 (unaudited) and December 31, 2019	—	—
Common stock, $0.0001 par value, 250,000,000 shares authorized, 4,532,039 shares issued and outstanding as of September 30, 2020 (unaudited); 2,271,833 shares issued and outstanding as of December 31, 2019	—	—
Additional paid-in capital	191,291	171,258
Accumulated deficit	(253,618)	(245,714)
Total stockholders' deficit	(62,327)	(74,456)
Total liabilities and stockholders' deficit	$ 11,204	$ 10,507

See accompanying notes to unaudited condensed financial statements

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

	Three months ended September 30, 2020	Three months ended September 30, 2019	Nine months ended September 30, 2020	Nine months ended September 30, 2019
Revenue	$ 1,925	$ 11,463	$ 10,922	$ 11,463
Operating expenses:				
Royalty and direct contract acquisition costs	—	1,000	1,305	1,000
Research and development	1,709	3,616	5,789	16,950
General and administrative	1,429	3,613	5,393	9,440
Severance expense	—	—	830	—
Total operating expenses	3,138	8,229	13,317	27,390
(Loss) income from operations	(1,213)	3,234	(2,395)	(15,927)
Other (expense) income:				
Interest expense related to amortization of debt issuance costs and discount	(578)	(371)	(1,723)	(981)
Interest expense on principal	(1,163)	(1,208)	(3,620)	(3,669)
Fair value adjustment related to derivative and warrant liability	(137)	1,351	(65)	1,783
Interest and other income (expense), net	48	60	(135)	295
Total other expenses	(1,830)	(168)	(5,543)	(2,572)
(Loss) income before income taxes	(3,043)	3,066	(7,938)	(18,499)
Income tax benefit (expense)	34	(3)	34	14
Net (loss) income	$ (3,009)	$ 3,063	$ (7,904)	$ (18,485)
Net (loss) income per share of common stock:				
Basic	$ (0.68)	$ 1.44	$ (2.08)	$ (10.41)
Diluted	$ (0.68)	$ 0.96	$ (2.08)	$ (10.41)
Weighted average number of shares of common stock outstanding:				
Basic	4,425,474	1,882,831	3,794,840	1,776,005
Diluted	4,425,474	1,979,422	3,794,840	1,776,005

See accompanying notes to unaudited condensed financial statements

KEMPHARM, INC.
UNAUDITED CONDENSED 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' Equity
Balance as of January 1, 2020	$ —	$ —	$ —	$ —	$ —	$ 171,258	$ (245,714)	$ (74,456)
Net loss	—	—	—	—	—	—	(5,754)	(5,754)
Stock-based compensation expense	—	—	—	—	—	1,029	—	1,029
Issuance of common stock in connection with equity line of credit	—	—	—	—	—	1,112	—	1,112
Issuance of common stock in connection with Deerfield Optional Conversion Feature	—	—	—	—	—	9,600	—	9,600
Recognition of deferred offering costs in connection with equity line of credit	—	—	—	—	—	121	—	121
Offering expenses charged to equity	—	—	—	—	—	(327)	—	(327)
Balance as of March 31, 2020	—	—	—	—	—	182,793	(251,468)	(68,675)
Net income	—	—	—	—	—	—	859	859
Stock-based compensation expense	—	—	—	—	—	620	—	620
Issuance of common stock in connection with equity line of credit	—	—	—	—	—	1,191	—	1,191
Issuance of common stock in connection with Deerfield Optional Conversion Feature	—	—	—	—	—	3,150	—	3,150
Offering expenses charged to equity	—	—	—	—	—	(92)	—	(92)
Issuance of common stock in exchange for consulting services	—	—	—	—	—	84	—	84
Balance as of June 30, 2020	—	—	—	—	—	187,746	(250,609)	(62,863)
Net loss	—	—	—	—	—	—	(3,009)	(3,009)
Stock-based compensation expense	—	—	—	—	—	385	—	385
Issuance of common stock in connection with Deerfield Optional Conversion Feature	—	—	—	—	—	3,113	—	3,113
Issuance of common stock in exchange for consulting services	—	—	—	—	—	47	—	47
Balance as of September 30, 2020	$ —	$ —	$ —	$ —	$ —	$ 191,291	$ (253,618)	$ (62,327)

See accompanying notes to unaudited condensed financial statements

KEMPHARM, INC.
UNAUDITED CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT, CONTINUED
(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	—	—	—	—	—	—	(12,291)	(12,291)
Stock-based compensation expense	—	—	—	—	—	1,290	—	1,290
Issuance of common stock in connection with equity line of credit	—	—	—	—	—	2,721	—	2,721
Change in estimated deferred offering costs	—	—	—	—	—	10	—	10
Balance as of March 31, 2019	—	—	—	—	—	158,647	(233,483)	(74,836)
Net loss	—	—	—	—	—	—	(9,257)	(9,257)
Stock-based compensation expense	—	—	—	—	—	1,317	—	1,317
Issuance of common stock in connection with equity line of credit	—	—	—	—	—	1,229	—	1,229
Balance as of June 30, 2019	—	—	—	—	—	161,193	(242,740)	(81,547)
Net loss	—	—	—	—	—	—	3,063	3,063
Stock-based compensation expense	—	—	—	—	—	1,057	—	1,057
Issuance of common stock in connection with equity line of credit	—	—	—	—	—	1,496	—	1,496
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
Balance as of September 30, 2019	$ —	$ —	$ —	$ —	$ —	$ 169,057	$ (239,677)	$ (70,620)

See accompanying notes to unaudited condensed financial statements

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

	Nine months ended September 30, 2020	Nine months ended September 30, 2019
Cash flows from operating activities:		
Net loss	$ (7,904)	$(18,485)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,034	3,664
Non-cash interest expense	3,583	988
Amortization of debt issuance costs and debt discount	1,723	981
Depreciation and amortization expense	207	229
Fair value adjustment related to derivative and warrant liability	65	(1,783)
Change in estimated deferred offering costs	130	10
Loss on sublease and disposal of property and equipment	251	—
Consulting fees paid in stock	131	—
Change in assets and liabilities:		
Accounts and other receivables	(337)	(1,498)
Prepaid expenses and other assets	537	1,420
Operating lease right-of-use assets	121	(1,649)
Accounts payable and accrued expenses	(1,299)	(6,073)
Operating lease liabilities	(194)	2,345
Other liabilities	72	(788)
Net cash used in operating activities	(880)	(20,639)
Cash flows from investing activities:		
Purchases of property and equipment	(7)	(21)
Maturities of marketable securities	—	3,260
Net cash (used in) provided by investing activities	(7)	3,239
Cash flows from financing activities:		
Proceeds from equity line of credit	2,303	5,446
Proceeds from Payment Protection Program loan	781	—
Payment of deferred offering costs	(97)	—
Repayment of principal on finance lease liabilities	(168)	(157)
Payment of debt issuance costs	(34)	—
Net cash provided by financing activities	2,785	5,289
Net increase (decrease) in cash, cash equivalents and restricted cash	1,898	(12,111)
Cash, cash equivalents and restricted cash, beginning of period	3,555	19,119
Cash, cash equivalents and restricted cash, end of period	$ 5,453	$ 7,008
Supplemental cash flow information:		
Cash paid for interest	$ 71	$ 4,602
2019 Notes principal converted to common stock	15,863	—
Commitment shares issued in connection with equity line of credit included in deferred offering costs	121	—
Property and equipment included in accounts payable and accrued expenses	4	—
Deferred offering costs included in accounts payable and accrued expenses	—	105
2021 Notes principal converted to common stock	—	1,424
2021 Notes principal converted to Series B-1 Preferred Stock	—	1,576
Change in fair value of embedded conversion feature recorded as debt discount in connection with debt modification	—	2,311

See accompanying notes to unaudited condensed financial statements.

KEMPHARM, INC.
NOTES TO UNAUDITED CONDENSED 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 prodrug product candidate pipeline is focused on the high need areas of attention deficit hyperactivity disorder (“ADHD”) and stimulant use disorder (“SUD”). The Company’s co-lead clinical development candidates for the treatment of ADHD, KP415 and KP484, are both based on a prodrug of d-methylphenidate, but have differing duration/effect profiles. In addition, the Company has received FDA approval for APADAZ®, an immediate-release combination product containing benzhydrocodone, a prodrug of hydrocodone, and acetaminophen.

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Rule 8-03 of Regulation S-X. Accordingly, they do not include all of the information and related notes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included in the accompanying financial statements. Operating results for the three and nine months ended September 30, 2020 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2020.

This interim information should be read in conjunction with the audited financial statements included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the Securities and Exchange Commission (“SEC”) on February 28, 2020, as amended on April 8, 2020 (the “Annual Report”).

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 will receive 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 unaudited condensed financial statements.

Going Concern

The unaudited condensed 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 net working capital (current assets less current liabilities) deficit, and its existing cash and cash equivalents and restricted cash are not sufficient to fund the Company’s operating expenses and capital expenditure requirements for at least one year from the date these unaudited condensed financial statements are issued. Various internal and external factors will affect whether and when product candidates become approved drugs and how significant the market share of those approved products will be. The length of time and cost of developing and commercializing these product and product candidates and/or failure of them at any stage of the drug approval or commercialization process will materially affect the Company’s financial condition and future operations. In order to continue as a going concern, the Company will need additional financing to fund its operations. The perception of the Company’s inability to continue as a going concern may make it more difficult to obtain financing for the continuation of operations and could result in the loss of confidence by investors, suppliers and employees. Adequate additional financing may not be available to the Company on acceptable terms, or at all.

Management believes these conditions raise substantial doubt about the Company’s ability to continue as a going concern within the twelve months after the date these unaudited condensed financial statements are issued. Based upon the Company’s current operating plan and projected revenues, the Company believes its cash resources, including the funds received through the Payroll Protection Program (“PPP”) (discussed below) will be sufficient to fund operating expense and capital investment requirements past the potential March 2, 2021 Prescription Drug User Fee Act (“PDUFA”) date for the KP415 New Drug Application (“NDA”) and up to the debt maturity date of March 31, 2021. The ability to continue as a going concern is dependent upon profitable future operations, positive cash flows, the forbearance of the Company’s lenders and additional financing. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Management intends to finance operating costs over the next twelve months with existing cash and cash equivalents and restricted cash, as well as anticipated payments arising from the Company’s license agreements and additional revenues received through consulting fee arrangements.

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. The Company cannot predict what the long-term effects of this pandemic and the resulting economic disruptions may have on the Company’s liquidity and results of operations. The extent of the effect of the COVID-19 pandemic on the Company’s 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 the Company to enroll patients in any future clinical trials or cause delays in the regulatory approval of the Company’s product candidates, including causing potential delay of the FDA’s review of the Company’s KP415 NDA. A portion of the Company’s projected revenue is based upon the achievement of milestones in the KP415 License Agreement (as defined below) associated with regulatory matters that may be impacted by the COVID-19 pandemic. As a result, the Company cannot predict what, if any, impact that the COVID-19 pandemic may have on the Company’s ability to achieve these milestones. The economic uncertainty surrounding the COVID-19 pandemic may also dramatically reduce the Company’s ability to secure debt or equity financing necessary to support the Company’s operations. The Company is 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 the Company’s business, results of operations, financial condition, and cash flows. The financial statements do not reflect any adjustments as a result of the COVID-19 pandemic.

On April 23, 2020 the Company received proceeds of $0.8 million from a loan (the “PPP Loan”) under the PPP of the recently enacted Coronavirus Aid, Relief, and Economic Security Act (the “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. Refer to Note C for a further discussion of the PPP Loan.

Entry into Prior Purchase Agreement

In February 2019, the Company entered into a purchase agreement (the “Prior Purchase Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”) which provided that, upon the terms and subject to the conditions and limitations set forth therein, the Company previously could sell to Lincoln Park up to $15.0 million of shares of common stock from time to time over the 36-month term of the Prior Purchase Agreement, and upon execution of the Prior Purchase Agreement the Company issued an additional 7,512 shares of common stock to Lincoln Park as commitment shares in accordance with the closing conditions within the Prior Purchase Agreement. Concurrently with entering into the Prior Purchase Agreement, the Company also entered into a registration rights agreement with

Lincoln Park (the “Prior 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 Prior Purchase Agreement pursuant to the Company’s existing shelf registration statement on Form S-3 or a new registration statement. The Prior Purchase Agreement was terminated in February 2020 in connection with entering into the Current Purchase Agreement (discussed below). Prior to the termination of the Prior Purchase Agreement, the Company sold 212,579 shares of common stock to Lincoln Park (exclusive of the 7,512 commitment shares) under the Prior Purchase Agreement for approximately $5.4 million in gross proceeds.

Entry into Current Purchase Agreement

In February 2020, the Company entered into a purchase agreement (the “Current Purchase 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 Current Purchase Agreement, and upon execution of the Current Purchase 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 Current Purchase Agreement. Concurrently with entering into the Current Purchase Agreement, the Company also entered into a registration rights agreement with Lincoln Park (the “Current 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 Current Purchase 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 Current Purchase Agreement and therefore cannot issue additional shares under the Current Purchase Agreement. As of September 30, 2020, the Company has sold 559,971 shares of common stock to Lincoln Park (exclusive of the 19,289 commitment shares) under the Current Purchase Agreement for approximately $2.3 million in gross proceeds.

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.

Entry into KP415 License Agreement

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

In May 2020, the FDA accepted the Company's NDA for KP415. Per the KP415 License Agreement, the Company received a regulatory milestone payment of $5.0 million following the FDA's acceptance of the KP415 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 KP415 and KP484. Subject to the oversight of the joint steering committee, the Company otherwise retains all responsibility for the conduct of all regulatory activities required to obtain new drug application approval of KP415 and KP484; provided that Commave shall be the sponsor of any clinical trials conducted by the Company on behalf of Commave.

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

B. Summary of Significant Accounting Policies

Use of Estimates

The preparation of unaudited condensed financial statements in conformity with U.S. GAAP requires the Company to make estimates and assumptions that affect the amounts reported in the unaudited condensed 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.

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 KP415, KP484, and, at the option of Commave, KP879, KP922 and/or any other product candidate developed by the Company containing SDX and developed to treat ADHD or any other central nervous system disorder. The license granted to Commave is distinct from other performance obligations as Commave can benefit from the license either on its own or together with other resources that are readily available and the license is separately identifiable from other promises in the KP415 License Agreement.

In exchange for the exclusive, worldwide license, discussed above, Commave paid the Company a non-refundable upfront payment of $10.0 million. The Company is also entitled to additional payments from Commave of up to $63.0 million, conditioned upon the achievement of specified regulatory milestones related to KP415 and KP484. In May 2020, the FDA accepted the Company's NDA for KP415. Per the KP415 License Agreement, the Company received a regulatory milestone payment of $5.0 million following the FDA's acceptance of the KP415 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 KP415 and its final approved label, if any. Further, Commave will pay the Company quarterly, tiered royalty payments ranging from a percentage in the high single digits to mid-twenties of Net Sales (as defined in the KP415 License Agreement) in the U.S. and a percentage in the low to mid-single digits of Net Sales in each country outside of the U.S., in each case subject to specified reductions under certain conditions as described in the KP415 License Agreement

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

The KP415 License Agreement is within the scope of ASC 606, as the transaction represents a contract with a customer where the 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 KP415 was the fair value of the Development Costs at inception. These Development Costs effectively created a cap on certain consulting services and out-of-pocket third-party research and development costs identified in the initial product development plan for KP415 which was anticipated at the inception date of the KP415 License Agreement. As of September 30, 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 option to include Additional Products as Product(s) (both as defined in the KP415 License Agreement) under the KP415 License Agreement (the "Additional Product Option"). In addition to the Additional Product Option, Commave was also granted a right of first refusal ("ROFR") to acquire, license and/or commercialize any of the Additional Product Candidates should they choose not to exercise the Additional Product Option. Should Commave choose to exercise the Additional Product Option on any Additional Product Candidates, Commave and the Company shall negotiate in good faith regarding the economic terms of such Additional Product. Further, should Commave exercise the ROFR on any Additional Product Candidate, the economic terms of the agreement shall be the same as those offered to the third-party. Under ASC 606 an option to acquire additional goods or services gives rise to a performance obligation if the option provides a material right to the customer. The Company concluded that the above described Additional Product Option and ROFR do not constitute material rights to the customer as Commave would acquire the goods or services at a to be negotiated price, which the Company expects to approximate fair value and therefore Commave would not receive a material discount on these goods or services compared to market rates.

The Company is entitled to additional payments from Commave conditioned upon the achievement of specified regulatory milestones related to KP415 and KP484 and the achievement of certain U.S. sales milestones, which are dependent upon, among other things, the timing of approval for a new drug application for KP415 and its final approved label, if any. Further, Commave will pay the Company quarterly, tiered royalty payments ranging from a percentage in the high single digits to mid-twenties of Net Sales (as defined in the KP415 License Agreement) in the U.S. and a percentage in the low to mid-single digits of Net Sales in each country outside of the U.S., in each case subject to specified reductions under certain conditions as described in the KP415 License Agreement. The Company concluded that these regulatory milestones, sales milestones and royalty payments each contain a significant uncertainty associated with a future event. As such, these milestone and royalty payments are constrained at contract inception and are not included in the transaction price as the Company could not conclude that it is probable a significant reversal in the amount of cumulative revenue recognized will not occur surrounding these 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 KP415. Per the KP415 License Agreement, the Company received a regulatory milestone payment of $5.0 million following the FDA's acceptance of the KP415 NDA. Since the FDA accepted the Company's NDA for KP415 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 three and nine months ended September 30, 2020, the Company recognized revenue under the KP415 License Agreement of $0 and $7.3 million, respectively. 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 September 30, 2020, the Company has recognized all of these incremental costs, $0 and $0.8 million of which was recognized in the three and nine months ended September 30, 2020, respectively, and are recorded in the line item titled royalty and direct contract acquisition costs in the unaudited condensed statement of operations. There was $11.5 million of revenue and $1.0 million of associated direct contract acquisition costs recognized for the three and nine months ended September 30, 2019 related to the KP415 License Agreement. There was no deferred revenue related to this agreement as of September 30, 2020 or December 31, 2019.

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 KP415 (together, "Corium Consulting Services"). Corium is a portfolio company of Gurnet Point Capital and has been tasked with leading all commercialization activities for KP415 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.

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 September 30, 2020, the Company has recognized approximately 15% of the consulting services and third-party pass-through costs under the Corium Consulting Agreement.

For the three and nine months ended September 30, 2020, the Company recognized revenue under the Corium Consulting Agreement of $1.9 million. There was no revenue recognized for the three and nine months ended September 30, 2019 related to the Corium Consulting Agreement. As of September 30, 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 three and nine months ended September 30, 2020, the Company recognized revenue under other consulting arrangements of $0 and $1.7 million, respectively. There was no revenue recognized from other consulting arrangements for the three and nine months ended September 30, 2019. There was no deferred revenue from other from consulting arrangements as of September 30, 2020 or December 31, 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 September 30, 2020, the Company had receivables related to the Corium Consulting Agreement in the amount of $2.0 million and no receivables related to the KP415 License Agreement or other consulting arrangements. 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 September 30, 2020 and December 31, 2019 no reserve or allowance for doubtful accounts has been established.

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 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. Debt Obligations

As of September 30, 2020 and December 31, 2019, the Company had convertible notes outstanding, in the aggregate principal amounts, as follows (in thousands):

	September 30, 2020	December 31, 2019
Deerfield Convertible Note	$ 7,340	$ 6,981
2021 Notes	—	3,000
December 2019 Notes	56,615	70,218
January 2020 Note	3,133	—
Total outstanding principal on debt obligations	67,088	80,199
Less: debt issuance costs and discounts	(1,168)	(2,856)
Convertible notes, net	$ 65,920	$ 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 exercise price of the Deerfield Warrant became $93.60 and the shares issuable upon conversion of the warrant became 120,192 shares of common stock. 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 I). 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 September 30, 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 will be effected at an exchange price of $1,000 per share. If the Deerfield Lenders choose to exchange any portion of the Optional Exchange Principal Amount for shares of common stock, such exchange will be effected at an exchange price equal to the greater of (i) $0.9494, or (ii) the average of the volume-weighted average price of the common stock on the 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 September 30, 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 Current Purchase Agreement, (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 September 30, 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.

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.

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, that the Company will ultimately apply for forgiveness, or that any amount of the PPP Loan will ultimately be forgiven by the SBA.

D. Commitments and Contingencies

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 September 30, 2020 and December 31, 2019, no accruals have been made related to commitments and contingencies.

E. Preferred Stock and Warrants

Authorized, Issued, and Outstanding Preferred Stock

As of September 30, 2020 and December 31, 2019, the Company had 10,000,000 shares of authorized preferred stock, of which 9,578 shares were designated as Series A Preferred Stock, 1,576 shares were designated as Series B-1 Preferred Stock and 27,000 shares were designated as Series B-2 Preferred Stock. Of the designated preferred stock 9,577 shares of Series A Preferred Stock and 1,576 shares of Series B-1 Preferred Stock were issued as of September 30, 2020 and December 31, 2019. No shares of Series A Preferred Stock or Series B-1 Preferred Stock were outstanding as of September 30, 2020 and December 31, 2019. No shares of Series B-2 Preferred Stock were issued or outstanding as of September 30, 2020 and December 31, 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 September 30, 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 September 30, 2020 all issued shares of Series B-1 Preferred Stock have been converted into shares of common stock.

F. Common Stock and Warrants

Authorized, Issued, and Outstanding Common Shares

As of September 30, 2020 and December 31, 2019, the Company had authorized shares of common stock of 250,000,000 shares. Of the authorized shares, 4,532,039 and 2,271,833 shares of common stock were issued and outstanding as of September 30, 2020 and December 31, 2019, respectively.

As of September 30, 2020 and December 31, 2019, the Company had reserved authorized shares of common stock for future issuance as follows:

	September 30, 2020	December 31, 2019
Conversion of Deerfield Convertible Note	79,748	75,850
Conversion of 2021 Notes	—	10,958
Conversion of January 2020 Note	34,037	—
Conversion of December 2019 Notes not subject to the Deerfield Optional Conversion Feature	615,307	199,172
Outstanding awards under equity incentive plans	354,379	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	50,273	5,325
Total common shares reserved for future issuance	1,285,186	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

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Common Stock Activity

The following table summarizes common stock activity for the nine months ended September 30, 2020:

	Shares of Common Stock
Balance as of December 31, 2019	2,271,833
Common stock issued under equity line of credit	269,289
Restricted stock vested during the period	3,806
Common stock issued as compensation to third-parties	2,484
Common stock issued as a result of Deerfield Optional Conversion Feature conversion	1,000,000
Balance as of March 31, 2020	3,547,412
Common stock issued under equity line of credit	309,971
Restricted stock vested during the period	4,015
Common stock issued as compensation to third-parties	11,873
Common stock issued as a result of Deerfield Optional Conversion Feature conversion	328,125
Balance as of June 30, 2020	4,201,396
Restricted stock vested during the period	1,384
Common stock issued as compensation to third-parties	4,668
Common stock issued as a result of Deerfield Optional Conversion Feature conversion	324,312
Common stock issued as a result of stock option exercise	279
Balance as of September 30, 2020	4,532,039

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 E). 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. 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 unaudited condensed 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 H).

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.

G. 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 September 30, 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, 2020, the common stock reserved for issuance under the 2014 Plan automatically increased by 90,876 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 three and nine months ended September 30, 2020, RSAs were granted for a total of 1,384 and 9,205 shares of common stock.

During the second quarter of 2019, the Company granted to each non-employee member of the Company's board of directors (each a "non-employee Director") two separate fully vested 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 three and nine months ended September 30, 2019, RSAs were granted for a total of 5,104 shares of common stock. No RSAs were granted during the three months ended September 30, 2019.

During the three and nine months ended September 30, 2020, stock options were exercised for a total of 279 shares of common stock. No stock options were exercised during the three and nine months ended September 30, 2019.

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

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Research and development	$ 157	$ 400	$ 748	$1,196
General and administrative	228	657	866	2,468
Severance expense	—	—	420	—
Total stock-based compensation expense	$ 385	$ 1,057	$2,034	$3,664

There was $0.3 million of stock-based compensation expense related to performance-based awards recognized during the three and nine months ended September 30, 2020. There was no stock-based compensation expense related to performance-based awards recognized during the three months ended September 30, 2020 or the three and nine months ended September 30, 2019.

H. Fair Value of Financial Instruments

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

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

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

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

The fair value of the Deerfield Convertible Note was $6.9 million and $6.0 million, respectively, as of September 30, 2020 and December 31, 2019. The fair value of the December 2019 Notes was $52.9 million and $57.0 million, respectively, as of September 30, 2020 and December 31, 2019. The fair value of the January 2020 Note was $2.9 million as of September 30, 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 September 30, 2020 and December 31, 2019. The Company also used a Tsiveriotis-Fernandes model to value the January 2020 Note as of September 30, 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 September 30, 2020 and December 31, 2019 (in thousands):

	Balance as of September 30, 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	$ 134	$ —	$ —	$ 134
Embedded Warrant Put Option	19	—	—	19
Deerfield Note Put Option	—	—	—	—
KVK Warrant liability	31	—	31	—
Total liabilities	$ 184	$ —	$ 31	$ 153

	Balance as of 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
Deerfield Note Put Option	—	—	—	—
Fundamental change and make-whole interest provisions embedded within 2021 Notes	—	—	—	—
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 make-whole interest provisions embedded in the 2021 Notes are measured at fair value on a recurring basis. As of September 30, 2020 and December 31, 2019, the Deerfield Warrant liability, embedded Warrant Put Option and embedded Deerfield Note Put Option are reported on the unaudited condensed balance sheets in derivative and warrant liability. As of December 31, 2019, the fundamental change and make-whole interest provisions embedded in the 2021 Notes is reported on the balance sheet 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 September 30, 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 unaudited condensed statements of operations for the three and nine months ended September 30, 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 unaudited condensed statements of operations for the three and nine months ended September 30, 2019 as a fair value adjustment related to derivative and warrant liability.

The Company's KVK Warrant liability is measured at fair value on a recurring basis. As of September 30, 2020 and December 31, 2019, the KVK Warrant liability is reported on the unaudited condensed 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 unaudited condensed statements of operations for the three and nine months ended September 30, 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):

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Balance as of beginning of period	$ 38	$ 1,437	$ 96	$ 1,845
Adjustment to fair value	115	(1,168)	57	(1,576)
Balance as of end of period	$ 153	$ 269	$ 153	$ 269

I. Net (Loss) Income 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) income 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) income 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) income per share of common stock during the period.

Diluted net loss per share of common stock is the same as basic net loss per share of common stock for the three and nine months ended September 30, 2020 and the nine months ended September 30, 2019 because the effects of potentially dilutive items were anti-dilutive for the respective periods. For the three months ended September 30, 2020, certain dilutive items were anti-dilutive for the period and are presented in the table immediately below. 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:

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Deerfield Convertible Note	79,748	74,557	79,748	74,557
2021 Notes*	—	1,947,924	—	1,947,924
January 2020 Note	34,037	—	34,037	—
December 2019 Notes	615,307	—	615,307	—
Awards under equity incentive plans	354,379	288,770	354,379	288,770
Common stock warrants	151,442	31,250	151,442	151,442
Series A Convertible Preferred Stock	—	—	—	69,521
Series B-1 Convertible Preferred Stock	—	—	—	51,941
Total securities excluded from the calculation of weighted average number of shares of common stock outstanding	1,234,913	2,342,501	1,234,913	2,584,155

* Inclusive 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.

The items which were dilutive for the three months ended September 30, 2019 are included in the reconciliation of basic net income per share of common stock to diluted net income per share of common stock below.

	Three months ended September 30, 2019
Basic net income per share of common stock:	
Net income	$ 3,063
Less: Net income attributable to participating securities	(348)
Net income attributable to shares of common stock	**2,715**
Less: Dividends declared or accumulated	—
Undistributed net income attributable to shares of common stock, basic	**$ 2,715**
Weighted average number of shares of common stock outstanding	1,883
Basic net income per share of common stock	**$ 1.44**
Diluted net income per share of common stock:	
Net income	$ 3,063
Less: Fair value adjustment income related to Deerfield Warrant liability	(1,019)
Less: Fair value adjustment income related to embedded Warrant Put Option	(135)
Less: Fair value adjustment income related to KVK Warrant liability	—
Net income attributable to shares of common stock, diluted	**$ 1,909**
Weighted average number of shares of common stock outstanding	1,883
Dilutive effect of Deerfield Warrant	—
Dilutive effect of Series A Preferred	70
Dilutive effect of Series B-1 Preferred	27
Weighted average number of shares of common stock outstanding, diluted	**1,980**
Diluted net income per share of common stock	**$ 0.96**

J. 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 unaudited condensed statements of operations for the nine months ended September 30, 2020. As of September 30, 2020, the Company had accrued severance expense recorded within accounts payable and accrued expenses in the amount of $0.1 million. As of September 30, 2019, there was no accrued severance. For the three months ended September 30, 2020 and three and nine months ended September 30, 2019 there was no severance expense.

K. Leases

The Company has operating and finance leases for office space, laboratory facilities and various laboratory equipment, furniture and office equipment and leasehold improvements. The Company's leases have remaining lease terms of less than 1 year to approximately 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. 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 payment, due to financial difficulties encountered by the subtenant as a result of COVID-19.

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

Lease Cost	Three months ended September 30, 2020	Three months ended September 30, 2019	Nine months ended September 30, 2020	Nine months ended September 30, 2019
Finance lease cost:				
Amortization of right-of-use assets	$ 31	$ 31	$ 92	$ 92
Interest on lease liabilities	4	9	19	31
Total finance lease cost	35	40	111	123
Operating lease cost	91	124	272	372
Short-term lease cost	49	58	160	173
Variable lease cost	14	14	41	35
Less: sublease income	(40)	(25)	(93)	(75)
Total lease costs	$ 149	$ 211	$ 491	$ 628

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

	Nine months ended September 30, 2020	Nine months ended September 30, 2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from finance leases	$ 19	$ 31
Financing cash flows from finance leases	168	157
Operating cash flows from operating leases	334	326
Operating cash flows from short-term leases	160	173
Operating cash flows from variable lease costs	41	35
Right-of-use assets obtained in exchange for lease liabilities:		
Finance leases	$ —	$ 737
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):

	September 30, 2020	December 31, 2019
Finance Leases		
Property and equipment, at cost	$ 1,013	$ 1,013
less: accumulated depreciation and amortization	(490)	(398)
Property and equipment, net	$ 523	$ 615
Other current liabilities	$ 214	$ 236
Other long-term liabilities	22	168
Total finance lease liabilities	$ 236	$ 404
Operating Leases		
Operating lease right-of-use assets	$ 1,357	$ 1,537
Total operating lease right-of-use assets	$ 1,357	$ 1,537
Current portion of operating lease liabilities	$ 318	$ 284
Operating lease liabilities, less current portion	1,673	1,901
Total operating lease liabilities	$ 1,991	$ 2,185
Weighted Average Remaining Lease Term		
Finance leases (years)	1	2
Operating leases (years)	5	6
Weighted Average Discount Rate		
Finance leases	7.8%	7.7%
Operating leases	7.5%	7.5%

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

	Finance Leases	Operating Leases
Year Ending December 31,		
2020 (excluding the nine months ended September 30, 2020)	$ 73	$ 114
2021	163	460
2022	11	463
2023	—	472
2024	—	484
Thereafter	—	420
Total lease payments	247	2,413
Less: future interest expense	(11)	(422)
Lease liabilities	$ 236	$ 1,991

K. Subsequent Events

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) upon closing of this offering 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.

4,784,688 Shares of Common Stock
Warrants to Purchase up to 4,784,688 Shares of Common Stock
Pre-Funded Warrants to Purchase Shares of Common stock

PROSPECTUS

Roth Capital Partners

The date of this prospectus is , 2021

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the estimated costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the offering of the securities being registered. All the amounts shown are estimates, except for the SEC registration fee.

SEC registration fee	$ 13,714
FINRA filing fee	18,613
Accounting fees and expenses	65,000
Legal fees and expenses	400,000
Transfer agent, trustee, printing and miscellaneous expenses	50,000
Miscellaneous expenses	12,673
Total	$560,000

Item 14. Indemnification of Directors and Officers.

Under Section 145 of the Delaware General Corporation Law, or DGCL, we have broad powers to indemnify our directors and officers against liabilities they may incur in such capacities, including liabilities under the Securities Act of 1933, as amended, or the Securities Act. Section 145 of the DGCL generally provides that a Delaware corporation has the power to indemnify its present and former directors, officers, employees and agents against expenses incurred by them in connection with any suit to which they are, or are threatened to be made, a party by reason of their serving in such positions so long as they acted in good faith and in a manner they reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action, they had no reasonable cause to believe their conduct was unlawful.

Our amended and restated certificate of incorporation and amended and restated bylaws include provisions that (i) eliminate the personal liability of our directors for monetary damages resulting from breaches of their fiduciary duty to the fullest extent permitted under applicable law, (ii) require us to indemnify our directors and executive officers to the fullest extent permitted by the DGCL or other applicable law and (iii) provide us with the power, in our discretion, to indemnify our other officers, employees and other agents as set forth in the DGCL or other applicable law. We believe that these provisions of our amended and restated certificate of incorporation and amended and restated bylaws are necessary to attract and retain qualified persons as directors and officers. These provisions do not eliminate our directors' or officers' duty of care, and, in appropriate circumstances, equitable remedies such as injunctive or other forms of non-monetary relief will remain available under the DGCL. In addition, each director will continue to be subject to liability pursuant to Section 174 of the DGCL, for breach of such director's duty of loyalty to us, for acts or omissions not in good faith or involving intentional misconduct, for knowing violations of law, for acts or omissions that such director believes to be contrary to our best interests or the best interests of our stockholders, for any transaction from which such director derived an improper personal benefit, for acts or omissions involving a reckless disregard for such director's duty to us or to our stockholders when such director was aware or should have been aware of a risk of serious injury to us or to our stockholders, for acts or omission that constitute an unexcused pattern of inattention that amounts to an abdication of such director's duty to us or to our stockholders, for improper transactions between such director and us and for improper loans to directors and officers. These provisions also do not affect a director's responsibilities under any other law, such as the federal securities laws or state or federal environmental laws.

As permitted by Delaware law, we have entered into indemnification agreements with each of our current directors and officers pursuant to the foregoing provisions. We have an insurance policy covering our officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act or otherwise.

The underwriting agreement, if any, entered into with respect to an offering of securities registered hereunder will provide for indemnification by any underwriters of any offering, our directors and officers who sign the registration statement and our controlling persons for some liabilities, including liabilities arising under the Securities Act.

Item 16. Exhibits and Financial Statement Schedules.

The exhibits to the registration statement are listed in the Exhibit Index attached hereto and are incorporated by reference herein.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

- (i) To include any prospectus required by Section 10(a)(3) of the Securities Act;
- (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the “Calculation of Registration Fee” table in the effective registration statement; and
- (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that the undertakings set forth in paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are incorporated by reference in this registration statement or are contained in a form of prospectus filed pursuant to Rule 424(b) that is part of this registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities

of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser: (i) any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424; (ii) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant; (iii) the portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and (iv) any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(5) That, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(6) That for purposes of determining any liability under the Securities Act, (i) the information omitted from the form of prospectus filed as part of the registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the registrant pursuant to Rule 424(b)(l) or (4) or 497(h) under the Securities Act shall be deemed to be a part of the registration statement as of the time it was declared effective; and (ii) each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offing of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

Table of Contents

EXHIBIT INDEX

Exhibit No.	Description
1.1	Form of Underwriting Agreement.
3.1	Amended and Restated Certificate of Incorporation of KemPharm, Inc. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on April 21, 2015).
3.1.1	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of KemPharm, Inc. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on October 5, 2018).
3.1.2	Certificate of Designation of Preferences, Rights and Limitations of Series B-1 Convertible Preferred Stock of KemPharm, Inc. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on September 4, 2019).
3.1.3	Certificate of Designation of Preferences, Rights and Limitations of Series B-2 Convertible Preferred Stock of KemPharm, Inc. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on September 4, 2019).
3.1.4	Form of Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series B-2 Convertible Preferred Stock (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on December 21, 2020).
3.1.5	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on December 26, 2020)
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 17, 2020).
4.1	Reference is made to Exhibits 3.1 and 3.2 hereof.
4.2	Specimen stock certificate evidencing shares of Common Stock (incorporated herein by reference to the Registrant's Amendment No. 2 to Registration Statement on Form S-1/A (File No. 333-202660) as filed with the SEC on April 9, 2015).
4.3	Senior Secured Convertible Note, dated as of January 13, 2020 (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on January 13, 2020).
4.4	Registration Rights Agreement dated February 17, 2020 by and between the Registrant and Lincoln Park Capital Fund, LLC (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on February 18, 2020).
4.5	Form of Senior Secured Convertible Note, with a schedule of noteholders (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on December 18, 2019).
4.6	Amended and Restated Senior Secured Convertible Note issued to Deerfield Private Design Fund III, L.P., dated as of December 18, 2019 (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on December 18.2019).
4.7	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).
4.8+	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).
4.9	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.9 of the Registrant's Annual Report on Form 10-K as filed with the SEC on February 28, 2020).

4.10◇	Form of Common Stock Warrant
4.11◇	Form of Pre-Funded Warrant
5.1	Opinion of Cooley LLP
10.1+	Material Supply Agreement, by and between the Registrant and Johnson Matthey, Inc., dated as of November 2, 2009 (incorporated by reference Registrant's Amendment No. 1 to Registration Statement on Form S-1/A (File No. 333-202660) as filed with the SEC on April 3, 2015).
10.2	Facility Agreement, by and between the Registrant and Deerfield Private Design Fund III, L.P., dated as of June 2, 2014 (incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.2.1	First Amendment to Facility Agreement, Senior Secured Convertible Note and Warrant, by and between Registrant and Deerfield Private Design Fund III, L.P., dated March 6, 2015 (incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.2.2	Second Amendment to Facility Agreement by and between Registrant and Deerfield Private Design Fund III, L.P., dated December 17, 2015 (incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-208633) as filed with the SEC on December 18, 2015).
10.2.3	Third Amendment to Facility Agreement, Senior Secured Convertible Note and Warrant, by and between Registrant and Deerfield Private Design Fund III, L.P., dated February 3, 2016 (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on February 9, 2016).
10.2.4	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated June 3, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 13, 2019).
10.2.5	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated June 17, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 13, 2019)
10.2.6	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated June 24, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 13, 2019)
10.2.7	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated June 28, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 13, 2019)
10.2.8	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated July 15, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 13, 2019)
10.2.9	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated July 31, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 13, 2019)
10.2.10	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated August 9, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 13, 2019)
10.2.11	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated August 16, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on November 14, 2019)
10.2.12	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated August 23, 2019. (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on November 14, 2019)

10.2.13	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated August 30, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on November 14, 2019)
10.3	Senior Secured Convertible Note issued to Deerfield Private Design Fund III, L.P., dated as of June 2, 2014 (incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.3.1	Second Amendment to Senior Secured Convertible Note and Warrant, by and between Registrant and Deerfield Private Design Fund III, L.P., dated January 6, 2016 (incorporated by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on January 11, 2016).
10.3.2	Fourth Amendment to Senior Secured Convertible Note and Warrant, effective as of October 3, 2016, by and between KemPharm, Inc. and Deerfield Private Design Fund III, L.P. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on October 3, 2016).
10.3.3	Facility Agreement Waiver and Fifth Amendment to Senior Secured Convertible Note by and between Registrant and Deerfield Private Design Fund III, L.P., dated as of June 11, 2018 (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on June 11, 2018).
10.3.4	Amendment to Convertible Note and Warrant Agreement, dated November 20, 2018, between the Company and Deerfield Private Design Fund III, L.P. (as incorporated herein by reference to the Company's Current Report on Form 8-K filed with the SEC on November 20, 2018).
10.3.5	Seventh Amendment to Senior Secured Convertible Note and Sixth Amendment to Warrant, dated February 28, 2019, between the Company and Deerfield Private Design Fund III, L.P. (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 1, 2019).
10.3.6	Amendment to December 2019 Notes and Consent, dated as of January 12, 2020, by and among the Registrant and the signatories party thereto (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on January 13, 2020)
10.3.7	Amendment to Senior Secured Convertible Notes and Amendment to Warrant, dated as of February 17, 2020, by and among Registrant and the noteholders party thereto (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on February 18, 2020)
10.4	Amended and Restated Investors' Rights Agreement, dated as of February 19, 2015, by and among the Registrant and certain of its stockholders (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015).
10.5+	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).
10.6#	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).
10.6.1#	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).
10.6.2#	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#	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).

10.7.1#	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).
10.7.2#	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).
10.7.3#	Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under 2014 Equity Incentive Plan (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on May 14, 2019)
10.8#	Fifth Amended and Restated Non-Employee Director Compensation Policy (incorporated by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on June 24, 2020)
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 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).
10.11.1#	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).
10.12#	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).
10.13	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).
10.13.1	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).
10.13.2	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).
10.13.3	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).
10.14	Common Stock Sales Agreement, dated September 4, 2018, by and between KemPharm, Inc. and RBC Capital Markets, LLC (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on September 4, 2018).
10.15+	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).

10.16	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	September 2019 Exchange Agreement and Amendment to Facility Agreement, dated as of September 3, 2019, by and among KemPharm, Inc., Deerfield Private Design Fund III, L.P. and Deerfield Special Situations Fund, L.P. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on September 4, 2019)
10.17.1	Amendment to September 2019 Exchange Agreement and Amendment to Facility Agreement, dated as of December 17, 2019, by and among KemPharm, Inc., Deerfield Private Design Fund III, L.P. and Deerfield Special Situations Fund, L.P. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on December 18.2019)
10.18+	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)
10.19	December 2019 Exchange Agreement and Amendment to Facility Agreement, Senior Secured Convertible Notes and Warrants, dated as of December 17, 2019, by and among KemPharm, Inc., Deerfield Private Design Fund III, L.P., Deerfield Special Situations Fund, L.P. and Delaware Street Capital Master Fund, L.P. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on December 18, 2019)
10.20	Amended and Restated Guaranty and Security Agreement, dated as of December 18, 2019, by and among KemPharm, Inc., each other Grantor party thereto, each Guarantor party thereto and Deerfield Private Design Fund III, L.P., as collateral agent (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on December 18, 2019)
10.21	December 2020 Exchange Agreement and Amendment to Facility Agreement, Notes and Investors' Rights Agreement (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on December 21, 2020).
10.22	Amendment to Facility Agreement, Notes and to December 2020 Exchange Agreement, dated as of December 24, 2020, by and among the Registrant, Deerfield Private Design Fund III, L.P. and Deerfield Special Situations Fund, L.P. (incorporated herein by reference to the Registrant's Current on Form 8-K as filed on December 28, 2020).
10.23	Joinder Agreement, dated as of December 23, 2020, by and between the Registrant and Delaware Street Capital Master Fund, L.P. (incorporated herein by reference to the Registrant's Current on Form 8-K as filed on December 28, 2020).
10.24	Joinder Agreement, dated as of December 23, 2020, by and between the Registrant and M. Kingdon Offshore Master Fund, LP (incorporated herein by reference to the Registrant's Current on Form 8-K as filed on December 28, 2020).
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	Consent of Cooley LLP (included in Exhibit 5.1).
24.1◇	Power of Attorney (see signature page to this registration statement)
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

◇ Previously filed.

# 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.

SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant has duly caused this Amendment No. 3 to Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Celebration, State of Florida, on the 5th day of January, 2021.

KEMPHARM, INC.

By: /s/ Travis C. Mickle
Travis C. Mickle, Ph.D.
President, Chief Executive Officer and
Chairman of the Board of Directors
(Principal Executive Officer)

Pursuant to the requirements of the Securities Act of 1933, as amended, this Amendment No. 3 to Registration Statement has been signed by the following persons 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)	January 5, 2021
/s/ R. LaDuane Clifton R. LaDuane Clifton, CPA	Chief Financial Officer, Secretary and Treasurer (Principal Financial Officer)	January 5, 2021
/s/ Timothy J. Sangiovanni Timothy J. Sangiovanni, CPA	Vice President, Corporate Controller (Principal Accounting Officer)	January 5, 2021
* Matthew R. Plooster	Director	January 5, 2021
* Richard W. Pascoe	Director	January 5, 2021
* Joseph B. Saluri	Director	January 5, 2021
* David S. Tierney	Director	January 5, 2021

*By: /s/ R. LaDuane Clifton
R. LaDuane Clifton, CPA
Attorney-in-Fact

Exhibit 1.1

____________ SHARES OF COMMON STOCK,

_____________ SERIES B WARRANTS (EXERCISABLE FOR _________SHARES)

AND

_____________ SERIES A WARRANTS (EXERCISABLE FOR _________SHARES)

OF

KEMPHARM, INC.

UNDERWRITING AGREEMENT

_______ _, 2021

Roth Capital Partners, LLC
As the Representative of the
Several underwriters, if any, named in Schedule I hereto
c/o Roth Capital Partners, LLC
888 San Clemente Drive, Suite 400
Newport Beach, CA 92660

Ladies and Gentlemen:

The undersigned, KemPharm, Inc., a company incorporated under the laws of Delaware (collectively with its subsidiaries and affiliates, including, without limitation, all entities disclosed or described in the Registration Statement as being subsidiaries or affiliates of KemPharm, Inc., the "Company"), hereby confirms its agreement (this "Agreement") with the several underwriters (such underwriters, including the Representative (as defined below), the "Underwriters" and each an "Underwriter") named in Schedule I hereto for which Roth Capital Partners, LLC is acting as representative to the several Underwriters (the "Representative" and if there are no Underwriters other than the Representative, references to multiple Underwriters shall be disregarded and the term Representative as used herein shall have the same meaning as Underwriter) on the terms and conditions set forth herein.

It is understood that the several Underwriters are to make a public offering of the Public Securities as soon as the Representative deems it advisable to do so. The Public Securities are to be initially offered to the public at the public offering price set forth in the Prospectus.

It is further understood that you will act as the Representative for the Underwriters in the offering and sale of the Closing Securities and, if any, the Option Securities in accordance with this Agreement.

ARTICLE I.
DEFINITIONS

1.1 Definitions. In addition to the terms defined elsewhere in this Agreement, for all purposes of this Agreement, the following terms have the meanings set forth in this Section 1.1:

"Affiliate" means with respect to any Person, any other Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with such Person as such terms are used in and construed under Rule 405 under the Securities Act.

"Business Day" means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; provided, however, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to "stay at home", "shelter-in-place", "non-essential employee" or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York generally are open for use by customers on such day.

"Closing" means the closing of the purchase and sale of the Closing Securities pursuant to Section 2.1.

"Closing Date" means the hour and the date on the Trading Day on which all conditions precedent to (i) the Underwriters' obligations to pay the Closing Purchase Price and (ii) the Company's obligations to deliver the Closing Securities, in each case, have been satisfied or waived, but in no event later than 10:00 a.m. (New York City time) on the second (2nd) Trading Day following the date hereof or at such earlier time as shall be agreed upon by the Representative and the Company.

"Closing Purchase Price" shall have the meaning ascribed to such term in Section 2.1(b), which aggregate purchase price shall be net of the underwriting discounts and commissions.

"Closing Securities" shall have the meaning ascribed to such term in Section 2.1(a)(ii).

"Closing Shares" shall have the meaning ascribed to such term in Section 2.1(a)(i).

"Closing Warrants" shall have the meaning ascribed to such term in Section 2.1(a)(ii).

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the common stock of the Company, par value $0.0001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Equivalents" means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Company Auditor" means RSM US LLP, with offices located in Orlando, Florida.

"Company Counsel" means Cooley LLP, with offices located at 1299 Pennsylvania Avenue, NW, Suite 700, Washington, DC 20004-2400

"Effective Date" shall have the meaning ascribed to such term in Section 3.1(f).

"EGS" means Ellenoff Grossman & Schole LLP, with offices located at 1345 Avenue of the Americas, New York, New York 10105.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Execution Date" shall mean the date on which the parties execute and enter into this Agreement.

"Exempt Issuance" means the issuance of (a) shares of Common Stock or options to employees, officers or directors of the Company pursuant to any stock or option plan duly adopted for such purpose by a majority of the non-employee members of the Board of Directors or a majority of the members of a committee of non-employee directors established for such purpose, (b) securities upon the exercise or exchange of or conversion of any Securities issued hereunder and/or other securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date of this Agreement, provided that such securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities (except for such decreases in exercise, exchange or conversion price in accordance with the terms of such securities) or to extend the term of such securities, (c) securities pursuant to the terms of that certain December 2020 Exchange Agreement and Amendment to Facility Agreement, Notes and Investors' Rights Agreement, dated as of December 20, 2020, by and among the Company and the other parties thereto, as amended as of the date hereof, or upon the exercise or exchange of or conversion of any securities issued pursuant to such agreement, provided that such securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities (except for such decreases in exercise, exchange or conversion price in accordance with the terms of such securities) or to extend the term of such securities, and (d) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, provided that such securities are issued as "restricted securities" (as defined in Rule 144) and carry no registration rights that require or permit the filing of any registration statement in connection therewith within 90 days following the Closing Date, and provided that any such issuance shall only be to a Person (or to the equity holders of a Person) which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

"FINRA" means the Financial Industry Regulatory Authority.

“GAAP” shall have the meaning ascribed to such term in Section 3.1(i).

“Indebtedness” means (a) any liabilities for borrowed money or amounts owed in excess of $50,000 (other than trade accounts payable incurred in the ordinary course of business), (b) all guaranties, endorsements and other contingent obligations in respect of indebtedness of others, whether or not the same are or should be reflected in the Company’s consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (c) the present value of any lease payments in excess of $50,000 due under leases required to be capitalized in accordance with GAAP.

“Liens” means a lien, charge, pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

“Lock-Up Agreements” means the lock-up agreements that are delivered on the date hereof by each of the Company’s officers and directors, in the form of Exhibit F attached hereto.

“Material Adverse Effect” means (i) a material adverse effect on the legality, validity or enforceability of any Transaction Document, (ii) a material adverse effect on the results of operations, assets, business, prospects or condition (financial or otherwise) of the Company and the Subsidiaries, taken as a whole or (iii) a material adverse effect on the Company’s ability to perform in any material respect on a timely basis its obligations under any Transaction Document.

“Offering” shall have the meaning ascribed to such term in Section 2.1(c).

“Option Closing Date” shall have the meaning ascribed to such term in Section 2.2(c).

“Option Closing Purchase Price” shall have the meaning ascribed to such term in Section 2.2(b), which aggregate purchase price shall be net of the underwriting discounts and commissions.

“Option Securities” shall have the meaning ascribed to such term in Section 2.2(a)(ii).

“Option Shares” shall have the meaning ascribed to such term in Section 2.2(a)(i).

“Option Warrants” shall have the meaning ascribed to such term in Section 2.2(a).

“Over-Allotment Option” shall have the meaning ascribed to such term in Section 2.2.

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Preliminary Prospectus" means, if any, any preliminary prospectus relating to the Securities included in the Registration Statement or filed with the Commission pursuant to Rule 424(b).

"Proceeding" means an action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced or threatened.

"Prospectus" means the final prospectus filed for the Registration Statement.

"Prospectus Supplement" means, if any, any supplement to the Prospectus complying with Rule 424(b) of the Securities Act that is filed with the Commission.

"Public Securities" means, collectively, the Closing Securities and, if any, the Option Securities.

"Registration Statement" means, collectively, the various parts of the registration statement prepared by the Company on Form S-1 (File No. 333-250495) with respect to the Securities, each as amended as of the date hereof, including the Prospectus and Prospectus Supplement, if any, the Preliminary Prospectus, if any, and all exhibits filed with or incorporated by reference into such registration statement, and includes any Rule 462(b) Registration Statement.

"Required Approvals" shall have the meaning ascribed to such term in Section 3.1(e).

"Rule 424" means Rule 424 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

"Rule 462(b) Registration Statement" means any registration statement prepared by the Company registering additional Public Securities, which was filed with the Commission on or prior to the date hereof and became automatically effective pursuant to Rule 462(b) promulgated by the Commission pursuant to the Securities Act.

"SEC Reports" shall have the meaning ascribed to such term in Section 3.1(i).

"Securities" means the Closing Securities, the Option Securities and the Warrant Shares.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Series A Warrants" means the Series A Common Stock purchase warrants delivered to the Underwriters in accordance with Section 2.1(a) and Section 2.2(a).

“Series B Warrants” means the Series B Pre-funded Common Stock purchase warrants delivered to the Underwriters in accordance with Section 2.1(a).

“Share Purchase Price” shall have the meaning ascribed to such term in Section 2.1(b).

“Shares” means, collectively, the shares of Common Stock delivered to the Underwriters in accordance with Section 2.1(a)(i) and Section 2.2(a).

“Subsidiary” means any subsidiary of the Company and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

“Trading Day” means a day on which the principal Trading Market is open for trading.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

“Transaction Documents” means this Agreement, the Warrants, the Lock-Up Agreements, and any other documents or agreements executed in connection with the transactions contemplated hereunder.

“Transfer Agent” means Computershare Trust Company, N.A., with offices located at 144 Fernwood Avenue, Edison, New Jersey 08837, and any successor transfer agent of the Company.

“Warrant Purchase Price” shall have the meaning ascribed to such term in Section 2.1(b).

“Warrant Shares” means the shares of Common Stock issuable upon exercise of the Warrants.

“Warrants” means, collectively, the Series A Warrants and the Series B Warrants.

ARTICLE II.
PURCHASE AND SALE

2.1 Closing.

(a) Upon the terms and subject to the conditions set forth herein, the Company agrees to sell in the aggregate (i) ________ shares of Common Stock, (ii) Series B Warrants exercisable for an aggregate of ________ shares of Common Stock, and (iii) Series A Warrants exercisable for an aggregate of ________ shares of Common Stock, and each Underwriter agrees to purchase, severally and not jointly, at the Closing, the following securities of the Company:

(i) the number of shares of Common Stock (the “Closing Shares”) set forth opposite the name of such Underwriter on Schedule I hereof;

(ii) Series B Warrants to purchase up to the number of shares of Common Stock set forth opposite the name of such Underwriter on Schedule I hereof, which shall have an exercise price equal to $0.0001 (subject to adjustment therein), and shall be exercisable immediately following their issuance and at any time thereafter, which warrants shall be in the form of Exhibit D-2 hereto (collectively, with the Series A Warrants delivered at Closing, the "Closing Warrants" and, collectively with the Closing Shares, the "Closing Securities"); and

(iii) Series A Warrants to purchase up to the number of shares of Common Stock equal to the sum of the number of Closing Shares and Series B Warrants set forth opposite the name of such Underwriter on Schedule I hereof, which shall have an exercise price of **$____** (subject to adjustment as provided therein), and shall be exercisable immediately following their issuance and have a term of exercise of ___ years, which warrants shall be in the form of Exhibit D-1 hereto.

(b) The aggregate purchase price for the Closing Securities shall equal the amount set forth opposite the name of such Underwriter on Schedule I hereto (the "Closing Purchase Price"). The combined purchase price for one Share and a Series A Warrant to purchase ___ Warrant Share shall be $___ which shall be allocated as $_____ per Share (the "Share Purchase Price") and $_____ per Series A Warrant (the "Warrant Purchase Price"). The combined purchase price for one Series B Warrant and a Series A Warrant to purchase ___ Warrant Share shall be $___ which shall be allocated as $_____ per Series B Warrant and $_____ per Series A Warrant.

(c) On the Closing Date, each Underwriter shall deliver or cause to be delivered to the Company, via wire transfer, immediately available funds equal to such Underwriter's Closing Purchase Price and the Company shall deliver to, or as directed by, such Underwriter its respective Closing Securities and the Company shall deliver the other items required pursuant to Section 2.3 deliverable at the Closing. Upon satisfaction of the covenants and conditions set forth in Sections 2.3 and 2.4, the Closing shall occur at the offices of EGS or such other location as the Company and Representative shall mutually agree. The Public Securities are to be offered initially to the public at the offering price set forth on the cover page of the Prospectus (the "Offering").

(d) The Company acknowledges and agrees that, with respect to any Notice(s) of Exercise (as defined in the Series A Warrants and the Series B Warrants, as applicable) delivered by a Holder (as defined in the Series A Warrants and Series B Warrants, as applicable) on or prior to 12:00 p.m. (New York City time) on the Closing Date, which Notice(s) of Exercise may be delivered at any time after the time of execution of this Agreement, the Company shall deliver the Warrant Shares (as defined in the Series A Warrants and Series B Warrants, as applicable) subject to such notice(s) to the Holder by 4:00 p.m. (New York City time) on the Closing Date. The Company acknowledges and agrees that the Holders are third-party beneficiaries of this covenant of the Company.

2.2 Over-Allotment Option.

(a) For the purposes of covering any over-allotments in connection with the distribution and sale of the Closing Securities, the Representative is hereby granted an option (the "Over-Allotment Option") to purchase, in the aggregate, up to _____ shares of Common Stock (the "Option Shares") and Series A Warrants to purchase up to ____ shares of Common Stock (the "Option Warrants" and, collectively with the Option Shares, the "Option Securities") which may be purchased in any combination of Option Shares and/or Option Warrants at the Share Purchase Price and/or Warrant Purchase Price, respectively.

(b) In connection with an exercise of the Over-Allotment Option, (a) the purchase price to be paid for the Option Shares is equal to the product of the Share Purchase Price multiplied by the number of Option Shares to be purchased and (b) the purchase price to be paid for the Option Warrants is equal to the product of the Warrant Purchase Price multiplied by the number of Option Warrants to be purchased (the aggregate purchase price to be paid on an Option Closing Date, the "Option Closing Purchase Price").

(c) The Over-Allotment Option granted pursuant to this Section 2.2 may be exercised by the Representative as to all (at any time) or any part (from time to time) of the Option Securities within forty-five (45) days after the Execution Date. An Underwriter will not be under any obligation to purchase any Option Securities prior to the exercise of the Over-Allotment Option by the Representative. The Over-Allotment Option granted hereby may be exercised by the giving of oral notice to the Company from the Representative, which must be confirmed in writing by overnight mail or facsimile or other electronic transmission setting forth the number of Option Shares and/or Option Warrants to be purchased and the date and time for delivery of and payment for the Option Securities (each, an "Option Closing Date"), which will not be later than two (2) full Business Days after the date of the notice or such other time as shall be agreed upon by the Company and the Representative, at the offices of EGS or at such other place (including remotely by facsimile or other electronic transmission) as shall be agreed upon by the Company and the Representative. If such delivery and payment for the Option Securities does not occur on the Closing Date, each Option Closing Date will be as set forth in the notice. Upon exercise of the Over-Allotment Option, the Company will become obligated to convey to the Underwriters, and, subject to the terms and conditions set forth herein, the Underwriters will become obligated to purchase, the number of Option Shares and/or Option Warrants specified in such notice. The Representative may cancel the Over-Allotment Option at any time prior to the expiration of the Over-Allotment Option by written notice to the Company.

2.3 Deliveries. The Company shall deliver or cause to be delivered to each Underwriter (if applicable) the following:

(i) On the Closing Date, the Closing Shares and, as to each Option Closing Date, if any, the applicable Option Shares, which shares shall be delivered via The Depository Trust Company Deposit or Withdrawal at Custodian system for the accounts of the several Underwriters;

(ii) On the Closing Date, the Closing Warrants and, as to each Option Closing Date, if any, the Option Warrants, in certificated form registered in the name or names and in such authorized denominations as the applicable Underwriter may request in writing at least one Business Day prior to the Closing Date and, if any, each Option Closing Date;

(iii) On the Closing Date, and each Option Closing Date, if any, to the Representative only, a Warrant to purchase up to a number of shares of Common Stock equal to 5.0% of the number of Closing Shares, Series A Warrants, Series B Warrants, Option Shares, and Option Warrants issued on such Closing Date and Option Closing Date, as applicable, for the account of the Representative (or its designees), which Warrant shall have an exercise price of $____, subject to adjustment therein, and registered in the name of the Representative, otherwise on the same terms as the Series A Warrants;

(iv) On the Closing Date, a legal opinion of Company Counsel addressed to the Underwriters, including, without limitation, a negative assurance letter, in form and substance reasonably satisfactory to the Representative;

(v) Contemporaneously herewith, a cold comfort letter, addressed to the Underwriters and in form and substance satisfactory in all respects to the Representative from the Company Auditor dated, respectively, as of the date of this Agreement and a bring-down letter dated as of the Closing Date and each Option Closing Date, if any;

(vi) On the Closing Date and on each Option Closing Date, the duly executed and delivered Officer's Certificate, substantially in the form required by Exhibit B attached hereto;

(vii) On the Closing Date and on each Option Closing Date, the duly executed and delivered Secretary's Certificate, substantially in the form required by Exhibit C attached hereto; and

(viii) Contemporaneously herewith, the duly executed and delivered Lock-Up Agreements.

2.4 Closing Conditions. The respective obligations of each Underwriter hereunder in connection with the Closing and each Option Closing Date are subject to the following conditions being met:

(i) the accuracy in all material respects when made and on the date in question (other than representations and warranties of the Company already qualified by materiality, which shall be true and correct in all respects) of the representations and warranties of the Company contained herein (unless as of a specific date therein);

(ii) all obligations, covenants and agreements of the Company required to be performed at or prior to the date in question shall have been performed;

(iii) the delivery by the Company of the items set forth in Section 2.3 of this Agreement;

(iv) the Registration Statement shall be effective on the date of this Agreement and at each of the Closing Date and each Option Closing Date, if any, no stop order suspending the effectiveness of the Registration Statement shall have been issued and no proceedings for that purpose shall have been instituted or shall be pending or, to the Company's knowledge, contemplated by the Commission and any request on the part of the Commission for additional information shall have been complied with to the reasonable satisfaction of the Representative;

(v) by the Execution Date, if required by FINRA, the Underwriters shall have received clearance from FINRA as to the amount of compensation allowable or payable to the Underwriters as described in the Registration Statement;

(vi) the Closing Shares, the Option Shares and the Warrant Shares have been approved for listing on the Trading Market; and

(vii) prior to and on each of the Closing Date and each Option Closing Date, if any: (i) there shall have been no material adverse change or development involving a prospective material adverse change in the condition or prospects or the business activities, financial or otherwise, of the Company from the latest dates as of which such condition is set forth in the Registration Statement and Prospectus; (ii) no action suit or proceeding, at law or in equity, shall have been pending or threatened against the Company or any Affiliate of the Company before or by any court or federal or state commission, board or other administrative agency wherein an unfavorable decision, ruling or finding could reasonably be expected to result in a Material Adverse Effect on the business, operations, prospects or financial condition or income of the Company, except as set forth in the Registration Statement and Prospectus; and (iii) the Registration Statement and the Prospectus and any amendments or supplements thereto shall contain all material statements which are required to be stated therein in accordance with the Securities Act and the rules and regulations thereunder and shall conform in all material respects to the requirements of the Securities Act and the rules and regulations thereunder, and neither the Registration Statement nor the Prospectus nor any amendment or supplement thereto shall contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

ARTICLE III.
REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of the Company. The Company represents and warrants to the Underwriters as of the Execution Date, as of the Closing Date and as of each Option Closing Date, if any, as follows:

(a) Subsidiaries. The Company currently has no Subsidiaries and all other references to the Subsidiaries or any of them in the Transaction Documents shall be disregarded.

(b) Organization and Qualification. The Company and each of its Subsidiaries is an entity duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, with the requisite corporate power and authority to own and use its properties and assets and to carry on its business as currently conducted. Neither the Company nor any of its Subsidiaries is in violation or default of any of the provisions of its respective certificate of incorporation, bylaws or other organizational or charter documents. Each of the Company and its Subsidiaries is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not have or reasonably be expected to result in a Material Adverse Effect and no proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

(c) Authorization; Enforcement. (i) The Company has the requisite corporate power and authority to enter into and perform its obligations under this Agreement and each of the other Transaction Documents to which it is a party, and to issue the Securities in accordance with the terms hereof and thereof, (ii) the execution and delivery of the Transaction Documents by the Company to which it is a party and the consummation by it of the transactions contemplated hereby and thereby, including without limitation, the issuance of the Public Securities and the reservation for issuance and the issuance of the Warrant Shares issuable under the Warrants, have been duly authorized by the Company's Board of Directors, or a validly authorized committee thereof (collectively, the "Board of Directors"), and no further consent or authorization is required by the Company, its Board of Directors or its stockholders, (iii) this Agreement has been, and each other Transaction Document shall be on the Commencement Date, duly executed and delivered by the Company and (iv) this Agreement constitutes, and each other Transaction Document upon its execution on behalf of the Company, shall constitute, the valid and binding obligations of the Company enforceable against the Company in accordance with their terms, except as such enforceability may be limited by general principles of equity or applicable bankruptcy, insolvency, reorganization, moratorium, liquidation or similar laws relating to, or affecting generally, the enforcement of creditors' rights and remedies. The Board of Directors has passed all applicable resolutions (the "Resolutions") to authorize this Agreement and the transactions contemplated hereby. The Resolutions are valid, in full force and effect and have not been modified or supplemented in any respect. The Company has delivered to the Investor a certified copy of the Resolutions passed by the Board of Directors. Except as set forth in this Agreement, no other approvals or consents of the Board of Directors and/or stockholders is necessary under applicable laws, and the certificate of incorporation and bylaws of the Company, to authorize the execution and delivery of this Agreement or any of the transactions contemplated hereby, including, but not limited to, the issuance of the Securities.

(d) No Conflicts. The execution, delivery and performance of the Transaction Documents by the Company and the consummation by the Company of the transactions contemplated hereby and thereby (including, without limitation, the reservation for issuance and issuance of the Securities) will not (i) result in a violation of the certificate of incorporation, any certificate of designations, preferences and rights of any outstanding series of preferred stock of the Company or the bylaws or (ii) conflict with, or constitute a default (or an event which with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any agreement, indenture or instrument to which the Company or any of its Subsidiaries is a party, or result in a violation of any law, rule, regulation, order, judgment or decree (including federal and state securities laws and regulations and the rules and regulations of the principal Trading Market applicable to the Company or any of its Subsidiaries) or by which any property or asset of the Company or any of its Subsidiaries is bound or affected, except in the case of conflicts, defaults, terminations, amendments, accelerations, cancellations and violations under clause (ii), which could not reasonably be expected to result in a Material Adverse Effect. Neither the Company nor its Subsidiaries is in violation of any term of or in default under its certificate of incorporation, any certificate of designation, preferences and rights of any outstanding series of preferred stock of the Company or bylaws or their organizational charter or bylaws, respectively. Neither the Company nor any of its Subsidiaries is in violation of any term of or is in default under any material contract, agreement, mortgage, indebtedness, indenture, instrument, judgment, decree or order or any statute, rule or regulation applicable to the Company or its Subsidiaries, except for possible conflicts, defaults, terminations or amendments that could not reasonably be expected to have a Material Adverse Effect. The business of the Company and its Subsidiaries is not being conducted, and shall not be conducted, in violation of any law, ordinance or regulation of any governmental entity, except for possible violations, the sanctions for which either individually or in the aggregate could not reasonably be expected to have a Material Adverse Effect. Except as specifically contemplated by this Agreement and as required under the Securities Act or applicable state securities laws and the rules and regulations of the principal Trading Market, the Company is not required to obtain any consent, authorization or order of, or make any filing or registration with, any court or governmental agency or any regulatory or self-regulatory agency in order for it to execute, deliver or perform any of its obligations under or contemplated by the Transaction Documents in accordance with the terms hereof or thereof. Except as set forth elsewhere in this Agreement, all consents, authorizations, orders, filings and registrations which the Company is required to obtain pursuant to the preceding sentence shall be obtained or effected on or prior to the Execution Date. Except as disclosed in the SEC Reports, since one year prior to the date hereof, the Company has not received nor delivered any notices or correspondence from or to the principal Trading Market, other than notices with respect to listing of additional shares of Common Stock and other routine correspondence. Except as disclosed in the SEC Reports, the principal Trading Market has not commenced any delisting proceedings against the Company.

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other Person in connection with the execution, delivery and performance by the Company of the Transaction Documents, other than: (i) the filing with the Commission of the Prospectus and (ii) such filings as are required to be made under applicable state securities laws (collectively, the "Required Approvals").

(f) Registration Statement. The Company has filed with the Commission the Registration Statement, including any related Prospectus or Prospectuses, for the registration of the Securities under the Securities Act, which Registration Statement has been prepared by the Company in all material respects in conformity with the requirements of the Securities Act and the rules and regulations of the Commission under the Securities Act. The Registration Statement has been declared effective by the Commission on _________ __, 2021 (the "Effective Date"). The Company has advised the Representative of all further information (financial and other) with respect to the Company required to be set forth therein in the Registration Statement and Prospectus. Any reference in this Agreement to the Registration Statement, the Prospectus or any Prospectus Supplement shall be deemed to refer to and include the documents incorporated by reference therein; and any reference in this Agreement to the terms "amend," "amendment" or "supplement" with respect to the Registration Statement, the Prospectus or any Prospectus Supplement shall be deemed to refer to and include the filing of any document under the Exchange Act after the date of this Agreement, or the issue date of the Prospectus or any Prospectus Supplement, as the case may be, deemed to be incorporated therein by reference. All references in this Agreement to financial statements and schedules and other information which is "contained," "included," "described," "referenced," "set forth" or "stated" in the Registration Statement, the Prospectus or any Prospectus Supplement (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information which is or is deemed to be incorporated by reference in the Registration Statement, the Prospectus or any Prospectus Supplement, as the case may be. No stop order suspending the effectiveness of the Registration Statement or the use of the Prospectus or any Prospectus Supplement has been issued, and no proceeding for any such purpose is pending or has been initiated or, to the Company's knowledge, is threatened by the Commission. For purposes of this Agreement, "free writing prospectus" has the meaning set forth in Rule 405 under the Securities Act. The Company will not, without the prior consent of the Representative, prepare, use or refer to, any free writing prospectus.

(g) Issuance of Securities. The Securities are duly authorized and, when issued and paid for in accordance with the applicable Transaction Documents, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The Warrant Shares, when issued in accordance with the terms of the Warrants, will be validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The Company has reserved from its duly authorized capital stock the maximum number of shares of Common Stock issuable pursuant to this Agreement and the Warrants. The holder of the Securities will not be subject to personal liability by reason of being such holders. The Securities are not and will not be subject to the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company. All corporate action required to be taken for the authorization, issuance and sale of the Securities has been duly and validly taken. The Securities conform in all material respects to all statements with respect thereto contained in the Registration Statement.

(h) Capitalization. As of the date hereof, the authorized capital stock of the Company is set forth in the SEC Reports (as defined below). Except as disclosed in the SEC Reports, (i) no shares of the Company's capital stock are subject to preemptive rights or any other similar rights or any liens or encumbrances suffered or permitted by the Company, (ii) there are no outstanding debt securities, (iii) there are no outstanding options, warrants, scrip, rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities or rights convertible into, any shares of capital stock of the Company or any of its Subsidiaries, or contracts, commitments, understandings or arrangements by which the Company or any of its Subsidiaries is or may become bound to issue additional shares of capital stock of the Company or any of its Subsidiaries or options, warrants, scrip, rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities or rights convertible into, any shares of capital stock of the Company or any of its Subsidiaries, (iv) there are no agreements or arrangements under which the Company or any of its Subsidiaries is obligated to register the sale of any of their securities under the Securities Act, (v) there are no outstanding securities or instruments of the Company or any of its Subsidiaries which contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company or any of its Subsidiaries is or may become bound to redeem a security of the Company or any of its Subsidiaries, (vi) there are no securities or instruments containing anti-dilution or similar provisions that will be triggered by the issuance of the Securities as described in this Agreement and (vii) the Company does not have any stock appreciation rights or "phantom stock" plans or agreements or any similar plan or agreement. The Company has furnished to the Underwriters true and correct copies of (A) the certificate of incorporation, (B) the bylaws, and (C) summaries of the material terms of all securities convertible into or exercisable for Common Stock, if any, and copies of any documents containing the material rights of the holders thereof in respect thereto, which in the case of these clauses (A), (B) and (C), are not disclosed in any SEC Report or filed as an exhibit thereto.

(i) SEC Reports; Financial Statements. The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two years preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such material) (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, together with the Prospectus and the Prospectus Supplement, being collectively referred to herein as the "SEC Reports") on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension, except as could not reasonably be expected to result in a Material Adverse Effect. As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments. The agreements and documents described in the Registration Statement, the Prospectus, the Prospectus Supplement and the SEC Reports conform to the descriptions thereof contained therein in all material respects and there are no agreements or other documents required by the Securities Act and the rules and regulations thereunder to be described in the Registration Statement, the Prospectus, the Prospectus Supplement or the SEC Reports or to be filed with the Commission as exhibits to the Registration Statement, that have not been so described or filed. Each agreement or other instrument (however characterized or described) to which the Company is a party or by which it is or may be bound or affected and (i) that is referred to in the Registration Statement, the Prospectus, the Prospectus Supplement or the SEC Reports, or (ii) is material to the Company's business, has been duly authorized and validly executed by the Company, is in full force and effect in all material respects and is enforceable against the Company and, to the Company's knowledge, the other parties thereto, in accordance with its terms, except (x) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally, (y) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws, and (z) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefore may be brought. None of such agreements or instruments has been assigned by the Company, and neither the Company nor, to the best of the Company's knowledge, any other party is in default thereunder and, to the best of the Company's knowledge, no event has occurred that, with the lapse of time or the giving of notice, or both, would constitute a default thereunder. To the best of the Company's knowledge, performance by the Company of the material provisions of such agreements or instruments will not result in a violation of any existing applicable law, rule, regulation, judgment, order or decree of any governmental agency or court, domestic or foreign, having jurisdiction over the Company or any of its assets or businesses, including, without limitation, those relating to environmental laws and regulations, except for any violations that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(j) Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the SEC Reports, except as specifically disclosed in a subsequent SEC Report filed prior to the date hereof, (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the Commission, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock, (v) the Company has not issued any equity securities to any officer, director or Affiliate, except pursuant to existing Company stock option plans and (vi) no officer or director of the Company has resigned from any position with the Company. The Company does not have pending before the Commission any request for confidential treatment of information. Except for the issuance of the Securities contemplated by this Agreement, no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, prospects, properties, operations, assets or financial condition that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least 1 Trading Day prior to the date that this representation is made. Unless otherwise disclosed in an SEC Report filed prior to the date hereof, the Company has not: (i) issued any securities or incurred any liability or obligation, direct or contingent, for borrowed money; or (ii) declared or paid any dividend or made any other distribution on or in respect to its capital stock.

(k) Litigation. Except as disclosed in the SEC Reports, there is no action, suit, proceeding, inquiry or investigation before or by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of the Company or any of its Subsidiaries, threatened against or affecting the Company, the Common Stock or any of the Company's or its Subsidiaries' officers or directors in their capacities as such, which could reasonably be expected to have a Material Adverse Effect.

(l) Labor Relations. No labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which could reasonably be expected to result in a Material Adverse Effect. None of the Company's or its Subsidiaries' employees is a member of a union that relates to such employee's relationship with the Company or such Subsidiary, and neither the Company nor any of its Subsidiaries is a party to a collective bargaining agreement, and the Company and its

Subsidiaries believe that their relationships with their employees are good. To the knowledge of the Company, no executive officer of the Company or any Subsidiary, is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of each such executive officer does not subject the Company or any of its Subsidiaries to any liability with respect to any of the foregoing matters. The Company and its Subsidiaries are in compliance with all U.S. federal, state, local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(m) Compliance. Neither the Company nor any Subsidiary: (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any judgment, decree or order of any court, arbitrator or other governmental authority or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case as could not have or reasonably be expected to result in a Material Adverse Effect.

(n) Regulatory Permits. Except as set forth in the SEC Reports, the Company and its Subsidiaries possess all material certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses, and neither the Company nor any such Subsidiary has received any notice of proceedings relating to the revocation or modification of any such certificate, authorization or permit, except, in the case of each of the two foregoing clauses, as could not reasonably be expected to have a Material Adverse Effect.

(o) Title to Assets. Except as set forth in the SEC Reports, the Company and its Subsidiaries have good and marketable title in fee simple to all real property owned by them and good and marketable title in all personal property owned by them that is material to the business of the Company and its Subsidiaries, in each case free and clear of all liens, encumbrances and defects ("Liens") and, except for Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and its Subsidiaries and Liens for the payment of federal, state or other taxes, the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by the Company and its Subsidiaries are held by them under valid, subsisting and enforceable leases with which the Company and its Subsidiaries are in compliance with such exceptions as are not material and do not interfere with the use made and proposed to be made of such property and buildings by the Company and its Subsidiaries.

(p) Intellectual Property. The Company and its Subsidiaries own or possess adequate rights or licenses to use all material trademarks, trade names, service marks, service mark registrations, service names, patents, patent rights, copyrights, inventions, licenses, approvals, governmental authorizations, trade secrets and rights necessary to conduct their respective businesses as now conducted. None of the Company's material trademarks, trade names, service marks, service mark registrations, service names, patents, patent rights, copyrights, inventions, licenses, approvals, government authorizations, trade secrets or other intellectual property rights have expired or terminated, or, by the terms and conditions thereof, could expire or terminate within two years from the date of this Agreement. The Company and its Subsidiaries do not have any knowledge of any infringement by the Company or its Subsidiaries of any material trademark, trade name rights, patents, patent rights, copyrights, licenses, service names, service marks, service mark registrations, trade secret or other similar rights of others, or of any such development of similar or identical trade secrets or technical information by others, and there is no claim, action or proceeding being made or brought against, or to the Company's knowledge, being threatened against, the Company or its Subsidiaries regarding trademark, trade name, patents, patent rights, invention, copyright, license, service names, service marks, service mark registrations, trade secret or other infringement, which could reasonably be expected to have a Material Adverse Effect.

(q) Insurance. The Company and each of its Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as management of the Company believes to be prudent and customary in the businesses in which the Company and its Subsidiaries are engaged. Neither the Company nor any such Subsidiary has been refused any insurance coverage sought or applied for and neither the Company nor any such Subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not materially and adversely affect the condition, financial or otherwise, or the earnings, business or operations of the Company and its Subsidiaries, taken as a whole.

(r) Transactions With Affiliates and Employees. Except as set forth in the SEC Reports, to the knowledge of the Company, none of the Company's stockholders, officers or directors or any family member or affiliate of any of the foregoing, has either directly or indirectly an interest in, or is a party to, any transaction that is required to be disclosed as a related party transaction pursuant to Item 404 of Regulation S-K promulgated under the Securities Act.

(s) Sarbanes-Oxley; Internal Accounting Controls. Except as set forth in the SEC Reports, the Company and the Subsidiaries are in compliance in all material respects with any and all applicable requirements of the Sarbanes-Oxley Act of 2002 that are effective as of the date hereof, and any and all applicable rules and regulations promulgated by the Commission thereunder that are effective as of the date hereof and as of the Closing Date. The Company and the Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company and the Subsidiaries have established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and the Subsidiaries and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company and the Subsidiaries as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) of the Company and its Subsidiaries that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company and its Subsidiaries.

(t) Certain Fees. Except as set forth in the Prospectus Supplement, no brokerage or finder's fees or commissions are or will be payable by the Company, any Subsidiary or Affiliate of the Company to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents. To the Company's knowledge, there are no other arrangements, agreements or understandings of the Company or, to the Company's knowledge, any of its stockholders that may affect the Underwriters' compensation, as determined by FINRA. The Company has not made any direct or indirect payments (in cash, securities or otherwise) to: (i) any person, as a finder's fee, consulting fee or otherwise, in consideration of such person raising capital for the Company or introducing to the Company persons who raised or provided capital to the Company; (ii) any FINRA member; or (iii) any person or entity that has any direct or indirect affiliation or association with any FINRA member, within the twelve months prior to the Execution Date. None of the net proceeds of the Offering will be paid by the Company to any participating FINRA member or its affiliates, except as specifically authorized herein.

(u) Investment Company. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Securities will not be or be an Affiliate of, an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become an "investment company" subject to registration under the Investment Company Act of 1940, as amended.

(v) Registration Rights. Except as set forth in the SEC Reports, no Person has any right to cause the Company or any Subsidiary to effect the registration under the Securities Act of any securities of the Company or any Subsidiary.

(w) Listing and Maintenance Requirements. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock pursuant to the Exchange Act nor has the Company received any notification that the SEC is currently contemplating terminating such registration. Except as disclosed in the SEC Reports, the Company has not, in the twelve (12) months preceding the date hereof, received any notice from any Person to the effect that the Company is not in compliance with the listing or maintenance requirements of the principal Trading Market. Except as disclosed in the SEC Reports, the Company is in compliance with all such listing and maintenance requirements.

(x) Application of Takeover Protections. The Company and its Board of Directors have taken or will take prior to the Commencement Date all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the certificate of incorporation, the laws of the state of its incorporation or otherwise which is or could become applicable to the Underwriters as a result of the transactions contemplated by this Agreement.

(y) Disclosure; 10b-5. The Registration Statement (and any further documents to be filed with the Commission) contains all exhibits and schedules as required by the Securities Act. Each of the Registration Statement and any post-effective amendment thereto, if any, at the time it became effective, complied in all material respects with the Securities Act and the Exchange Act and the applicable rules and regulations under the Securities Act and did not and, as amended or supplemented, if applicable, will not, contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Preliminary Prospectus, Prospectus and the Prospectus Supplement, each as of its respective date, comply in all material respects with the Securities Act and the Exchange Act and the applicable rules and regulations. Each of the Preliminary Prospectus, Prospectus and the Prospectus Supplement, as amended or supplemented, did not and will not contain as of the date thereof any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The SEC Reports, when they were filed with the Commission, conformed in all material respects to the requirements of the Exchange Act and the applicable rules and regulations, and none of such documents, when they were filed with the Commission, contained any untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein (with respect to the SEC Reports incorporated by reference in the Preliminary Prospectus, Prospectus or Prospectus

Supplement), in light of the circumstances under which they were made not misleading; and any further documents so filed and incorporated by reference in the Preliminary Prospectus, Prospectus or Prospectus Supplement, when such documents are filed with the Commission, will conform in all material respects to the requirements of the Exchange Act and the applicable rules and regulations, as applicable, and will not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made not misleading. No post-effective amendment to the Registration Statement reflecting any facts or events arising after the date thereof which represent, individually or in the aggregate, a fundamental change in the information set forth therein is required to be filed with the Commission. There are no documents required to be filed with the Commission in connection with the transaction contemplated hereby that (x) have not been filed as required pursuant to the Securities Act or (y) will not be filed within the requisite time period. There are no contracts or other documents required to be described in the Preliminary Prospectus, Prospectus or Prospectus Supplement, or to be filed as exhibits or schedules to the Registration Statement, which have not been described or filed as required.

(z) No Integrated Offering. Neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Securities to be integrated with prior offerings by the Company for purposes of any applicable shareholder approval provisions of any Trading Market on which any of the securities of the Company are listed or designated.

(aa) Solvency. Based on the consolidated financial condition of the Company as of the Closing Date, after giving effect to the receipt by the Company of the proceeds from the sale of the Securities hereunder, (i) the fair saleable value of the Company’s assets exceeds the amount that will be required to be paid on or in respect of the Company’s existing debts and other liabilities (including known contingent liabilities) as they mature, (ii) the Company’s assets do not constitute unreasonably small capital to carry on its business as now conducted and as proposed to be conducted including its capital needs taking into account the particular capital requirements of the business conducted by the Company, consolidated and projected capital requirements and capital availability thereof, and (iii) the current cash flow of the Company, together with the proceeds the Company would receive, were it to liquidate all of its assets, after taking into account all anticipated uses of the cash, would be sufficient to pay all amounts on or in respect of its liabilities when such amounts are required to be paid. The Company does not intend to incur debts beyond its ability to pay such debts as they mature (taking into account the timing and amounts of cash to be payable on or in respect of its debt). The Company has no knowledge of any facts or circumstances which lead it to believe that it will file for reorganization or liquidation under the bankruptcy or reorganization laws of any jurisdiction within one year from the Closing Date. The SEC Reports sets forth as of the date hereof all outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments. Neither the Company nor any Subsidiary is in default in respect of any Indebtedness.

(bb) Tax Status. Except as set forth in the SEC Reports, the Company and each of its Subsidiaries has made or filed all federal and state income and all other material tax returns, reports and declarations required by any jurisdiction to which it is subject (unless and only to the extent that the Company and each of its Subsidiaries has set aside on its books provisions reasonably adequate for the payment of all unpaid and unreported taxes) and has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations, except those being contested in good faith and has set aside on its books provision reasonably adequate for the payment of all taxes for periods subsequent to the periods to which such returns, reports or declarations apply, and except as could not reasonably be expected to have a Material Adverse Effect.

(cc) Foreign Corrupt Practices; Money Laundering Laws; Sanctions. Neither the Company nor any of the Subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee or affiliate of the Company or any of the Subsidiaries is aware of or has taken any action, directly or indirectly, that would result in a violation by such persons of the Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (the "FCPA"), including, without limitation, making use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay or authorization of the payment of any money, or other property, gift, promise to give, or authorization of the giving of anything of value to any "foreign official" (as such term is defined in the FCPA) or any foreign political party or official thereof or any candidate for foreign political office, in contravention of the FCPA; and the Company, the Subsidiaries and, to the knowledge of the Company, its affiliates have conducted their businesses in compliance with the FCPA and have instituted and maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith. The operations of the Company and the Subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements and the money laundering statutes and the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any applicable governmental agency, including, without limitation, Title 18 U.S. Code section 1956 and 1957, the Patriot Act, the Bank Secrecy Act, and international anti-money laundering principles or procedures by an intergovernmental group or organization, such as the Financial Action Task Force on Money Laundering, of which the United States is a member and with which designation the United States representative to the group or organization continues to concur, all as amended, and any Executive order, directive or regulation pursuant to the authority of any of the foregoing, or any orders or licenses issued thereunder (collectively, the "Money Laundering Laws"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its Subsidiaries with respect to the Money Laundering Laws is pending or, to the best knowledge of the Company, threatened. Neither the Company nor any of its Subsidiaries, nor to the knowledge of the Company any of the directors, officers or employees, agents, affiliates or representatives of the Company or its Subsidiaries, is an individual or entity that is, or is owned or controlled by an individual or entity that is: (i) the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign

Assets Control, the United Nations Security Council, the European Union, Her Majesty's Treasury, or other relevant sanctions authority (collectively, "Sanctions"), nor (ii) located, organized or resident in a country or territory that is the subject of Sanctions (including, without limitation, Burma/Myanmar, Cuba, Iran, Libya, North Korea, Venezuela, Sudan and Syria). Neither the Company nor any of its Subsidiaries will, directly or indirectly, use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any Subsidiary, joint venture partner or other individual or entity: (i) to fund or facilitate any activities or business of or with any individual or entity or in any country or territory that, at the time of such funding or facilitation, is the subject of Sanctions or (ii) in any other manner that will result in a violation of Sanctions by any individual or entity (including any individual or entity participating in the offering, whether as underwriter, advisor, investor or otherwise). For the past five years, neither the Company nor any of its Subsidiaries has knowingly engaged in, and is not now knowingly engaged in, any dealings or transactions with any individual or entity, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions.

(dd) Accounting Controls; Sarbanes-Oxley. The Company maintains a system of internal accounting controls sufficient to provide reasonable assurances that (A) transactions are executed in accordance with management's general or specific authorization; (B) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain accountability for assets; (C) access to assets is permitted only in accordance with management's general or specific authorization; and (D) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company has concluded that its internal control over financial reporting is effective and none of the Company, its board of directors and audit committee is aware of any "significant deficiencies" or "material weaknesses" (each as defined by the rules adopted by the SEC) in its internal control over financial reporting, or any fraud, whether or not material, that involves management or other employees of the Company and its Subsidiaries who have a significant role in the Company's internal controls; and since the end of the latest audited fiscal year, there has been no change in the Company's internal control over financial reporting (whether or not remediated) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Board of Directors has, subject to the exceptions, cure periods and the phase in periods specified in the applicable stock exchange rules of the Principal Market ("Exchange Rules"), validly appointed an audit committee to oversee internal accounting controls whose composition satisfies the applicable independence and other requirements of the Exchange Rules and the rules under the Exchange Act, and the Board of Directors and/or the audit committee has adopted a charter that satisfies the requirements of the Exchange Rules and the rules under the Exchange Act. Neither the Board of Directors nor the audit committee has been informed, nor is any director of the Company or the Company aware, of (A) any significant deficiencies in the design or operation of the Company's internal controls which could adversely affect the Company's ability to record, process, summarize and report financial data or any material weakness in the Company's internal controls; or (B) any fraud, whether or not material, that involves management or other employees of the Company who have a significant role in the Company's internal controls.

No relationship, direct or indirect, exists between or among the Company, on the one hand, and the directors, officers, stockholders, customers or suppliers of the Company, on the other hand, which is required to be described in the Registration Statement and the Prospectuses which is not so described. The Company has not, directly or indirectly, extended or maintained credit, or arranged for the extension of credit, or renewed an extension of credit, in the form of a personal loan to or for any of its directors or executive officers in violation of applicable laws, including Section 402 of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith (the "Sarbanes-Oxley Act").

(ee) FDA. As to each product subject to the jurisdiction of the U.S. Food and Drug Administration ("FDA") under the Federal Food, Drug and Cosmetic Act, as amended, and the regulations thereunder ("FDCA") that is manufactured, packaged, labeled, tested, distributed, sold, and/or marketed by the Company or any of its Subsidiaries (each such product, a "Pharmaceutical Product"), such Pharmaceutical Product is being manufactured, packaged, labeled, tested, distributed, sold and/or marketed by the Company in compliance with all applicable requirements under FDCA and similar laws, rules and regulations relating to registration, investigational use, premarket clearance, licensure, or application approval, good manufacturing practices, good laboratory practices, good clinical practices, product listing, quotas, labeling, advertising, record keeping and filing of reports, except where the failure to be in compliance would not have a Material Adverse Effect. There is no pending, completed or, to the Company's knowledge, threatened, action (including any lawsuit, arbitration, or legal or administrative or regulatory proceeding, charge, complaint, or investigation) against the Company or any of its Subsidiaries, and none of the Company or any of its Subsidiaries has received any notice, warning letter or other communication from the FDA or any other governmental entity, which (i) contests the premarket clearance, licensure, registration, or approval of, the uses of, the distribution of, the manufacturing or packaging of, the testing of, the sale of, or the labeling and promotion of any Pharmaceutical Product, (ii) withdraws its approval of, requests the recall, suspension, or seizure of, or withdraws or orders the withdrawal of advertising or sales promotional materials relating to, any Pharmaceutical Product, (iii) imposes a clinical hold on any clinical investigation by the Company or any of its Subsidiaries, (iv) enjoins production at any facility of the Company or any of its Subsidiaries, (v) enters or proposes to enter into a consent decree of permanent injunction with the Company or any of its Subsidiaries, or (vi) otherwise alleges any violation of any laws, rules or regulations by the Company or any of its Subsidiaries, and which, either individually or in the aggregate, would have a Material Adverse Effect. The properties, business and operations of the Company have been and are being conducted in all material respects in accordance with all applicable laws, rules and regulations of the FDA. The Company has not been informed by the FDA that the FDA will prohibit the marketing, sale, license or use in the United States of any product proposed to be developed, produced or marketed by the Company.

(ff) Office of Foreign Assets Control. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.

(gg) U.S. Real Property Holding Corporation. The Company is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended, and the Company shall so certify upon the Representative's request.

(hh) Bank Holding Company Act. Neither the Company nor any of its Subsidiaries or Affiliates is subject to the Bank Holding Company Act of 1956, as amended (the "BHCA") and to regulation by the Board of Governors of the Federal Reserve System (the "Federal Reserve"). Neither the Company nor any of its Subsidiaries or Affiliates owns or controls, directly or indirectly, five percent (5%) or more of the outstanding shares of any class of voting securities or twenty-five percent (25%) or more of the total equity of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve. Neither the Company nor any of its Subsidiaries or Affiliates exercises a controlling influence over the management or policies of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve.

(ii) D&O Questionnaires. To the Company's knowledge, all information contained in the questionnaires completed by each of the Company's directors and officers prior to the Offering as well as in the Lock-Up Agreement provided to the Underwriters is true and correct in all material respects and the Company has not become aware of any information which would cause the information disclosed in such questionnaires become inaccurate and incorrect.

(jj) FINRA Affiliation. No officer, director or any beneficial owner of 5% or more of the Company's unregistered securities has any direct or indirect affiliation or association with any FINRA member (as determined in accordance with the rules and regulations of FINRA) that is participating in the Offering. The Company will advise the Representative and EGS if it learns that any officer, director or owner of 5% or more of the Company's outstanding shares of Common Stock or Common Stock Equivalents is or becomes an affiliate or associated person of a FINRA member firm.

(kk) Officers' Certificate. Any certificate signed by any duly authorized officer of the Company and delivered to the Representative or EGS shall be deemed a representation and warranty by the Company to the Underwriters as to the matters covered thereby.

(ll) Board of Directors. The Board of Directors is comprised of the persons set forth under the heading of the Prospectus captioned "Management." The qualifications of the persons serving as board members and the overall composition of the Board of Directors comply with the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder applicable to the Company and the rules of the Trading Market. At least one member of the Board of Directors qualifies as a "financial expert" as such term is defined under the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder and the rules of the Trading Market. In addition, at least a majority of the persons serving on the Board of Directors qualify as "independent" as defined under the rules of the Trading Market.

(mm) Stock Option Plans. Each stock option granted by the Company under the Company's stock option plan was granted (i) in accordance with the terms of the Company's stock option plan and (ii) with an exercise price at least equal to the fair market value of the Common Stock on the date such stock option would be considered granted under GAAP and applicable law. No stock option granted under the Company's stock option plan has been backdated. The Company has not knowingly granted, and there is no and has been no Company policy or practice to knowingly grant, stock options prior to, or otherwise knowingly coordinate the grant of stock options with, the release or other public announcement of material information regarding the Company or its Subsidiaries or their financial results or prospects.

(nn) Environmental Laws. The Company and its Subsidiaries (i) are in compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants ("Environmental Laws"), (ii) have received all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses and (iii) are in compliance with all terms and conditions of any such permit, license or approval, except where, in each of the three foregoing clauses, the failure to so comply could not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

ARTICLE IV.
OTHER AGREEMENTS OF THE PARTIES

4.1 Amendments to Registration Statement. The Company has delivered, or will as promptly as practicable deliver, to the Underwriters complete conformed copies of the Registration Statement and of each consent and certificate of experts, as applicable, filed as a part thereof, and conformed copies of the Registration Statement (without exhibits), the Prospectus and the Prospectus Supplement, as amended or supplemented, in such quantities and at such places as an Underwriter reasonably requests. Neither the Company nor any of its directors and officers has distributed and none of them will distribute, prior to the Closing Date, any offering material in connection with the offering and sale of the Securities other than the Prospectus, the Prospectus Supplement, the Registration Statement, and copies of the documents incorporated by reference therein. The Company shall not file any such amendment or supplement to which the Representative shall reasonably object in writing.

4.2 Federal Securities Laws.

(a) Compliance. During the time when a Prospectus is required to be delivered under the Securities Act, the Company will use commercially reasonable efforts to comply with all requirements imposed upon it by the Securities Act and the rules and regulations thereunder and the Exchange Act and the rules and regulations thereunder, as from time to time in force, so far as necessary to permit the continuance of sales of or dealings in the Securities in accordance with the provisions hereof and the Prospectus. If at any time when a Prospectus relating to the Securities is required to be delivered under the Securities Act, any event shall have occurred as a result of which, in the opinion of counsel for the

Company or counsel for the Underwriters, the Prospectus, as then amended or supplemented, includes an untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, or if it is necessary at any time to amend the Prospectus to comply with the Securities Act, the Company will notify the Underwriters promptly and prepare and file with the Commission, subject to Section 4.1 hereof, an appropriate amendment or supplement in accordance with Section 10 of the Securities Act.

(b) Filing of Final Prospectus. The Company will file the Prospectus (in form and substance reasonably satisfactory to the Representative) with the Commission pursuant to the requirements of Rule 424.

(c) Exchange Act Registration. For a period of three years from the Execution Date, the Company will use commercially reasonable efforts to maintain the registration of the Common Stock under the Exchange Act. For a period of 12 months from the Execution Date, the Company will not deregister the Common Stock under the Exchange Act without the prior written consent of the Representative, which shall not be unreasonably withheld.

(d) Free Writing Prospectuses. The Company represents and agrees that it has not made and will not make any offer relating to the Securities that would constitute an issuer free writing prospectus, as defined in Rule 433 of the rules and regulations under the Securities Act, without the prior written consent of the Representative. Any such free writing prospectus consented to by the Representative is herein referred to as a **"**Permitted Free Writing Prospectus." The Company represents that it will treat each Permitted Free Writing Prospectus as an "issuer free writing prospectus" as defined in rule and regulations under the Securities Act, and has complied and will comply with the applicable requirements of Rule 433 of the Securities Act, including timely Commission filing where required, legending and record keeping.

4.3 Delivery to the Underwriters of Prospectuses. The Company will deliver to the Underwriters, without charge, from time to time during the period when the Prospectus is required to be delivered under the Securities Act or the Exchange Act such number of copies of each Prospectus as the Underwriters may reasonably request and, as soon as the Registration Statement or any amendment or supplement thereto becomes effective, deliver to you two original executed Registration Statements, including exhibits, and all post-effective amendments thereto and copies of all exhibits filed therewith or incorporated therein by reference and all original executed consents of certified experts.

4.4 Effectiveness and Events Requiring Notice to the Underwriters. The Company will use commercially reasonable efforts to cause the Registration Statement to remain effective with a current prospectus until the later of nine (9) months from the Execution Date and the date on which the Warrants are no longer outstanding, and will notify the Underwriters and holders of the Warrants immediately and confirm the notice in writing: (i) of the effectiveness of the Registration Statement and any amendment thereto, provided that the filing of an amendment to the Registration

Statement on the SEC's EDGAR system, and the posting of the notice of effectiveness on EDGAR, shall be deemed to be such notification; (ii) of the issuance by the Commission of any stop order or of the initiation, or the threatening, of any proceeding for that purpose; (iii) of the issuance by any state securities commission of any proceedings for the suspension of the qualification of the Securities for offering or sale in any jurisdiction or of the initiation, or the threatening, of any proceeding for that purpose; (iv) of the mailing and delivery to the Commission for filing of any amendment or supplement to the Registration Statement or Prospectus, provided that the filing of an amendment or supplement to the Registration Statement on the SEC's EDGAR system shall be deemed to be such notification; (v) of the receipt of any comments or request for any additional information from the Commission; and (vi) of the happening of any event during the period described in this Section 4.4 that, in the judgment of the Company, makes any statement of a material fact made in the Registration Statement or the Prospectus untrue or that requires the making of any changes in the Registration Statement or the Prospectus in order to make the statements therein, in light of the circumstances under which they were made, not misleading. If the Commission or any state securities commission shall enter a stop order or suspend such qualification at any time, the Company will make every reasonable effort to obtain promptly the lifting of such order.

4.5 Expenses of the Offering. The Company hereby agrees to pay on each of the Closing Date and each Option Closing Date, if any, to the extent not paid at the Closing Date, all expenses incident to the performance of the obligations of the Company under this Agreement, including, but not limited to: (a) all filing fees and communication expenses relating to the registration of the Securities to be sold in the Offering (including the Option Securities) with the Commission; (b) all FINRA Public Offering Filing System fees associated with the review of the Offering by FINRA; all fees and expenses relating to the listing of such Closing Shares, Option Shares and Warrant Shares on the Trading Market and such other stock exchanges as the Company and the Representative together determine (provided, that any and all fees and expenses by Underwriters' legal counsel incurred in connection with this clause (b) and clause (c) below shall not exceed $10,000 in the aggregate; provided, however, the actual FINRA Public Offering Filing System fees paid by the Company to FINRA shall not be subject to the foregoing $10,000 cap); (c) all fees, expenses and disbursements relating to the registration or qualification of such Securities under the "blue sky" securities laws of such states and other foreign jurisdictions as the Representative may reasonably designate (provided, that any and all fees and expenses by Underwriters' legal counsel incurred in connection with clause (b) above and this clause (c) shall not exceed $10,000 in the aggregate); (d) the costs of all mailing and printing of the underwriting documents (including, without limitation, the Underwriting Agreement, any Blue Sky Surveys and, if appropriate, any Agreement Among Underwriters, Selected Dealers' Agreement, Underwriters' Questionnaire and Power of Attorney), Registration Statements, Prospectuses and all amendments, supplements and exhibits thereto and as many preliminary and final Prospectuses as the Representative may reasonably deem necessary; (e) the costs and expenses of the Company's public relations firm; (f) the costs of preparing, printing and delivering the Securities; (g) fees and expenses of the Transfer Agent for the Securities (including, without limitation, any fees required for same-day processing of any instruction letter delivered by the Company); (h) stock transfer and/or stamp taxes, if any, payable upon the transfer of securities from the Company to the Underwriters; (i) the fees and expenses of the Company's accountants; (j) the fees and expenses of the Company's legal counsel and other agents and representatives; (k) the Underwriters' costs of mailing prospectuses to prospective investors; and (l) up to $50,000 for the fees and expenses of the Underwriters' legal counsel. The Underwriters may also deduct from the net proceeds of the Offering payable to the Company on the Closing Date, or each Option Closing Date, if any, the expenses set forth herein to be paid by the Company to the Underwriters.

4.6 Application of Net Proceeds. The Company will apply the net proceeds from the Offering received by it in a manner consistent with the application described under the caption "Use of Proceeds" in the Prospectus.

4.7 Delivery of Earnings Statements to Security Holders. The Company will make generally available to its security holders as soon as practicable, but not later than the first day of the fifteenth full calendar month following the Execution Date, an earnings statement (which need not be certified by independent public or independent certified public accountants unless required by the Securities Act or the Rules and Regulations under the Securities Act, but which shall satisfy the provisions of Rule 158(a) under Section 11(a) of the Securities Act) covering a period of at least twelve consecutive months beginning after the Execution Date.

4.8 Stabilization. Neither the Company, nor, to its knowledge, any of its employees, directors or shareholders (without the consent of the Representative) has taken or will take, directly or indirectly, any action designed to or that has constituted or that might reasonably be expected to cause or result in, under the Exchange Act, or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

4.9 Internal Controls. The Company will maintain a system of internal accounting controls sufficient to provide reasonable assurances that: (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary in order to permit preparation of financial statements in accordance with GAAP and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

4.10 Accountants. The Company shall continue to retain a nationally recognized independent certified public accounting firm for a period of at least three years after the Execution Date. The Underwriters acknowledge that the Company Auditor is acceptable to the Underwriters.

4.11 FINRA. The Company shall advise the Underwriters (who shall make an appropriate filing with FINRA) if it is aware that any 5% or greater shareholder of the Company becomes an affiliate or associated person of an Underwriter.

4.12 No Fiduciary Duties. The Company acknowledges and agrees that the Underwriters' responsibility to the Company is solely contractual and commercial in nature, based on arms-length negotiations and that neither the Underwriters nor their affiliates or any selected dealer shall be deemed to be acting in a fiduciary capacity, or otherwise owes any fiduciary duty to the Company or any of its affiliates in connection with the Offering and the other transactions contemplated by this Agreement. Notwithstanding anything in this Agreement to the contrary, the Company acknowledges that the Underwriters may have financial interests in the success of the Offering that are not limited to the difference between the price to the public and the purchase price paid to the Company by the Underwriters for the shares and the Underwriters have no obligation to disclose, or account to the Company for, any of such additional financial interests. The Company hereby waives and releases, to the fullest extent permitted by law, any claims that the Company may have against the Underwriters with respect to any breach or alleged breach of fiduciary duty.

4.13 Warrant Shares. If all or any portion of a Warrant is exercised at a time when there is an effective registration statement to cover the issuance of the Warrant Shares or if the Warrant is exercised via cashless exercise at a time when such Warrant Shares would be eligible for resale under Rule 144 by a non-affiliate of the Company, the Warrant Shares issued pursuant to any such exercise shall be issued free of all restrictive legends. If at any time following the date hereof the Registration Statement (or any subsequent registration statement registering the sale or resale of the Warrant Shares) is not effective or is not otherwise available for the sale of the Warrant Shares, the Company shall immediately notify the holders of the Warrants in writing that such registration statement is not then effective and thereafter shall promptly notify such holders when the registration statement is effective again and available for the sale of the Warrant Shares (it being understood and agreed that the foregoing shall not limit the ability of the Company to issue, or any holder thereof to sell, any of the Warrant Shares in compliance with applicable federal and state securities laws).

4.14 Board Composition and Board Designations. The Company shall ensure that: (i) the qualifications of the persons serving as board members and the overall composition of the Board of Directors comply with the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder and with the listing requirements of the Trading Market and (ii) if applicable, at least one member of the Board of Directors qualifies as a “financial expert” as such term is defined under the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder.

4.15 Securities Laws Disclosure; Publicity. At the request of the Representative, by ____ a.m. (New York City time) on the date hereof, the Company shall issue a press release disclosing the material terms of the Offering. The Company and the Representative shall consult with each other in issuing any other press releases with respect to the Offering, and neither the Company nor any Underwriter shall issue any such press release nor otherwise make any such public statement without the prior consent of the Company, with respect to any press release of such Underwriter, or without the prior consent of such Underwriter, with respect to any press release of the Company, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law, in which case the disclosing party shall promptly provide the other party with prior notice of such public statement or communication. The Company will not issue press releases or engage in any other publicity, without the Representative’s prior written consent, for a period ending at 5:00 p.m. (New York City time) on the first business day following the 45th day following the Closing Date, other than normal and customary releases issued in the ordinary course of the Company’s business.

4.16 Shareholder Rights Plan. No claim will be made or enforced by the Company or, with the consent of the Company, any other Person, that any Underwriter of the Securities is an “Acquiring Person” under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter adopted by the Company, or that any Underwriter of Securities could be deemed to trigger the provisions of any such plan or arrangement, by virtue of receiving Securities.

4.17 Reservation of Common Stock. As of the date hereof, the Company has reserved and the Company shall continue to reserve and keep available at all times, free of preemptive rights, a sufficient number of shares of Common Stock for the purpose of enabling the Company to issue Option Shares pursuant to the Over-Allotment Option and Warrant Shares pursuant to any exercise of the Warrants.

4.18 Listing of Common Stock. The Company hereby agrees to use commercially reasonable efforts to maintain the listing or quotation of the Common Stock on the Trading Market on which it is currently listed for a period of one year from the Closing Date, and concurrently with the Closing, the Company shall apply to list or quote all of the Closing Shares, Option Shares and Warrant Shares on such Trading Market and promptly secure the listing of all of the Closing Shares, Option Shares and Warrant Shares on such Trading Market. The Company further agrees, if the Company applies to have the Common Stock traded on any other Trading Market, it will then include in such application all of the Closing Shares, Option Shares and Warrant Shares, and will take such other action as is necessary to cause all of the Closing Shares, Option Shares and Warrant Shares to be listed or quoted on such other Trading Market as promptly as possible. The Company will then take all action reasonably necessary to continue the listing and trading of its Common Stock on a Trading Market and will comply in all respects with the Company’s reporting, filing and other obligations under the bylaws or rules of the Trading Market for a period of one year from the Closing Date. The Company agrees to maintain the eligibility of the Common Stock for electronic transfer through the Depository Trust Company or another established clearing corporation, including, without limitation, by timely payment of fees to the Depository Trust Company or such other established clearing corporation in connection with such electronic transfer for a period of one year from the Closing Date.

4.19 Subsequent Equity Sales.

(a) From the date hereof until ninety (90) days following the Closing Date, neither the Company nor any Subsidiary shall issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or Common Stock Equivalents.

(b) From the date hereof until ninety (90) days following the Closing Date, the Company shall be prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its Subsidiaries of Common Stock or Common Stock Equivalents (or a combination of units thereof) involving a Variable Rate Transaction. “Variable Rate Transaction” means a transaction in which the Company (i) issues or sells any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive, additional shares of Common Stock either (A) at a conversion price, exercise price or exchange rate or other price that is based upon, and/or varies with, the trading prices of or quotations for the shares of Common Stock at any time after the initial issuance of such debt or equity securities or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the Common Stock or (ii) enters into, or effects a transaction under, any agreement, including, but not limited to, an equity line of credit, whereby the Company may issue securities at a future determined price. Any Underwriter shall be entitled to obtain injunctive relief against the Company to preclude any such issuance, which remedy shall be in addition to any right to collect damages.

(c) Notwithstanding the foregoing, this Section 4.19 shall not apply in respect of an Exempt Issuance, except that no Variable Rate Transaction shall be an Exempt Issuance.

4.20 Research Independence. The Company acknowledges that each Underwriter’s research analysts and research departments, if any, are required to be independent from their respective investment banking divisions and are subject to certain regulations and internal policies, and that such Underwriter’s research analysts may hold and make statements or investment recommendations and/or publish research reports with respect to the Company and/or the offering that differ from the views of its investment bankers. The Company hereby waives and releases, to the fullest extent permitted by law, any claims that the Company may have against such Underwriter with respect to any conflict of interest that may arise from the fact that the views expressed by their independent research analysts and research departments may be different from or inconsistent with the views or advice communicated to the Company by such Underwriter’s investment banking divisions. The Company acknowledges that the Representative is a full service securities firm and as such from time to time, subject to applicable securities laws, may effect transactions for its own account or the account of its customers and hold long or short position in debt or equity securities of the Company.

ARTICLE V.
DEFAULT BY UNDERWRITERS

If on the Closing Date or any Option Closing Date, if any, any Underwriter shall fail to purchase and pay for the portion of the Closing Securities or Option Securities, as the case may be, which such Underwriter has agreed to purchase and pay for on such date (otherwise than by reason of any default on the part of the Company), the Representative, or if the Representative is the defaulting Underwriter, the non-defaulting Underwriters, shall use their reasonable efforts to procure within 36 hours thereafter one or more of the other Underwriters, or any others, to purchase from the Company such amounts as may be agreed upon and upon the terms set forth herein, the Closing Securities or Option Securities , as the case may be, which the defaulting Underwriter or Underwriters failed to purchase. If during such 36 hours the Representative shall not have procured such other Underwriters, or any others, to purchase the Closing Securities or Option Securities, as the case may be, agreed to be purchased by the defaulting Underwriter or

Underwriters, then (a) if the aggregate number of Closing Securities or Option Securities, as the case may be, with respect to which such default shall occur does not exceed 10% of the Closing Securities or Option Securities, as the case may be, covered hereby, the other Underwriters shall be obligated, severally, in proportion to the respective numbers of Closing Securities or Option Securities, as the case may be, which they are obligated to purchase hereunder, to purchase the Closing Securities or Option Securities, as the case may be, which such defaulting Underwriter or Underwriters failed to purchase, or (b) if the aggregate number of Closing Securities or Option Securities, as the case may be, with respect to which such default shall occur exceeds 10% of the Closing Securities or Option Securities, as the case may be, covered hereby, the Company or the Representative will have the right to terminate this Agreement without liability on the part of the non-defaulting Underwriters or of the Company except to the extent provided in Article VI hereof. In the event of a default by any Underwriter or Underwriters, as set forth in this Article V, the applicable Closing Date may be postponed for such period, not exceeding seven days, as the Representative, or if the Representative is the defaulting Underwriter, the non-defaulting Underwriters, may determine in order that the required changes in the Prospectus or in any other documents or arrangements may be effected. The term "Underwriter" includes any person substituted for a defaulting Underwriter. Any action taken under this Section shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

ARTICLE VI.
INDEMNIFICATION

6.1 Indemnification of the Underwriters. Subject to the conditions set forth below, the Company agrees to indemnify and hold harmless the Underwriters, and each dealer selected by each Underwriter that participates in the offer and sale of the Securities (each a "Selected Dealer") and each of their respective directors, officers and employees and each Person, if any, who controls such Underwriter or any Selected Dealer ("Controlling Person") within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, against any and all loss, liability, claim, damage and expense whatsoever (including but not limited to any and all legal or other documented expenses reasonably incurred in investigating, preparing or defending against any litigation, commenced or threatened, or any claim whatsoever, whether arising out of any action between such Underwriter and the Company or between such Underwriter and any third party or otherwise) to which they or any of them may become subject under the Securities Act, the Exchange Act or any other statute or at common law or otherwise or under the laws of foreign countries, arising out of or based upon any untrue statement or alleged untrue statement of a material fact contained in (i) any Preliminary Prospectus, if any, the Registration Statement or the Prospectus (as from time to time each may be amended and supplemented); (ii) any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Securities, including any "road show" or investor presentations made to investors by the Company (whether in person or electronically); or (iii) any application or other document or written communication (in this Article VI, collectively called "application") executed by the Company or based upon written information furnished by the Company in any jurisdiction in order to qualify the Securities under the securities laws thereof or filed with the Commission, any state securities commission or agency, Trading Market or any securities exchange; or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, unless such statement or omission was made in reliance upon and in conformity with written information furnished to the Company with respect to the applicable Underwriter by or on behalf of such Underwriter expressly for use in any Preliminary Prospectus, if any, the Registration Statement or Prospectus, or any amendment or supplement thereto, or in any application, as the case may be. With respect to any untrue statement or omission or alleged untrue statement or omission made in the Preliminary Prospectus, if any, the indemnity agreement contained in this Section 6.1 shall not inure to the benefit of an Underwriter to the extent that any loss, liability, claim, damage or expense of such Underwriter results from the fact that a copy of the Prospectus was not given or sent to the Person asserting any such loss, liability, claim or damage at or prior to the written confirmation of sale of the Securities to such Person as required by the Securities Act and the rules and regulations thereunder, and if the untrue statement or omission has been corrected in the Prospectus, unless such failure to deliver the Prospectus was a result of non-compliance by the Company with its obligations under this Agreement. The Company agrees promptly to notify each Underwriter of the commencement of any litigation or proceedings against the Company or any of its officers, directors or Controlling Persons in connection with the issue and sale of the Public Securities or in connection with the Registration Statement or Prospectus.

6.2 Procedure. If any action is brought against an Underwriter, a Selected Dealer or a Controlling Person in respect of which indemnity may be sought against the Company pursuant to Section 6.1, such Underwriter, such Selected Dealer or Controlling Person, as the case may be, shall promptly notify the Company in writing of the institution of such action and the Company shall assume the defense of such action, including the employment and fees of counsel (subject to the reasonable approval of such Underwriter or such Selected Dealer, as the case may be) and payment of actual expenses. Such Underwriter, such Selected Dealer or Controlling Person shall have the right to employ its or their own counsel in any such case, but the fees and expenses of such counsel shall be at the expense of such Underwriter, such Selected Dealer or Controlling Person unless (i) the employment of such counsel at the expense of the Company shall have been authorized in writing by the Company in connection with the defense of such action, or (ii) the Company shall not have employed counsel to have charge of the defense of such action, or (iii) such indemnified party or parties shall have reasonably concluded that there may be defenses available to it or them which are different from or additional to those available to the Company (in which case the Company shall not have the right to direct the defense of such action on behalf of the indemnified party or parties), in any of which events the reasonable fees and expenses of not more than one additional firm of attorneys selected by such Underwriter (in addition to local counsel), Selected Dealer and/or Controlling Person shall be borne by the Company. Notwithstanding anything to the contrary contained herein, if any Underwriter, Selected Dealer or Controlling Person shall assume the defense of such action as provided above, the Company shall have the right to approve the terms of any settlement of such action which approval shall not be unreasonably withheld.

6.3 Indemnification of the Company. Each Underwriter severally and not jointly agrees to indemnify and hold harmless the Company, its directors, officers and employees and agents who control the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any and all loss, liability, claim, damage and expense described in the foregoing indemnity from the Company to such Underwriter, as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions made in any Preliminary Prospectus, if any, the Registration Statement or Prospectus or any amendment or supplement thereto or in any application, in reliance upon, and in strict conformity with, written information furnished to the Company with respect to such Underwriter by or on behalf of such Underwriter expressly for use in such Preliminary Prospectus, if any, the Registration Statement or Prospectus or any amendment or supplement thereto or in any such application. In case any action shall be brought against the Company or any other Person so indemnified based on any Preliminary Prospectus, if any, the Registration Statement or Prospectus or any amendment or supplement thereto or any application, and in respect of which indemnity may be sought against such Underwriter, such Underwriter shall have the rights and duties given to the Company, and the Company and each other Person so indemnified shall have the rights and duties given to such Underwriter by the provisions of this Article VI. Notwithstanding the provisions of this Section 6.3, no Underwriter shall be required to indemnify the Company for any amount in excess of the underwriting discounts and commissions applicable to the Securities purchased by such Underwriter. The Underwriters' obligations in this Section 6.3 to indemnify the Company are several in proportion to their respective underwriting obligations and not joint.

6.4 Contribution.

(a) Contribution Rights. In order to provide for just and equitable contribution under the Securities Act in any case in which (i) any Person entitled to indemnification under this Article VI makes a claim for indemnification pursuant hereto but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case notwithstanding the fact that this Article VI provides for indemnification in such case, or (ii) contribution under the Securities Act, the Exchange Act or otherwise may be required on the part of any such Person in circumstances for which indemnification is provided under this Article VI, then, and in each such case, the Company and each Underwriter, severally and not jointly, shall contribute to the aggregate losses, liabilities, claims, damages and expenses of the nature contemplated by said indemnity agreement incurred by the Company and such Underwriter, as incurred, in such proportions that such Underwriter is responsible for that portion represented by the percentage that the underwriting discount appearing on the cover page of the Prospectus bears to the initial offering price appearing thereon and the Company is responsible for the balance; provided, that, no Person guilty of a fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation. For purposes of this Section, each director, officer and employee of such Underwriter or the Company, as applicable, and each Person, if any, who controls such Underwriter or the Company, as applicable, within the meaning of Section 15 of the Securities Act shall have the same rights to contribution as such Underwriter or the Company, as applicable. Notwithstanding the provisions of this Section 6.4, no Underwriter shall be required to contribute any amount in excess of the underwriting discounts and commissions applicable to the Securities purchased by such Underwriter. The Underwriters' obligations in this Section 6.4 to contribute are several in proportion to their respective underwriting obligations and not joint.

(b) Contribution Procedure. Within fifteen days after receipt by any party to this Agreement (or its representative) of notice of the commencement of any action, suit or proceeding, such party will, if a claim for contribution in respect thereof is to be made against another party (“contributing party”), notify the contributing party of the commencement thereof, but the failure to so notify the contributing party will not relieve it from any liability which it may have to any other party other than for contribution hereunder. In case any such action, suit or proceeding is brought against any party, and such party notifies a contributing party or its representative of the commencement thereof within the aforesaid fifteen days, the contributing party will be entitled to participate therein with the notifying party and any other contributing party similarly notified. Any such contributing party shall not be liable to any party seeking contribution on account of any settlement of any claim, action or proceeding affected by such party seeking contribution without the written consent of such contributing party. The contribution provisions contained in this Section 6.4 are intended to supersede, to the extent permitted by law, any right to contribution under the Securities Act, the Exchange Act or otherwise available.

ARTICLE VII.
MISCELLANEOUS

7.1 Termination.

(a) Termination Right. The Representative shall have the right to terminate this Agreement at any time prior to any Closing Date, (i) if any domestic or international event or act or occurrence has materially disrupted, or in its reasonable opinion will in the immediate future materially disrupt, general securities markets in the United States other than events relating to, or arising from, the COVID-19 pandemic; or (ii) if trading on any Trading Market shall have been suspended or materially limited, or minimum or maximum prices for trading shall have been fixed, or maximum ranges for prices for securities shall have been required by FINRA or by order of the Commission or any other government authority having jurisdiction, or (iii) if the United States shall have become involved in a new war or an increase in major hostilities, or (iv) if a banking moratorium has been declared by a New York State or federal authority, or (v) if a moratorium on foreign exchange trading has been declared which materially adversely impacts the United States securities markets, or (vi) if the Company shall have sustained a material loss by fire, flood, accident, hurricane, earthquake, theft, sabotage or other calamity or malicious act which, whether or not such loss shall have been insured, will, in the Representative’s reasonable opinion, make it inadvisable to proceed with the delivery of the Securities, or (vii) if the Company is in material breach of any of its representations, warranties or covenants hereunder, or (viii) if the Representative shall have become aware after the date hereof of such a material adverse change in the conditions or prospects of the Company, or such adverse material change in general market conditions as in the Representative’s reasonable judgment would make it impracticable to proceed with the offering, sale and/or delivery of the Securities or to enforce contracts made by the Underwriters for the sale of the Securities.

(b) Expenses. In the event this Agreement shall be terminated pursuant to Section 7.1(a), within the time specified herein or any extensions thereof pursuant to the terms herein, the Company shall be obligated to pay to the Representative its reasonable and documented out of pocket expenses related to the transactions contemplated herein then due and payable, including the fees and disbursements of EGS up to $50,000 (provided, however, that such expense cap in no way limits or impairs the indemnification and contribution provisions of this Agreement). Notwithstanding the foregoing, the maximum amount the Company shall be obligated to pay under this Section 7.1(b) shall be $50,000.

(c) Indemnification. Notwithstanding any contrary provision contained in this Agreement, any election hereunder or any termination of this Agreement, and whether or not this Agreement is otherwise carried out, the provisions of Article VI shall not be in any way effected by such election or termination or failure to carry out the terms of this Agreement or any part hereof.

7.2 Entire Agreement. The Transaction Documents, together with the exhibits and schedules thereto, the Prospectus and the Prospectus Supplement, contain the entire understanding of the parties with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits and schedules. Notwithstanding anything herein to the contrary, the Investment Banking Agreement, dated November 5, 2020 ("Engagement Agreement"), by and between the Company and the Representative, shall continue to be effective and the terms therein shall continue to survive and be enforceable by the Representative in accordance with its terms, provided that, in the event of a conflict between the terms of the Engagement Agreement and this Agreement, the terms of this Agreement shall prevail.

7.3 Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earliest of: (a) the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number or e-mail attachment at the email address set forth on the signature pages attached hereto at or prior to 5:30 p.m. (New York City time) on a Trading Day, (b) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number or e-mail attachment at the e-mail address as set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (c) the second (2nd) Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (d) upon actual receipt by the party to whom such notice is required to be given. The address for such notices and communications shall be as set forth on the signature pages attached hereto.

7.4 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and the Representative. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right.

7.5 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

7.6 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns.

7.7 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any action, suit or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action or proceeding to enforce any provisions of the Transaction Documents, then, in addition to the obligations of the Company under Article VI, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for its reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

7.8 Survival. The representations and warranties contained herein shall survive the Closing and the Option Closing, if any, and the delivery of the Securities.

7.9 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

7.10 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

7.11 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, the Underwriters and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents and hereby agree to waive and not to assert in any action for specific performance of any such obligation the defense that a remedy at law would be adequate.

7.12 Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

7.13 Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments thereto. In addition, each and every reference to share prices and shares of Common Stock in any Transaction Document shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

7.14 **WAIVER OF JURY TRIAL. IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVE FOREVER ANY RIGHT TO TRIAL BY JURY.**

(Signature Pages Follow)

If the foregoing correctly sets forth the understanding between the Underwriters and the Company, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement among the Company and the several Underwriters in accordance with its terms.

Very truly yours,

KEMPHARM, INC.

By: ______________________________
Name:
Title:

Address for Notice:

Copy to:

Accepted on the date first above written.
ROTH CAPITAL, PARTNERS, LLC
As the Representative of the several
Underwriters listed on Schedule I

By: ______________________________
Name:
Title:

Address for Notice:
888 San Clemente Drive, Suite 400
Newport Beach, CA 926690

Copy to:
Ellenoff Grossman & Schole LLP
1345 Avenue of the Americas
New York, New York 10105
E-mail: capmkts@egsllp.com
Attn: Charles E. Phillips

SCHEDULE I

Schedule of Underwriters

Underwriters	Closing Shares	Closing Series B Warrants	Closing Series A Warrants	Closing Purchase Price
Roth Capital Partners, LLC				$
Total				**$**

Exhibit 5.1

Cooley

Brent B. Siler
+1 202 728 7040
bsiler@cooley.com

January 5, 2021

KemPharm, Inc.
1180 Celebration Boulevard, Suite 103
Celebration, FL 34747

Ladies and Gentlemen:

You have requested our opinion with respect to certain matters in connection with the offering by KemPharm, Inc., a Delaware corporation (the "***Company***"), of up to (i) 5,502,391 shares (the "***Shares***") of its common stock, par value $0.0001 per share (the "***Common Stock***") and pre-funded warrants (the "***Pre-Funded Warrants***") to purchase shares of Common Stock (the "***Pre-Funded Warrant Shares***") and (ii) warrants (the "***Purchase Warrants***", and, collectively with the Pre-Funded Warrants, the "***Warrants***") to purchase up to 6,052,630 shares of Common Stock (the "***Purchase Warrant Shares***", and, collectively with the Pre-Funded Warrant Shares, the "***Warrant Shares***"), including up to 717,703 Shares and 717,703 Warrant Shares that may be sold pursuant to the exercise of an option to purchase additional Shares and Warrant Shares, pursuant to a Registration Statement on Form S-1 (No. 333-250945) (the "***Registration Statement***") filed with the Securities and Exchange Commission (the "***Commission***") under the Securities Act of 1933, as amended (the "***Act***"), including a related prospectus included in the Registration Statement (the "***Prospectus***").

In connection with this opinion, we have examined and relied upon the Registration Statement, the Prospectus, the form of Purchase Warrant, the form of Pre-Funded Warrant, the Company's Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, each as currently in effect, and originals or copies certified to our satisfaction of such records, documents, certificates, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. We have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals, the conformity to originals of all documents submitted to us as copies, the accuracy, completeness and authenticity of certificates of public officials, and the due authorization, execution and delivery of all documents by all persons other than the Company where authorization, execution and delivery are prerequisites to the effectiveness thereof. In addition, we have assumed that the Board of Directors of the Company or a duly authorized committee thereof has taken action to set the sale price of the Shares and Warrants and the exercise price of the Warrants. As to certain factual matters, we have relied upon a certificate of an officer of the Company and have not independently verified such matters.

With regard to our opinion regarding the Warrants and the Warrant Shares, we express no opinion to the extent that, notwithstanding its current reservation of shares of Common Stock, future issuances of securities, including the Warrant Shares, of the Company and/or antidilution adjustments to outstanding securities, including the Warrants, of the Company cause the Warrants to be exercisable for more shares of Common Stock than the number that then remain authorized but unissued.

With regard to our opinion concerning the Warrants constituting valid and binding obligations of the Company:

(i) Our opinion is subject to, and may be limited by, (a) applicable bankruptcy, reorganization, insolvency, moratorium, fraudulent conveyance, debtor and creditor, and similar laws which relate to or affect creditors' rights generally, and (b) general principles of equity (including, without limitation, concepts of materiality, reasonableness, good faith and fair dealing) regardless of whether considered in a proceeding in equity or at law.

(ii) Our opinion is subject to the qualification that the availability of specific performance, an injunction or other equitable remedies is subject to the discretion of the court before which the request is brought.

(iii) We express no opinion as to any provision of the Warrants that: (a) provides for liquidated damages, buy-in damages, monetary penalties, prepayment or make-whole payments or other economic remedies to the extent such provisions may constitute unlawful penalties, (b) relates to advance waivers of claims, defenses, rights granted by law, or notice, opportunity for hearing, evidentiary requirements, statutes of limitations, trial by jury, or procedural rights, (c) restricts non-written modifications and waivers, (d) provides for the payment of legal and other professional fees where such payment is contrary to law or public policy, (e) relates to exclusivity, election or accumulation of rights or remedies, (f) authorizes or validates conclusive or discretionary determinations, or (g) provides that provisions of the Warrants are severable to the extent an essential part of the agreed exchange is determined to be invalid and unenforceable.

(iv) We express no opinion as to whether a state court outside of the State of New York or a federal court of the United States would give effect to the choice of New York law or jurisdiction provided for in the Warrants.

Our opinion herein is expressed solely with respect to the General Corporation Law of the State of Delaware and, as to the Warrants constituting valid and legally binding obligations of the Company, the laws of the State of New York. Our opinion is based on these laws as in effect on the date hereof. We express no opinion to the extent that any other laws are applicable to the subject matter hereof and express no opinion and provide no assurance as to compliance with any federal or state securities law, rule or regulation. Further, we have assumed the Exercise Price (as defined in the Warrants) will not be adjusted to an amount below the par value per share of the Common Stock.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that (i) the Shares, when sold and issued in accordance with the Registration Statement and the Prospectus, will be validly issued, fully paid and nonassessable, (ii) provided that the Warrants have been duly executed and delivered by the Company to the purchasers thereof against payment therefor, the Warrants, when issued and sold as contemplated in the Registration Statement and the Prospectus will be valid and legally binding obligations of the Company, enforceable against the Company in accordance with their terms, and (iii) the Warrant Shares, when issued and paid for in accordance with the terms of the Warrants, will be validly issued, fully paid and nonassessable.

We consent to the reference to our firm under the caption “Legal Matters” in the Prospectus and to the filing of this opinion as an exhibit to the Registration Statement.

Sincerely,

COOLEY LLP

By: /s/ Brent B. Siler
Brent B. Siler

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the use in this Amendment No. 3 to the Registration Statement (No. 333-250945) on Form S-1 of KemPharm, Inc. of our report dated February 28, 2020, except for the Reverse Stock Split paragraph of Note A as to which the date is December 27, 2020, relating to the financial statements of KemPharm, Inc., appearing in the Prospectus, which is part of this Registration Statement.

We also consent to the reference to our firm under the heading “Experts” in such Prospectus.

/s/ RSM US LLP

Orlando, Florida
January 5, 2021