

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2020

OR

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

For the Transition Period From _____ to _____

Commission File No. 001-36913

KemPharm, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of Incorporation or Organization)

20-5894398
(I.R.S. Employer Identification No.)

1180 Celebration Boulevard, Suite 103, Celebration, FL
(Address of Principal Executive Offices)

34747
(Zip Code)

(321) 939-3416
(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address, and Former Fiscal Year if Changed Since Last Report)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common	KMPH	Nasdaq Capital Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company
Emerging growth company

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

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

Total shares of common stock outstanding as of May 11, 2020: 65,762,630

INDEX**KEMPHARM, INC.
FORM 10-Q**

	<u>PAGE</u>	
<u>PART I — FINANCIAL INFORMATION</u>		
<u>ITEM 1.</u>	<u>FINANCIAL STATEMENTS</u>	
	<u>CONDENSED BALANCE SHEETS AS OF MARCH 31, 2020 (UNAUDITED) AND DECEMBER 31, 2019</u>	3
	<u>UNAUDITED CONDENSED STATEMENTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2020 AND 2019</u>	4
	<u>UNAUDITED CONDENSED STATEMENTS OF STOCKHOLDERS' DEFICIT FOR THE THREE MONTHS ENDED MARCH 31, 2020 AND 2019</u>	5
	<u>UNAUDITED CONDENSED STATEMENTS OF CASH FLOWS FOR THE THREE MONTHS ENDED MARCH 31, 2020 AND 2019</u>	6
	<u>NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS</u>	7
<u>ITEM 2.</u>	<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	31
<u>ITEM 3.</u>	<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	48
<u>ITEM 4.</u>	<u>CONTROLS AND PROCEDURES</u>	48
<u>PART II — OTHER INFORMATION</u>		
<u>ITEM 1.</u>	<u>LEGAL PROCEEDINGS</u>	49
<u>ITEM 1A.</u>	<u>RISK FACTORS</u>	49
<u>ITEM 2.</u>	<u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u>	104
<u>ITEM 3.</u>	<u>DEFAULTS UPON SENIOR SECURITIES</u>	104
<u>ITEM 4.</u>	<u>MINE SAFETY DISCLOSURES</u>	104
<u>ITEM 5.</u>	<u>OTHER INFORMATION</u>	104
<u>ITEM 6.</u>	<u>EXHIBITS</u>	105
	<u>SIGNATURES</u>	106

PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2020 (unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,356	\$ 3,217
Accounts and other receivables	2,265	1,865
Prepaid expenses and other current assets	890	1,552
Total current assets	5,511	6,634
Property and equipment, net	1,210	1,471
Operating lease right-of-use assets	1,451	1,537
Restricted cash	186	338
Other long-term assets	527	527
Total assets	<u>\$ 8,885</u>	<u>\$ 10,507</u>
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,415	\$ 4,911
Current portion of convertible notes	68,606	—
Current portion of operating lease liabilities	301	284
Other current liabilities	237	236
Total current liabilities	75,559	5,431
Convertible notes, less current portion, net	—	77,343
Derivative and warrant liability	44	120
Operating lease liabilities, less current portion	1,836	1,901
Other long-term liabilities	121	168
Total liabilities	77,560	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 March 31, 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 March 31, 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 March 31, 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 March 31, 2020 (unaudited) and December 31, 2019	—	—
Common stock, \$0.0001 par value, 250,000,000 shares authorized, 56,760,111 shares issued and outstanding as of March 31, 2020 (unaudited); 36,350,785 shares issued and outstanding as of December 31, 2019	6	4
Additional paid-in capital	182,787	171,254
Accumulated deficit	(251,468)	(245,714)
Total stockholders' deficit	(68,675)	(74,456)
Total liabilities and stockholders' deficit	<u>\$ 8,885</u>	<u>\$ 10,507</u>

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 March 31,	
	2020	2019
Revenue	\$ 2,089	\$ —
Operating expenses:		
Royalty and direct contract acquisition costs	663	—
Research and development	2,126	8,531
General and administrative	2,245	2,838
Severance expense	830	—
Total operating expenses	<u>5,864</u>	<u>11,369</u>
Loss from operations	<u>(3,775)</u>	<u>(11,369)</u>
Other (expense) income:		
Interest expense related to amortization of debt issuance costs and discount	(571)	(305)
Interest expense on principal	(1,260)	(1,229)
Fair value adjustment related to derivative and warrant liability	75	453
Interest and other (expense) income, net	<u>(223)</u>	<u>151</u>
Total other (expense) income	<u>(1,979)</u>	<u>(930)</u>
Loss before income taxes	<u>(5,754)</u>	<u>(12,299)</u>
Income tax benefit	—	8
Net loss	<u>\$ (5,754)</u>	<u>\$ (12,291)</u>
Net loss per share of common stock:		
Basic and diluted	<u>\$ (0.12)</u>	<u>\$ (0.46)</u>
Weighted average number of shares of common stock outstanding:		
Basic and diluted	<u>48,073,641</u>	<u>26,701,891</u>

See accompanying notes to unaudited condensed financial statements

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

	Preferred Stock				Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Series A Convertible Preferred Stock	Series B-1 Convertible Preferred Stock	Series B-2 Convertible Preferred Stock	Undesignated Preferred Stock				
Balance as of January 1, 2020	\$ —	\$ —	\$ —	\$ —	\$ 4	\$ 171,254	\$ (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	—	—	—	—	2	9,598	—	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	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 6</u>	<u>\$ 182,787</u>	<u>\$ (251,468)</u>	<u>\$ (68,675)</u>

	Preferred Stock			Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Series A Convertible Preferred Stock	Undesignated Preferred Stock					
Balance as of January 1, 2019	\$ —	\$ —	\$ 3	\$ 154,623	\$ (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	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3</u>	<u>\$ 158,644</u>	<u>\$ (233,483)</u>	<u>\$ (74,836)</u>	

See accompanying notes to unaudited condensed financial statements

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

	Three months ended March 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	\$ (5,754)	\$ (12,291)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,029	1,290
Non-cash interest expense	1,244	863
Amortization of debt issuance costs and debt discount	571	305
Depreciation and amortization expense	72	78
Fair value adjustment related to derivative and warrant liability	(75)	(453)
Change in estimated deferred offering costs	—	10
Loss on sublease and disposal of property and equipment	200	—
Change in assets and liabilities:		
Accounts and other receivables	(400)	(20)
Prepaid expenses and other assets	455	206
Operating lease right-of-use assets	86	(1,785)
Accounts payable and accrued expenses	586	(1,027)
Operating lease liabilities	(48)	2,537
Other liabilities	12	(779)
Net cash used in operating activities	<u>(2,022)</u>	<u>(11,066)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(11)	(17)
Maturities of marketable securities	—	3,260
Net cash (used in) provided by investing activities	<u>(11)</u>	<u>3,243</u>
Cash flows from financing activities:		
Proceeds from equity line of credit	1,112	2,721
Repayment of principal on finance lease liabilities	(58)	(51)
Payment of debt issuance costs	(34)	—
Net cash provided by financing activities	<u>1,020</u>	<u>2,670</u>
Net decrease in cash, cash equivalents and restricted cash	(1,013)	(5,153)
Cash, cash equivalents and restricted cash, beginning of period	3,555	19,119
Cash, cash equivalents and restricted cash, end of period	<u>\$ 2,542</u>	<u>\$ 13,966</u>
Supplemental cash flow information:		
Cash paid for interest	\$ 52	\$ 2,287
Deferred offering costs included in accounts payable and accrued expenses	123	105
2019 Notes principal converted to common stock	9,600	—
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	—

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 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.

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 months ended March 31, 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").

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 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 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 into, but not through, the first quarter of 2021. A significant portion of the Company's projected revenues 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. 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 \$80.0 million of the Company's common stock, preferred stock, and debt and/or warrants, if available (the "Current Registration Statement").

In order to issue securities under the Current Registration Statement, the Company 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 Current Registration Statement during any twelve-month period. At the time it sells securities pursuant to the Current 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. Based on this calculation, as of March 31, 2020, the amount of securities the Company is able to sell under the Current Registration Statement is approximately \$6.8 million, of which the Company (i) has filed a prospectus supplement to register approximately \$2.7 million for sales under the Current Purchase Agreement (as defined below); and (ii) has 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, the Company expects it will be unable to sell additional securities beyond those amounts pursuant to the Current Registration Statement 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 Current Purchase Agreement, stockholder approval may be required to access a portion of the amounts available under the Current Purchase Agreement. As of March 31, 2020, the Company has sold 4,000,000 shares of common stock (exclusive of the 308,637 commitment shares previously issued to Lincoln Park) under the Current Purchase Agreement for approximately \$1.1 million in gross proceeds.

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 of 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 new drug application ("NDA"). A significant 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, or the CARES Act, a portion of which may be forgiven, which the Company intends to use 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 will be deferred for the first six months of the PPP Loan term. Thereafter, the Company is 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 is 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 is 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 will qualify for forgiveness. 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, and 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 U.S. Small Business Administration, or the SBA.

Entry into ATM Agreement

In September 2018, the Company entered into a Common Stock Sales Agreement (the “ATM Agreement”) with RBC Capital Markets, LLC (“RBCCM”). The prospectus supplement covering the ATM Agreement was terminated in February 2020. The Company did not make any sales under the ATM Agreement prior to termination.

Entry into Prior Purchase Agreement

In February 2019, the Company entered into a purchase agreement (the “Prior Purchase Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”) which provided that, upon the terms and subject to the conditions and limitations set forth therein, the Company previously could sell to Lincoln Park up to \$15.0 million of shares of common stock from time to time over the 36-month term of the Prior Purchase Agreement, and upon execution of the Prior Purchase Agreement the Company issued an additional 120,200 shares of common stock to Lincoln Park as commitment shares in accordance with the closing conditions within the Prior Purchase Agreement. Concurrently with entering into the Prior Purchase Agreement, the Company also entered into a registration rights agreement with Lincoln Park (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 the Current Purchase Agreement. Prior to the termination of the Prior Purchase Agreement, the Company sold 3,401,271 shares of common stock to Lincoln Park (exclusive of the 120,200 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 308,637 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. As of March 31, 2020, the Company has sold 4,000,000 shares of common stock to Lincoln Park (exclusive of the 308,637 commitment shares) under the Current Purchase Agreement for approximately \$1.1 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 is entitled to receive 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.

Reclassifications

During the third quarter of 2019, the Company began presenting accounts and other receivables as a separate line item on the unaudited condensed 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 unaudited condensed statements of cash flows. In accordance with U.S. GAAP, the change in current period presentation requires a reclassification of prior period balances. The reclassification of prior period balances resulted in an increase in change in prepaid expenses and other assets of \$20,000 on the Company's unaudited condensed statement of cash flows for the three month period ended March 31, 2019. This reclassification had no effect on the unaudited condensed balance sheets, unaudited condensed statements of operations and unaudited condensed statements of changes in stockholders' deficit.

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, 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 is entitled to receive 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 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 March 31, 2020, the Company has recognized approximately 95% 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 three months ended March 31, 2020, the Company recognized revenue of \$2.1 million, which is comprised of \$1.6 million for the performance of consulting services and \$0.5 million of reimbursement of out-of-pocket third-party research and development costs. In addition, as of March 31, 2020, the Company had receivables in the amount of \$1.6 million and \$0.5 million related to the performance of consulting services and the reimbursement of out-of-pocket third-party research and development costs, respectively. 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 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 March 31, 2020, the Company has recognized approximately \$2.6 million of these incremental costs, \$0.7 million of which was recognized in the three months ended March 31, 2020 and are recorded in the line item titled royalty and direct contract acquisition costs in the unaudited condensed statement of operations. The remaining incremental contract costs to be amortized, approximately \$0.2 million as of March 31, 2020, are recorded in prepaid expense and other currents on the unaudited condensed balance sheets. There was no revenue recognized, or associated direct contract acquisition costs for the three months ended March 31, 2019. There was no deferred revenue related to this agreement as of March 31, 2020 or December 31, 2019.

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 March 31, 2020 and December 31, 2019 no reserve or allowance 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.

C. Debt Obligations

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

	March 31, 2020	December 31, 2019
Deerfield Convertible Note	\$ 7,100	\$ 6,981
2021 Notes	—	3,000
December 2019 Notes	60,789	70,218
January 2020 Note	3,037	—
Total outstanding principal on debt obligations	70,926	80,199
Less: debt issuance costs and discounts	(2,320)	(2,856)
Convertible notes, net	\$ 68,606	\$ 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").

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

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

The Company also issued to Deerfield a warrant to purchase 14,423,076 shares of Series D Preferred at an initial exercise price of \$0.78 per share, which is exercisable until June 2, 2024 (the "Deerfield Warrant"). Upon completion of the Company's initial public offering, the Deerfield Warrant automatically converted into a warrant to purchase 1,923,077 shares of the Company's common stock at an exercise price of \$5.85 per share. This warrant qualifies as a participating security under ASC Topic 260, Earnings per Share, and is treated as such in the net loss per share calculation (Note 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.

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 598,568 shares of the Company's common stock, with such principal conversion amount being applied against and in full satisfaction of the amortization payment due June 2, 2018; (ii) Deerfield waived specified rights under the Deerfield Facility Agreement with regards to such principal and interest amount; and (iii) amended specified provisions of the Deerfield Convertible Note as they relate to the delivery of shares of the Company's common stock in connection with any conversion of the Deerfield Convertible Note.

2021 Note Exchange Effected in October 2018

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

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

Each share of Series A Preferred Stock has an aggregate stated value of \$1,000 and is convertible into shares of common stock at a price equal to \$3.00 per share (subject to adjustment to reflect stock splits and similar events). Immediately following the exchange under the October 2018 Exchange Agreement, there were an aggregate of 3,192,333 shares of common stock issuable upon conversion of the then outstanding Series A Preferred Stock (without giving effect to the limitation on conversion described below). As of March 31, 2020, all 9,577 shares of Series A Preferred Stock issued under the October 2018 Exchange Agreement have been converted into an aggregate 3,192,333 shares of the Company's common stock.

2021 Note Exchange Effected in September 2019

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

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

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

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

As of March 31, 2020, 1,576 shares of Series B-1 Preferred Stock have been converted into 1,659,966 shares of common stock, and there were no shares of Series B-2 Preferred Stock outstanding.

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

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

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

2021 Note Exchange Effected in December 2019

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

The December 2019 Notes bear interest at 6.75% per annum. The December 2019 Notes are convertible into shares of the Company’s common stock at an initial conversion price of \$17.11 per share (which represents the conversion price of the 2021 Notes), subject to adjustment in accordance with the terms of the December 2019 Notes. As of the date of issuance, the December 2019 Notes were convertible, by their terms, into an aggregate of 4,174,051 shares of the Company’s common stock. The Company subsequently amended the December 2019 Notes to provide that such notes shall be convertible into shares of the Company’s common stock at a conversion price of \$5.85 per share (which represents the conversion price of the Deerfield Convertible Note). The conversion price of the December 2019 Notes will be adjusted downward if the Company issues or sells any shares of common stock, convertible securities, warrants or options at a sale or exercise price per share less than the greater of the December 2019 Notes’ conversion price or the closing sale price of the Company’s common stock as reported on the Nasdaq Stock Market on the last trading date immediately prior to such issuance, or, in the case of a firm commitment underwritten offering, on the date of execution of the underwriting agreement between the Company and the underwriters for such offering. However, if the Company effects an “at the market offering” as defined in Rule 415 of the Securities Act, 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 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 \$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 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 the Nasdaq Stock Market on each of the 15 trading days immediately preceding such exchange, (iii) provide that no more than 28,439,015 of shares of the Company's common stock shall be issued pursuant to optional exchanges under the September 2019 Exchange Agreement (whether by common stock exchange or upon conversion of Series B-2 Shares (as defined in the September 2019 Exchange Agreement Amendment)), subject to adjustment to reflect stock splits and similar events and (iv) eliminate limitations regarding the timing and aggregate amount of principal which may be exchanged under the September 2019 Exchange Agreement. These changes in the September 2019 Exchange Agreement Amendment significantly modified the Optional Exchange Principal Amount, as such after giving effect to the September Exchange Agreement Amendment the Optional Exchange Principal Amount ceases to exist the new optional exchanges are referred to as the Deerfield Optional Conversion Feature.

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

As of March 31, 2020, the Deerfield Lenders have converted \$10.8 million of principal under the December 2019 Notes into 18,000,000 shares of common stock.

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

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

2021 Note Exchange Effected in January 2020

In January 2020, 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).

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 intends to use 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 will be deferred for the first six months of the PPP Loan term. Thereafter, the Company is 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 is 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 is 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 will qualify for forgiveness. 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, and the Company cannot provide any assurance that we 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 March 31, 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 March 31, 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 March 31, 2020 and December 31, 2019. No shares of Series A Preferred Stock or Series B-1 Preferred Stock were outstanding as of March 31, 2020 and December 31, 2019. No shares of Series B-2 Preferred Stock were issued or outstanding as of March 31, 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 March 31, 2020 all issued shares of Series A Preferred Stock had been converted into shares of common stock.

In September 2019, the Company entered into the September 2019 Exchange Agreement. Under the September 2019 Exchange Agreement the Company issued to the Holders 1,576 shares of Series B-1 Preferred Stock. Each share of Series B-1 Preferred Stock had an aggregate stated value of \$1,000 and was convertible into shares of common stock at a price equal to the greater of (i) \$0.9494, or (ii) the average of the volume-weighted average price of the Common Stock on the Nasdaq Capital Market on each of the 15 trading days immediately preceding such exchange (subject to adjustment to reflect stock splits and similar events). Immediately following the exchange under the September 2019 Exchange Agreement, there were an aggregate of 1,659,996 shares of common stock issuable upon conversion of the Series B-1 Preferred Stock (without giving effect to the limitation on conversion described below). The Series B Preferred Stock is convertible at any time at the option of the Holders; provided that the Holders are prohibited from converting shares of Series B Preferred Stock into shares of common stock if, as a result of such conversion, such Holders (together with certain affiliates and “group” members of such Holders) would beneficially own more than 4.985% of the total number of shares of common stock then issued and outstanding. The Series B Preferred Stock is not redeemable. In the event of the Company’s liquidation, dissolution or winding up, the Holders will receive an amount equal to \$0.0001 per share, plus any declared but unpaid dividends, and thereafter will share ratably in any distribution of the Company’s assets with holders of common stock and with the holders of any shares of any other class or series of capital stock of the Company entitled to share in such remaining assets of the Company (including Series A Preferred Stock on an as-converted basis. With respect to rights upon liquidation, the Series B Preferred Stock ranks senior to the common stock, on parity with the Series A Preferred Stock, if any is then outstanding, and junior to existing and future indebtedness. Except as otherwise required by law (or with respect to approval of certain actions involving the Company’s organizational documents that materially and adversely affect the holders of Series B Preferred Stock), the Series B Preferred Stock does not have voting rights. The Series B Preferred Stock is not subject to any price-based anti-dilution protections and does not provide for any accruing dividends, but provides that holders of Series B Preferred Stock will participate in any dividends on the common stock on an as-converted basis (without giving effect to the limitation on conversion described above). The Series B-1 Certificate of Designation and the Series B-2 Certificate of Designation also provide for partial liquidated damages in the event that the Company fails to timely convert shares of Series B-1 Preferred Stock or Series B-2 Preferred Stock, respectively, into Common Stock in accordance with the applicable Certificate of Designation. As of March 31, 2020, 1,576 shares of Series B-1 Preferred Stock have been converted into 1,659,996 shares of common stock.

F. Common Stock and Warrants

Authorized, Issued, and Outstanding Common Shares

As of March 31, 2020 and December 31, 2019, the Company had authorized shares of common stock of 250,000,000 shares. Of the authorized shares, 56,760,111 and 36,350,785 shares of common stock were issued and outstanding as of March 31, 2020 and December 31, 2019, respectively.

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

	March 31, 2020	December 31, 2019
Conversion of Deerfield Convertible Note	1,233,973	1,213,606
Conversion of 2021 Notes	—	175,336
Conversion of January 2020 Note	526,674	—
Conversion of December 2019 Notes not subject to the Deerfield Optional Conversion Feature	9,504,813	3,186,770
Outstanding awards under equity incentive plans	6,323,822	5,192,222
Outstanding common stock warrants	2,423,077	2,423,077
In exchange for the Deerfield Optional Conversion Feature*	10,439,015	26,439,015
Possible future issuances under the equity line of credit	4,959,545	9,553,046
Possible future issuances under equity incentive plans	346,125	84,616
Total common shares reserved for future issuance	<u>35,757,044</u>	<u>48,267,688</u>

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

Common Stock Activity

The following table summarizes common stock activity for the three months ended March 31, 2020:

	Shares of Common Stock
Balance as of December 31, 2019	36,350,785
Common stock issued under equity line of credit	4,308,637
Restricted stock vested during the period	60,922
Common stock issued as compensation to third-parties	39,767
Common stock issued as a result of Deerfield Optional Conversion Feature conversion	16,000,000
Balance as of March 31, 2020	<u>56,760,111</u>

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 Company’s initial public offering (the “IPO”), the 2013 Warrants automatically converted into warrants to purchase 143,466 shares of the Company’s common stock at an exercise price of \$5.85 per share. The 2013 Warrants expired on June 2, 2019.

On June 2, 2014, pursuant to the terms of the Deerfield Facility Agreement, the Company issued the Deerfield Warrant to purchase 14,423,076 shares of Series D Preferred (Note 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 IPO, the Deerfield Warrant automatically converted into a warrant to purchase 1,923,077 shares of the Company’s common stock at an exercise price of \$5.85 per share. The Company is amortizing the debt discount over the term of the Deerfield Convertible Note and the expense is recorded as interest expense related to amortization of debt issuance costs and discount in the condensed statements of operations.

The Company determined that the 2013 Warrants and Deerfield Warrant should be recorded as a liability and stated at fair value at each reporting period upon inception. As stated above, upon completion of the IPO, the 2013 Warrants and the Deerfield Warrant automatically converted into warrants to purchase the Company’s common stock. The Company marked the 2013 Warrants to fair value and reclassified them to equity upon closing of the IPO. The Deerfield Warrant remains classified as a liability and is recorded at fair value at each reporting period since it can be settled in cash. Changes to the fair value of the warrant liability are recorded through the condensed statements of operations as a fair value adjustment (Note 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 Global Market on the execution date of the APADAZ License Agreement (the “KVK Warrant”). The KVK Warrant is initially not exercisable for any shares of common stock. Upon the achievement of each of four specified milestones under the KVK Warrant, the KVK Warrant will become exercisable for an additional 125,000 shares, up to an aggregate of 500,000 shares of the Company’s common stock. The exercise price and the number and type of shares underlying the KVK Warrant are subject to adjustment in the event of specified events, including a reclassification of the Company’s common stock, a subdivision or combination of the Company’s common stock, or in the event of specified dividend payments. The KVK Warrant is exercisable until October 24, 2023. Upon exercise, the aggregate exercise price may be paid, at KVK’s election, in cash or on a net issuance basis, based upon the fair market value of the Company’s common stock at the time of exercise.

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

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 6,530,725 as of March 31, 2020. The number of shares of common stock reserved for issuance under the 2014 Plan will automatically increase on January 1 of each year, beginning on January 1, 2016, and ending on and including January 1, 2024, by 4% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Board. Pursuant to the terms of the 2014 Plan, on January 1, 2020, the common stock reserved for issuance under the 2014 Plan automatically increased by 1,454,031 shares.

During the first quarter of 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 in the first quarter of 2020. For the first quarter of 2020, RSAs were granted for a total of 60,922 shares of common stock.

During the three months ended March 31, 2020 and 2019, no stock options were exercised.

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

	Three months ended March 31,	
	2020	2019
Research and development	\$ 246	\$ 433
General and administrative	363	857
Severance expense	420	—
Total stock-based compensation expense	<u>\$ 1,029</u>	<u>\$ 1,290</u>

There was no stock-based compensation expense related to performance-based awards recognized during the three months ended March 31, 2020 or 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 \$6.1 million and \$6.0 million, respectively, as of March 31, 2020 and December 31, 2019. The fair value of the December 2019 Notes was \$52.2 million and \$57.0 million, respectively, as of March 31, 2020 and December 31, 2019. The fair value of the January 2020 Note was \$2.6 million as of March 31, 2020 and the fair value of the 2021 Notes was \$2.4 million as of December 31, 2019. The Deerfield Convertible Note, December 2019 Notes and January 2020 Note 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 March 31, 2020 and December 31, 2019. The Company also used a Tsiveriotis-Fernandes model to value the January 2020 Note as of March 31, 2020 and the 2021 Notes as of December 31, 2019.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company evaluates its financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level in which to classify them for each reporting period. This determination requires significant judgments to be made. The following table summarizes the conclusions reached regarding fair value measurements as of March 31, 2020 and December 31, 2019 (in thousands):

	Balance as of March 31, 2020	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Deerfield Warrant liability	\$ 38	\$ —	\$ —	\$ 38
Embedded Warrant Put Option	—	—	—	—
Deerfield Note Conversion Feature	—	—	—	—
KVK Warrant liability	6	—	6	—
Total liabilities	\$ 44	\$ —	\$ 6	\$ 38

	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
Fundamental change and make-whole interest provisions embedded within 2021 Notes	—	—	—	—
Deerfield Note Conversion Feature	—	—	—	—
KVK Warrant liability	24	—	24	—
Total liabilities	\$ 120	\$ —	\$ 24	\$ 96

The Company's Deerfield Warrant liability, embedded Warrant Put Option, the fundamental change and make-whole interest provisions embedded in the 2021 Notes and the embedded Deerfield Note Put Option are measured at fair value on a recurring basis. As of March 31, 2020 and December 31, 2019, the Deerfield Warrant liability, embedded Warrant Put Option, embedded Deerfield Note Put Option and the KVK Warrant liability 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 March 31, 2020 and December 31, 2019. The Company also used a Monte Carlo simulation to value the fundamental change and make-whole interest provisions embedded in the 2021 Notes as of December 31, 2019. Significant unobservable inputs used in measuring the fair value of these financial instruments included the Company's estimated enterprise value, an estimate of the timing of a liquidity or fundamental change event and a present value discount rate. Changes in the fair value of the Deerfield Warrant liability, embedded Warrant Put Option and the embedded Deerfield Note Put Option are reflected in the unaudited condensed statements of operations for the three months ended March 31, 2020 and 2019 as a fair value adjustment related to derivative and warrant liability. In addition, changes in the fair value of the fundamental change and make-whole interest provisions embedded in the 2021 Notes are reflected in the unaudited condensed statements of operations for the three months ended March 31, 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 March 31, 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 months ended March 31, 2020 and 2019 as a fair value adjustment related to derivative and warrant liability.

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

	Three months ended March 31,	
	2020	2019
Balance as of beginning of period	\$ 96	\$ 1,845
Adjustment to fair value	(58)	(424)
Balance as of end of period	<u>\$ 38</u>	<u>\$ 1,421</u>

I. 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.

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:

	Three months ended March 31,	
	2020	2019
Deerfield Convertible Note	1,233,973	1,166,998
2021 Notes	—	4,481,182
January 2020 Note	526,674	—
December 2019 Notes*	19,943,828	—
Awards under equity incentive plans	6,323,822	5,117,655
Common stock warrants	2,423,077	2,527,763
Series A Convertible Preferred Stock	—	1,112,334
Total securities excluded from the calculation of weighted average number of shares of common stock outstanding	30,451,374	14,405,932

Inclusive of 10,439,015 of shares of Common Stock issuable (i) in exchange of the Deerfield Optional Conversion

* Feature, or (ii) upon conversion of the Series B-2 Preferred Stock issuable in exchange of the Deerfield Optional Conversion Feature.

J. Severance Expense

On February 7, 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 three months ended March 31, 2020. As of March 31, 2020, the Company had accrued severance expense recorded within accounts payable and accrued expenses in the amount of \$0.3 million. As of March 31, 2019, there was accrued severance of \$0.1 million, related to the resignation of our executive vice president, government and public relations in August 2018. For the three months ended March 31, 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. 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. 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.

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

Lease Cost	Three months ended March 31,	
	2020	2019
Finance lease cost:		
Amortization of right-of-use assets	\$ 31	\$ 31
Interest on lease liabilities	8	11
Total finance lease cost	39	42
Operating lease cost	89	124
Short-term lease cost	57	57
Variable lease cost	14	15
Less: sublease income	(13)	(25)
Total lease costs	<u>\$ 186</u>	<u>\$ 213</u>

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

	Three months ended March 31,	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from finance leases	\$ 8	\$ 11
Financing cash flows from finance leases	58	51
Operating cash flows from operating leases	109	108
Operating cash flows from short-term leases	57	57
Operating cash flows from variable lease costs	14	15
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):

	March 31, 2020	December 31, 2019
Finance Leases		
Property and equipment, at cost	\$ 1,013	\$ 1,013
less: accumulated depreciation and amortization	(429)	(398)
Property and equipment, net	<u>\$ 584</u>	<u>\$ 615</u>
Other current liabilities	\$ 237	\$ 236
Other long-term liabilities	108	168
Total finance lease liabilities	<u>\$ 345</u>	<u>\$ 404</u>
Operating Leases		
Operating lease right-of-use assets	\$ 1,451	\$ 1,537
Total operating lease right-of-use assets	<u>\$ 1,451</u>	<u>\$ 1,537</u>
Current portion of operating lease liabilities	\$ 301	\$ 284
Operating lease liabilities, less current portion	1,836	1,901
Total operating lease liabilities	<u>\$ 2,137</u>	<u>\$ 2,185</u>
Weighted Average Remaining Lease Term		
Finance leases (years)	2	2
Operating leases (years)	6	6
Weighted Average Discount Rate		
Finance leases	7.7%	7.7%
Operating leases	7.5%	7.5%

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

Year Ending December 31,	Finance Leases	Operating Leases
2020 (excluding the three months ended March 31, 2020)	\$ 193	\$ 338
2021	163	460
2022	11	463
2023	—	472
2024	—	484
Thereafter	—	420
Total lease payments	<u>\$ 367</u>	<u>\$ 2,637</u>
Less: future interest expense	(22)	(500)
Lease liabilities	<u>\$ 345</u>	<u>\$ 2,137</u>

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

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

Forward-Looking Statements

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

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

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

Overview

We are a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs to treat serious medical conditions through our proprietary Ligand Activated Therapy, or LAT®, technology. We utilize our proprietary LAT technology to generate improved prodrug versions of drugs approved by the U.S. Food and Drug Administration, or FDA, as well as to generate prodrug versions of existing compounds that may have applications for new disease indications. Our product candidate pipeline is focused on the high need areas of attention deficit hyperactivity disorder, or ADHD, and stimulant use disorder, or SUD. Our co-lead clinical development candidates, KP415 and KP484, are both based on a prodrug of d-methylphenidate, or d-MPH, but with differing extended-release, or ER, effect profiles, and are intended for the treatment of ADHD. Our preclinical product candidate for the treatment of SUD is KP879, based on a prodrug of d-MPH. In September 2019, we entered into a Collaboration and License Agreement, or the KP415 License Agreement, with Commave Therapeutics SA, an affiliate of Gurnet Point Capital, or Commave. Under the KP415 License Agreement, we granted to Commave an exclusive, worldwide license to develop, manufacture and commercialize our product candidates containing serdexmethylphenidate, or SDX, and d-MPH, including KP415 and KP484. In addition, we have announced our commercial partnership with KVK Tech, Inc., or KVK, of APADAZ®, an FDA approved immediate-release, or IR, combination product of benzhydrocodone, our prodrug of hydrocodone, and acetaminophen, or APAP, for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

We expect that our only source of revenues will be through payments arising from our license agreements with KVK and Commave, and through any other future arrangements we might enter into related to one of our other product candidates. To date, we have only generated revenue from the KP415 License Agreement in the form of the non-refundable upfront payment of \$10.0 million, of which we paid Aquestive Therapeutics, or 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. In May 2020, the FDA accepted our NDA for KP415. Per the KP415 License Agreement, we are entitled to receive a regulatory milestone payment of \$5.0 million following the FDA's acceptance of the KP415 NDA.

We had negative cash flows from operations since our inception and, as of March 31, 2020, had an accumulated deficit of \$251.5 million and a net working capital (current assets less current liabilities) deficit of \$70.0 million. Our negative cash flows from operations for the three months ended March 31, 2020 and 2019 were \$2.0 million and \$11.1 million, respectively.

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

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

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

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

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 Submission - 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 submitted a 505(b)(2) NDA for KP415 in March 2020 which was accepted by the FDA in May 2020. We anticipate initiating additional pharmacokinetic, or PK, and pivotal efficacy trials for KP484 in 2021, subject to Commave's approval.

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.

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 the Company's NDA for KP415. Per the KP415 License Agreement, the Company is entitled to receive 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 Pharmaceuticals, LLC, or 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.

Results of Operations

Comparison of the three months ended March 31, 2020 and 2019 (in thousands):

	Three months ended March 31,		Period-to- Period Change
	2020	2019	
Revenue	\$ 2,089	\$ —	\$ 2,089
Operating expenses:			
Royalty and direct contract acquisition costs	663	—	663
Research and development	2,126	8,531	(6,405)
General and administrative	2,245	2,838	(593)
Severance expense	830	—	830
Total operating expenses	5,864	11,369	(5,505)
Loss from operations	(3,775)	(11,369)	7,594
Other (expense) income:			
Interest expense related to amortization of debt issuance costs and discount	(571)	(305)	(266)
Interest expense on principal	(1,260)	(1,229)	(31)
Fair value adjustment related to derivative and warrant liability	75	453	(378)
Interest and other (expense) income, net	(223)	151	(374)
Total other (expense) income	(1,979)	(930)	(1,049)
Loss before income taxes	(5,754)	(12,299)	6,545
Income tax benefit	—	8	(8)
Net loss	\$ (5,754)	\$ (12,291)	\$ 6,537

Net Loss

Net loss for the three months ended March 31, 2020 was \$5.8 million, a decrease of \$6.5 million compared to a net loss for the three months ended March 31, 2019 of \$12.3 million. The decrease was primarily attributable to a decrease in loss from operations of \$7.6 million, partially offset by a decrease in fair value adjustment related to derivative and warrant liability of \$0.4 million and an increase in net interest expense and other items of \$0.7 million.

Revenue

Revenue for the three months ended March 31, 2020 was \$2.1 million, which was comprised of \$1.6 million of consulting fees earned and \$0.5 million of reimbursements for out-of-pocket third-party research and development costs, all related to the KP415 License Agreement. We had no revenue in the three months ended March 31, 2019.

Royalty and direct contract acquisition costs

Royalties and direct contract acquisition costs for the three months ended March 31, 2020 was \$0.7 million, which was comprised of royalty payments and contract costs which are directly attributable to the revenue recognized under the KP415 License Agreement for the period. We had no royalties and direct contract acquisition costs for the three months ended March 31, 2019.

Research and Development

Research and development expenses decreased by \$6.4 million, from \$8.5 million for the three months ended March 31, 2019, to \$2.1 million for the three months ended March 31, 2020. This decrease was primarily attributable to a decrease in net third-party research and development costs.

General and Administrative

General and administrative expenses decreased by \$0.6 million, from \$2.8 million for the three months ended March 31, 2019, to \$2.2 million for the three months ended March 31, 2020. This decrease was primarily attributable to a decrease in personnel-related costs and other miscellaneous general and administrative costs, partially offset by an increase in professional fees.

Severance Expense

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

Other (Expense) Income

Other expense increased by \$1.1 million, from \$0.9 million for the three months ended March 31, 2019, to \$2.0 million for the three months ended March 31, 2020. This period-to-period increase in expense was primarily attributable to a decrease in fair value adjustment income related to derivative and warrant liability of \$0.4 million and an increase in net interest expense and other items of \$0.7 million.

Liquidity and Capital Resources

Sources of Liquidity

Through March 31, 2020, we have funded our research and development and operating activities primarily through the issuance of debt, private placements of redeemable convertible preferred stock and the sale of common stock in our initial public offering, at-the-market offering, underwritten public offerings, through our purchase agreements with Lincoln Park Capital Fund, LLC, or Lincoln Park, and from revenue received under the KP415 License Agreement. As of March 31, 2020, we had cash and cash equivalents of \$2.4 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 imposes a limitation on the maximum amount of securities that we may sell pursuant to the Current Registration Statement 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, 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, 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 September 2018, we entered into Common Stock Sales Agreement, or the ATM Agreement, with RBC Capital Markets, LLC, or RBCCM, under which we may offer and sell, from time to time, in our sole discretion, shares of common stock having an aggregate offering price of up to \$50,000,000 through RBCCM as our sales agent. The Prior Registration Statement previously included a prospectus supplement covering the offering of up to \$50,000,000 of shares of common stock in accordance with the ATM Agreement, but in February 2020, we filed a prospectus supplement to the Prior Registration Statement to terminate this offering in its entirety. Through the date of termination, we did not sell any shares of common stock under the ATM Agreement.

In February 2019, we entered into a purchase agreement, or the Prior Purchase Agreement, with Lincoln Park, which provided that, upon the terms and subject to the conditions and limitations set forth therein, we may sell to Lincoln Park up to \$15.0 million of shares of our common stock, from time to time over the 36-month term of the Prior Purchase Agreement, and upon execution of the Prior Purchase Agreement we issued an additional 120,200 shares of our common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Prior Purchase Agreement. Concurrently with entering into the Prior Purchase Agreement, we also entered into a registration rights agreement with Lincoln Park, pursuant to which we agreed to register the sale of the shares of our common stock that have been and may be issued to Lincoln Park under the Prior Purchase Agreement pursuant to our existing shelf registration statement on Form S-3 or a new registration statement. In February 2020, upon entering into a subsequent purchase agreement, or 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 3,401,271 shares of our common stock (exclusive of the 120,200 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 are entitled to receive a regulatory milestone payment of \$5.0 million following the FDA's acceptance of the KP415 NDA.

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 308,637 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. As of March 31, 2020, we have sold 4,000,000 shares of common stock (exclusive of the 308,637 commitment shares previously issued to Lincoln Park) under the Current Purchase Agreement for approximately \$1.1 million in gross proceeds.

We had negative operating cash flows since our inception and, as of March 31, 2020, had an accumulated deficit of \$251.5 million. We anticipate that we will continue to incur negative operating flows for at least the next several years. Our recurring negative cash flows from operations, 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 source of revenues will be through payments arising from our license agreements with KVK and Commave, or through any other future arrangements related to one of our other product candidates. Accordingly, our ability to continue as a going concern may require us to obtain additional financing to fund our operations. The perception of our inability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or debt, the terms of these securities may restrict our ability to operate. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

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 of 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 significant 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 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 intend to use 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 will be deferred for the first six months of the PPP Loan term. Thereafter, we are 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 is 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 is 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 will qualify for forgiveness. 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, and 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 U.S. Small Business Administration, or the SBA.

Convertible Debt

As of March 31, 2020, we had \$70.9 million of convertible notes outstanding, consisting of senior secured convertible promissory notes issued, under our multi-tranche credit facility, or the Deerfield Facility Agreement, with Deerfield Private Design Fund III, L.P., or Deerfield, (i) in June 2014, or the Deerfield Convertible Note (as described below), in the principal amount of \$7.1 million, (ii) in December 2019, or the December 2019 Notes (as described below), in the aggregate principal amount of \$60.8 million and (iii) in January 2020, or the January 2020 Note (as described below), in the principal amount of \$3.0 million.

Deerfield Facility Agreement

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

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

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

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

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

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

2021 Notes

In February 2016, we issued 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 the Company and U.S. Bank National Association, as trustee. Interest on the 2021 Notes was payable semi-annually in cash in arrears on February 1 and August 1 of each year, beginning on August 1, 2016, at a rate of 5.50% per year. The 2021 Notes originally matured on February 1, 2021 unless earlier converted or repurchased.

The 2021 Notes were not redeemable prior to the maturity date, and no sinking fund was provided for the 2021 Notes. The 2021 Notes were convertible at an initial conversion rate of 58.4454 shares of our common stock per \$1,000 principal amount of the 2021 Notes, subject to adjustment under the indenture, which was equal to an initial conversion price of approximately \$17.11 per share of our common stock.

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

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

As described in more detail below, in multiple exchanges occurring in October 2018, December 2019 and January 2020, all outstanding 2021 Notes were exchanged by the holders thereof for either shares of our common stock or 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 Deerfield and Deerfield Special Situations Fund, L.P., or the Deerfield Lenders. Under the October 2018 Exchange Agreement, the Deerfield Lenders exchanged an aggregate of \$9,577,000 principal amount of our 2021 Notes for an aggregate of 9,577 shares of our Series A Convertible Preferred Stock, par value \$0.0001, or the Series A Preferred Stock.

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

Each share of Series A Preferred Stock has an aggregate stated value of \$1,000 and is convertible into shares of our common stock at a price equal to \$3.00 per share (subject to adjustment to reflect stock splits and similar events). Immediately following the exchange under the October 2018 Exchange Agreement, an aggregate of 3,192,333 shares of common stock were issuable upon conversion of the Series A Preferred Stock. As of March 31, 2020, all 9,577 shares of Series A Preferred Stock issued under the October 2018 Exchange Agreement have been converted into an aggregate 3,192,333 shares of our common stock.

2021 Note Exchange Effected in September 2019

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

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

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

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

As of March 31, 2020, 1,576 shares of Series B-1 Preferred Stock have been converted into 1,659,996 shares of common stock, and there were no shares of Series B-2 Preferred Stock outstanding.

2021 Note Exchange Effected in December 2019

In December 2019, we entered into the December 2019 Exchange Agreement and Amendment to Facility Agreement, Senior Secured Convertible Notes and Warrants, or the December 2019 Exchange Agreement, with the Deerfield Lenders and Delaware Street Capital Master Fund, L.P., or DSC and, collectively with the Deerfield Lenders, the December 2019 Holders. Under the December 2019 Exchange Agreement, we issued 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 4,174,051 shares of our common stock. We subsequently amended the December 2019 Notes to provide that such notes shall be convertible into shares of our common stock at a conversion price of \$5.85 per share (which represents the conversion price of the Deerfield Convertible Note). The conversion price of the December 2019 Notes will be adjusted downward if we issue or sell any shares of common stock, convertible securities, warrants or options at a sale or exercise price per share less than the greater of the December 2019 Notes' conversion price or the closing sale price of our common stock as reported on the Nasdaq Stock Market on the last trading date immediately prior to such issuance, or, in the case of a firm commitment underwritten offering, on the date of execution of the underwriting agreement between us and the underwriters for such offering. However, if we effect an "at the market offering" as defined in Rule 415 of the Securities Act or 1933, as amended, or the Securities Act, of our common stock, the conversion price of the December 2019 Notes will be adjusted downward pursuant to this anti-dilution adjustment only if such sales are made at a price less than \$5.85 per share, provided that this anti-dilution adjustment will not apply to any sales made under (x) the Current Purchase Agreement, (y) ATM Agreement, or (z) the September 2019 Exchange Agreement (as amended). Notwithstanding anything in the contrary in the December 2019 Notes, the anti-dilution adjustment of such notes shall not result in the conversion price of the December 2019 Notes being less than \$0.583 per share. The December 2019 Notes are convertible at any time at the option of the holders thereof, provided that a holder of a December 2019 Note is prohibited from converting such note into shares of our common stock if, as a result of such conversion, such holder (together with certain affiliates and "group" members) would beneficially own more than 4.985% of the total number of shares of common stock then issued and outstanding. However, the December 2019 Note issued to DSC, due to the fact DSC was a beneficial owner of more than 4.985% of the total number of shares of our common stock then issued and outstanding, has a beneficial ownership cap equal to 19.985% of the total number of shares of our common stock then issued and outstanding. Pursuant to the December 2019 Notes, the December 2019 Holders have the option to demand repayment of all outstanding principal, and any unpaid interest accrued thereon, in connection with a Major Transaction (as defined in the December 2019 Notes), which shall include, among others, any acquisition or other change of control of the Company; a liquidation, bankruptcy or other dissolution of the Company; or if at any time after March 31, 2021, shares of our common stock are not listed on an Eligible Market (as defined in the December 2019 Notes). The December 2019 Notes are subject to specified events of default, the occurrence of which would entitle the December 2019 Holders to immediately demand repayment of all outstanding principal and accrued interest on the December 2019 Notes. Such events of default include, among others, failure to make any payment under the December 2019 Notes when due, failure to observe or perform any covenant under the Deerfield Facility Agreement or the other transaction documents related thereto (subject to a standard cure period), the failure of the Company to be able to pay debts as they come due, the commencement of bankruptcy or insolvency proceedings against the Company, a material judgement levied against the Company and a material default by the Company under the Deerfield Warrant, the December 2019 Notes or the Deerfield Convertible Note.

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

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

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

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

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

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

As of March 31, 2020, the Deerfield Lenders have converted \$10.8 million of principal on the December 2019 Notes into 18,000,000 shares of common stock.

2021 Note Exchange Effected in January 2020

In January 2020, we entered into a January 2020 Exchange Agreement, or the January 2020 Exchange Agreement, with M. Kingdon Offshore Master Fund, LP, or Kingdon. Under the January 2020 Exchange Agreement, we issued 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 \$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 Deerfield Facility Agreement to (x) provide for the Kingdon to join the Deerfield Facility Agreement as a Lender (as defined in the Deerfield Facility Agreement) and (y) provide that the 2020 Note and shall constitute a “Senior Secured Convertible Note” (as defined in the Deerfield Facility Agreement) for purposes of the Deerfield Facility Agreement and other Transaction Documents (as defined in the Deerfield Facility Agreement). As a result of the December 2019 Note Amendment, the December 2019 Notes were convertible, by their terms, into an aggregate of 11,753,016 shares of the Company’s common stock, assuming a conversion date of January 13, 2020.

Cash Flows

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

	Three months ended March 31,	
	2020	2019
Net cash used in operating activities	\$ (2,022)	\$ (11,066)
Net cash (used in) provided by investing activities	(11)	3,243
Net cash provided by financing activities	1,020	2,670
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (1,013)</u>	<u>\$ (5,153)</u>

Operating Activities

For the three months ended March 31, 2020, net cash used in operating activities of \$2.0 million consisted of a net loss of \$5.8 million partially offset by \$0.7 million in changes in working capital and \$3.0 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. The changes in working capital consisted of \$0.6 million related to a change in accounts payable and accrued expenses, \$0.5 million related to a change in prepaid expenses and other assets and \$0.1 million related to operating lease right-of-use assets, partially offset by \$0.4 million related to a change in accounts and other receivables and \$0.1 million related to operating lease liabilities. The adjustments for non-cash items primarily consisted of stock-based compensation expense of \$1.0 million, non-cash interest expense of \$1.2 million, amortization of debt issuance costs and debt discount of \$0.6 million, loss on sublease and disposal of property and equipment of \$0.2 million and \$0.1 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 \$0.1 million.

For the three months ended March 31, 2019, net cash used in operating activities of \$11.1 million consisted of a net loss of \$12.3 million, primarily attributable to our spending on research and development programs and \$0.9 million in changes in working capital, partially offset by \$2.1 million in adjustments for non-cash items. The adjustments for non-cash items primarily consisted of stock-based compensation expense of \$1.3 million, non-cash interest expense of \$0.9 million, amortization of debt issuance costs and debt discount of \$0.3 million and \$0.1 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 \$0.5 million. The changes in working capital consisted of \$1.0 million related to a change in accounts payable and accrued expenses, \$1.8 million related to operating lease right-of-use assets and \$0.8 million related to a change in other liabilities, partially offset by \$0.2 million related to a change in prepaid expenses and other assets and \$2.5 million related to operating lease liabilities.

Investing Activities

For the three months ended March 31, 2020, net cash used in investing activities was \$11,000, which was primarily attributable to purchases of property and equipment.

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

Financing Activities

For the three months ended March 31, 2020, net cash provided by financing activities was \$1.0 million, which was primarily attributable to proceeds from sales of our common stock under the Current Purchase Agreement of \$1.1 million, partially offset by repayment of principal on finance lease liabilities and payment of debt issuance costs of \$0.1 million.

For the three months ended March 31, 2019, net cash provided by financing activities was \$2.7 million, which was primarily attributable to proceeds from sales of our common stock under the Prior Purchase Agreement of \$2.7 million, partially offset by repayment of principal on finance lease liabilities of \$0.1 million.

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 March 31, 2020, we believe our cash resources will be sufficient to fund operating expense and capital investment requirements into, but not through, the first quarter of 2021. A significant 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:

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

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

To date, we have only generated revenue from the non-refundable upfront payment, reimbursements of out-of-pocket third-party research and development costs and consulting services under the KP415 License Agreement, and, as of March 31, 2020, we have a net working capital (current assets less current liabilities) deficit of \$70.0 million. We do not know when, or if, we will generate any additional revenue. We expect that our only source of revenues will be through payments arising from our license agreements with KVK and Commave, or through any other future arrangements related to one of our product candidates. While we have entered into the APADAZ License Agreement to commercialize APADAZ in the United States, and entered into the KP415 License Agreement to develop, manufacture and commercialize KP415 and KP484, we cannot guarantee that this, or any strategy we adopt in the future, will be successful. For instance, we are entitled to 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 of 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 significant 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 the PPP Loan, under the PPP, of the recently enacted CARES Act, a portion of which may be forgiven, which we intend to use 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 will be deferred for the first six months of the PPP Loan term. Thereafter, we are 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 is 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 is 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 will qualify for forgiveness. 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, and 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.

Our unaudited condensed financial statements for the quarter ended March 31, 2020, includes an explanatory paragraph, within Note A, 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 source of revenues will be through payments arising from our license agreements with KVK and Commave, or through any other future arrangements related to one of our other product candidates. Accordingly, our ability to continue as a going concern will require us to obtain additional financing to fund our operations. The perception of our inability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or debt, the terms of these securities may restrict our ability to operate. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

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

We have filed a shelf registration statements on Form S-3 with the SEC. Based on the market value of our outstanding common stock held by non-affiliates in order to issue securities under our Current Registration Statement we must rely on Instruction I.B.6. of Form S-3, which imposes a limitation on the maximum amount of securities that we may sell pursuant to the registration statements during any twelve-month period. At the time we sell securities pursuant to the 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 date we filed amendment No. 1 to the Current Registration Statement, the amount of securities we were able to sell under a registration statement on Form S-3 during a 12-month period 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 offering son 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 the Current Registration Statement for a period of twelve months, 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.

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 unaudited condensed financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of our unaudited condensed 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 unaudited condensed financial statements, as well as the reported revenues and expenses during the reported periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies have not changed materially from those described in Note B of our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on February 28, 2020.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Our management, with the participation of our chief executive officer and our chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2020. Based on the evaluation of our disclosure controls and procedures as of March 31, 2020, our chief executive officer and our chief financial officer concluded that, as of such date, with the exception of the material weakness discussed below, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

Based on our evaluation of internal control over financial reporting as of December 31, 2019, which was the end of our most recent fiscal year, management concluded that our internal control over financial reporting was not effective as of December 31, 2019, because certain controls over non-routine transactions were not designed at the appropriate level of precision to ensure the accuracy of calculations supporting non-routine transactions, and subsequently to ensure that appropriate conclusions related to accounting treatment were reached. This control deficiency resulted in misstatements to research and development expenses, debt discount, interest expense related to amortization of debt discount, fair value adjustment related to derivative and warrant liability, revenue, accounts and other receivables, accounts payable and accrued expenses, prepaid expenses and other current assets, royalty and direct contract acquisition costs and general and administrative expenses all of which were corrected prior to issuance of our financial statements as of and for the year ended December 31, 2019 included in the annual report on Form 10-K, as filed with the SEC on February 28, 2020, as amended on April 8, 2020. As this deficiency created a reasonable possibility that a material misstatement would not be prevented or detected in a timely manner, management concluded that the control deficiency represented a material weakness and accordingly our internal control over financial reporting were not effective as of December 31, 2019.

During the quarter ended March 31, 2020, we began evaluating the internal controls related to the material weakness described above, including a review of the design of those internal control elements related to calculations and conclusions associated with non-routine transactions in order to assess how to improve their level of precision. As of March 31, 2020, our evaluation remains in process, and therefore we have not yet determined whether the material weakness described above has been remediated. However, with the exception of this material weakness, management has concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2020. In addition, except for the material weakness described above, there was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the most recent fiscal quarter ended March 31, 2020 that materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

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

Risks Related to Our Financial Position and Capital Needs

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

Based on our current operating plan, our existing resources and projected revenues are expected to be sufficient to fund our operating expense and capital investment requirements into, but not through, the first quarter of 2021. A significant 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 source of revenues will be through payments arising from our license agreements with KVK and Commave, and/or through any other future arrangements related to one of our other product candidates. Accordingly, our ability to continue as a going concern will require us to obtain, in the short term, additional financing to fund our operations. In order to substantially advance development of our product candidates, we will need to obtain additional funding in connection with our continuing operations from one or more equity offerings, including pursuant to the Current Purchase Agreement with Lincoln Park, debt financings, the APADAZ License Agreement, the KP415 License Agreement or other third-party funding, including potential strategic alliances and licensing or collaboration arrangements, and we cannot guarantee that we will be able to generate sufficient proceeds from sales under the Current Purchase Agreement, the APADAZ License Agreement or the KP415 License Agreement, 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, included in our annual report on Form 10-K, and our unaudited condensed financial statements included in this quarterly report on Form 10-Q, 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 quarterly report on Form 10-Q 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 the annual report on Form 10-K filed with the SEC on February 28, 2020, as amended on April 8, 2020. As this deficiency created a reasonable possibility that a material misstatement would not be prevented or detected in a timely basis, management concluded that the control deficiency represented a material weakness and accordingly our internal control over financial reporting was not effective as of December 31, 2019.

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

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

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

We have had negative operating cash flows since our inception and, as of March 31, 2020, had an accumulated deficit of \$251.5 million. Our negative operating cash flows for the three months ended March 31, 2020 and 2019, were \$2.0 million and \$11.1 million, respectively. We have financed our operations through March 31, 2020 with funds raised in private placements of redeemable convertible preferred stock, in the issuance of convertible promissory notes and term debt, our initial public offering and other public and private offerings of our common stock, as well as through revenue received under the KP415 License Agreement.

In February 2019, we entered into the Prior Purchase Agreement which provided that, upon the terms and subject to the conditions and limitations set forth therein, we could sell to Lincoln Park up to \$15.0 million of shares of our common stock, from time to time over the 36-month term of the Prior Purchase Agreement, and upon execution of the Prior Purchase Agreement we issued 120,200 shares of our common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Prior Purchase Agreement. We terminated the Prior Purchase Agreement in February 2020 in connection with entering into the Purchase Agreement. We sold 3,401,271 shares of our common stock (exclusive of the 120,200 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 new purchase agreement with Lincoln Park, or the Current Purchase Agreement, which provides that, upon the terms and subject to the conditions and limitations set forth therein, we may sell to Lincoln Park up to \$4.0 million of shares of our common stock, from time-to-time over the 12-month term of the Current Purchase Agreement, and upon execution of the Current Purchase Agreement we issued 308,637 shares of our common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Current Purchase Agreement. There are no assurances whether we will utilize all of, or receive all proceeds from, the Current Purchase Agreement. As of March 31, 2020, we sold 4,000,000 shares of our common stock (exclusive of the 308,637 commitment shares) to Lincoln Park under the Current Purchase Agreement for approximately \$1.1 million in gross proceeds.

Our 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 of 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 significant 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 the Deerfield Facility Agreement. 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 March 31, 2020, we had \$70.9 million of outstanding borrowings under the Deerfield Facility Agreement. Amounts outstanding under the Deerfield Facility Agreement bear interest at a rate of 6.75% per annum, and all outstanding principal and accrued interest for our outstanding borrowings under the Deerfield Facility Agreement are due and payable on March 31, 2021. Our obligations under the Deerfield Facility Agreement are secured by substantially all of our assets. We could in the future incur additional indebtedness beyond our borrowings under our Deerfield Facility Agreement.

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

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

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

We may 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 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 intend to use 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 will be deferred for the first six months of the PPP Loan term. Thereafter, we are 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 is 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 is 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 will qualify for forgiveness. 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, and 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 U.S. Small Business Administration, or 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.

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 SEC. 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 is 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, 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. If we cannot sell securities on Form S-3, we may be required to utilize more costly and time-consuming means of accessing the capital markets, which could materially adversely affect our liquidity and cash position.

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

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

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

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

Risks Related to the Development of Our Product Candidates

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

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

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

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

Even if regulatory approval is obtained, subsequent safety, efficacy, quality or other issues can result in a product approval being suspended or withdrawn. In February 2018, we announced that the FDA approved the NDA for APADAZ for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Even with the regulatory approval of APADAZ by the FDA, we cannot guarantee that the FDA will approve any of our other product candidates for commercial sale. For example, our NDA submission for KP415 may encounter review difficulties and may ultimately receive a Complete Response Letter for any deficiencies in nonclinical, clinical or manufacturing of KP415. If our development efforts for our product candidates, including regulatory approval, are not successful for their planned indications or are delayed, or if adequate demand for our product candidates that are approved for marketing, if any, is not generated, our business will be harmed.

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

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

- we may fail to seek patent protection for inventions that are important to our success;
- our pending patent applications may not result in issued patents;
- we cannot be certain that we are the first to invent the inventions covered by pending patent applications or that we are the first to file such applications and, if we are not, we may be subject to priority disputes or lose rights;
- we may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications;
- we may file patent applications but have claims restricted or we may not be able to supply sufficient data to support our claims and, as a result, may not obtain the original claims desired or we may receive restricted claims; alternatively, it is possible that we may not receive any patent protection from an application;
- even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, and may not be of sufficient scope or strength to provide us with any commercial advantage;
- our competitors may be able to design around our owned or licensed patents by developing similar or alternative technologies or drugs without infringing on our intellectual property rights;

- we could inadvertently abandon a patent or patent application, resulting in the loss of protection of intellectual property rights in a particular country, and we, our collaborators or our patent counsel may take action resulting in a patent or patent application becoming abandoned which may not be able to be reinstated or if reinstated, may suffer patent term adjustments;
- the claims of our issued patents or patent applications when issued may not cover our product candidates;
- no assurance can be given that our patents would be declared by a court to be valid or enforceable or that a competitor's technology or product would be found by a court to infringe our patents and our patents or patent applications may be challenged by third parties in patent litigation or in proceedings before the United States Patent and Trademark Office, or the USPTO, or its foreign counterparts, and may ultimately be declared invalid or unenforceable or narrowed in scope;
- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim and there may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim;
- third parties may develop products that have the same or similar effect as our products without infringing our patents;
- third parties may intentionally circumvent our patents by means of alternate designs or processes or file applications or be granted patents that would block or hurt our efforts;
- there may be dominating patents relevant to our product candidates of which we are not aware;
- obtaining regulatory approval for pharmaceutical products is a lengthy and complex process, and as a result, any patents covering our product candidates may expire before or shortly after such product candidates are approved and commercialized;
- the patent and patent enforcement laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions; and
- we may not develop additional proprietary technologies that are patentable.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We expect to rely on trademarks as one means to distinguish APADAZ and any of our product candidates that are approved for marketing from the products of our competitors. We have registered trademarks for APADAZ, 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.

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 are expected to occur in the fall. 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 produg 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 \$11.00 per share, our stock price has ranged from a low of \$0.18 to a high of \$26.15 through May 12, 2020. In addition, the stock market in general and the market for pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- actual or anticipated variations in our operating results;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry, including without limitation changes in the structure of healthcare payment systems;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the pharmaceutical industry;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- adverse regulatory announcements or determinations regarding our product candidates;
- capital commitments;
- investors' general perception of us and our business;
- recruitment or departure of key personnel; and
- sales of our common stock, including sales by our directors and officers or specific stockholders.

Many of the factors described above are not within our control. For instance, in May 2016, we announced that the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the FDA voted 16 to 4 for the approval of APADAZ but voted 18 to 2 against inclusion of abuse-deterrent labeling for APADAZ. The announcement was followed by a substantial decrease in the trading price of our common stock on Nasdaq. Additionally, when we announced in June 2016 that the FDA had issued a CRL for the APADAZ NDA, the trading price of our common stock on Nasdaq was subject to another substantial decrease. We cannot guarantee that future announcements will not have similar effects on the trading price of our common stock.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. For instance, in December 2016, we received notice of a class action suit filed against us in the Iowa District Court in Johnson County by a stockholder alleging that we, certain of our senior executives and directors who signed the registration statement in connection with our initial public offering, and each of the investment banks that acted as underwriters for the offering negligently issued untrue statements of material facts and omitted to state material facts required to be stated in the registration statement and incorporated offering materials that we filed with the SEC in support of the offering. In June 2018, the case was dismissed without prejudice to members of the putative class. Future litigation could cause us to incur substantial costs and divert management's attention and resources from our business. Further, companies listed on The Nasdaq Capital Market, and biotechnology and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

If we fail to maintain compliance with the listing requirements of The Nasdaq Stock Market, we may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

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

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

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

On March 27, 2020, we announced that we received a letter from the Nasdaq Listing Panel notifying us that our continued non-compliance with the minimum bid price of listed securities requirement for continued listing on the Nasdaq Capital Market as set forth in Nasdaq Listing Rule 5450(a)(1) may serve as an additional basis for delisting our securities from Nasdaq. Previously, on September 27, 2019, we received notice from Nasdaq that we were not in compliance with the continued listing requirement to maintain a minimum bid price of \$1.00. On April 16, 2020, Nasdaq issued Issuer Alert 2020-2 which granted temporary relief from the continued listing bid price and market value of publicly held shares listing requirements through June 30, 2020 in response to the COVID-19 pandemic and extraordinary market conditions. Accordingly, even if we regain compliance with the minimum MVLS requirement within the applicable compliance period, if we do not regain compliance with the \$1.00 minimum bid price requirement prior to June 30, 2020, we may still be subject to a final delisting determination by Nasdaq.

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

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

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

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

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

Our outstanding senior secured convertible promissory notes and the Deerfield Warrant each include conversion or exercise, as applicable, price protection provision, pursuant to which the conversion or exercise, as applicable, price of each note or the Deerfield Warrant will be adjusted downward on a broad-based weighted-average basis if we issue or sell any shares of common stock, convertible securities, warrants or options at a sale or exercise price per share less than the greater of (i) \$5.85 per share, which represents the Deerfield Warrant's exercise price and the conversion price of our outstanding senior secured convertible promissory notes, or (ii) the closing sale price of our common stock as reported on The Nasdaq Capital Market on the last trading date immediately prior to such issuance or, in the case of a firm commitment underwritten offering, on the date of execution of the underwriting agreement between us and the underwriters for such offering. Additionally, if we effect an "at the market offering", as defined in Rule 415 of the Securities Act, of our common stock, the exercise price of the Deerfield Warrant and conversion price of our outstanding senior secured convertible promissory notes will be adjusted downward pursuant to this anti-dilution adjustment only if such sales are made at a price less than \$5.85 per share, provided that this anti-dilution adjustment will not apply to any sales made under the Current Purchase Agreement, the ATM Agreement or the September 2019 Exchange Agreement, as amended.

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

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

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

According to the terms of our outstanding senior secured convertible promissory notes in no event may any holder thereof convert such holder's note to the extent such conversion would result in such holder beneficially owning more than 4.985% of the then issued and outstanding shares of our common stock, provided that this limitation is 19.985% of our issued and outstanding common stock for any holder of our senior secured convertible promissory note who owned more than 4.985% of our issued and outstanding common stock at the time the issuance of such note. This conversion limitation may not be waived and any purported conversion that is inconsistent with this conversion limitation will be null and void. This conversion limitation will not apply to any conversion made immediately prior to a change of control transaction. If noteholder is only able to convert such holder's senior secured convertible promissory note into a limited number of shares due to this conversion limitation, such note could subsequently become convertible into the remainder of the shares as a result of a variety of events. This could occur, for example, if we issue more shares or such holder sells some of its existing shares.

In September 2019, we entered into the September 2019 Exchange Agreement, which was subsequently amended in December 2019. Under the September 2019 Exchange Agreement, we issued an aggregate of 1,499,894 shares of our common stock and an aggregate of 1,576 shares of our Series B-1 Preferred Stock in exchange for the cancellation of an aggregate of \$3,000,000 principal amount of our then outstanding convertible debt. As of March 31, 2020, 1,576 shares of Series B-1 Preferred Stock have been converted into 1,659,996 shares of common stock. The September 2019 Exchange Agreement provides the Deerfield Lenders the option to exchange the principal amount of their outstanding senior secured convertible promissory notes for shares of common stock or shares of our Series B-2 convertible preferred stock, subject to the terms and conditions set forth in the September 2019 Exchange Agreement. In December 2019, we amended the September 2019 Exchange Agreement, to, among other things, (i) to allow the Deerfield Lenders to effect optional exchanges of all their outstanding senior secured convertible promissory notes under the terms of the September 2019 Exchange Agreement; (ii) amend the common stock exchange price under the September 2019 Exchange Agreement to be a per share price equal to the greater of (x) \$0.60, subject to adjustment to reflect stock splits and similar events, or (y) the average of the volume-weighted average prices of our common stock on the Nasdaq Capital Market on each of the 15 trading days immediately preceding such exchange, (iii) provide that no more than 28,439,015 of shares of our common stock shall be issued pursuant to optional exchanges under the September 2019 Exchange Agreement (whether by common stock exchange or upon conversion of shares of Series B-2 convertible preferred stock), subject to adjustment to reflect stock splits and similar events and (iv) eliminate limitations regarding the timing and aggregate amount of principal which may be exchanged under the September 2019 Exchange Agreement. If the Deerfield Lenders choose to exchange any portion of their senior secured convertible promissory notes for shares of Series B-2 convertible preferred stock, such exchange will be effected at an exchange price of \$1,000 per share. As of March 31, 2020, there was an aggregate of 10,439,015 shares of our common stock issuable (i) in exchange of the then outstanding principal amount of our senior secured convertible promissory notes held by the Deerfield Lenders, or (ii) upon conversion of the Series B-2 convertible preferred stock issuable in exchange of the then outstanding principal amount of such senior secured convertible promissory notes.

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

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

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

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

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

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

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

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

Anti-takeover provisions in our certificate of incorporation and bylaws, as well as provisions of Delaware law and the terms of some of 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 the holders of our Series B-2 convertible preferred stock, if any, will share ratably in any distribution of our assets or other proceeds with holders of common stock on an as-converted basis without giving effect to any limitation on conversion of the Series B-2 convertible preferred stock. This would in turn reduce the distribution to the holders of our common stock in such change of control.

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

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

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provisions of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (iv) any action asserting a claim against us that is governed by the internal affairs doctrine. While these choice of forum provisions do not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction, the choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

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

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

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

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th and (2) the date on which we have issued more than \$1.00 billion in non-convertible debt during the prior three-year period.

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

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

As of March 31, 2020, we had federal net operating loss carryforwards of approximately \$221.0 million, due to prior period losses, \$138.1 million of which if not utilized, will begin to expire in 2027. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities, which could adversely affect our profitability. On December 22, 2017, the U.S. government enacted H.R. 1, “An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018” (informally titled the Tax Cuts and Jobs Act). Under the Tax Cuts and Jobs Act, U.S. federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act. To the extent that we continue to generate taxable losses in the United States, unused losses will carry forward to offset future taxable income (subject to any applicable limitations), if any. In addition, under Section 382 and Section 383 of the Code, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We performed a Section 382 ownership change analysis in 2017 and determined that we experienced an ownership change in 2010, which resulted in a portion of our net operating loss carryforwards being subject to an annual limitation under Section 382 through 2012. No other ownership changes or limitations on our historical net operating loss carryforwards were noted through the year ended December 31, 2017. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, including as a result of the conversion of our outstanding convertible debt or as a result of future changes in our stock ownership. If we determine that an ownership change has occurred and our ability to use our historical net operating loss carryforwards is materially limited, it would harm our future operating results by increasing our future tax obligations.

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

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

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

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. For our fiscal year ended December 31, 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.

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

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

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

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

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

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Date of Annual Meeting of Stockholders

The date of our 2020 annual meeting of stockholders, or the 2020 Annual Meeting, is scheduled for June 19, 2020, which will be more than 30 calendar days after the anniversary date of our 2019 annual meeting of stockholders. In accordance with Rule 14a-5(f) under the Exchange Act, we are hereby notifying our stockholders that April 23, 2020 was the deadline for submitting stockholder proposals for inclusion in our proxy statement for the 2020 Annual Meeting, either pursuant to Rule 14a-8 under the Exchange Act or outside the processes of Rule 14a-8 under the Exchange Act. To be considered for inclusion in next year's proxy materials, your proposal must be submitted in writing by March 21, 2021, to our Corporate Secretary at 1180 Celebration Boulevard, Suite 103, Celebration, FL 34747. If you wish to submit a proposal (including a director nomination) at the meeting that is not to be included in next year's proxy materials, you must do so by March 21, 2021, but no earlier than February 20, 2021; provided, however that if next year's annual meeting is advanced more than 30 days prior to or delayed by more than 30 days after June 19, 2021, your proposal must be submitted (i) not earlier than the close of business on the 120th day prior to such annual meeting and not later than the close of business on the later of the 90th day prior to such annual meeting; or (ii) the tenth day following the day on which public announcement of the date of such meeting is first made. You are also advised to review our bylaws, which contain additional requirements about advance notice of stockholder proposals and director nominations.

ITEM 6. EXHIBITS

The following is a list of exhibits filed as part of this Form 10-Q (the SEC file number for all items incorporated by reference herein from reports on Forms 10-K, 10-Q, and 8-K is 001-36913):

Exhibit No.	Description
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	KemPharm, Inc. Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (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	KemPharm, Inc. Certificate of Designation of Preferences, Rights and Limitations of Series B-1 Convertible Preferred Stock (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	KemPharm, Inc. 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 September 4, 2019).
3.2	Amended and Restated Bylaws, as currently in effect, of KemPharm, Inc. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on April 21, 2015).
4.1	Reference is made to Exhibit 3.1 , Exhibit 3.1.1 , Exhibit 3.1.2 , Exhibit 3.1.3 and Exhibit 3.2 hereof.
4.2	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).
4.3	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).
10.1	January 2020 Exchange Agreement, dated as of January 12, 2020, by and between KemPharm, Inc. and M. Kingdon Offshore Master Fund, LP (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on January 13, 2020).
10.2	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	Agreement to Sublease, by and between KemPharm, Inc. and Ciber Global, LLC, dated as of January 15, 2020 (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on February 28, 2020).
10.4	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).
10.5	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).
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (1)
32.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (1)
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith

** Attached as Exhibit 101 to this Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, formatted in XBRL (Extensible Business Reporting Language): (i) Unaudited Condensed Balance Sheets, (ii) Unaudited Condensed Statements of Operations, (iii) Unaudited Condensed Statements of Changes in Stockholders' Deficit, (iv) Unaudited Condensed Statements of Cash Flows, and (v) Notes to Unaudited Condensed Financial Statements, tagged as blocks of text and including detailed tags.

(1) This certification accompanies the Quarterly Report on Form 10-Q to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Registrant under the Securities Act or the Exchange Act (whether made before or after the date of the Quarterly Report on Form 10-Q), irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

KemPharm, Inc.

Date: May 13, 2020

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

Date: May 13, 2020

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

CERTIFICATIONS

I, Travis C. Mickle, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of KemPharm, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 13, 2020

/s/ Travis C. Mickle

Name: Travis C. Mickle, Ph.D.

Title: President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATIONS

I, R. LaDuane Clifton, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of KemPharm, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 13, 2020

/s/ R. LaDuane Clifton

Name: R. LaDuane Clifton, CPA

Title: Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer)

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of KemPharm, Inc., (the "Company") for the quarterly period ended March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Travis C. Mickle, Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 13, 2020

/s/ Travis C. Mickle

Name: Travis C. Mickle, Ph.D.

Title: President and Chief Executive Officer
(Principal Executive Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350, is not being "filed" by the Company as part of the Report or as a separate disclosure document and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of KemPharm, Inc., (the "Company") for the quarterly period ended March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, R. LaDuane Clifton, Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 13, 2020

/s/ R. LaDuane Clifton

Name: R. LaDuane Clifton, CPA

Title: Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350, is not being "filed" by the Company as part of the Report or as a separate disclosure document and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.