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 September 30, 2019

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	**20-5894398**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
1180 Celebration Boulevard, Suite 103, Celebration, FL	**34747**
(Address of Principal Executive Offices)	**(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 Global 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 November 14, 2019: 33,223,877

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KEMPHARM, INC.
FORM 10-Q

PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2019 (unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 6,518	$ 18,409
Marketable securities	—	3,260
Accounts and other receivables	1,638	140
Prepaid expenses and other current assets	528	1,912
Total current assets	8,684	23,721
Property and equipment, net	1,541	1,753
Operating lease right-of-use assets	1,649	—
Restricted cash	490	710
Other long-term assets	526	562
Total assets	$ 12,890	$ 26,746
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,095	$ 8,342
Current portion of convertible notes	6,718	3,333
Current portion of capital lease obligation	—	214
Current portion of operating lease liabilities	369	—
Other current liabilities	227	115
Total current liabilities	10,409	12,004
Convertible notes, less current portion, net	70,553	78,105
Derivative and warrant liability	335	2,118
Capital lease obligation, less current portion	—	396
Operating lease liabilities, less current portion	1,976	—
Other long-term liabilities	237	689
Total liabilities	83,510	93,312
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 3,337 shares outstanding as of September 30, 2019 (unaudited) and December 31, 2018	—	—
Series B-1 convertible preferred stock, $0.0001 par value, 1,576 shares authorized, 1,576 shares issued and 789 shares outstanding as of September 30, 2019 (unaudited); no shares authorized, issued or outstanding as of December 31, 2018	—	—
Series B-2 convertible preferred stock, $0.0001 par value, 27,000 shares authorized, no shares issued or outstanding as of September 30, 2019 (unaudited); no shares authorized, issued or outstanding as of December 31, 2018	—	—
Undesignated preferred stock, $0.0001 par value, 9,961,846 shares authorized, no shares issued or outstanding as of September 30, 2019 (unaudited); 9,990,422 shares authorized, no shares issued or outstanding as of December 31, 2018	—	—
Common stock, $0.0001 par value, 250,000,000 shares authorized, 32,387,382 shares issued and outstanding as of September 30, 2019 (unaudited); 26,455,352 shares issued and outstanding as of December 31, 2018	3	3
Additional paid-in capital	169,054	154,623
Accumulated deficit	(239,677)	(221,192)
Total stockholders' deficit	(70,620)	(66,566)
Total liabilities and stockholders' deficit	$ 12,890	$ 26,746

See accompanying notes to unaudited condensed financial statements

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

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Revenue	$ 11,463	$ —	$ 11,463	$ —
Operating expenses:				
Cost of revenue	1,000	—	1,000	—
Research and development	3,616	13,330	16,950	35,455
General and administrative	3,613	2,992	9,440	9,544
Severance expense	—	1,636	—	1,636
Total operating expenses	8,229	17,958	27,390	46,635
Income (loss) from operations	3,234	(17,958)	(15,927)	(46,635)
Other (expense) income:				
Interest expense related to amortization of debt issuance costs and discount	(371)	(326)	(981)	(1,106)
Interest expense on principal	(1,208)	(1,367)	(3,669)	(4,228)
Fair value adjustment related to derivative and warrant liability	1,351	4,468	1,783	289
Interest and other income, net	60	52	295	290
Total other (expense) income	(168)	2,827	(2,572)	(4,755)
Income (loss) before income taxes	3,066	(15,131)	(18,499)	(51,390)
Income tax (expense) benefit	(3)	60	14	107
Net income (loss)	$ 3,063	$ (15,071)	$ (18,485)	$ (51,283)
Net income (loss) per share of common stock:				
Basic	$ 0.09	$ (0.94)	$ (0.65)	$ (3.33)
Diluted	$ 0.06	$ (0.94)	$ (0.65)	$ (3.33)
Weighted average number of shares of common stock outstanding:				
Basic	30,126,704	16,033,923	28,417,450	15,385,663
Diluted	31,672,149	16,033,923	28,417,450	15,385,663

See accompanying notes to unaudited condensed financial statements

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

	Preferred Stock							
	Series A Convertible Preferred Stock	Series B-1 Convertible Preferred Stock	Series B-2 Convertible Preferred Stock	Undesignated Preferred Stock	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance as of January 1, 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 Purchase Agreement	—	—	—	—	—	2,721	—	2,721
Write-off of deferred offering costs	—	—	—	—	—	10	—	10
Balance as of March 31, 2019	—	—	—	—	3	158,644	(233,483)	(74,836)
Net loss	—	—	—	—	—	—	(9,257)	(9,257)
Stock-based compensation expense	—	—	—	—	—	1,317	—	1,317
Issuance of common stock in connection with Purchase Agreement	—	—	—	—	—	1,229	—	1,229
Balance as of June 30, 2019	—	—	—	—	3	161,190	(242,740)	(81,547)
Net income	—	—	—	—	—	—	3,063	3,063
Stock-based compensation expense	—	—	—	—	—	1,057	—	1,057
Issuance of common stock in connection with Purchase Agreement	—	—	—	—	—	1,496	—	1,496
Conversion of principal on 2021 Notes	—	—	—	—	—	3,000	—	3,000
Change in fair value of embedded conversion feature in connection with debt modification	—	—	—	—	—	2,311	—	2,311
Balance as of September 30, 2019	$ —	$ —	$ —	$ —	$ 3	$ 169,054	$ (239,677)	$ (70,620)

See accompanying notes to financial statements

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

	Preferred Stock							
	Series A Convertible Preferred Stock	Series B-1 Convertible Preferred Stock	Series B-2 Convertible Preferred Stock	Undesignated Preferred Stock	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance as of January 1, 2018	$ —	$ —	$ —	$ —	$ 1	$ 107,209	$ (164,726)	$ (57,516)
Net loss	—	—	—	—	—	—	(26,219)	(26,219)
Stock-based compensation expense	—	—	—	—	—	1,281	—	1,281
Issuance of common stock in connection with ATM, net of commissions	—	—	—	—	1	2,797	—	2,798
Offering expenses charged to equity	—	—	—	—	—	(27)	—	(27)
Balance as of March 31, 2018	—	—	—	—	2	111,260	(190,945)	(79,683)
Net loss	—	—	—	—	—	—	(9,993)	(9,993)
Stock-based compensation expense	—	—	—	—	—	1,378	—	1,378
Issuance of common stock in connection with ATM, net of commissions	—	—	—	—	—	1,194	—	1,194
Offering expenses charged to equity	—	—	—	—	—	(11)	—	(11)
Conversion of principal and interest on Deerfield Convertible Note	—	—	—	—	—	3,502	—	3,502
Exercise of stock options	—	—	—	—	—	68	—	68
Balance as of June 30, 2018	—	—	—	—	2	117,391	(200,938)	(83,545)
Net loss	—	—	—	—	—	—	(15,071)	(15,071)
Stock-based compensation expense	—	—	—	—	—	2,586	—	2,586
Issuance of common stock in connection with ATM, net of commissions	—	—	—	—	—	836	—	836
Offering expenses charged to equity	—	—	—	—	—	(151)	—	(151)
Balance as of September 30, 2018	$ —	$ —	$ —	$ —	$ 2	$ 120,662	$ (216,009)	$ (95,345)

See accompanying notes to financial statements

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

	Nine months ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (18,485)	$ (51,283)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,664	5,245
Non-cash interest expense	988	1,123
Amortization of debt issuance costs and debt discount	981	1,106
Depreciation and amortization expense	229	245
Fair value adjustment related to derivative and warrant liability	(1,783)	(289)
Write-off of deferred offering costs	10	—
Change in assets and liabilities:		
Accounts and other receivables	(1,498)	(86)
Prepaid expenses and other assets	1,420	(960)
Operating lease right-of-use assets	(1,649)	—
Accounts payable and accrued expenses	(6,073)	5,780
Operating lease liabilities	2,345	—
Other liabilities	(788)	(86)
Net cash used in operating activities	(20,639)	(39,205)
Cash flows from investing activities:		
Purchases of property and equipment	(21)	(6)
Maturities of marketable securities	3,260	25,374
Net cash provided by investing activities	3,239	25,368
Cash flows from financing activities:		
Proceeds from equity line of credit	5,446	—
Proceeds from at-the-market offering, net of commissions	—	4,828
Repayment of obligations under capital lease	—	(142)
Repayment of principal on finance lease liabilities	(157)	—
Proceeds from exercise of common stock options	—	68
Net cash provided by financing activities	5,289	4,754
Net decrease in cash, cash equivalents and restricted cash	(12,111)	(9,083)
Cash, cash equivalents and restricted cash, beginning of period	19,119	11,971
Cash, cash equivalents and restricted cash, end of period	$ 7,008	$ 2,888
Supplemental cash flow information:		
Cash paid for interest	$ 4,602	$ 5,280
Deferred offering costs included in accounts payable and accrued expenses	105	68
Deerfield Convertible Note principal and interest converted to common stock	—	3,502
Property and equipment financed under a lease agreement	—	52
2021 Notes principal converted to common stock	1,424	—
2021 Notes principal converted to Series B-1 Preferred Stock	1,576	—
Change in fair value of embedded conversion feature recorded as debt discount in connection with debt modification	2,311	—

See accompanying notes to unaudited condensed financial statements.

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 and nine months ended September 30, 2019 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2019.

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, 2018, filed with the Securities and Exchange Commission (“SEC”) on March 1, 2019 (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 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. The Company's ability to continue as a going concern may require additional financing to fund its operations. The perception of the Company's inability to continue as a going concern may make it more difficult to obtain financing for the continuation of operations and could result in the loss of confidence by investors, suppliers and employees. Adequate additional financing may not be available to the Company on acceptable terms, or at all.

Management believes these conditions raise substantial doubt about the Company’s ability to continue as a going concern within the twelve months after the date these financial statements are issued. Based upon the Company's current operating plan the Company believes existing cash resources are sufficient to fund operating expense and capital investment requirements into, but not through, the second quarter of 2020. The ability to continue as a going concern is dependent upon profitable future operations, positive cash flows, the forebearance of the Company's lenders and additional financing. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

After the Company filed its Annual Report, in order to issue securities under the Current Registration Statement and the Replacement Registration Statement, once effective, it must rely on Instruction I.B.6. of Form S-3, which imposes a limitation on the maximum amount of securities that the Company may sell pursuant to the registration statements during any twelve-month period. At the time it sells securities pursuant to the applicable registration statement, the amount of securities to be sold plus the amount of any securities it has sold during the prior twelve months in reliance on Instruction I.B.6. may not exceed one-third of the aggregate market value of its outstanding common stock held by non-affiliates as of a day during the 60 days immediately preceding such sale, as computed in accordance with Instruction I.B.6. This calculation was updated immediately after the Company’s filed the Annual Report and the amount of securities the Company was then able to sell under a registration statement on Form S-3 during a 12-month period was approximately $18.5 million, of which the Company filed prospectus supplements to register (i) approximately $15.3 million for sales under the Purchase Agreement (as defined below); and (ii) approximately $3.2 million for sales under the Second ATM Agreement (as defined below). Based on this calculation, the Company expects it will be unable to sell additional securities beyond those amounts pursuant to the Current Registration Statement or the Replacement Registration Statement, once effective, for a period of twelve months, unless and until the market value of its outstanding common stock held by non-affiliates increases significantly. In addition, under the terms of the Purchase Agreement, stockholder approval may be required to access a portion of the amounts available under the Purchase Agreement. As of September 30, 2019, the Company has sold 3,401,271 shares of common stock for approximately $5.4 million in gross proceeds under the Purchase Agreement and no shares of common stock under the Second ATM Agreement.

Reclassifications

During the third quarter of 2019, the Company began presenting accounts and other receivables as a separate line item on the condensed balance sheets and 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 condensed balance sheets and condensed statements of cash flows. In accordance with GAAP, the change in current period presentation requires a reclassification of prior period balances. The reclassification of prior period balances resulted in a reduction of prepaid expenses and other current assets of $0.1 million on the Company’s condensed balance sheet for the period ended December 31, 2018 and a reduction in change in prepaid expenses and other assets of $0.1 million on the Company's condensed statement of cash flows for the nine month period ended September 30, 2018. This reclassification had no effect on the condensed statements of operations.

Entry into First ATM Agreement

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

Entry into Second ATM Agreement

In September 2018, the Company entered into a Common Stock Sales Agreement (the "Second ATM Agreement") with RBC Capital Markets, LLC ("RBCCM") under which the Company may offer and sell, from time to time, in its sole discretion, shares of common stock having an aggregate offering price of up to $50,000,000 through RBCCM as its sales agent. The Company's registration statement on Form S-3 contemplated under the Second ATM Agreement was declared effective by the SEC on October 17, 2016. The registration statement on Form S-3 includes a prospectus supplement covering the offering of up to $50,000,000 of shares of common stock in accordance with the Second ATM Agreement. In March 2019, the Company filed an updated prospectus supplement regarding the Second ATM Agreement covering the offering of up to $3.2 million of shares of common stock in order to be in compliance with Instruction I.B.6 of Form S-3. As of September 30, 2019, the Company has not sold any shares of common stock under the Second ATM Agreement.

RBCCM may sell common stock under the Second ATM Agreement by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act of 1933, as amended (the "Securities Act"), including without limitation sales made by means of ordinary brokers' transactions on the Nasdaq Global Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise directed by the Company. RBCCM will use commercially reasonable efforts to sell the common stock from time to time, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company will pay RBCCM a commission of up to three percent (3.0%) of the gross sales proceeds of any common stock sold through RBCCM under the Second ATM Agreement, and also has provided RBCCM with customary indemnification rights.

The Company is not obligated to make any sales of common stock under the Second ATM Agreement. The offering of shares of common stock pursuant to the Second ATM Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the Second ATM Agreement, or (ii) termination of the Second ATM Agreement in accordance with its terms.

Underwritten Public Offering

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

Entry into Purchase Agreement

In February 2019, the Company entered into a purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("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 $15.0 million of shares of common stock from time to time over the 36-month term of the Purchase Agreement, and upon execution of the 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 Purchase Agreement. Concurrently with entering into the Purchase Agreement, the Company also entered into a registration rights agreement with Lincoln Park (the "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 Purchase Agreement pursuant to the Company's existing shelf registration statement on Form S-3 or a new registration statement. As of September 30, 2019, the Company has sold 3,401,271 shares of common stock to Lincoln Park under the Purchase Agreement for approximately $5.4 million in gross proceeds.

Entry into License Agreement

In September 2019, the Company entered into a Collaboration and License Agreement (the "KP415/484 License Agreement") with Commave Therapeutics SA, an affiliate of Gurnet Point Capital ("Commave"). Under the KP415/484 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 KP415/484 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 KP415/484 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 KP415/484 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 KP415/484 License Agreement) for the applicable product.

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

The KP415/484 License Agreement also establishes a joint steering committee, which will monitor progress in the development of the 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 KP415/484 License Agreement.

B. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires the Company to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

On an ongoing basis, the Company evaluates its estimates and assumptions, including those related to revenue recognition, the useful lives of property and equipment, the recoverability of long-lived assets, the incremental borrowing rate for leases, and assumptions used for purposes of determining stock-based compensation, income taxes, and the fair value of the derivative and warrant liability, among others. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable, the results of which form the basis for making judgments about the carrying value of assets and liabilities.

Revenue Recognition

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

Arrangements with Multiple-Performance Obligations

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

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

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

Licensing Agreements

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

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

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.

KP415/484 License Agreement

In September 2019, the Company entered into the KP415/484 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 KP415/484 License Agreement.

In exchange for the exclusive, worldwide license, discussed above, Commave paid the Company a non-refundable upfront payment of $10.0 million. The Company is also entitled to additional payments from Commave of up to $63.0 million, conditioned upon the achievement of specified regulatory milestones related to KP415 and KP484. In addition, the Company is entitled to payments from Commave of up to $420.0 million in the aggregate, conditioned upon the achievement of certain U.S. sales milestones, which are dependent upon, among other things, the timing of approval for a new drug application for KP415 and its final approved label, if any. Further, Commave will pay the Company quarterly, tiered royalty payments ranging from a percentage in the high single digits to mid-twenties of Net Sales (as defined in the KP415/484 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 KP415/484 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 KP415/484 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 KP415/484 License Agreement is considered to be 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 KP415/484 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 KP415/484 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 KP415/484 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 the inception of the KP415/484 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 KP415/484 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 notes 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.

Under the KP415/484 License Agreement, Commave was granted an exclusive option to include Additional Products as Product(s) (both as defined in the KP415/484 License Agreement) under the KP415/484 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 just 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 on 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 and would obtain at 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 KP415/484 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 KP415/484 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 will update its assessment of whether the milestone and royalty payments are constrained by considering both the likelihood and magnitude of the potential revenue reversal.

During the three and nine months ended September 30, 2019, the Company recognized revenue of $11.5 million, which is comprised of a $10.0 million non-refundable payment for an exclusive, worldwide license, $1.2 million of reimbursement of out-of-pocket third-party research and development costs and $0.3 million for the performance of consulting services. In addition, as of September 30, 2019, the Company had receivables in the amount of $0.3 million and $1.2 million related to the performance of consulting services and the reimbursement of out-of-pocket third-party research and development costs, respectively. The cost of revenue associated with revenue recognized under the agreement with Commave was $1.0 million for the three and nine months ended September 30, 2019. There was no revenue recognized, or associated receivables and cost revenue, for the three and nine months ended September 30, 2018 or as of December 31, 2018. There was no deferred revenue related to this agreement as of September 30, 2019 or December 31, 2018.

Accounts and Other Receivables

Accounts and other receivables consists of receivables under the KP415/484 License Agreement, as well as income tax and other receivables due to the Company. Receivables under the KP415/484 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 September 30, 2019 and December 31, 2018 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 February 2016, the FASB issued ASU 2016-02, *Leases (Topic* 842*)* ("ASU 2016-02"), which requires lessees to recognize operating and finance lease liabilities and corresponding right-of-use assets on the balance sheet and to provide enhanced disclosures surrounding the amount, timing and uncertainty of cash flows arising from leases. The Company leases office space and laboratory facilities under non-cancelable operating leases. In addition, the Company leases various laboratory equipment, furniture and office equipment and leasehold improvements that are accounted for as capital leases. The Company adopted the new standard effective January 1, 2019 on a modified retrospective basis and did not restate comparative periods. The Company elected the package of practical expedients permitted under the transition guidance, which allowed the Company to carryforward its historical lease classification and its assessment on whether a contract is or contains a lease for any leases that existed prior to adoption of the new standard. The Company also elected to combine lease and non-lease components and to keep leases with an initial term of 12 months or less off the balance sheet and recognize the associated lease payments in the condensed statements of operations on a straight-line basis over the lease term. The Company did not elect the hindsight practical expedient, which would have allowed the Company to use hindsight in determining the lease term and in assessing any impairment of right-of-use assets during the lookback period. The adoption of ASU 2016-02 resulted in the recognition of total right-of-use assets and total lease liabilities of approximately $2.6 million on the condensed balance sheets as of January 1, 2019.

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

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

Application of New or Revised Accounting Standards—Not Yet Adopted

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

C. Debt Obligations

Deerfield Facility Agreement

In June 2014, the Company entered into a $60 million facility agreement (the “Deerfield Facility Agreement”) with Deerfield Private Design Fund III, LP (“Deerfield”). The first payment to the Company under the terms of the Deerfield Facility Agreement consisted of a term loan of $15 million (the “Term Note”) and a senior secured loan of $10 million (the “Deerfield Convertible Note”). As of June 30, 2016, Deerfield was no longer obligated to provide the Company any additional disbursements under the Deerfield Facility Agreement. All loans issued under the Deerfield Facility Agreement originally bore interest at 9.75% per annum, and now bear interest at 6.75% per annum. 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 Company also issued to Deerfield a warrant to purchase 14,423,076 shares of Series D redeemable convertible preferred stock (“Series D Preferred”) at an exercise price of $0.78 per share, which is exercisable until June 2, 2024 (the “Deerfield Warrant”). Upon completion of the Company's initial public offering (the "IPO"), the Deerfield Warrant automatically converted into a warrant to purchase 1,923,077 shares of the Company’s common stock at an exercise price of $5.85 per share. 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 below, Deerfield may require the Company to redeem the Deerfield Warrant for a cash amount equal to the Black-Scholes value of the portion of the Deerfield Warrant to be redeemed (the “Warrant Put Option”). A Major Transaction is (i) a consolidation, merger, exchange of shares, recapitalization, reorganization, business combination or other similar event; (ii) the sale or transfer in one transaction or a series of related transactions of all or substantially all of the assets of the Company; (iii) a third-party purchase, tender or exchange offer made to the holders of outstanding shares, such that following such purchase, tender or exchange offer a change of control has occurred; (iv) the liquidation, bankruptcy, insolvency, dissolution or winding-up affecting the Company; (v) the shares of the Company’s common stock cease to be listed on any eligible market; and (vi) at any time, the shares of the Company’s common stock cease to be registered under Section 12 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”).

In addition, the Company issued to Deerfield 1,923,077 shares of Series D Preferred as consideration for the loans provided to the Company under the Deerfield Facility Agreement. Upon completion of the IPO, these shares automatically reclassified into 256,410 shares of the Company’s common stock. The Company recorded the fair value of the shares of Series D Preferred of $1.5 million, to debt issuance costs on the date of issuance. The Company recorded the fair value of the Deerfield Warrant and the embedded 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 condensed 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 Deerfield. Additionally, if the Company were to enter into a major transaction, including a merger, consolidation, sale of substantially all of its assets or other change of control transaction, Deerfield would have the ability to demand that prior to consummation of such transaction the Company repay all outstanding principal and accrued interest of any notes issued under the Deerfield Facility Agreement. Under 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 Company originally had to repay one-third of the outstanding principal amount of all debt issued under the Deerfield Facility Agreement on the fourth and fifth anniversaries of the Deerfield Facility Agreement. On September 3, 2019, the Company entered into an exchange agreement and amendment to facility agreement (discussed below) with Deerfield and Deerfield Special Situations Fund, L.P., which 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 due pursuant to the Deerfield Facility Agreement until June 1, 2020. The Company is also obligated to repay $3,333,333 of principal, as well as interest capitalized from the date of the amendment through the payment date of February 14, 2020. The Company prepaid all outstanding interest and principal on the Term Note in February 2016. The outstanding principal amount due on the fourth anniversary of the Deerfield Facility Agreement and the related accrued but unpaid interest as of such date was converted in common stock of the Company in accordance with the provisions of the Deerfield Convertible Note, as amended. Refer to the section entitled Facility Agreement Waiver and Fifth Amendment to Senior Secured Convertible Note below.

Interest accrued on outstanding debt under the Deerfield Facility Agreement is due quarterly in arrears. Upon notice to Deerfield, the Company had the option to have one or more of the first eight of such scheduled interest payments added to the outstanding principal amount of the debt issued under the Deerfield Facility Agreement, provided that all such interest was due on July 1, 2016. The Company elected this option on all eight of the scheduled interest payments through June 30, 2016. The accrued interest added to outstanding principal, was paid to Deerfield on July 1, 2016.

First Amendment to Facility Agreement, Senior Secured Convertible Note and Warrant

In connection with the IPO, in March 2015, the Company entered into a First Amendment (the "First Amendment) to the Deerfield Facility Agreement, the Deerfield Convertible Note and Deerfield Warrant, by and between the Company and Deerfield. The First Amendment, among other things, clarified that all references to the conversion of shares of Series D Preferred into the Company's common stock in the Deerfield Facility Agreement, the Deerfield Convertible Note and Deerfield Warrant shall include any reclassification of the outstanding shares of Series D Preferred into shares of the Company's common stock.

Second Amendment to Senior Secured Convertible Note and Warrant

In January 2016, the Company entered into a Second Amendment (the "Second Amendment") to the Deerfield Convertible Note and Deerfield Warrant, by and between the Company and Deerfield. The Second Amendment, among other things, clarified the calculation of an anti-dilution adjustment of the conversion price and exercise price of the Deerfield Convertible Note and Deerfield Warrant, respectively, in the event that the Company effects a firm commitment underwritten public offering of its securities.

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

In February 2016, the Company issued $86.3 million aggregate principal amount of its 5.50% Senior Convertible Notes due 2021 (the "2021 Notes") to Cowen and RBC Capital Markets, LLC, as representatives of the several initial purchasers (the "Initial Purchasers"), who subsequently resold the 2021 Notes to qualified institutional buyers (the "Note Offering") in reliance on the exemption from registration provided by Rule 144A under the Securities Act.

The 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 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 is payable semi-annually in cash in arrears on February 1 and August 1 of each year, beginning on August 1, 2016, at a rate of 5.50% per year. The 2021 Notes mature on February 1, 2021 unless earlier converted or repurchased. The 2021 Notes are not redeemable prior to the maturity date, and no sinking fund is provided for the 2021 Notes.

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

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

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

In connection with the Note Offering, in February 2016, the Company entered into a Third Amendment (the "Third Amendment") to the Deerfield Facility Agreement, Deerfield Convertible Note and Deerfield Warrant with Deerfield. The Third Amendment, among other things, eliminated the Company's ability to require Deerfield to convert the Deerfield Convertible Note into Company common stock. In addition, pursuant to the Third Amendment, Deerfield consented to the prepayment of the Term Note and the issuance of the 2021 Notes.

Refer to the sections entitled Exchange Agreement and Exchange Agreement and Fifth Amendment to Facility Agreement below for a further discussion of the exchange of a portion of the 2021 Notes for shares of Series A Convertible Preferred Stock, par value $0.0001 per share (the "Series A Preferred Stock") and Series B-1 Convertible Preferred Stock, par value $0.0001 per share (the "Series B-1 Preferred Stock").

Fourth Amendment to Senior Secured Convertible Note and Warrant

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

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.

Exchange Agreement

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 "Holders"). Under the October 2018 Exchange Agreement, the Holders exchanged an aggregate of $9,577,000 principal amount of the 2021 Notes for an aggregate of 9,577 shares of Series A Preferred Stock. The Company also agreed to pay the Holders an amount of $95,105 in cash, which represented the amount of accrued and unpaid interest on the exchanged notes. The October 2018 Exchange Agreement contains customary representations, warranties and covenants made by the Company and the Holders. The October 2018 Exchange Agreement required the Company to reimburse the Holders for up to $25,000 of expenses relating to the exchange.

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 3,192,334 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), and, as of September 30, 2019, there were an aggregate of 1,112,334 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). The Series A Preferred Stock is convertible at any time at the option of the Holders, provided that the Holders are prohibited from converting shares of Series A Preferred Stock into shares of common stock if, as a result of such conversion, such Holders (together with certain affiliates and "group" members) would beneficially own more than 4.985% of the total number of shares of the Company's common stock then issued and outstanding. The Series A 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 of Series A Preferred Stock, plus any declared but unpaid dividends, and thereafter will share ratably in any distribution of the Company's assets with holders of common stock on an as-converted basis. With respect to rights upon liquidation, the Series A Preferred Stock ranks senior to the common stock 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 A Preferred Stock), the Series A Preferred Stock does not have voting rights. The Series A Preferred Stock is not subject to any price-based anti-dilution protections and does not provide for any accruing dividends, but provides that holders of Series A Preferred Stock will participate in any dividends on the common stock on an as-converted basis (without giving effect to the limitation on conversion described above). The Series A Certificate of Designation also provides for partial liquidated damages in the event that the Company fails to timely convert shares of Series A Preferred Stock into common stock in accordance with the Series A Certificate of Designation.

First Supplemental Indenture, Sixth Amendment to Deerfield Convertible Note and Fifth Amendment to Deerfield Warrant

In November 2018, the Company entered into a First Supplemental Indenture (the "Supplemental Indenture") with the Trustee. Pursuant to the Supplemental Indenture, the Indenture was amended to allow each Holder (as defined in the Indenture) or any beneficial holder of any 2021 Notes to, at its option, elect a limit on beneficial ownership as to such Holder or beneficial owner (but not as to any other Holder or beneficial owner) that is less than or equal to the 9.985% Cap (as defined in the Indenture) or any other limit previously elected and then applicable to such Holder or beneficial owner upon written notice delivered to the Company at least three (3) business days prior to the date of effectiveness of such beneficial ownership limit (or such shorter period as may be agreed upon by the Company), specifying the percentage of shares of the Company's common stock outstanding for the beneficial ownership limit that shall apply to such Holder or beneficial owner.

Also in November 2018, in connection with entering into the Supplemental Indenture, the Company entered into an amendment (the "Sixth Amendment") with Deerfield to the Deerfield Convertible Note and Deerfield Warrant. The Sixth Amendment, among other things, lowers the beneficial ownership limit under both the Deerfield Convertible Note and Deerfield Warrant to 4.985% of the Company's outstanding common stock. The Sixth Amendment also includes a notice from Deerfield that it has elected to lower the beneficial ownership limit under the 2021 Notes, as to Deerfield and its affiliates, to 4.985%.

Seventh Amendment to Deerfield Convertible Note and Sixth Amendment to Deerfield Warrant

In February 2019, in connection with entering into the Purchase Agreement, the Company entered into an amendment (the "Seventh Amendment"), with Deerfield to the Deerfield Convertible Note and Deerfield Warrant. The Seventh Amendment, among other things, clarified that the anti-dilution protections contained in the Deerfield Convertible Note and Deerfield Warrant would not apply to sales made under the Purchase Agreement or Second ATM Agreement. The Seventh Amendment also included a waiver from Deerfield regarding any registration rights it may have under the Company's amended and restated investor rights agreement in connection with the Registration Rights Agreement.

Exchange Agreement and Fifth Amendment to Facility Agreement

On September 3, 2019, the Company entered into an Exchange Agreement and Amendment to Facility Agreement (the "September 2019 Exchange Agreement") with the Holders. 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 (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 provides the Holders 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 Holders 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 Holders 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, which represents the last sale price of the common stock on the Nasdaq Global Market on September 3, 2019, or (ii) the average of the volume-weighted average price of the common stock on the Nasdaq Global Market on each of the 15 trading days immediately preceding such exchange.

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.

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), and, as of September 30, 2019, there was an aggregate of 831,051 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 Global Market on each of the 15 trading days immediately preceding such exchange. Immediately following the exchange under the September 2019 Exchange Agreement and as of September 30, 2019, 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 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 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 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.

Except as modified by the First Amendment, Second Amendment, Third Amendment, Fourth Amendment, Fifth Amendment, Sixth Amendment, Seventh Amendment and the September 2019 Exchange Agreement, all terms and conditions of the Deerfield Facility Agreement, Deerfield Warrant and Deerfield Convertible Note remained in full force and effect.

Line of Credit

During the second quarter of 2016, the Company opened a line of credit with a total borrowing capacity of $1.1 million with City National Bank of Florida (the "Line of Credit Agreement") to support several irrevocable letters of credit issued by the bank on behalf of the Company. The line of credit had an original maturity date of January 31, 2018. On January 31, 2018, the line of credit was renewed for an additional two-year term and was set to mature on January 31, 2020. The Line of Credit Agreement was collateralized by a restricted money market account, equal to the total amount of the letters of credit outstanding which are supported by the line of credit. In March 2019, the line of credit was closed. The irrevocable letters of credit and associated money market account remain and the money market account is reported as restricted cash on the condensed balance sheets.

D. Commitments and Contingencies

From time to time, the Company is involved in various legal proceedings arising in the normal course of business. For some matters, a liability is not probable, or the amount cannot be reasonably estimated and, therefore, an accrual has not been made. However, for such matters when it is probable that the Company has incurred a liability and can reasonably estimate the amount, the Company accrues and discloses such estimates. As of September 30, 2019 and December 31, 2018, no accruals have been made related to commitments and contingencies.

E. Preferred Stock and Warrants

Authorized, Issued, and Outstanding Preferred Stock

As of September 30, 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 3,337 shares of Series A Preferred Stock and 789 shares of Series B Preferred Stock were issued and outstanding as of September 30, 2019. As of December 31, 2018, 3,337 shares of Series A Preferred Stock were issued and outstanding and no shares of Series B-1 Preferred stock were issued or outstanding. No shares of Series B-2 Preferred Stock were issued or outstanding as of September 30, 2019 or December 31, 2018.

In October 2018, the Company entered into the October 2018 Exchange Agreement. Under the October 2018 Exchange Agreement the Company issued to the Holders 9,577 shares of Series A Preferred Stock. Each share of Series A Preferred Stock has an aggregate stated value of $1,000 and is convertible into shares of common stock at a price equal to $3.00 per share (subject to adjustment to reflect stock splits and similar events). Immediately following the exchange under the October 2018 Exchange Agreement, there were an aggregate of 3,192,334 shares of common stock issuable upon conversion of the Series A Preferred Stock (without giving effect to the limitation on conversion described below). The Series A Preferred Stock is convertible at any time at the option of the Holders, provided that the Holders are prohibited from converting shares of Series A Preferred Stock into shares of common stock if, as a result of such conversion, such Holders (together with certain affiliates and “group” members) would beneficially own more than 4.985% of the total number of shares of the Company's common stock then issued and outstanding. The Series A 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 of Series A Preferred Stock, plus any declared but unpaid dividends, and thereafter will share ratably in any distribution of the Company’s assets with holders of common stock on an as-converted basis. With respect to rights upon liquidation, the Series A Preferred Stock ranks senior to the common stock 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 A Preferred Stock), the Series A Preferred Stock does not have voting rights. The Series A Preferred Stock is not subject to any price-based anti-dilution protections and does not provide for any accruing dividends, but provides that the holders of Series A 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 A Certificate of Designation also provides for partial liquidated damages in the event that the Company fails to timely convert shares of Series A Preferred Stock into common stock in accordance with the Series A Certificate of Designation. As of September 30, 2019, 6,240 shares of Series A Preferred Stock have been converted into 2,080,000 shares of common stock.

As of September 30, 2019, the Company has 3,337 shares of Series A Preferred Stock outstanding, which are convertible into 1,112,334 shares of common stock. Refer to Note C for a further discussion of the October 2018 Exchange Agreement.

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 has an aggregate stated value of $1,000 and is convertible into shares of common stock at a price equal to the greater of (i) $0.9494, which represents the last sale price of the common stock on the Nasdaq Global Market on September 3, 2019, or (ii) the average of the volume-weighted average price of the Common Stock on the Nasdaq Global 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 and junior to existing and future indebtedness. Except as otherwise required by law (or with respect to approval of certain actions involving the Company's organizational documents that materially and adversely affect the holders of Series B Preferred Stock), the Series B Preferred Stock does not have voting rights. The Series B Preferred Stock is not subject to any price-based anti-dilution protections and does not provide for any accruing dividends, but provides that holders of Series B Preferred Stock will participate in any dividends on the common stock on an as-converted basis (without giving effect to the limitation on conversion described above). The Series B-1 Certificate of Designation and the Series B-2 Certificate of Designation also provide for partial liquidated damages in the event that the Company fails to timely convert shares of Series B-1 Preferred Stock or Series B-2 Preferred Stock, respectively, into Common Stock in accordance with the applicable Certificate of Designation. As of September 30, 2019, 787 shares of Series B-1 Preferred Stock have been converted into 828,945 shares of common stock.

As of September 30, 2019, the Company has 789 shares of Series B-1 Preferred Stock outstanding, which are convertible into 831,051 shares of common stock, and no shares of Series B-2 Preferred Stock outstanding. Refer to Note C for a further discussion of the September 2019 Exchange Agreement.

F. Common Stock and Warrants

Authorized, Issued, and Outstanding Common Shares

As of September 30, 2019 and December 31, 2018, the Company had authorized shares of common stock of 250,000,000 shares. Of the authorized shares, 32,387,382 and 26,455,352 shares of common stock were issued and outstanding as of September 30, 2019 and December 31, 2018, respectively.

As of September 30, 2019 and December 31, 2018, the Company had reserved authorized shares of common stock for future issuance as follows:

	September 30, 2019	December 31, 2018
Conversion of Deerfield Convertible Note	1,192,918	1,167,607
Conversion of 2021 Notes not subject to the Optional Exchange Principal Amount	2,727,820	4,481,182
Outstanding awards under equity incentive plans	4,620,891	3,704,755
Outstanding common stock warrants	2,423,077	2,527,763
Conversion of Series A Preferred Stock	1,112,334	1,112,334
Conversion of Series B-1 Preferred Stock	831,051	—
In exchange for the Optional Exchange Principal Amount*	28,439,015	
Possible future issuances under equity incentive plans	675,966	648,272
Total common shares reserved for future issuance	42,023,072	13,641,913

* Represents the aggregate number of 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.

Common Stock Activity

The following table summarizes common stock activity for the nine months ended September 30, 2019:

	Shares of Common Stock
Balance as of December 31, 2018	26,455,352
Common stock issued under Purchase Agreement	1,521,471
Balance as of March 31, 2019	27,976,823
Common stock issued under Purchase Agreement	800,000
Restricted stock awards vested during the period	81,720
Balance as of June 30, 2019	28,858,543
Common stock issued under Purchase Agreement	1,200,000
Common stock issued as a result of 2021 Notes principal conversion	1,499,894
Common stock issued as a result of Series B-1 Preferred Stock conversion	828,945
Balance as of September 30, 2019	32,387,382

In September 2018, the Company terminated the First ATM Agreement with Cowen. Prior to termination of the First ATM Agreement, the Company sold an aggregate of 762,338 shares of common stock under the First ATM Agreement resulting in gross proceeds to the Company of $4.9 million. As of September 30, 2019, the Company has not sold any shares of common stock under the Second ATM Agreement. Refer to Note A for a further discussion of the First and Second ATM Agreements.

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

Also in October 2018, the Company entered into the October 2018 Exchange Agreement pursuant to which the Company issued to the Holders 9,577 shares of Series A Preferred Stock. As of September 30, 2019, 6,240 shares of Series A Preferred Stock have been converted into 2,080,000 shares of common stock. Refer to Note C for a further discussion of the October 2018 Exchange Agreement.

On September 3, 2019, the Company entered into the September 2019 Exchange Agreement pursuant to which the Company issued to the Holders 1,499,894 shares of common stock and 1,576 shares of Series B-1 Preferred Stock. As of September 30, 2019, 787 shares of Series B-1 Preferred Stock have been converted into 828,945 shares of common stock. Refer to Note C for a further discussion of the September 2019 Exchange Agreement.

Warrants

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

On June 2, 2014, pursuant to the terms of the Deerfield Facility Agreement, the Company issued the Deerfield Warrant to purchase 14,423,076 shares of Series D Preferred (Note C). 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 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 condensed 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 condensed 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 5,076,694 as of September 30, 2019. The number of shares of common stock reserved for issuance under the 2014 Plan will automatically increase on January 1 of each year, beginning on January 1, 2016, and ending on and including January 1, 2024, by 4% of the total number of shares of the Company’s capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Board. Pursuant to the terms of the 2014 Plan, on January 1, 2019, the common stock reserved for issuance under the 2014 Plan automatically increased by 1,058,214 shares.

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

During the three months ended September 30, 2019 and 2018 and the nine months ended September 30, 2019, no stock options were exercised. During the nine months ended September 30, 2018, stock options were exercised for a total of 23,682 shares of common stock.

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

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Research and development	$ 400	$ 409	$ 1,196	$ 1,196
General and administrative	657	941	2,468	2,813
Severance expense	—	1,236	—	1,236
Total stock-based compensation expense	$ 1,057	$ 2,586	$ 3,664	$ 5,245

There was no stock-based compensation expense related to performance-based awards recognized during the three or nine months ended September 30, 2019 or 2018.

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 $6.5 million and $6.2 million, respectively, as of September 30, 2019 and December 31, 2018. The fair value of the 2021 Notes was $57.9 million and $51.2 million, respectively, as of September 30, 2019 and December 31, 2018. Both the Deerfield Convertible Note and 2021 Notes fall within Level 3 of the fair value hierarchy as their value is based on the credit worthiness of the Company, which is an unobservable input. The Company used a Tsiveriotis-Fernandes model to value the Deerfield Convertible Note and 2021 Notes as of September 30, 2019 and December 31, 2018.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company evaluates its financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level in which to classify them for each reporting period. This determination requires significant judgments to be made. The following table summarizes the conclusions reached regarding fair value measurements as of September 30, 2019 and December 31, 2018 (in thousands):

	Balance as of September 30, 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	$ 192	$ —	$ —	$ 192
Embedded Warrant Put Option	77	—	—	77
Fundamental change and make-whole interest provisions embedded in 2021 Notes	—	—	—	—
Deerfield Note Conversion Feature	—	—	—	—
KVK Warrant liability	66	—	66	—
Total liabilities	$ 335	$ —	$ 66	$ 269

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

The Company's Deerfield Warrant liability, embedded Warrant Put Option, the fundamental change and the make-whole interest provisions embedded in the 2021 Notes and the embedded Deerfield Note Put Option, as well as the trading securities are measured at fair value on a recurring basis. As of September 30, 2019 and December 31, 2018, the Deerfield Warrant liability, embedded Warrant Put Option, the fundamental change and make-whole interest provisions embedded in the 2021 Notes and the embedded Deerfield Note Put Option are reported on the condensed balance sheets in derivative and warrant liability. As of December 31, 2018, the trading securities are reported on the condensed balance sheets in marketable securities. The Company used a Monte Carlo simulation to value the Deerfield Warrant liability, embedded Warrant Put Option, the fundamental change and make-whole interest provisions embedded in the 2021 Notes, and the embedded Deerfield Note Put Option as of September 30, 2019 and December 31, 2018. Significant unobservable inputs used in measuring the fair value of these financial instruments included the Company's estimated enterprise value, an estimate of the timing of a liquidity or fundamental change event and a present value discount rate. Changes in the fair value of the Deerfield Warrant liability, embedded Warrant Put Option, the fundamental change and make-whole interest provisions embedded in the 2021 Notes and the embedded Deerfield Note Put Option are reflected in the condensed statements of operations for the three and nine months ended September 30, 2019 and 2018 as a fair value adjustment related to derivative and warrant liability.

The Company's KVK Warrant liability is measured at fair value on a recurring basis. As of September 30, 2019 and December 31, 2018, the KVK Warrant liability is reported on the 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 statements of operations for the three and nine months ended September 30, 2019 as a fair value adjustment related to derivative and warrant liability. The changes in the fair value of the KVK Warrant liability are not reflected in the condensed statements of operations for the three and nine months ended September 30, 2018 since it was not issued until October 2018.

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

	Three months ended September 30,		Nine months ended September 30,	
	2019	**2018**	**2019**	**2018**
Balance as of beginning of period	$ 1,437	$ 11,888	$ 1,845	$ 7,709
Adjustment to fair value	(1,168)	(4,468)	(1,576)	(289)
Balance as of end of period	$ 269	$ 7,420	$ 269	$ 7,420

I. Net Income (Loss) Per Share of Common Stock

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 the nine months ended September 30, 2019 and the three and nine months ended September 30, 2018 because the effects of potentially dilutive items were anti-dilutive for the respective periods. The following securities, presented on a common stock equivalent basis, have been excluded from the calculation of weighted average number of shares of common stock outstanding because their effect is anti-dilutive:

	Three months ended September 30,		Nine months ended September 30,	
	2019	**2018**	**2019**	**2018**
Warrants to purchase common stock	500,000	2,027,763	2,423,077	2,027,763
Awards under equity incentive plans	4,620,891	3,707,421	4,620,891	3,707,421
Deerfield Convertible Note	1,192,918	1,167,607	1,192,918	1,167,607
2021 Notes*	31,166,835	5,040,914	31,166,835	5,040,914
Series A Preferred Stock	—	—	1,112,334	—
Series B-1 Preferred Stock	—	—	831,051	—
Total securities excluded from the calculation of weighted average number of shares of common stock outstanding	37,480,644	11,943,705	41,347,106	11,943,705

* Inclusive of 28,439,015 of shares of Common Stock issuable (i) in exchange of the Optional Exchange Principal Amount, or (ii) upon conversion of the Series B-2 Preferred Stock issuable in exchange of the Optional Exchange Principal Amount.

The following table reconciles basic net income per share of common stock to diluted net income per share of common stock for the three months ended September 30, 2019 (in thousands, except per share data):

	Three months ended September 30, 2019
Basic net income per share of common stock:	
Net income	$ 3,063
Less: Net income attributable to participating securities	(348)
Net income attributable to shares of common stock	**2,715**
Less: Dividends declared or accumulated	—
Undistributed net income attributable to shares of common stock, basic	**$ 2,715**
Weighted average number of shares of common stock outstanding	30,127
Basic net income per share of common stock	**$ 0.09**
Diluted net income per share of common stock:	
Net income	$ 3,063
Less: Fair value adjustment income related to Deerfield Warrant liability	(1,019)
Less: Fair value adjustment income related to embedded Warrant Put Option	(135)
Net income attributable to shares of common stock, diluted	**$ 1,909**
Weighted average number of shares of common stock outstanding	30,127
Dilutive effect of Deerfield Warrant	—
Dilutive effect of Series A Preferred	1,112
Dilutive effect of Series B-1 Preferred	433
Weighted average number of shares of common stock outstanding, diluted	**31,672**
Diluted net income per share of common stock	**$ 0.06**

J. Severance Expense

In August 2018, Daniel L. Cohen resigned from his position as the executive vice president, government and public relations of the Company, effective immediately. In connection with his resignation, Mr. Cohen and the Company entered into a separation and release agreement which included among other items, severance benefits. The severance benefits consisted of personnel and other related charges of approximately $0.4 million and stock compensation expense of approximately $1.2 million related to the acceleration of vesting on unvested shares subject to certain stock options and the extension of the exercise period for certain stock options. These severance benefits are presented as severance expense in the condensed statements of operations. As of September 30, 2018, the Company had accrued severance expense recorded within accounts payable and accrued expenses in the amount of $0.3 million. As of and for the three and nine months ended September 30, 2019 there was no severance expense or accrued severance expense.

K. Leases

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

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

Lease Cost	Three months ended September 30, 2019	Nine months ended September 30, 2019
Finance lease cost:		
Amortization of right-of-use assets	$ 31	$ 92
Interest on lease liabilities	9	31
Total finance lease cost	40	123
Operating lease cost	124	372
Short-term lease cost	58	173
Variable lease cost	14	35
Less: sublease income	(25)	(75)
Total lease costs	$ 211	$ 628

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

	Nine months ended September 30, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from finance leases	$ 31
Financing cash flows from finance leases	157
Operating cash flows from operating leases	326
Operating cash flows from short-term leases	173
Operating cash flows from variable lease costs	35
Right-of-use assets obtained in exchange for lease liabilities:	
Finance leases	$ 737
Operating leases	1,852

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

	September 30, 2019
Finance Leases	
Property and equipment, at cost	$ 1,013
less: accumulated depreciation and amortization	(368)
Property and equipment, net	$ 645
Other current liabilities	$ 227
Other long-term liabilities	227
Total finance lease liabilities	$ 454
Operating Leases	
Operating lease right-of-use assets	$ 1,649
Total operating lease right-of-use assets	$ 1,649
Current portion of operating lease liabilities	$ 369
Operating lease liabilities, less current portion	1,976
Total operating lease liabilities	$ 2,345
Weighted Average Remaining Lease Term	
Finance leases	2 years
Operating leases	6 years
Weighted Average Discount Rate	
Finance leases	7.7%
Operating leases	7.5%

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

Year Ending December 31,	Finance Leases	Operating Leases
2019 (excluding the nine months ended September 30, 2019)	$ 66	$ 144
2020	251	499
2021	163	449
2022	11	461
2023	—	472
Thereafter	—	903
Total lease payments	491	2,928
Less: future interest expense	(37)	(583)
Lease liabilities	$ 454	$ 2,345

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;*
- *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 addition, we have announced our commercial partnership with KVK Tech, Inc., or KVK, of APADAZ®, an FDA approved immediate-release, or IR, combination product of benzhydrocodone, our prodrug of hydrocodone, and acetaminophen, or APAP, for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. We have entered into a collaboration and license agreement with Commave Therapeutics SA, an affiliate of Gurnet Point Capital, or Commave, for the development, manufacture and commercialization of our product candidates containing serdexmethylphenidate, or SDX, and d-MPH.

In September 2019, we entered into a Collaboration and License Agreement, or the KP415/484 License Agreement, with Commave. Under the KP415/484 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.

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. To date, we have only generated revenue from the KP415/484 License Agreement in the form of the non-refundable upfront payment of $10.0 million, reimbursement of out-of-pocket third-party research and development costs and payments related to the performance of consulting services. We had negative cash flows from operations since our inception and, as of September 30, 2019, had an accumulated deficit of $239.7 million and a net working capital (current assets less current liabilities) deficit of $1.7 million. Our negative cash flows from operations for the nine months ended September 30, 2019 and 2018 were $20.6 million and $39.2 million, respectively.

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

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

Our commercial revenue, if any, will be derived from sales of APADAZ or any other product candidates for which we obtain regulatory approval. In October 2018, we entered into a collaboration and license agreement, or 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 KP415/484 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 KP415/484 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 KP415/484 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 Partnered Product Candidates and Product

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

Our pipeline of partnered assets is summarized in the table below:

KemPharm Partnered Assets

Indication / Parent Drug	Product Candidate	Development Status	Key Milestone
ADHD			
Methylphenidate (ER)	KP415	Clinical	NDA Submission - Q4 2019
Methylphenidate (ER)	KP484	Clinical	NDA Submission - 2020 Pivotal Efficacy Trial Data - 2020
SUD			
Methylphenidate (ER)*	KP879	Preclinical	

Product Name	Key Milestone
APADAZ	Commercial Launch - November 2019

* This product candidate is subject to an option in favor of Commave under the terms of the KP415/484 License Agreement, but is not currently licensed to Commave thereunder.

Subject to Commave's approval, we intend to seek approval of KP415 and KP484 under the 505(b)(2) NDA pathway, which will allow us to rely on the FDA's previous findings of safety and effectiveness for one or more approved products. We anticipate submitting a 505(b)(2) NDA for KP415 in the fourth quarter of 2019 and reporting additional pharmacokinetic, or PK, and pivotal efficacy trial data and submitting a 505(b)(2) NDA for KP484 in 2020.

In September 2019, we entered into the KP415/484 License Agreement with Commave. Under the KP415/484 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.

In October 2018, we entered into the APADAZ License Agreement with KVK pursuant to which we have granted an exclusive license to KVK to conduct regulatory activities for, manufacture and commercialize APADAZ in the United States. Under the terms of the APADAZ License Agreement we are eligible to receive milestone payments of up to $53.0 million and royalties based on the net profits of APADAZ sales in the United States. We anticipate that KVK’s commercialization strategy will target outreach to pharmacy benefit managers, managed care organizations and integrated delivery networks for the exclusive utilization of APADAZ as an alternative to currently available hydrocodone/acetaminophen products. In November 2019, APADAZ and its authorized generic (AG-APADAZ) became nationally available. In support of this commercial launch, we have begun the technology transfer process outlined under the APADAZ License Agreement. As part of this process, in February 2019 we completed the transfer of the NDA for APADAZ to KVK.

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 pre-launch payments and cost reimbursements of an estimated $3.4 million, which includes a pre-launch 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 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 establishes a joint steering committee, which will monitor progress in the development and commercialization of APADAZ.

KP415/484 License Agreement

In September 2019, we entered into the KP415/484 License Agreement with Commave. Under the KP415/484 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 KP415/484 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 KP415/484 License Agreement related thereto. If Commave exercises its option related to any Additional Product Candidate under the KP415/484 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 KP415/484 License Agreement.

Pursuant to the KP415/484 License Agreement, Commave paid the Company an upfront payment of $10,000,000 and agreed to pay up to $63,000,000 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 $420,000,000 in the aggregate, depending, among other things, on timing of approval for a new drug applicable for KP415 and its final approved label, if any. Further, Commave will pay us quarterly, tiered royalty payments ranging from a percentage in the high single digits to the mid-twenties of Net Sales (as defined in the KP415/484 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 KP415/484 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 KP415/484 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 KP415/484 License Agreement.

The KP415/484 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 KP415/484 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 KP415/484 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 KP415/484 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 KP415/484 License Agreement (i) upon a material breach of the KP415/484 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 KP415/484 License Agreement) by us, subject to a cure period, Commave may choose not to terminate the KP415/484 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 KP415/484 License Agreement would revert to us. During the term of the KP415/484 License Agreement, we may not develop or commercialize any Competing Product (as defined in the KP415/484 License Agreement).

The KP415/484 License Agreement also establishes a joint steering committee, which will monitor progress in the development of the 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 the us on behalf of Commave.

JMI Agreement

In November 2009, we entered into a 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 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 active pharmaceutical ingredient, or 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, who took over this right of first refusal at that time. Takeda did not exercise this right of first refusal as part of the KP415/484 License Agreement discussed above.

Under our March 2012 termination agreement with Aquestive Therapeutics, or Aquestive, Aquestive has the right to receive a royalty amount equal to 10% of any value generated by KP415, KP484 or KP879, and any product candidates arising therefrom, 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 KP415/484 License Agreement Aquestive received a royalty equal to 10% of the upfront license payment from us.

Results of Operations

Comparison of the three months ended September 30, 2019 and 2018 (in thousands):

	Three months ended September 30,		Period-to-Period Change
	2019	2018	
Revenue	$ 11,463	$ —	$ 11,463
Operating expenses:			
Cost of revenue	1,000	—	1,000
Research and development	3,616	13,330	(9,714)
General and administrative	3,613	2.992	621
Severance expense	—	1,636	(1,636)
Total operating expenses	8,229	17,958	(9,729)
Income (loss) from operations	3,234	(17,958)	21,192
Other (expense) income:			
Interest expense related to amortization of debt issuance costs and discount	(371)	(326)	(45)
Interest expense on debt principal	(1,208)	(1,367)	159
Fair value adjustment related to derivative and warrant liability	1,351	4,468	(3,117)
Interest and other income, net	60	52	8
Total other (expense) income	(168)	2,827	(2,995)
Income (loss) before income taxes	3,066	(15,131)	18,197
Income tax (expense) benefit	(3)	60	(63)
Net income (loss)	$ 3,063	$ (15,071)	$ 18,134

Net Income (Loss)

Net income for the three months ended September 30, 2019 was $3.1 million, an increase of $18.1 million compared to a net loss for the three months ended September 30, 2018 of $15.1 million. The increase was primarily attributable to an increase in income from operations of $21.2 million and a decrease in net interest expense and other items of $0.1 million; partially offset by a change in fair value adjustment related to a decrease of $1.4 million in the derivative and warrant liability compared to a decrease in this liability of $4.5 million in the prior-year period.

Revenue

Revenue for the three months ended September 30, 2019 was $11.5 million, which was comprised of a $10.0 million non-refundable up-front payment, $1.2 million of reimbursements for out-of-pocket third-party research and development costs and $0.3 million of consulting fees earned, all related to the KP415/484 License Agreement.

Cost of Revenue

Cost of revenue for the three months ended September 30, 2019 was $1.0 million, which was comprised of a royalty payment to Aquestive related to the $10.0 million non-refundable upfront payment under the KP415/484 License Agreement.

Research and Development

Research and development expenses decreased by $9.7 million, from $13.3 million for the three months ended September 30, 2018, to $3.6 million for the three months ended September 30, 2019. This decrease was primarily attributable to a decrease in net third-party research and development costs.

General and Administrative

General and administrative expenses increased by $0.6 million, from $3.0 million for the three months ended September 30, 2018, to $3.6 million for the three months ended September 30, 2019. This increase was primarily attributable to an increase in professional fees; partially offset by a decrease in personnel-related costs and other miscellaneous general and administrative costs.

Severance Expense

Severance expense of $1.6 million was recognized for the three months ended September 30, 2018 due to the resignation of our executive vice president, government and public relations in August 2018. Severance expense is comprised of $0.4 million of personnel and other related charges and $1.2 million of stock compensation expense related to the acceleration of vesting on certain stock options upon employee termination.

Other (Expense) Income

We had other expense of $0.2 million for the three months ended September 30, 2019 compared to other income of $2.8 million for the three months ended September 30, 2018. This period-to-period change was primarily attributable to the change in the fair value adjustment related to changes in derivative and warrant liability.

Comparison of the nine months ended September 30, 2019 and 2018 (in thousands):

	Nine months ended September 30,		Period-to-Period Change
	2019	2018	
Revenue	$ 11,463	$ —	$ 11,463
Operating expenses:			
Cost of revenue	1,000	—	1,000
Research and development	16,950	35,455	(18,505)
General and administrative	9,440	9,544	(104)
Severance expense	—	1,636	(1,636)
Total operating expenses	27,390	46,635	(19,245)
Loss from operations	(15,927)	(46,635)	30,708
Other (expense) income:			
Interest expense related to amortization of debt issuance costs and discount	(981)	(1,106)	125
Interest expense on debt principal	(3,669)	(4,228)	559
Fair value adjustment related to derivative and warrant liability	1,783	289	1,494
Interest and other income, net	295	290	5
Total other (expense) income	(2,572)	(4,755)	2,183
Loss before income taxes	(18,499)	(51,390)	32,891
Income tax benefit	14	107	(93)
Net loss	$ (18,485)	$ (51,283)	$ 32,798

Net Loss

Net loss for the nine months ended September 30, 2019 was $18.5 million, a decrease of $32.8 million compared to net loss for the nine months ended September 30, 2018 of $51.3 million. The decrease was primarily attributable to a decrease in loss from operations of $30.7 million, a change in fair value adjustment related to a decrease of $1.8 million in the derivative and warrant liability compared to a decrease in this liability of $0.3 million in the prior-year period and a decrease in net interest expense and other items of $0.6 million.

Revenue

Revenue for the nine months ended September 30, 2019 was $11.5 million, which was comprised of a $10.0 million non-refundable upfront payment, $1.2 million of reimbursements for out-of-pocket third-party research and development costs and $0.3 million of consulting fees earned, all related to the KP415/484 License Agreement.

Cost of Revenue

Cost of revenue for the nine months ended September 30, 2019 was $1.0 million, which was comprised of a royalty payment to Aquestive related to the $10.0 million non-refundable upfront payment under the KP415/484 License Agreement.

Research and Development

Research and development expenses decreased by $18.5 million, from $35.5 million for the nine months ended September 30, 2018, to $17.0 million for the nine months ended September 30, 2019. This decrease was primarily attributable to a decrease in net third-party research and development costs and personnel-related costs.

General and Administrative

General and administrative expenses decreased by $0.1 million, from $9.5 million for the nine months ended September 30, 2018, to $9.4 million for the nine months ended September 30, 2019. This decrease was primarily attributable to a decrease in personnel-related costs and other miscellaneous general and administrative costs.

Other (Expense) Income

Other (expense) income decreased by $2.2 million, from expense of $4.8 million for the nine months ended September 30, 2018, to expense of $2.6 million for the nine months ended September 30, 2019. This period-to-period change was primarily attributable to the change in the fair value adjustment related to changes in derivative and warrant liability.

Liquidity and Capital Resources

Sources of Liquidity

Through September 30, 2019, we have funded our research and development and operating activities primarily through the issuance of debt, private placements of redeemable convertible preferred stock and the sale of common stock in our initial public offering, or IPO, at-the-market offering, underwritten public offerings, through our purchase agreement, or the Purchase Agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park, and from revenue received under the KP415/484 License Agreement. As of September 30, 2019, we had cash and cash equivalents of $6.5 million and restricted cash of $0.5 million.

We filed a registration statement on Form S-3 covering the sale from time to time of up to $150.0 million of our common stock, preferred stock, debt and/or warrants, which was declared effective by the Securities and Exchange Commission, or SEC, on October 17, 2016, or the Current Registration Statement. In October 2019, the Company filed a registration on Form S-3 covering the sale of up to $80.0 million of the Company's common stock, preferred stock, and debt and/or warrants, or the Replacement Registration Statement. Once the Replacement Registration Statement is declared effective by the SEC, the Company will no longer make any sales under the Current Registration Statement.

Based on the market value of our outstanding common stock held by non-affiliates as of March 1, 2019, the date we filed our Annual Report on Form 10-K for the year ended December 31, 2018, in order to issue securities under the Current Registration Statement and the Replacement Registration Statement, once effective, we must rely on Instruction I.B.6. of Form S-3, which imposes a limitation on the maximum amount of securities that we may sell pursuant to the registration statements during any twelve-month period. At the time we sell securities pursuant to the applicable registration statement, the amount of securities to be sold plus the amount of any securities we have sold during the prior twelve months in reliance on Instruction I.B.6. may not exceed one-third of the aggregate market value of our outstanding common stock held by non-affiliates as of a day during the 60 days immediately preceding such sale, as computed in accordance with Instruction I.B.6. This calculation was updated immediately after we filed our Annual Report on Form 10-K for the year ended December 31, 2018 on March 1, 2019. As of that date, the amount of securities we are able to sell under a registration statement on Form S-3 during a 12-month period was approximately $18.5 million, of which prospectus supplements were filed to register (i) approximately $15.3 million for sales under the Purchase Agreement, and (ii) approximately $3.2 million for sales under our Common Stock Sales Agreement, or the Second ATM Agreement, with RBC Capital Markets, LLC, or RBCCM. Based on this calculation, we expect that we will be unable to sell additional securities beyond those amounts pursuant to our Current Registration Statement or the Replacement Registration Statement, once effective, 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 Purchase Agreement, stockholder approval may be required to access a portion of the amounts available under the Purchase Agreement.

In September 2018, we entered into the Second ATM Agreement with RBCCM, under which we may offer and sell, from time to time, in our sole discretion, shares of common stock having an aggregate offering price of up to $50,000,000 through RBCCM as our sales agent. The registration statement on Form S-3 contemplated under the Second ATM Agreement includes a prospectus supplement covering the offering of up to $50,000,000 of shares of common stock in accordance with the Second ATM Agreement. In March 2019, we filed an updated prospectus supplement regarding the Second ATM Agreement covering the offering of up to $3.2 million of shares of common stock in order to be in compliance with Instruction I.B.6 of Form S-3. As of September 30, 2019, we have not sold any shares of common stock under the Second ATM Agreement.

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

In February 2019, we entered into the 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 $15.0 million of shares of our common stock, from time to time over the 36-month term of the Purchase Agreement, and upon execution of the 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 Purchase Agreement. Concurrently with entering into the Purchase Agreement, we also entered into a Registration Rights Agreement with Lincoln Park, pursuant to which we agreed to register the sale of the shares of our common stock that have been and may be issued to Lincoln Park under the Purchase Agreement pursuant to our existing shelf registration statement on Form S-3 or a new registration statement. As of September 30, 2019, we have sold 3,401,271 shares of our common stock to Lincoln Park under the Purchase Agreement for approximately $5.4 million in gross proceeds.

In September 2019, we entered into the KP415/484 License Agreement with Commave and Commave paid us a non-refundable upfront payment of $10.0 million.

We had negative operating cash flows since our inception and, as of September 30, 2019, had an accumulated deficit of $239.7 million and a net working capital (current assets less current liabilities) deficit of $1.7 million. We anticipate that we will continue to incur negative operating flows for at least the next several years. Our recurring negative cash flows from operations, stockholders' deficit and net working capital 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/or through any other future arrangements related to one of our other product candidates. Accordingly, our ability to continue as a going concern may require us to obtain additional financing to fund our operations. The perception of our inability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or debt, the terms of these securities may restrict our ability to operate. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

Convertible Debt

As of September 30, 2019, we had $80.5 million of convertible notes outstanding, consisting of the 6.75% senior secured loan due 2020, or the Deerfield Convertible Note, in the principal amount of $6.8 million and the 5.50% Senior Convertible Notes due 2021, or the 2021 Notes, in the aggregate principal amount of $73.7 million.

Deerfield Facility Agreement

In June 2014, we entered into the $60.0 million multi-tranche credit facility, or the Deerfield Facility Agreement, with Deerfield Private Design Fund III, LP, or 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. 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 is 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. We are also obligated to repay principal in the amount of $3,333,333 plus any capitalized interest to date on February 14, 2020. 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 IPO, these shares of Series D Preferred reclassified into 256,410 shares of our common stock.

We also issued to Deerfield a 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 IPO, 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 Deerfield. Additionally, if we were to enter into a major transaction, including a merger, consolidation, sale of substantially all of our assets or other change of control transaction, Deerfield would have the ability to demand that prior to consummation of such transaction we repay all outstanding principal and accrued interest of the Deerfield 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 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.

2021 Notes

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

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

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

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

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

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

2021 Note Exchange

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. Under the October 2018 Exchange Agreement, Deerfield and Deerfield Special Situations Fund, L.P. 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 3,192,334 shares of common stock were issuable upon conversion of the Series A Preferred Stock. The Series A Preferred Stock is convertible at any time at the option of the holders thereof, provided that a holder of Series A Preferred Stock is prohibited from converting shares of Series A Preferred Stock into shares of 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. The Series A Preferred Stock is not redeemable. In the event of the our liquidation, dissolution or winding up, the holders of Series A Preferred Stock will receive an amount equal to $0.0001 per share, plus any declared but unpaid dividends, and thereafter will share ratably in any distribution of our assets with holders of common stock on an as-converted basis. With respect to rights upon liquidation, the Series A Preferred Stock ranks senior to the common stock and junior to existing and future indebtedness. Except as otherwise required by law (or with respect to approval of certain actions involving our organizational documents that materially and adversely affect the holders of Series A Preferred Stock), the Series A Preferred Stock does not have voting rights. The Series A Preferred Stock is not subject to any price-based anti-dilution protections and does not provide for any accruing dividends, but provides that holders of Series A Preferred Stock will participate in any dividends on the common stock on an as-converted basis (without giving effect to the limitation on conversion described above). The Series A Certificate of Designation also provides for partial liquidated damages in the event that we fail to timely convert shares of Series A Preferred Stock into common stock in accordance with the Series A Certificate of Designation.

As of September 30, 2019, 6,240 shares of Series A Preferred Stock have been converted into 2,080,000 shares of common stock.

2021 Note Exchange Effected in September 2019

In September 2019, we entered into an September 2019 Exchange Agreement with Deerfield and Deerfield Special Situations Fund, L.P. 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 provides Deerfield and Deerfield Special Situations Fund, L.P. 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 Deerfield or Deerfield Special Situations Fund, L.P. 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 Deerfield or Deerfield Special Situations Fund, L.P. 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, which represents the last sale price of the common stock on the Nasdaq Global Market on September 3, 2019, or (ii) the average of the volume-weighted average price of the common stock on the Nasdaq Global 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 Global Market on each of the 15 trading days immediately preceding such exchange. Immediately following the exchange under the September 2019 Exchange Agreement and as of September 30, 2019, 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 Deerfield or Deerfield Special Situations Fund, L.P.; provided that Deerfield and Deerfield Special Situations Fund, L.P. 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, Deerfield and Deerfield Special Situations Fund, L.P. 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 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 September 30, 2019, 787 shares of Series B-1 Preferred Stock have been converted into 828,945 shares of common stock.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2019 and 2018 (in thousands):

	Nine months ended September 30,	
	2019	2018
Net cash used in operating activities	$ (20,639)	$ (39,205)
Net cash provided by investing activities	3,239	25,368
Net cash provided by financing activities	5,289	4,754
Net decrease in cash, cash equivalents and restricted cash	$ (12,111)	$ (9,083)

Operating Activities

For the nine months ended September 30, 2019, net cash used in operating activities of $20.6 million consisted of a net loss of $18.5 million, primarily attributable to our spending on research and development programs, partially offset by revenue received under the KP415/484 License Agreement, and $6.2 million in changes in working capital; partially offset by $4.1 million in adjustments for non-cash items. The adjustments for non-cash items primarily consisted of stock-based compensation expense of $3.7 million, non-cash interest expense of $1.0 million, amortization of debt issuance costs and debt discount of $1.0 million and $0.2 million related to depreciation, amortization and other items; partially offset by non-cash income related to the change in the fair value of our derivative and warrant liabilities of $1.8 million. The changes in working capital consisted of $1.5 million related to a change in accounts and other receivables, $6.1 million related to a change in accounts payable and accrued expenses, $1.6 million related to operating lease right-of-use assets and $0.8 million related to a change in other liabilities; partially offset by $1.4 million related to a change in prepaid expenses and other assets and $2.3 million related to operating lease liabilities.

For the nine months ended September 30, 2018, net cash used in operating activities of $39.2 million consisted of a net loss of $51.3 million, primarily attributable to our spending on research and development programs, partially offset by $7.4 million in adjustments for non-cash items and $4.7 million in changes in working capital. The adjustments for non-cash items primarily consisted of stock-based compensation expense of $5.2 million, non-cash interest expense of $1.1 million, amortization of debt issuance costs and debt discount of $1.1 million and $0.3 million related to depreciation, amortization and other items; partially offset by non-cash income related to the change in the fair value of our derivative and warrant liabilities of $0.3 million. The changes in working capital consisted of $5.8 million related to an increase in accounts payable and accrued expenses, partially offset by a change of $0.1 million related to accounts and other receivables, $1.0 million related to an increase in prepaid expenses and other assets and a change of $0.1 million related to a decrease in other liabilities.

Investing Activities

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

For the nine months ended September 30, 2018, net cash provided by investing activities was $25.4 million, which was primarily attributable to maturities and sales of marketable securities.

Financing Activities

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

For the nine months ended September 30, 2018, net cash provided by financing activities was $4.8 million. This consisted of net proceeds from the issuance of common stock under the First ATM agreement of $4.8 million and proceeds from the exercise of common stock options of $0.1 million, partially offset by repayment of $0.1 million of obligations under capital lease arrangements.

Future Funding Requirements

We anticipate that we will need substantial additional funding in connection with our continuing operations. Based upon our current operating plan and existing cash resources as of September 30, 2019, we believe our existing resources are sufficient to fund operating expense and capital investment requirements into, but not through, the second quarter of 2020.

Potential near-term sources of additional funding include:

- sales of common stock under the Second ATM Agreement;
- sales of common stock under the Purchase Agreement;
- any revenues generated under the APADAZ License Agreement; and
- any out-of-pocket third-party research and development cost reimbursements, consulting services revenue or short-term milestone payments generated under the KP415/484 License Agreement.

We cannot guarantee that we will be able to generate sufficient proceeds from any of these potential sources to fund our operating expenses. For instance, pursuant to the terms of the Purchase Agreement, stockholder approval may be required to access a portion of the amounts available under the Purchase Agreement. Accordingly, we cannot guarantee that we will be able to sell the full $15.0 million subject to the terms of the Purchase Agreement.

To date, we have only generated revenue from the non-refundable upfront payment and consulting services under the KP415/484 License Agreement, and, as of September 30, 2019, we have a net working capital (current assets less current liabilities) deficit of $1.7 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, and/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 KP415/484 License Agreement to develop, manufacture and commercialize KP415 and KP484, we cannot guarantee that this, or any strategy we adopt in the future, will be successful. We also expect to continue to incur additional costs associated with operating as a public company. In addition, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution of any of our product candidates that achieve regulatory approval.

Our unaudited condensed financial statements for the quarter ended September 30, 2019, includes an explanatory paragraph, within Note A, stating that our recurring losses, negative operating cash flows and stockholders' deficit raise substantial doubt about our ability to continue as a going concern. We expect that our only source of revenues will be through payments arising from our license agreements with KVK and Commave, 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 additional financing to fund our operations. The perception of our inability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or debt, the terms of these securities may restrict our ability to operate. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

We have based our estimates of our cash needs and cash runway on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect and we cannot guarantee that we will be able to generate sufficient proceeds from our license agreements with KVK and Commave, sales under our Purchase Agreement or Second ATM 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 as of March 1, 2019, the date we filed our Annual Report on Form 10-K for the year ended December 31, 2018, in order to issue securities under our Current Registration Statement or our Replacement Registration Statement, once effective, we must rely on Instruction I.B.6. of Form S-3, which imposes a limitation on the maximum amount of securities that we may sell pursuant to the registration statements during any twelve-month period. At the time we sell securities pursuant to the applicable registration statement, the amount of securities to be sold plus the amount of any securities we have sold during the prior twelve months in reliance on Instruction I.B.6. may not exceed one-third of the aggregate market value of our outstanding common stock held by non-affiliates as of a day during the 60 days immediately preceding such sale, as computed in accordance with Instruction I.B.6. This calculation was updated immediately after we filed our Annual Report on Form 10-K for the year ended December 31, 2018 on March 1, 2019. As of that date, the amount of securities we are be able to sell under a registration statement on Form S-3 during a 12-month period was approximately $18.5 million, of which prospectus supplements were filed to register (i) approximately $15.3 million for sales under the Purchase Agreement, and (ii) approximately $3.2 million for sales under our Second ATM Agreement. Based on this calculation, we expect that we will be unable to sell additional securities beyond those amounts pursuant to the Current Registration Statement or the Replacement Registration Statement, once effective, 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 Purchase Agreement, stockholder approval may be required to access a portion of the amounts available under the 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 Judgements and Estimates

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

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, 2018, filed with the SEC on March 1, 2019.

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 September 30, 2019. Based on the evaluation of our disclosure controls and procedures as of September 30, 2019, our chief executive officer and our chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during our fiscal quarter ended September 30, 2019 that materially affected, or is reasonably likely to materially affect, our internal control 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 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 are expected to be sufficient to fund our operating expense and capital investment requirements into, but not through, the second quarter of 2020. We do not currently have sufficient funds to finance our continuing operations beyond the short-term or to substantially advance our product candidates further into clinical development. We expect that our only source of revenues will be through payments arising from our license agreements with KVK and Commave, and/or through any other future arrangements related to one of our other product candidates. Accordingly, our ability to continue as a going concern will require us to obtain, in the short term, additional financing to fund our operations. In order to substantially advance development of our product candidates, we will need to obtain additional funding in connection with our continuing operations from one or more equity offerings, including pursuant to our Purchase Agreement with Lincoln Park, the Second ATM Agreement with RBCCM, debt financings, the APADAZ License Agreement, the KP415/484 License Agreement or other third-party funding, including potential strategic alliances and licensing or collaboration arrangements, and we cannot guarantee that we will be able to generate sufficient proceeds from sales under the Purchase Agreement, the Second ATM Agreement, the APADAZ License Agreement or the KP415/484 License Agreement, or be successful in completing other transactions, that will fund our operating expenses. If we are delayed in obtaining additional funding or are unable to complete a strategic transaction, we may discontinue our development activities on our product candidates or discontinue our operations. Even if we are able to fund continued development and any of our product candidates 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 KP415/484 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 KP415/484 License Agreement 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, 2018, included in our annual report on Form 10-K, contained 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, 2018 included 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.

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 September 30, 2019, had an accumulated deficit of $239.7 million and a net working capital (current assets less current liabilities) deficit of $1.7 million. Our negative cash flows from operations for the nine months ended September 30, 2019 and 2018, were $20.6 million and $39.2 million, respectively. We have financed our operations through September 30, 2019 with funds raised in private placements of redeemable convertible preferred stock, in the issuance of convertible promissory notes and term debt, our initial public offering and other public and private offerings of our common stock, as well as through revenue received under the KP415/484 License Agreement. In February 2019, we also 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 $15.0 million of shares of our common stock, from time to time over the 36-month term of the Purchase Agreement, and upon execution of the 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 Purchase Agreement. Concurrently with entering into the Purchase Agreement, we also entered into a Registration Rights Agreement with Lincoln Park, pursuant to which we agreed to register the sale of the shares of our common stock that have been and may be issued to Lincoln Park under the Purchase Agreement pursuant to our existing shelf registration statement on Form S-3 or a new registration statement. As of September 30, 2019, we have sold 3,401,271 shares of our common stock to Lincoln Park under the Purchase Agreement for approximately $5.4 million in gross proceeds.

Our negative cash flows from operations, accumulated deficit and net working capital 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 KP415/484 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 KP415/484 License Agreement. We may never succeed in commercialization activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

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

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

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may not generate the necessary data or results required to obtain regulatory approval for our product candidates or claims necessary to make such candidates profitable and achieve product sales. In addition, APADAZ or our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of prodrug products. We cannot guarantee that KVK will be able to successfully commercialize APADAZ, that Commave will be able to successfully commercialize any product candidates subject to the KP415/484 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 KP415/484 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. In June 2014, we entered into the Deerfield Facility Agreement with Deerfield. The Deerfield Facility Agreement includes, and any future debt financing and equity financing, if available, may involve agreements that include, covenants limiting and restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, entering into profit-sharing or other arrangements or declaring dividends. The Deerfield Facility Agreement also includes high yield discount obligation protections that went into effect in June 2019. Going forward, if at any interest payment date our outstanding indebtedness under the Deerfield facility 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. Additionally, in February 2016, we issued the 2021 Notes. We are required to make periodic interest payments to the holders of the 2021 Notes and to make payments of principal upon maturity. In this regard, if holders of the 2021 Notes do not convert their 2021 Notes prior to the maturity date, we will be required to repay the principal amount of all then outstanding 2021 Notes plus any accrued and unpaid interest. We may also be required to repurchase the 2021 Notes for cash upon the occurrence of a change of control or certain other fundamental changes involving us. If our capital resources are insufficient to satisfy our debt service obligations, we will be required to seek to sell additional equity or debt 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.

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

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 as of March 1, 2019, the date we filed our Annual Report on Form 10-K for the year ended December 31, 2018, in order to issue securities under our Current Registration Statement or our Replacement Registration Statement, once effective, we must rely on Instruction I.B.6. of Form S-3, which imposes a limitation on the maximum amount of securities that we may sell pursuant to the registration statements during any twelve-month period. At the time we sell securities pursuant to the applicable registration statement, the amount of securities to be sold plus the amount of any securities we have sold during the prior twelve months in reliance on Instruction I.B.6. may not exceed one-third of the aggregate market value of our outstanding common stock held by non-affiliates as of a day during the 60 days immediately preceding such sale, as computed in accordance with Instruction I.B.6. This calculation was updated immediately after we filed our Annual Report on Form 10-K for the year ended December 31, 2018 on March 1, 2019. As of that date, the amount of securities we are be able to sell under a registration statement on Form S-3 during a 12-month period was approximately $18.5 million, of which prospectus supplements were filed to register (i) approximately $15.3 million for sales under the Purchase Agreement, and (ii) approximately $3.2 million for sales under our Second ATM Agreement. Based on this calculation, we expect that we will be unable to sell additional securities beyond those amounts pursuant to the Current Registration Statement or the Replacement Registration Statement, once effective, 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 Purchase Agreement, stockholder approval may be required to access a portion of the amounts available under the Purchase Agreement. If we cannot sell securities under our Current Registration Statement or the Replacement Registration Statement, once effective, 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 KP415/484 License Agreement, if approved, or that we will ever receive any payments under the APADAZ License Agreement or the KP415/484 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 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. On February 23, 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. 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 2 against inclusion of abuse-deterrent labeling for APADAZ. Additionally, in June 2016, we received a CRL from the FDA for the APADAZ NDA. Following a FDRR process and detailed discussions with the FDA, we responded to the CRL we received in June 2016 by submitting an amended NDA for APADAZ for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. In February 2018, we announced that the FDA approved the NDA for APADAZ.

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

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

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

We are early in our development efforts and have only one product that has completed development and been approved by the FDA, APADAZ. All of our other active product candidates are in clinical or preclinical development. We currently generate no commercial revenue from the sale of any prodrugs and we may never be able to successfully commercialize a prodrug product. For instance, while we have entered into the APADAZ License Agreement with KVK pursuant to which we granted an exclusive license to KVK to commercialize APADAZ in the United States, we cannot guarantee that KVK will be able to successfully commercialize APADAZ or that we will ever receive any payments under the APADAZ License Agreement from commercial sales of APADAZ. In addition, we entered into the KP415/484 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 KP415/484 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 KP415 or KP484. However, we do not anticipate that the 505(b)(2) pathway will be available for every product candidate. For instance, it is possible we will only be permitted to utilize the 505(b)(2) NDA pathway for either KP415 or KP484, but not both. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates, and complications and risks associated with our product candidates, would likely substantially increase.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our prodrug development costs may also increase if we experience delays in testing or obtaining marketing approvals. Additionally, if we do not successfully develop any product candidates subject to the KP415/484 License Agreement, we may not be eligible to receive any future payments under the KP415/484 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, and we anticipate that any of our other opioid analgesic product candidates that we may choose to develop in the future, if approved by the FDA, will be, 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 of our other 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 that it will 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 KP415/484 License Agreement with Commave pursuant to which we granted an exclusive, worldwide license to Commave to develop, manufacture and commercialize KP415 and KP484. We cannot guarantee that the K415/484 License Agreement with Commave will be successful or that we will receive any future payments under the KP415/484 License Agreement. For instance, Commave has the option to terminate the KP415/484 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 KP415/484 License Agreement, we cannot guarantee that we will receive any additional milestone or royalty payments under the KP415/484 License Agreement. In addition, under the KP415/484 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 KP415/484 License Agreement will depend, in part, on Commave's ability to successfully perform the functions assigned to it under the KP415/484 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 KP415/484 License Agreement, or those that are subject to the KP415/484 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, KP415 or KP484 or may elect not to continue or renew commercialization programs based on post-approval clinical trial results, changes in the Collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- The Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with APADAZ, KP415 or KP484 if they 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, KP415 or KP484 may be viewed by the Collaborators as competitive with their own product candidates or products, which may cause them to cease to devote resources to the commercialization of APADAZ, KP415 of KP484;
- The Collaborators may not commit sufficient resources to the development, marketing and distribution of APADAZ, KP415 or KP484, 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 commercialization or development of, as applicable, APADAZ, KP415 or KP484, might lead to additional responsibilities for us with respect to APADAZ, KP415 or KP484 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, as applicable, of APADAZ, KP415 or KP484.

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

The APADAZ License Agreement, KP415/484 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 KP415/484 License Agreement, we may need to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

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

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

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

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

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

We are party to a termination agreement with Aquestive that may limit the value of any sale, license or commercialization of KP415, KP484 or KP879. Under this termination agreement, Aquestive has the right to receive a royalty amount equal to 10% of any value generated by KP415, KP484 or KP879, and any product candidates arising therefrom, 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 KP415/484 License Agreement, Aquestive received a royalty equal to 10% of the upfront payment.

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 KP415/484 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 our facility agreement with Deerfield may inhibit our ability to enter into specified transactions, including any joint venture, partnership or any other profit-sharing arrangement.

Pursuant to the Deerfield Facility Agreement, we may not enter into specified transactions, including any joint venture, partnership or any other profit-sharing arrangement, without the prior approval of Deerfield. Deerfield's interests may not always coincide with our corporate interests or the interests of our other stockholders, and Deerfield may act in a manner with which you may not agree or that may not be in the best interests of our other stockholders. If Deerfield does not approve our entry into specified transactions, it could significantly delay or inhibit the commercialization of our product candidates. For instance, Deerfield consented to our entry into the APADAZ License Agreement and KP415/484 License Agreement, but we cannot guarantee that Deerfield 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 KP415/484 License Agreement, Commave obtained from us an exclusive, worldwide license to certain patents that cover KP415 and KP484.

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

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

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

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

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

- we could inadvertently abandon a patent or patent application, resulting in the loss of protection of intellectual property rights in a particular country, and we, our collaborators or our patent counsel may take action resulting in a patent or patent application becoming abandoned which may not be able to be reinstated or if reinstated, may suffer patent term adjustments;

- the claims of our issued patents or patent applications when issued may not cover our product candidates;

- no assurance can be given that our patents would be declared by a court to be valid or enforceable or that a competitor's technology or product would be found by a court to infringe our patents and our patents or patent applications may be challenged by third parties in patent litigation or in proceedings before the United States Patent and Trademark Office, or the USPTO, or its foreign counterparts, and may ultimately be declared invalid or unenforceable or narrowed in scope;

- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim and there may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim;

- third parties may develop products that have the same or similar effect as our products without infringing our patents;

- third parties may intentionally circumvent our patents by means of alternate designs or processes or file applications or be granted patents that would block or hurt our efforts;

- there may be dominating patents relevant to our product candidates of which we are not aware;

- obtaining regulatory approval for pharmaceutical products is a lengthy and complex process, and as a result, any patents covering our product candidates may expire before or shortly after such product candidates are approved and commercialized;

- the patent and patent enforcement laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions; and

- we may not develop additional proprietary technologies that are patentable.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We expect to rely on trademarks as one means to distinguish APADAZ and any of our product candidates that are approved for marketing from the products of our competitors. We have registered trademarks for APADAZ and KemPharm. In addition, we have solicited and applied for trademarks for the KemPharm Logo, LAT and several potential tradenames and logos for KP415. For our other product candidates, we have not yet solicited trademarks and have not yet begun the process of applying to register trademarks. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. If our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

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

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

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

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

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

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

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

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

We have only a limited sales and marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product candidate for which we may obtain marketing approval in the United States, we will need to enter into collaborations with one or more parties or establish our own sales and marketing organization. While we entered into the APADAZ License Agreement to establish a collaboration for the commercialization of APADAZ and we entered into the KP415/484 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 products 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. If APADAZ, or our product candidates, 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 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 will compete 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, 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 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.

Since its enactment, there have been judicial and congressional challenges to numerous provisions 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, two 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, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. 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". Congress will likely consider additional legislation to repeal or repeal and replace other elements of the ACA. We continue to evaluate the effect that the ACA and its possible repeal and replacement could have on 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 2027 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2020 contains further drug price control measures that could be enacted during the 2020 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, establish an international price index for Medicare Part B pricing and to eliminate the Medicaid drug rebate cap. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. These new laws may result in additional reductions in Medicare and other healthcare funding, which could negatively impact customers for our product candidates, if approved, and, accordingly, our financial operations.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Employee Matters and Managing Our Growth

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

We are highly dependent on the management, research and development, clinical, financial and business development expertise of Travis C. Mickle, Ph.D., our president and chief executive officer, Gordon K. Johnson, our chief business 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.

If we implement sales, marketing and distribution capabilities, we may encounter difficulties in managing our growth, which could disrupt our operations.

If we implement sales, marketing and distribution capabilities to support any future approved product, we would experience growth in the number of our employees and the scope of our operations. To manage such potential future growth, we would need to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel.

Due to our limited financial resources and the limited experience of our management team in managing a company with such potential growth, we may not be able to effectively manage the expansion of our operations, if any, or recruit and train additional qualified personnel. The potential expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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 IPO 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 IPO in April 2015 at a price of $11.00 per share, our stock price has ranged from $0.45 to $26.15 through November 13, 2019. In addition, the stock market in general and the market for pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- actual or anticipated variations in our operating results;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the pharmaceutical industry;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- adverse regulatory announcements or determinations regarding our product candidates;
- capital commitments;
- investors' general perception of us and our business;
- recruitment or departure of key personnel; and
- sales of our common stock, including sales by our directors and officers or specific stockholders.

Many of the factors described above are not within our control. For instance, in May 2016, we announced that the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the FDA voted 16 to 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 the Nasdaq Global Market. 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 the Nasdaq Global Market was subject to another substantial decrease. We cannot guarantee that future announcements will not have similar effects on the trading price of our common stock.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. For instance, in December 2016, we received notice of a class action suit filed against us 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 IPO, 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 Global Market, and biotechnology and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

If we fail to maintain compliance with the listing requirements of the Nasdaq Global 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 Global Market. To maintain the listing of our common stock on the Nasdaq Global Market, we are required to meet certain listing requirements, including, among others, either: (i) a minimum closing bid price of $1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least $5 million and stockholders' equity of at least $10 million; or (ii) a minimum closing bid price of $1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors, affiliates and 10% or more stockholders) of at least $15 million and a total market value of listed securities of at least $50.0 million.

On May 17, 2019, we received a letter from the Listing Qualifications Department of The Nasdaq Stock Market, LLC notifying us that the listing of our common stock was not in compliance with Nasdaq Listing Rule 5450(b)(2)(A) for continued listing on the Nasdaq Global Market, as the market value of our listed securities was less than $50.0 million for the previous 30 consecutive business days. Under Nasdaq Listing Rule 5810(c)(3)(C), we have a period of 180 calendar days, or until November 13, 2019, to regain compliance with the rule. To regain compliance, during this 180-day compliance period, the market value of our listed securities must be at least $50.0 million or more (measured based on closing prices) for a minimum of 10 consecutive business days.

We have not regained compliance with the Nasdaq Listing Rules prior to the expiration of the 180-day compliance period, as a result, we expect that we will receive written notification from Nasdaq that our securities are subject to delisting. At that time, we intend to request a hearing with the Nasdaq Hearings Panel to present a plan for regaining compliance with Nasdaq Listing Rules and to request an extension of up to an additional 180 days to implement the plan. Such plan may include a request to transfer the listing of our common stock to the Nasdaq Capital Market, as well as other corporate actions that would support regaining compliance.

In addition, on September 27, 2019, we received another letter from the Listing Qualifications Department of The Nasdaq Stock Market, LLC notifying us that the listing of our common stock was not in compliance with Nasdaq Listing Rule 5450(a)(1) for continued listing on the Nasdaq Global Market, as the minimum bid price of our listed securities was less than $1.00 per share for the previous 30 consecutive business days. Under Nasdaq Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days, or until March 25, 2020, to regain compliance with the rule referred to in this paragraph. To regain compliance, during this 180-day compliance period, our minimum bid price of listed securities must close at $1.00 per share or more for a minimum of 10 consecutive business days.

In the event that we do not regain compliance with the Nasdaq Listing Rules prior to the expiration of the 180-day compliance period, we may be eligible for additional time to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A)(ii) by transferring to the Nasdaq Capital Market. To qualify, we would need to submit a Transfer Application and a $5,000 application fee. In addition, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the minimum bid price requirement. In addition, we would need to provide written notice to Nasdaq of our intention to cure the minimum bid price deficiency during the second compliance period by effecting a reverse stock split, if necessary. As part of its review process, the Nasdaq staff will make a determination of whether it believes we will be able to cure the deficiency. Should the Nasdaq staff conclude that we will not be able to cure the deficiency, or should we determine not to submit a Transfer Application or make the required representation, Nasdaq will provide notice that our shares of common stock will be subject to delisting.

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.

There can be no assurance that we will be successful in maintaining the listing of our common stock on the Nasdaq Global Market, or, if transferred, 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.

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

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.

Deerfield may convert all or any portion of the outstanding principal and any accrued but unpaid interest on the Deerfield Convertible Note into shares of our common stock at a conversion price of $5.85 per share. For instance, in June 2018, $3,333,333 of the principal amount, plus $168,287 of accrued interest, of the Deerfield Convertible Note was converted into 598,568 shares of our common stock.

According to the terms of the Deerfield Convertible Note, as amended, in no event may Deerfield convert the Deerfield Convertible Note to the extent such conversion would result in Deerfield beneficially owning more than 4.985% of the then issued and outstanding shares of our common stock. This conversion limitation may not be waived and any purported conversion that is inconsistent with this conversion limitation will be null and void. This conversion limitation will not apply to any conversion made immediately prior to a change of control transaction. If Deerfield is only able to convert the Deerfield Convertible Note into a limited number of shares due to this conversion limitation, the Deerfield Convertible Note could subsequently become convertible into the remainder of the shares as a result of a variety of events. This could occur, for example, if we issue more shares or Deerfield sells some of its existing shares. Without regard to this conversion limitation, the Deerfield Convertible Note is convertible into 1,192,918 shares of our common stock, assuming a conversion date of September 30, 2019. The conversion price of the Deerfield Convertible Note will be adjusted downward if we issue or sell any shares of common stock, convertible securities, warrants or options at a sale or exercise price per share less than the greater of the Deerfield Convertible Note’s conversion price or the closing sale price of our common stock as reported on the Nasdaq Global Market on the last trading date immediately prior to such issuance, or, in the case of a firm commitment underwritten offering, on the date of execution of the underwriting agreement between us and the underwriters for such offering. Although, if we effect an "at the market offering" as defined in Rule 415 of the Securities Act, of our common stock, the exercise price of the Deerfield Warrant and conversion price of the Deerfield Convertible Note will be adjusted downward pursuant to this anti-dilution adjustment only if such sales are made at a price less than $5.85 per share, provided that this anti-dilution adjustment will not apply to any sales made under the Purchase Agreement or the Second ATM Agreement.

Additionally, in February 2016, we issued the 2021 Notes. The 2021 Notes are convertible at an initial conversion rate of 58.4454 shares of our common stock per $1,000 principal amount of the 2021 Notes, subject to adjustment under the indenture governing the 2021 Notes, which is equal to an initial conversion price of approximately $17.11 per share of our common stock. Upon conversion, the 2021 Notes will be settled in shares of our common stock, together with a cash payment in lieu of delivering any fractional shares. The conversion rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date, we will increase the conversion rate for a holder who elects to convert its 2021 Notes in connection with such a corporate event in certain circumstances. Holders who convert on or after the date that is one year after the last date of original issuance of the 2021 Notes may also be entitled to receive, under certain circumstances, an interest make-whole payment payable in shares of common stock. In November 2018, we entered into a supplemental indenture with U.S. Bank National Association, as trustee, to that certain Indenture, dated as of February 9, 2016, relating to our 2021 Notes. Pursuant to the supplemental indenture, the Indenture was amended to allow each Holder, as defined in the Indenture, or any beneficial holder of any 2021 Notes to, at its option, elect a limit on beneficial ownership as to such Holder or beneficial owner, but not as to any other Holder or beneficial owner, that is less than or equal to the 9.985% Cap, as defined in the Indenture, or any other limit previously elected and then applicable to such Holder or beneficial owner upon written notice delivered to us at least three business days prior to the date of effectiveness of such beneficial ownership limit, or such shorter period as may be agreed upon by the us, specifying the percentage of shares of our common stock outstanding for the beneficial ownership limit that shall apply to such Holder or beneficial owner. Without regard to this conversion limitation, the 2021 Notes are convertible into 31,166,835 shares of our common stock, assuming a conversion date of September 30, 2019, which amount is inclusive of 28,439,015 of shares of our 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 October 2018, we entered into the October 2018 Exchange Agreement with Deerfield and Deerfield Special Situations Fund, L.P. Under the October 2018 Exchange Agreement, Deerfield and Deerfield Special Situations Fund, L.P. exchanged an aggregate of $9,577,000 principal amount of our 2021 Notes for an aggregate of 9,577 shares of our Series A Preferred Stock. 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 3,192,334 shares of common stock were issuable upon conversion of the Series A Preferred Stock. The Series A Preferred Stock is convertible at any time at the option of the holders thereof, provided that a holder of Series A Preferred Stock is prohibited from converting shares of Series A Preferred Stock into shares of 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. As of September 30, 2019, 6,240 shares of Series A Preferred Stock have been converted into 2,080,000 shares of common stock.

In September 2019, we entered into the September 2019 Exchange Agreement with Deerfield and Deerfield Special Situations Fund, L.P. 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 2021 Notes. As of September 30, 2019, 787 shares of Series B-1 Preferred Stock have been converted into 828,945 shares of common stock. The September 2019 Exchange Agreement provides Deerfield and Deerfield Special Situations Fund, L.P. 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 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 Deerfield or Deerfield Special Situations Fund, L.P. 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 Deerfield or Deerfield Special Situations Fund, L.P. 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, which represents the last sale price of the common stock on the Nasdaq Global Market on September 3, 2019, or (ii) the average of the volume-weighted average price of the common stock on the Nasdaq Global Market on each of the 15 trading days immediately preceding such exchange. As of September 30, 2019, 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 in exchange of the Optional Exchange Principal Amount (in each case without giving effect to the limitation on conversion under the September 2019 Exchange Agreement).

If Deerfield, the holders of the 2021 Notes, Series A Preferred Stock and Series B-1 Preferred Stock elect to convert more of the Deerfield Convertible Note, the 2021 Notes or additional shares of Series A Preferred Stock or Series B-1 Preferred 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 September 2018, we entered into the Second ATM Agreement under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $50,000,000 through RBCCM as our sales agent. RBCCM may sell common stock under the Second ATM Agreement by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act, including without limitation sales made by means of ordinary brokers' transactions on the Nasdaq Global Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise directed by us. RBCCM will use commercially reasonable efforts to sell the common stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). To the extent that we direct RBCCM to make any sales of our common stock under the Second ATM Agreement, our stockholders may experience additional dilution, which could cause our stock price to fall. As of September 30, 2019, we have not sold any shares of common stock under the Second ATM Agreement.

In February 2019, 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 $15.0 million of shares of our common stock, from time to time over the 36-month term of the Purchase Agreement, and we issued an additional 120,200 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. As of September 30, 2019, we have sold 3,401,271 shares of common stock to Lincoln Park under the Purchase Agreement for approximately $5.4 million in gross proceeds.

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

As of September 30, 2019, we had $80.5 million of convertible notes outstanding, consisting of $6.8 million of the Deerfield Convertible Note and $73.7 million of 2021 Notes.

The Deerfield Convertible Note bears interest at 6.75% per annum. Interest accrued on outstanding debt under the Deerfield Convertible Note is due quarterly in arrears. In accordance with the September 2019 Exchange Agreement, this interest will be capitalized and added to principal as due for the remainder of the debt term. We are obligated to repay $3,333,333 of outstanding principal plus all capitalized interest to date on February 14, 2020 and then all remaining outstanding principal and accrued interest on June 1, 2020. We cannot guarantee that Deerfield will agree to convert any future principal amount owed under the Deerfield Convertible Note into shares of our common stock or further extend the period in which we are required to make any repayments under the Deerfield Convertible Note. If we are required to pay additional outstanding amounts due under the Deerfield Convertible Note prior to or at maturity or otherwise incur unanticipated monetary obligations under the Deerfield Convertible Note, our cash flow available to invest in the ongoing needs of our business may be limited.

In February 2016, we issued the 2021 Notes. In October 2018, we entered into the October 2018 Exchange Agreement pursuant to which Deerfield and Deerfield Special Situations Fund, L.P. exchanged an aggregate of $9,577,000 principal amount of the 2021 Notes for an aggregate of 9,577 shares of Series A Preferred Stock. Further, in September 2019, we entered into the September 2019 Exchange Agreement pursuant to which Deerfield and Deerfield Special Situations Fund, L.P. exchanged an aggregate of $3,000,000 principal amount of the 2021 Notes for 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. Following the effectiveness of both exchanges, the outstanding principal amount of the 2021 Notes is $73.7 million. Our ability to make payments on, and to refinance, the 2021 Notes, and to fund planned capital expenditures, sales and marketing efforts, research and development efforts, working capital and other general corporate purposes depends on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, legislative, regulatory and other factors, some of which are beyond our control. If we do not ever generate sufficient cash flow from operations or if future borrowings are not available to us in an amount sufficient to repay our indebtedness, including any amounts due under the 2021 Notes at their maturity, or to fund our liquidity needs, we may be forced to refinance all or a portion of the 2021 Notes, on or before the maturity thereof, sell assets, reduce or delay capital expenditures, seek to raise additional capital or take other similar actions. We may not be able to affect any of these actions on commercially reasonable terms or at all. Our ability to refinance our indebtedness will depend on our financial condition at the time, the restrictions in the instruments governing our present and potential future indebtedness and other factors, including market conditions. In addition, in the event of a default with respect to the 2021 Notes, the holders of the 2021 Notes and/or the trustee under the indenture governing the 2021 Notes may accelerate the payment of our obligations under 2021 Notes. A default under the indenture governing the 2021 Notes could also lead to a default under agreements governing future indebtedness. Our inability to generate sufficient cash flow to satisfy our debt service obligations, or to refinance or restructure our obligations on commercially reasonable terms or at all, would likely have a material adverse effect on our business, financial condition and results of operations.

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

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

The accounting method for the Deerfield Warrant, Deerfield Convertible Note, 2021 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, Deerfield Convertible Note, 2021 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. Additionally, certain features of the 2021 Notes may result in the yield on the 2021 Notes not being deductible by us for tax purposes.

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

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

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 the Deerfield Convertible Note and Deerfield Warrant, as applicable, or to include such shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

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

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

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

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

In addition, the provisions of our termination agreement with Aquestive and our agreements with Deerfield, the holders of our 2021 Notes and the holders of our Series A Preferred Stock and Series B-1 Preferred Stock may discourage, delay or prevent a change in control of our company. For example, if we enter into a merger, an asset sale or any other change of control transaction, then Aquestive will be entitled to a royalty equal to 10% of the price being paid to us and our stockholders in such transaction which is attributable to the value of KP415, KP484 or KP879, as was the case with the KP415/484 License Agreement. Pursuant to the Deerfield Facility Agreement, we may not enter into any major transaction without the prior approval of Deerfield, including a merger, asset sale or change of control transaction, and pursuant to the Deerfield Convertible Note, Deerfield has the option to demand repayment of all outstanding principal, and any unpaid interest accrued thereon, of the Deerfield Convertible Note immediately prior to consummation of such event. Further, under the Deerfield Warrant, Deerfield has the right to demand that we redeem the Deerfield Warrant for a cash amount equal to the Black-Scholes value of a portion of the warrant upon the occurrence of specified events, including a merger, an asset sale or any other change of control transaction. Furthermore, the indenture governing the 2021 Notes requires us to repurchase the 2021 Notes for cash if we undergo certain fundamental changes. A takeover of us may trigger the requirement that we repurchase the 2021 Notes, which could make it more costly for a potential acquirer to engage in a business combination transaction with us. Finally, in the event of a sale of the Company the holders of Series A Preferred Stock and Series B-1 Preferred Stock 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 A Preferred Stock and Series B-1 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 IPO, (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 September 30, 2019, we had federal net operating loss carryforwards of approximately $211.6 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.

Comprehensive tax reform bills could adversely affect our business and financial condition.

The Tax Cuts and Jobs Act includes significant changes to the taxation of business entities. The Tax Cuts and Jobs Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the Tax Cuts and Jobs Act remains subject to interpretation and further guidance from U.S. taxing authorities and as a result, the overall impact of this tax reform is uncertain and may change due to interpretation changes, and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act. The impact of the Tax Cuts and Jobs Act on holders of our common stock is also uncertain and could be adverse. We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our effective tax rates in the future in countries where we have operations and have an adverse effect on our overall tax rate in the future, along with increasing the complexity, burden and cost of tax compliance. We urge our stockholders to consult with their legal and tax advisors with respect to the Tax Cuts and Jobs Act and the potential tax consequences of investing in or holding our common stock.

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, 2018, we performed system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K, as required by Section 404 of the Sarbanes-Oxley Act. We will be required to perform this evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting on an annual basis. This requires that we incur substantial additional professional fees and internal costs and that we expend significant management efforts on an annual basis. We have and will be required to test our internal controls within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements.

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

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

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

On November 14, 2019, the Company clarified that while its 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 its behalf, (ii) any action asserting a breach of fiduciary duty owed by any of its directors, officers or other employees to the Company or its stockholders, (iii) any action asserting a claim against the Company arising pursuant to any provisions of the Delaware General Corporation Law, the Company's certificate of incorporation or bylaws, or (iv) any action asserting a claim against the Company that is governed by the internal affairs doctrine, 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.

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.
10.1	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated July 15, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 13, 2019).
10.2	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated July 31, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 13, 2019).
10.3	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated August 9, 2019 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 13, 2019).
10.4*	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated August 16, 2019.
10.5*	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated August 23, 2019.
10.6*	Amendment to Facility Agreement, by and between Registrant and Deerfield Private Design Fund III, L.P., dated August 30, 2019.
10.7	September 2019 Exchange Agreement and Amendment to Facility Agreement, dated September 3, 2019, by and among Registrant, Deerfield Private Design Fund III, L.P. and Deerfield Special Situations Fund, L.P. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on September 4, 2019).
10.8^	Collaboration and License Agreement, dated September 3, 2019, by and between Registrant and Boston Pharmaceuticals Holdings SA (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on September 4, 2019).
10.9#*	Fourth Amended and Restated Non-Employee Director Compensation Policy.
10.10^*	Agreement to Terminate CLA, by and between MonoSol Rx, LLC and the Registrant, dated as of March 20, 2012.
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 September 30, 2019, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Balance Sheets, (ii) Condensed Statements of Operations, (iii) Condensed Statements of Changes in Stockholders' Deficit, (iv) Condensed Statements of Cash Flows, and (v) Notes to Condensed Financial Statements, tagged as blocks of text and including detailed tags.

^ Portions of this exhibit (indicated by asterisks) have been omitted as the registrant has determined that (i) the omitted information is not material and (ii) the omitted information would likely cause competitive harm to the registrant if publicly disclosed.

# Indicates management contract or compensatory plan.

(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: November 14, 2019

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

Date: November 14, 2019

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

Exhibit 10.4

August 16, 2019

KemPharm, Inc.
1180 Celebration Boulevard, Suite 103
Celebration, FL 34747

Re: Amendment to Facility Agreement

Ladies and Gentlemen:

Reference is hereby made to that certain Facility Agreement, dated as of June 2, 2014 (as the same may have been previously or in the future be amended, modified, restated or otherwise supplemented from time to time, the "**Facility Agreement**"), by and between KemPharm, Inc., a Delaware corporation (the "**Company**"), and Deerfield Private Design Fund III, L.P. (the "**Lender**"). Capitalized terms used herein which are defined in the Facility Agreement, unless otherwise defined herein, shall have the meanings ascribed to them in the Facility Agreement. The Company and the Lender desire to amend the Facility Agreement on the terms set forth in this letter agreement (this "**Letter**").

The Facility Agreement obligated the Company to pay to the Lender (i) $3,333,333.33 of the outstanding principal amount of the Senior Secured Convertible Note (the "**2019 Principal Payment**") and (ii) accrued and unpaid interest on the entire principal amount of the Senior Secured Convertible Note (the "**June 2019 Interest Payment**"), in each case, on June 3, 2019. The Company and the Lender entered into letter agreements, dated as of June 3, 2019, June 17, 2019, June 24, 2019, June 28, 2019, July 15, 2019, July 31, 2019, and August 9, 2019, which extended the due date for the June 2019 Principal Payment and the June 2019 Interest Payment from June 3, 2019 to June 17, 2019, June 24, 2019, June 28, 2019, July 12, 2019, July 31, 2019, August 9, 2019, and August 16, 2019, respectively. Effective upon the execution and delivery of this Letter by the Company and the Lender, the Facility Agreement is hereby amended to provide that the due date for payment of the 2019 Principal Payment and the June 2019 Interest Payment shall be extended from the date hereof to August 23, 2019; provided, that the foregoing shall not limit the rights of the Lender under Section 5.4 or Section 5.5 of the Facility Agreement.

Except as expressly set forth herein, (i) the Facility Agreement and the other Transaction Documents remain unchanged and in full force and effect, (ii) this Letter shall not be deemed to be a waiver, amendment or modification of, or consent to or departure from, any provision of the Facility Agreement or any other Transaction Document or to be a waiver of any Default or Event of Default under the Facility Agreement or any other Transaction Document, whether arising before or after the date hereof or as a result of the transactions contemplated hereby, and (iii) this Letter shall not preclude the future exercise of any right, remedy, power or privilege available to the Lender, whether under the Facility Agreement, any other Transaction Document or otherwise, and shall not be construed or deemed to be a satisfaction, novation, cure, modification, amendment or release of the Obligations, the Facility Agreement or any other Transaction Document (or any other liability or obligation thereunder) or establish a course of conduct with respect to future requests for amendments, modifications or consents.

The Company hereby reaffirms, confirms and ratifies its obligations and liabilities set forth in the Facility Agreement and the other Transaction Documents, all of which shall remain in full force and effect, as modified by this Letter.

This Letter (i) is a Transaction Document and constitutes the entire understanding of the parties with respect to the subject matter hereof, and any other prior or contemporaneous agreements, whether written or oral, with respect thereto are expressly superseded hereby, and (ii) shall be binding upon and inure to the benefit of the successors and assigns of the parties hereto. This Letter may be executed in counterparts (which taken together shall constitute one and the same instrument) and by facsimile or other electronic transmission, which facsimile or other electronic signatures shall be considered original executed counterparts.

This Letter, and disputes concerning the interpretation, enforceability, performance, breach, termination or validity of all or any portion of this Letter, shall be governed by the laws of the State of New York without giving effect to any laws, rules or provisions that would cause the application of the laws of any jurisdiction other than the State of New York.

[Signature pages follow]

Very truly yours,

DEERFIELD PRIVATE DESIGN FUND III, L.P.

By: Deerfield Mgmt III, L.P., its General Partner
By: J.E. Flynn Capital III, LLC, its General Partner

By: /s/ David Clark
Name: David Clark
Title: Authorized Signatory

Acknowledged and Agreed To
as of the date set forth above

KEMPHARM, INC.

By: /s/ R. LaDuane Clifton
Name: R. LaDuane Clifton
Title: CFO

Exhibit 10.5

August 23, 2019

KemPharm, Inc.
1180 Celebration Boulevard, Suite 103
Celebration, FL 34747

Re: Amendment to Facility Agreement

Ladies and Gentlemen:

Reference is hereby made to that certain Facility Agreement, dated as of June 2, 2014 (as the same may have been previously or in the future be amended, modified, restated or otherwise supplemented from time to time, the "**Facility Agreement**"), by and between KemPharm, Inc., a Delaware corporation (the "**Company**"), and Deerfield Private Design Fund III, L.P. (the "**Lender**"). Capitalized terms used herein which are defined in the Facility Agreement, unless otherwise defined herein, shall have the meanings ascribed to them in the Facility Agreement. The Company and the Lender desire to amend the Facility Agreement on the terms set forth in this letter agreement (this "**Letter**").

The Facility Agreement obligated the Company to pay to the Lender (i) $3,333,333.33 of the outstanding principal amount of the Senior Secured Convertible Note (the "**2019 Principal Payment**") and (ii) accrued and unpaid interest on the entire principal amount of the Senior Secured Convertible Note (the "**June 2019 Interest Payment**"), in each case, on June 3, 2019. The Company and the Lender entered into letter agreements, dated as of June 3, 2019, June 17, 2019, June 24, 2019, June 28, 2019, July 15, 2019, July 31, 2019, August 9, 2019 and August 23, 2019, which extended the due date for the June 2019 Principal Payment and the June 2019 Interest Payment from June 3, 2019 to June 17, 2019, June 24, 2019, June 28, 2019, July 12, 2019, July 31, 2019, August 9, 2019, August 16, 2019 and August 23, 2019, respectively. Effective upon the execution and delivery of this Letter by the Company and the Lender, the Facility Agreement is hereby amended to provide that the due date for payment of the 2019 Principal Payment and the June 2019 Interest Payment shall be extended from the date hereof to August 30, 2019; provided, that the foregoing shall not limit the rights of the Lender under Section 5.4 or Section 5.5 of the Facility Agreement.

Except as expressly set forth herein, (i) the Facility Agreement and the other Transaction Documents remain unchanged and in full force and effect, (ii) this Letter shall not be deemed to be a waiver, amendment or modification of, or consent to or departure from, any provision of the Facility Agreement or any other Transaction Document or to be a waiver of any Default or Event of Default under the Facility Agreement or any other Transaction Document, whether arising before or after the date hereof or as a result of the transactions contemplated hereby, and (iii) this Letter shall not preclude the future exercise of any right, remedy, power or privilege available to the Lender, whether under the Facility Agreement, any other Transaction Document or otherwise, and shall not be construed or deemed to be a satisfaction, novation, cure, modification, amendment or release of the Obligations, the Facility Agreement or any other Transaction Document (or any other liability or obligation thereunder) or establish a course of conduct with respect to future requests for amendments, modifications or consents.

The Company hereby reaffirms, confirms and ratifies its obligations and liabilities set forth in the Facility Agreement and the other Transaction Documents, all of which shall remain in full force and effect, as modified by this Letter.

This Letter (i) is a Transaction Document and constitutes the entire understanding of the parties with respect to the subject matter hereof, and any other prior or contemporaneous agreements, whether written or oral, with respect thereto are expressly superseded hereby, and (ii) shall be binding upon and inure to the benefit of the successors and assigns of the parties hereto. This Letter may be executed in counterparts (which taken together shall constitute one and the same instrument) and by facsimile or other electronic transmission, which facsimile or other electronic signatures shall be considered original executed counterparts.

This Letter, and disputes concerning the interpretation, enforceability, performance, breach, termination or validity of all or any portion of this Letter, shall be governed by the laws of the State of New York without giving effect to any laws, rules or provisions that would cause the application of the laws of any jurisdiction other than the State of New York.

[Signature pages follow]

Very truly yours,

DEERFIELD PRIVATE DESIGN FUND III, L.P.

By: Deerfield Mgmt III, L.P., its General Partner
By: J.E. Flynn Capital III, LLC, its General Partner

By: /s/ David Clark
Name: David Clark
Title: Authorized Signatory

Acknowledged and Agreed To
as of the date set forth above

KEMPHARM, INC.

By: /s/ R. LaDuane Clifton
Name: R. LaDuane Clifton
Title: CFO

Exhibit 10.6

August 30, 2019

KemPharm, Inc.
1180 Celebration Boulevard, Suite 103
Celebration, FL 34747

Re: Amendment to Facility Agreement

Ladies and Gentlemen:

Reference is hereby made to that certain Facility Agreement, dated as of June 2, 2014 (as the same may have been previously or in the future be amended, modified, restated or otherwise supplemented from time to time, the "**Facility Agreement**"), by and between KemPharm, Inc., a Delaware corporation (the "**Company**"), and Deerfield Private Design Fund III, L.P. (the "**Lender**"). Capitalized terms used herein which are defined in the Facility Agreement, unless otherwise defined herein, shall have the meanings ascribed to them in the Facility Agreement. The Company and the Lender desire to amend the Facility Agreement on the terms set forth in this letter agreement (this "**Letter**").

The Facility Agreement obligated the Company to pay to the Lender (i) $3,333,333.33 of the outstanding principal amount of the Senior Secured Convertible Note (the "**2019 Principal Payment**") and (ii) accrued and unpaid interest on the entire principal amount of the Senior Secured Convertible Note (the "**June 2019 Interest Payment**"), in each case, on June 3, 2019. The Company and the Lender entered into letter agreements, dated as of June 3, 2019, June 17, 2019, June 24, 2019, June 28, 2019, July 15, 2019, July 31, 2019, August 9, 2019, August 16, 2019 and August 23, 2019, which extended the due date for the June 2019 Principal Payment and the June 2019 Interest Payment from June 3, 2019 to June 17, 2019, June 24, 2019, June 28, 2019, July 12, 2019, July 31, 2019, August 9, 2019, August 16, 2019, August 23, 2019 and August 30, 2019, respectively. Effective upon the execution and delivery of this Letter by the Company and the Lender, the Facility Agreement is hereby amended to provide that the due date for payment of the 2019 Principal Payment and the June 2019 Interest Payment shall be extended from the date hereof to September 4, 2019; provided, that the foregoing shall not limit the rights of the Lender under Section 5.4 or Section 5.5 of the Facility Agreement.

Except as expressly set forth herein, (i) the Facility Agreement and the other Transaction Documents remain unchanged and in full force and effect, (ii) this Letter shall not be deemed to be a waiver, amendment or modification of, or consent to or departure from, any provision of the Facility Agreement or any other Transaction Document or to be a waiver of any Default or Event of Default under the Facility Agreement or any other Transaction Document, whether arising before or after the date hereof or as a result of the transactions contemplated hereby, and (iii) this Letter shall not preclude the future exercise of any right, remedy, power or privilege available to the Lender, whether under the Facility Agreement, any other Transaction Document or otherwise, and shall not be construed or deemed to be a satisfaction, novation, cure, modification, amendment or release of the Obligations, the Facility Agreement or any other Transaction Document (or any other liability or obligation thereunder) or establish a course of conduct with respect to future requests for amendments, modifications or consents.

The Company hereby reaffirms, confirms and ratifies its obligations and liabilities set forth in the Facility Agreement and the other Transaction Documents, all of which shall remain in full force and effect, as modified by this Letter.

This Letter (i) is a Transaction Document and constitutes the entire understanding of the parties with respect to the subject matter hereof, and any other prior or contemporaneous agreements, whether written or oral, with respect thereto are expressly superseded hereby, and (ii) shall be binding upon and inure to the benefit of the successors and assigns of the parties hereto. This Letter may be executed in counterparts (which taken together shall constitute one and the same instrument) and by facsimile or other electronic transmission, which facsimile or other electronic signatures shall be considered original executed counterparts.

This Letter, and disputes concerning the interpretation, enforceability, performance, breach, termination or validity of all or any portion of this Letter, shall be governed by the laws of the State of New York without giving effect to any laws, rules or provisions that would cause the application of the laws of any jurisdiction other than the State of New York.

[Signature pages follow]

Very truly yours,

DEERFIELD PRIVATE DESIGN FUND III, L.P.

By: Deerfield Mgmt III, L.P., its General Partner
By: J.E. Flynn Capital III, LLC, its General Partner

By: /s/ David Clark
Name: David Clark
Title: Authorized Signatory

Acknowledged and Agreed To
as of the date set forth above

KEMPHARM, INC.

By: /s/ R. LaDuane Clifton
Name: R. LaDuane Clifton
Title: CFO

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

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

Cash Compensation

Cash compensation shall be paid in the following annual amounts. Payments shall be made in quarterly installments in arrears on the last day of each calendar quarter in which service occurred, and shall be *prorated* as appropriated for a director who does not serve for the full quarter.

1. Annual Board Service Retainer:

   a. All non-employee directors: $26,250
   b. Chairman of the Board, if not an employee, or lead independent director, if any (in addition to the retainer for all non-employee directors): $11,250

2. Annual Committee Member Service Retainer:

   a. Member of the Audit Committee: $5,625
   b. Member of the Compensation Committee: $3,750
   c. Member of the Nominating and Corporate Governance Committee: $3,750

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

   a. Chairman of the Audit Committee: $11,250
   b. Chairman of the Compensation Committee: $7,500
   c. Chairman of the Nominating and Corporate Governance Committee: $5,625

Equity Compensation

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

Annual Grant: On the date of each annual stockholders meeting of the Company, each director who continues to serve as a non-employee member of the Board following such stockholders meeting will be automatically, and without further action by the Board or the Compensation Committee of the Board, be granted a stock option for 30,000 shares of common stock. The stock options will vest and become exercisable in full on the earlier of (1) the first anniversary of the grant date, (2) the day before the first annual stockholders meeting occurring after the grant date or (3) immediately prior to a "Change in Control" as defined in the Plan, subject in each case to the director's continued service on such vesting date.

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

Exhibit 10.10

AGREEMENT TO TERMINATE CLA

BETWEEN

MONOSOL RX, LLC

AND

KEMPHARM, INC.

DATED AS OF MARCH 20, 2012

Agreement to Terminate CLA
Between
MONOSOL, RX and KemPharm,

This Agreement to Terminate CLA ("Agreement"), dated as of March 20, 2012 (the "Effective Date"), is between KemPharm, Inc., an Iowa corporation with its principal offices at 7 Hawkeye Drive, Suite 103, North Liberty, Iowa 52317 ("KemPharm"), and MonoSol Rx, LLC, a Delaware limited liability company with its principal offices at 30 Technology Drive, Warren, New Jersey, 07059 ("MSRx").

RECITALS:

WHEREAS, KemPharm and MSRx entered into that certain Collaboration and License Agreement dated April 20, 2011 (the "CLA");

WHEREAS, Shire LLC, a Kentucky limited liability company ("Shire"), has prosecuted, and KemPharm and Travis C. Mickle ("Mickle") have defended, an action in the United States District Court for the Western District of Virginia Roanoke Division (the "Court") captioned *Shire LLC v. Travis C. Mickle Ph.D. et. al*., No. 7:10-cv-00434 (SGW) (PMS) (W.D. Va.) (the "Shire Litigation");

WHEREAS, KemPharm, Mickle and Shire have entered into a binding letter of intent dated as of February 9, 2010 (the "Shire LOI"), wherein Shire and KemPharm agree, among other things, that (a) Shire and KemPharm shall enter into a joint stipulation of dismissal, dismissing with prejudice all claims and counterclaims relating to the Shire Litigation, and (b) Shire shall acquire for the monetary and nonmonetary consideration set forth in the Shire LOI the assets specifically identified in section 1 of Exhibit A of the Shire LOI, including, without limitation, KP106 and KemPharm's other amphetamine amino acid conjugate products, all inventory of such conjugate products, and all of KemPharm's intellectual property related to such conjugate products; and

WHEREAS, the obligations of Shire and KemPharm to consummate the transactions set forth in the Shire LOI are subject to the condition that, within sixty (60) days following the date of the Shire LOI, MSRx executes the Release and Consent in the form attached hereto as Exhibit A (the "Shire Release");

WHEREAS, MSRx is willing to execute the Shire Release in accordance with and subject to the terms and conditions set forth in this Agreement; and

WHEREAS, KemPharm and MSRx desire to terminate the CLA in accordance with the terms and conditions set forth in this Agreement;

NOW, THEREFORE, in consideration of the covenants, terms and conditions set forth in this Agreement, the receipt and sufficiency of which the Parties hereby acknowledge, MSRx and KemPharm agree as follows:

ARTICLE 1
Definitions

As used herein, the following terms shall have the following meanings:

1.1 "Affiliate" of a Party hereto means any entity which controls, is controlled by or is under common control with, such Party. For purposes of this definition, a Party shall be deemed to control another entity if it owns or controls, directly or indirectly, at least fifty percent (50%) of the voting equity of another entity (or other comparable ownership interest for an entity other than a corporation) or if it has management control of the other entity. Any reference in this Agreement to a Party shall include the Affiliates of that Party (unless the context requires otherwise).

1.2 "Agent" has the meaning provided in Section 5.1.

1.3 "Agreement" means this Agreement to Terminate CLA.

1.4 "Arising Product" means one or more pharmaceutical products in any dosage form for any indication relating to KP415 including products based upon, incorporating or manufactured from any IP or technology included in or stemming from KP415.

1.5 "Business Day" means any day other than a Saturday, Sunday or other day on which commercial banks in New York, New York are authorized or required by law to close.

1.6 "Change of Control" means the occurrence after the Effective Date, in one or a series of transactions, of any of the following: (i) any person (as such term is used in Sections 13(d) and 14(d)(2) of the Securities Exchange Act of 1934, as amended from time to time (the "Exchange Act")), acting alone or in concert with others, assumes or otherwise gains, directly or indirectly, beneficial ownership (as defined in Rule 13d-3 of the Exchange Act) of securities representing 50% or more of the combined voting power of the then outstanding securities of KemPharm and/or its Affiliates or its or their successors; (ii) any merger, consolidation, security exchange, division, or sale or other disposition of all or substantially all of the assets of KemPharm and/or its Affiliates or its or their successors or any other transaction in which KemPharm and/or its Affiliates or its or their successors become the subsidiary of another company which is consummated or approved by the equity holders of KemPharm and/or its Affiliates or its or their successors; and (iii) any approval by the equity holders of KemPharm and/or its Affiliates or its or their successors of a plan of liquidation. Notwithstanding the forgoing, a Change of Control shall not include a spin-off by KemPharm of assets including, without limitation, its rights and interests in KP415, to a wholly-owned subsidiary of KemPharm or the distribution of securities of such subsidiary to KemPharm's securities holders in accordance with section 355 of the Internal Revenue Code of 1986, as amended, so long as each of the following conditions are met: (i) such subsidiary agrees in a writing in a form reasonably acceptable to [*] to assume all of the obligations, representations, warranties and covenants of KemPharm under this Agreement upon the consummation of such transaction and (ii) no value (including, without limitation, any cash, securities or other property) is received by any of KemPharm, such subsidiary being spun-off or other Affiliate or any of its or their security holders other than the securities of such subsidiary in such spin-off which are being issued in such spin-off (a "355 Spin-Off Transaction").

1.7 "CLA" has the meaning set forth in the Recitals to this Agreement;

1.8 "Claims" means any and all causes of action, charges, complaints, actions, suits, proceedings, hearings, investigations, allegations, demands and claims of any kind.

1.9 "Commercialize" or "Commercialization" means the marketing, promoting, distributing, offering for sale and selling, licensing, or otherwise realizing Value from or in connection with an Arising Product(s), and conducting clinical studies after Approval, if necessary and required. When used as a verb, Commercialize means to engage in Commercialization.

1.10 "Confidential Information" means or includes any and all Proprietary Information exchanged between the Parties or their representatives prior to the Effective Date under the provisions of the CLA or in contemplation of the transactions contemplated thereby or on or subsequent to the Effective Date under the provisions of this Agreement or in contemplation of the transactions contemplated hereby.

1.11 "Direct Claim" has the meaning provided in Section 8.3(F).

1.12 "Disclosing Party" has the meaning provided in Section 5.1.

1.13 "Effective Date" has the meaning set forth in the Preamble to this Agreement.

1.14 "Indemnitee" has the meaning provided in Section 8.2.

1.15 "Indemnitor" has the meaning provided in Section 8.2.

1.16 "Intellectual Property" or simply "IP" means or includes Patent Rights, Know-How, copyrights, trademarks, mask works, data, other forms of intellectual property, Confidential Information and Proprietary Information.

1.17 "KemPharm" has the meaning set forth in the preamble to this Agreement.

1.18 "KemPharm Sale Price" means the aggregate consideration and/or other Value actually received at any time in a KemPharm Sale Transaction from the acquiring Third Party(ies) by KemPharm and its Affiliates, and/or their respective equity holders (including, without limitation, the aggregate of any and all amounts received for any options, warrants or convertible securities, dividends, distributions, deferred, contingent, earn-outs, restrictive covenants, license (including under sublicenses), milestone, and Royalties payments, engagement fees and all other payments similar to any of the foregoing).

1.19 "KemPharm Sale Transaction" means a bona fide transaction (or a series of related bona fide transactions) between one or more Third Parties and KemPharm and/or its Affiliates, and/or their respective equity holders, pursuant to which there occurs a Change of Control, which transaction(s) includes KemPharm's rights and interests in KP415. Notwithstanding the forgoing, a KemPharm Sale Transaction shall not include a 355 Spin-off Transaction by KemPharm.

1.20 "Know-How" means any unpatented technical information, know-how, show how and materials including, without limitation, all biological, chemical, pharmacological, toxicological, clinical, assay and other information, data, discoveries, inventions, improvements, processes, formula and trade secrets, patentable or otherwise.

1.21 "KP415" means (i) the molecule(s) involved in the covalent conjugation of methylphenidate (or methylpheny(piperidin-2-yl) acetate) currently referred to as KP415, and any and all [*] thereof, and (ii) any and all other [*], and any and all [*] thereof. KP415 is not restricted to indication, dosage, use or territory, all of which are covered under this definition.

1.22 "Losses" means any and all damages (including all incidental, consequential, statutory and treble damages), awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties, costs, fees, liabilities, obligations, taxes, liens, losses, lost profits and expenses (including, without limitation, court costs, interest and reasonable fees of attorneys, accountants and other experts) incurred by or awarded to Third Parties and required to be paid to Third Parties with respect to a Claim by reason of any judgment, order, decree, stipulation or injunction, or any settlement entered into in accordance with the provisions of this Agreement, together with all documented out-of-pocket costs and expenses incurred in complying with any judgments, orders, decrees, stipulations and injunctions that arise from or relate to a Claim of a Third Party.

1.23 "Material Changes to the Shire LOI" means, with respect to any of the Shire Definitive Settlement Documents, any term or condition which either (a) modifies, limits or affects, in any manner, the monetary benefits required to be provided by Shire under the Shire LOI or any other rights of MSRx under the Shire LOI and/or this Agreement, (b) creates a risk of a potential Claim by Shire or any of its Affiliates against MSRx or any of its Affiliates or successors or assigns, or any of its or their respective officers, directors, managers, members, shareholders, employees, agents and representatives (collectively, the "MSRx Parties") or increases a material risk of such a potential Claim against any of the MSRx Parties in a manner that is not contemplated in the Shire LOI, or (c) in any way conveys, grants, or otherwise effects any of MSRx's rights or interests in or to MSRx's Intellectual Property.

1.24 "Mickle" has the meaning set forth in the Recitals to this Agreement.

1.25 "MSRx" has the meaning set forth in the preamble to this Agreement.

1.26 "Net Revenues" means the amount of money, net of any sums paid to MSRx pursuant to any supply or manufacturing agreement or otherwise for the manufacture of KP415, which either Party or both Parties earn or receive at any time from the Commercialization of KP415 or otherwise from the exploitation of any licenses granted for the development and/or commercialization of KP415 (including, without limitation, monies which continue to be earned under such licenses after the expiration or termination of this Agreement and whether or not fully developed or Commercialized and all payments for upfront license payments, milestone events, Royalties, engagement fees and similar payments under sublicenses), less any applicable value added tax, sales tax or withholding tax or other deduction required by applicable law.

1.27 "Party" means either KemPharm or MSRx, and "Parties" means both KemPharm and MSRx.

1.28 "Patent Rights" means all existing patents and patent applications and all patent applications hereafter filed, including any continuations, continuations-in-part, divisions, or any substitute applications, any patent issued with respect to any such patent applications, any reissue, re-examination, renewal or extension (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all foreign counterparts of any of the foregoing, or as applicable portions thereof or individual claims therein.

1.29 "Program Sale Transaction" means a transaction (or a series of transactions), other than a Third Party License or KemPharm Sale Transaction, pursuant to which one or more Third Parties purchases and/or acquires (alone or with other assets, rights or interests) KemPharm's and MSRx's respective rights and interests in and to KP415 or other transaction (or a series of transactions) at any time involving the monetization (including, without limitation, the issuance of any securities) of KP415 whether or not at the time of any such transaction or monetization event KP415 is fully developed or Commercialized. A KemPharm Sale Transaction does not constitute a "Program Sale Transaction." Notwithstanding the forgoing, a Program Sale Transaction shall not include a 355 Spin-off Transaction by KemPharm.

1.30 "Proprietary Information" means or includes information or data owned or licensed by a Party that such Party treats as proprietary and confidential including, but not limited to, data, documents, trade secrets, methods, processes, techniques, and scientific and business information.

1.31 "Receiving Party" has the meaning provided in Section 5.1.

1.32 "Royalty" means monies or other consideration paid by either Party to the other Party or to either or both of the Parties by a Third Party Licensee on sales of KP415 and/or Arising Products in any country of the world.

1.33 "Shire" has the meaning set forth in the Recitals to this Agreement.

1.34 "Shire Closing" means the closing of the transactions contemplated under the Shire LOI in accordance with the terms of the Shire LOI or, if elected by KemPharm in accordance with Section 2.2, in accordance with the Shire Definitive Settlement Documents.

1.35 "Shire Definitive Settlement Documents" means any settlement agreement and/or asset purchase agreement or other documents entered into by and between KemPharm and Shire which contain the terms and conditions set forth in the Shire LOI and such other and additional terms and conditions of the transaction contemplated in the Shire LOI.

1.36 "Shire Litigation" has the meaning set forth in the Recitals to this Agreement.

1.37 "Shire LOI" has the meaning set forth in the Recitals to this Agreement.

1.38 "Shire Release" has the meaning set forth in the Recitals to this Agreement.

1.39 "Shire Payment" has the meaning set forth in Section 2.3 below.

1.40 "Third Party" means any person or entity other than either Party or its Affiliates.

1.41 "Third Party Claim" has the meaning provided in Section 8.2.

1.42 "Third Party License" means a license by either or both of the Parties to a Third Party granting development, Commercialization and/or other exploitation rights with respect to KP415 or any Arising Product.

1.43 "Third Party Licensee" means a Third Party which is granted development, Commercialization and/or other exploitation rights under a Third Party License, including the Third Party's sublicensees, if any.

1.44 "Value" means value which is associated with KP415 and/or any Arising Product received by either or both Parties (excluding sums paid to MSRx pursuant to any supply or manufacturing agreement or otherwise for the manufacture of KP415 and/or any Arising Product), including, by way of illustration, without limitation: the purchase price and other net consideration actually received at any time under a Program Sale Transaction; Net Revenues received by either Party; payments received from a Third Party License (such as, without limitation, upfront license payments, milestone payments, Royalties, engagement fees, discontinuance or standstill payments and similar payments under sublicenses); that portion of the KemPharm Sale Price attributable to KP415 in accordance with Section 4.2 below; and other transactions involving the monetization (including, without limitation, the issuance of securities (other than a 355 Spin-Off Transaction), options, warrants or convertible securities, dividends, distributions, and deferred, contingent, earn-outs, and restrictive covenants payments); whether or not KP415 is fully developed or Commercialized at the time of calculation of such value and covering KP415 in any dosage form for any application or indication anywhere in the world.

ARTICLE 2
EXECUTION OF SHIRE RELEASE; CONSUMMATION OF THE SHIRE LOI

2.1 Execution of Shire Release. Simultaneous with the Shire Closing, and the receipt of payment by MSRx of the amount payable to MSRx in accordance with Section 2.3 below, MSRx shall execute and deliver to KemPharm the Shire Release in the form attached hereto as Exhibit A.

2.2 Consummation of the Shire LOI. Following the execution of this Agreement, KemPharm shall close upon the transactions provided in the Shire LOI; provided, however, that KemPhann, in its discretion, may negotiate, execute and close upon Shire Definitive Settlement Documents. In the event KemPharm and Shire agree upon final drafts of Shire Definitive Settlement Documents, KemPhann shall provide to MSRx a copy of such final drafts at least three (3) Business Days prior to the Shire Closing. In furtherance of the Shire Closing, MSRx shall deliver to KemPharm or directly to Shire within three (3) Business Days after the date of the Shire Closing the complete inventory in MSRx's possession of any KP106 active pharmaceutical ingredient as of such date and a certificate signed by MSRx acknowledging that any KP106 manufactured in any dosage form in MSRx's possession as of such date has been destroyed.

2.3 Shire Payment. Upon the Shire Closing, out of the single one-time payment of $22,000,000 (the "Shire Payment") to be paid by Shire thereunder, KemPharm shall arrange for $[*] of the $22,000,000 to be paid directly by Shire via bank transfer to MSRx consistent with wiring instructions given by MSRx to KemPharm. Such payment of $[*] to MSRx shall be inclusive of any portion of the $22,000,000 Shire Payment which MSRx is due under the CLA for a "Program Sale Transaction" (as defined under the CLA). MSRx shall have no right or Claim under this Agreement or the CLA to any portion of the aforementioned $22,000,000 Shire Payment except for the aforementioned $[*] sum.

2.4 MSRx's Revocation Rights. In the event that KemPharm negotiates final drafts of Shire Settlement Documents, then KemPharm shall provide a copy of such final drafts in accordance with Section 2.2 hereof. If the Shire Settlement Documents include any Material Changes to the Shire LOI, then MSRx shall have the following right to revoke this Agreement: by no later than 5:00 P.M. E.S.T. on the third (3rd) Business Day following the date on which MSRx receives a copy of such final signed or unsigned drafts of the Shire Settlement Documents, MSRx may deliver written notice to KemPharm which states that the Shire Definitive Settlement Documents includes Material Changes to the Shire LOI, describes in reasonable detail the Material Changes to the Shire LOI and declares that MSRx is revoking this Agreement. Such revocation shall be effective immediately upon KemPharm's receipt of the notice required herein. In addition to the foregoing, MSRx shall have the right to revoke this Agreement by written notice to KemPhann under either of the following events: (i) KemPharm shall have failed to deliver to MSRx a written notice that the Shire Closing has occurred within thirty (30) days after the Effective Date, or (ii) MSRx shall not have received its share of the Shire Payment in accordance with Section 2.3 above or the Shire Release executed by Shire. In the event that MSRx revokes this Agreement in accordance with this Section 2.4, then each of the following shall terminate effective simultaneous with such revocation: (i) MSRx's right to receive the payment provided under Section 2.3, (ii) the termination of the CLA pursuant to Article 3 (and the CLA shall be reinstated automatically thereon in full force and effect and all of the rights and obligations of the Parties under the CLA shall continue and survive); and (iii) MSRx's rights and interest in KP415 under Article 4.

ARTICLE 3
TERMINATION OF THE CLA

3.1 Termination of the CLA. Subject to the terms and conditions of this Agreement, including, without limitation, the revocation rights of MSRx under Section 2.4, the CLA shall terminate upon the Shire Closing and payment to MSRx of the amount due under Section 2.3 above. Upon termination of the CLA pursuant to this Section 3.1, no rights or obligations of either Party under the CLA shall survive the termination. The Parties acknowledge and agree that, following the assignment to Shire of the "Acquired Assets" (as defined under the Shire LOI), there are no remaining "Arising Technology," "Arising Patents" or "Arising IP" as those terms are defined in the CLA. Except as otherwise provided in Section 2.2 with respect to inventory and manufactured KP106, following the termination of the CLA, each Party shall promptly transfer to the other Party, at the other Party's cost, or destroy at the other Party's written request, all relevant records and materials in its possession or control containing Confidential Information of

the other Party; provided, however, that each Party may keep one archival copy of the Confidential Information of the other Party in the legal department files of such Party or its legal representative in accordance with the provisions of Article 5 below. Subject to the terms and conditions of this Agreement, including, without limitation, the revocation rights of MSRx under Section 2.4, each Party hereby forever releases and discharges the other Party and each of the other Party's officers, directors, shareholders, members, managers, employees and agents from any and all Claims, known or suspected by the releasing Party as of the date of Shire Closing, at law or in equity, arising from or related to the CLA. Nothing in this Section 3.1 shall limit, impair or affect any of the rights of the Parties under this Agreement and no Party shall be deemed to release, waive or discharge any of its rights or remedies under this Agreement or at law or in equity with respect to the transactions contemplated under this Agreement.

ARTICLE 4
GRANT OF INTEREST IN KP415

4.1 Division of Value Generally. Subject to the terms and conditions set forth in this Agreement, the Parties acknowledge and agree that MSRx shall have the right to receive an amount equal to ten percent (10.0%) of any and all Value. Upon the occurrence of a Program Sale Transaction or KemPharm Sale Transaction, the Value to be paid to MSRx (or the amount to be deposited in escrow in accordance with Section 4.2, as the case may be) shall be paid to MSRx (or the escrow agent, as the case may be) directly out of the closing proceeds and any other consideration (and post-closing proceeds and/or other consideration, if any) of such Program Sale Transaction or KemPharm Sale Transaction simultaneously with and when each payment by such Third Party is made to KemPharm or any of its Affiliates, and/or any of their respective equity holders, of any and all such proceeds or the delivery of other consideration therefore whenever made. KemPharm shall arrange in the agreement for a Program Sale Transaction or KemPharm Sale Transaction that payment of such Value to MSRx (or the amount to be deposited in escrow pursuant to Section 4.2, as the case may be) shall be made by wire transfer of immediately available funds to an account designated by MSRx (or to the escrow agent, as the case may be), and the delivery of such other consideration representing any such Value (or the amount to be deposited in escrow pursuant to Section 4.2, as the case may be) shall be made to the address of MSRx set forth in this Agreement or as otherwise designated by MSRx (or to the escrow agent, as the case may be). In the event that MSRx is properly paid in full all of its share under this Agreement of the Value of a Program Sale Transaction or KemPharm Sale Price directly by the Third Party purchaser in such Program Sale Transaction or KemPharm Sale Transaction out of the proceeds thereof in accordance with this Article 4, MSRx shall have no right to make a Claim against KemPharm for KemPharm's share of the Value received from such Third Party purchaser out of the proceeds of such Program Sale Transaction or KemPharm Sale Transaction, as the case may be.

4.2 KemPharm Sale Transaction. If KemPharm or an Affiliate holding rights, title or interests in or to KP415 enters into a KemPharm Sale Transaction, then such transaction shall include MSRx's rights and interests in and to KP415; provided that MSRx shall be paid its share of the Value of the KemPharm Sale Price. The KemPharm Sale Price shall constitute Value to the extent that the KemPharm Sale Price is attributable, in whole or in part, to any of KemPharm's or an Affiliate's rights, title or interests in or to KP415. Upon proper payment of such Value to MSRx in connection with a KemPharm Sale Transaction, MSRx's rights and interests in and to KP415 shall be terminated unless after the consummation of such KemPharm Sale Transaction KemPharm or

any of its Affiliates, and/or any of their respective equity holders, retains directly or indirectly any rights, title or interests in and to KP415, in which event such rights and interests of MSRx shall continue and survive the consummation of such KemPharm Sale Transaction and MSRx shall be paid its share of the Value of the KemPharm Sale Price with respect to such KemPharm Sale Transaction. The interests of MSRx which shall survive pursuant to the foregoing sentence shall be limited to the extent of the remaining interest in KemPharm and its Affiliates held by their respective equity holders, including future Value payments made to such equity holders and Value received by such equity holders in any subsequent transactions including, without limitation, any Program Sale Transactions and any KemPharm Sale Transactions. KemPharm or the Affiliate who is a party to the KemPharm Sale Transaction shall provide to MSRx written notice of its intent to enter into a KemPharm Sale Transaction, which notice shall specify the consideration and purchase price to be paid to KemPharm, its Affiliates and/or their respective equity holders in such KemPharm Sale Transaction. Such notice shall be delivered to MSRx as soon as reasonably practicable, but in no event later than five (5) Business Days after the execution of any agreement contemplating such KemPharm Sale Transaction and no later than ninety (90) days prior to the consummation of such KemPharm Sale Transaction. If the Parties cannot agree on the determination of the Value contained within a KemPharm Sale Price within ten (10) days of such notice by KemPharm to MSRx, then such Value shall be determined by an independent valuation expert selected by mutual written agreement of the Parties. In the event that the Parties are unable to mutually agree upon the selection of an independent valuation expert within five (5) Business Days of the expiration of such ten-day period, then such Value shall be determined in accordance with the following procedures: Each of the Parties shall select its own independent valuation expert and pay all costs associated with its own valuation expert. The two independent valuation experts shall prepare a written determination of such Value within three (3) months of selection. If the determination of the two valuation experts vary by [*] or less, the Parties shall accept as final and binding the average of the determination by the two independent valuation experts as the Value attributed in such KemPharm Sale Transaction. If the results of the foregoing two determinations vary by more than [*], then the two valuation experts shall select a third independent valuation expert to prepare its own valuation of the Value attributed to such KemPharm Sale Transaction. The third valuation expert will, at a minimum, evaluate the valuations of the first two valuation experts and conduct its own analyses as necessary to support its own valuation. The three independent valuation experts shall agree to comply with this schedule of performance before accepting appointment. The Parties shall accept as final and binding the average of the determinations by the three independent valuation experts as the Value attributed in such KemPharm Sale Transaction. The Parties agree that each independent valuation expert engaged for the purposes of determining Value pursuant to this Section 4.2 shall be at least a partner or director of a nationally recognized appraisal firm, which may be an investment banking firm, a certified public accounting firm, or any other firm that performs appraisal and valuation services in the pharmaceutical industry. The Parties agree that any and all costs associated with the first (and, if applicable, the third) valuation expert and its valuation determination shall be paid equally by MSRx and KemPharm. The Parties also agree that the Value shall be equal to a percentage of the KemPharm Sale Price, which percentage shall be proportionate to the value of KemPharm's and/or its Affiliate's rights, title or interests in KP415 expressed as a percentage of the aggregate value of the overall portfolio of tangible and intangible assets as a going concern that are included within the KemPharm Sale Transaction. For the sake of clarity, each individual asset of KemPharm or its Affiliates included within the

KemPharm Sale Transaction, including KP415, shall be assigned a percentage that represents each individual asset's relative contribution to the KemPharm Sale Price, such that the Value in question to be shared by the Parties shall be clearly defined and distinct from all other assets solely owned by KemPharm and/or its Affiliates. The Parties also agree that any valuation shall be conducted in accordance with the terms set forth generally in Exhibit B. The Parties agree that, in the event that such valuation determination is not made prior to the scheduled closing of the KemPharm Sale Transaction despite the Parties acting in good faith and with reasonable diligence to obtain such valuation determination in accordance with this Section 4.2, KemPharm shall have the right to close the KemPharm Sale Transaction on or after the schedule closing date; provided, however, that [*] of the KemPharm Sale Price shall be deposited into an escrow account out of the proceeds or other consideration paid under the KemPharm Sale Transaction and released upon completion of the determination of Value in accordance with this Section 4.2. The agent of the aforementioned escrow account shall be mutually agreed upon in writing by the Parties, who shall be instructed to distribute the escrowed proceeds and consideration upon completion of the Value determination in such proportions as shall correctly pay MSRx its share of the Value of the KemPharm Sale Price, and the remaining balance shall be paid to KemPharm (or to its Affiliates as instructed by KemPharm). In the event that the share of the Value upon completion of the Value determination exceeds the amount held in such escrow, KemPharm or its Affiliates shall pay to MSRx within five (5) days of such determination the difference between the share of the Value determined in accordance with this Section 4.2 and the amount in escrow.

4.3 Limitation on MSRx's Rights to KP415. Except as otherwise expressly provided in this Article 4, MSRx shall have no rights or interest in or to KP415. Further, KemPharm shall have no obligations to MSRx to take any actions to develop or Commercialize KP415. Moreover, MSRx acknowledges the option to purchase KP415 which is granted to Shire under the Shire LOI, which, if such option is exercised by Shire under the Shire LOI, shall be deemed to be a Program Sale Transaction and MSRx shall be entitled to its share of Value with respect thereto under Section 4.1.

ARTICLE 5
CONFIDENTIAL INFORMATION

5.1 Confidential Information. Each of the Parties ("Receiving Party") shall keep all Confidential Information received from the other Party ("Disclosing Party") with the same degree of care it maintains the confidentiality of its own Confidential Information, which in no event shall be less than a reasonable degree of care. The Receiving Party shall not use such Confidential Information for any purpose other than in performance of this Agreement or disclose the same to any other Third Party other than to such of its employees, directors, officers, representatives, consultants, and agents (collectively, an "Agent") who have a need to know such Confidential Information to implement the terms of this Agreement or enforce its rights under this Agreement, or to a Third Party Licensee. A Receiving Party shall advise any Agent or Third Party Licensee who receives such Confidential Information of the confidential nature thereof and of the obligations contained in this Agreement relating thereto. Upon termination of this Agreement, the Receiving Party shall use Commercially Reasonable Efforts to return or destroy all documents, tapes or other media containing Confidential Information of the Disclosing Party that remain in the Receiving Party's or its Agents' possession, except that the Receiving Party may keep one (1) archival copy of the Confidential Information in the legal department files of

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

the Receiving Party or its outside counsel. Such archival copy shall be deemed to be the property of the Disclosing Party, and shall continue to be subject to the provisions of this Section 5.1. The above restrictions set forth in this Section 5.1 on the use and disclosure of Confidential Information shall not apply to any information which (a) is already known to the Receiving Party at the time of disclosure by the Disclosing Party, as demonstrated by competent proof (other than as a result of prior disclosure under any agreement between the Parties with respect to confidentiality), (b) is or becomes generally available to the public other than through any act or omission of the Receiving Party in breach of this Agreement, (c) is acquired by the Receiving Party from a Third Party who is not directly or indirectly under an obligation of confidentiality to the Disclosing Party with respect to same, or (d) is developed independently by the Receiving Party without use, direct or indirect, of Confidential Information. In addition, nothing in this Article 5 shall be interpreted to limit the ability of either Party to disclose its own Confidential Information to any other Person on such terms and subject to such conditions as it deems advisable or appropriate.

A specific item of Confidential Information shall not be covered or deemed to be covered by the foregoing exclusions merely because a general category of information containing such specific item is within the scope of such exclusions. Notwithstanding anything in this Agreement to the contrary, in the event the Receiving Party becomes, or anticipates that it may become, legally compelled to disclose any of the Confidential Information, the Receiving Party will provide the Disclosing Party with prompt notice so that the Disclosing Party may seek a protective order or other appropriate remedy or waive compliance with the provisions of this Agreement. If a full protective order or other appropriate remedy is not obtained, the Receiving Party will disclose only that portion of the Confidential Information which it remains legally compelled to disclose, and will exercise its reasonable efforts to obtain reliable assurance that confidential treatment will be accorded the Confidential Information.

If any portion of the Confidential Information falls into one of the above exceptions, the remainder of the information shall continue to be subject to the requirements of the Agreement. Further, Confidential Information shall not be deemed within the foregoing exceptions if such Confidential Information: (i) is specific and merely embraced by more general information in the public domain or in the receiving party’s possession; or (ii) is a combination which might be pieced together so as to reconstruct such Confidential Information from multiple sources, none of which show the whole combination, the principles of operation and/or method of use.

5.2 Permitted Disclosure and Use. Notwithstanding Section 5.1, a Party may use and disclose Confidential Information belonging to the other Party only to the extent such use and/or disclosure is reasonably necessary to perform its obligations under this Agreement or comply with applicable laws or the regulations of any government authority or any security exchange on which its shares or those of any group company are, or in the process of being, listed. If a Party deems it necessary to disclose Confidential Information of the other Party pursuant to this Section 5.2, such Party shall where lawful to do so give such reasonable advance notice of such disclosure, to the other Party as it is able to do to permit such other Party to object to such disclosure or to take measures to ensure confidential treatment of Confidential Information that is being disclosed.

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

5.3 Public Announcements; Press Release. Except as may be expressly permitted under this Section 5.3 or required by applicable laws or the regulations of any security exchange on which its shares or those of any group company are listed or in the process of being listed, neither Party will make any public announcement of any information regarding the existence, terms or conditions of this Agreement without the prior written approval of the Parties. Once any written statement is approved for disclosure by the other Party or information is otherwise made public in accordance with this Section 5.3, either Party may make a subsequent public disclosure of the contents of such statement without further approval of the other Party. Nothing in the foregoing, however, shall prohibit a Party from making such disclosures as may be necessary or reasonably appropriate in order to comply with applicable law or any rule or regulation of any nationally recognized securities exchange; in such event, however, the Party making the disclosure shall use good faith efforts to consult with the other Party prior to such disclosure and consider in good faith such other Party's proposed modifications and, where applicable, shall request confidential treatment to the extent available.

5.4 Confidentiality of this Agreement. The terms of this Agreement shall be Confidential Information of each Party and, as such, shall be subject to the provisions of this Article 5.

5.5 Confidentiality of Shire LOI. The existence and terms of the Shire LOI and any Shire Definitive Settlement Documents shall be Confidential Information subject to the provisions of this Article 5. MSRx shall not make any disclosure to the public or any Third Party (other than to its employees, officers, directors, members, managers, legal counsel and financial advisors) regarding the transactions contemplated by the Shire LOI or any Shire Definitive Settlement Documents or the terms and conditions thereof except to the limited extent that KemPharm is permitted to do so under the Shire LOI and/or the Shire Definitive Settlement Documents.

5.6 Intellectual Property of MSRx. KemPharm acknowledges and agrees, for itself and its Affiliates, that neither it nor any of its Affiliates shall have any rights, title or interests in, and shall not, and shall not permit others to, misappropriate, use, disclose or otherwise exploit, any Intellectual Property of MSRx in its or their possession or control, notwithstanding anything to the contrary contained in this Agreement or the Shire LOI (or the Shire Definitive Settlement Documents, if applicable) or the transactions contemplated hereunder or thereunder, or as a result of the disclosure or delivery to Shire or any of its Affiliates of any data, materials, reports or documents containing any Intellectual Property of MSRx required pursuant to the Shire LOI (or the Shire Definitive Settlement Documents, if applicable). KemPharm acknowledges and agrees that nothing contained in this Agreement, the Shire LOI (or the Shire Definitive Settlement Documents, if applicable) or the transactions contemplated hereunder or thereunder shall constitute or be construed as creating an express or implied grant of any rights, title, interests or licenses to KemPharm or Shire or their respective Affiliates of the Intellectual Property of MSRx and KemPharm hereby agrees to irrevocably waive, and agrees not to assert, any claim that KemPharm or any of its Affiliates has any rights, title or interests in or license to any of MSRx's Intellectual Property.

5.7 Equitable Remedies. Each Party specifically recognizes that any breach by it of this Article 5 may cause irreparable injury to the other Party and that actual damages may be difficult to ascertain and, in any event, may be inadequate. Accordingly (and without limiting the availability of legal or equitable, including injunctive, remedies under any other provisions of this Agreement), each Party agrees that in the event of any such breach, the other Party shall be entitled to seek injunctive relief and such other legal and equitable remedies as may be available.

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

5.8 Survival. The obligations and prohibitions contained in this Article 5 shall survive the expiration or termination of this Agreement for a period of [*] years thereafter; provided, however, that Confidential Information which is a trade secret of the Disclosing Party if disclosed in writing or, if disclosed orally and confirmed within thirty (30) days in writing as being a trade secret of the Disclosing Party, shall be maintained in secret until such time as it no longer qualifies as a trade secret or until such time as Disclosing Party advises Receiving Party in writing that such information is no longer a trade secret.

ARTICLE 6
REPRESENTATIONS AND WARRANTIES; CERTAIN COVENANTS OF KEMPHARM

KemPharm represents, warrants and covenants to MSRx as of the Effective Date that:

6.1 Existence. KemPharm (a) is a company duly organized, validly existing, and in good standing under the laws of the State of Iowa; (b) is duly qualified as an entity and in good standing under the laws of each jurisdiction where its ownership or lease of property or the conduct of its business requires such qualification, where the failure to be so qualified would have a material adverse effect on its financial condition or its ability to perform its obligations under this Agreement; and (c) has the requisite power and authority to execute, deliver, grant and perform the covenants and transactions contemplated in this Agreement.

6.2 Authority. The execution, delivery and performance of this Agreement by KemPharm and all instruments and documents to be delivered by KemPharm hereunder (a) have been duly authorized by all necessary or proper action; (b) do not conflict with any provision of the charter documents of KemPharm; (c) will not violate any applicable law or regulation or any order or decree of any court or governmental authority having jurisdiction over KemPhann where such violation would have a material adverse effect on its ability to perform its obligations under this Agreement; and (d) will not violate or conflict with any terms of any indenture, mortgage, deed of trust, lease, agreement, or other instrument to which KemPharm is a party, or by which KemPharm or any of its property is bound, which violation or conflict would have a material adverse effect on its financial condition or on its ability to perform its obligations under this Agreement.

6.3 Binding Effect. This Agreement has been duly executed and delivered by KemPharm and constitutes a legal, valid and binding obligation of KemPharm, enforceable against it in accordance with its terms, except as such enforceability may be limited by (a) applicable bankruptcy, insolvency, reorganization, moratorium, and other laws generally applicable to creditors' rights; and (b) judicial discretion in the availability of equitable relief.

6.4 Existence of Claims. As of the time of the Agreement, KemPharm has not received notice, whether written or oral, from any Third Party of any, and knows of no facts or circumstances which would lead to any, Claim asserting the invalidity, misuse, unregisterability or unenforceability of any of its patents, or challenging its right to use or ownership of any of its patent rights or Know-How, or making any adverse Claim of ownership thereof, or asserting that

any trade secrets or other intellectual property rights of such Third Party would be misappropriated by KP415, or that any issued patent of such Third Party in the Territory would be infringed by KP415 or the manufacture, distribution, marketing or sale of the Arising Product(s) in the Territory.

6.5 IP Rights. To the best of its knowledge, KemPharm owns or has licenses to all of its patent rights, Know-How and all other Intellectual Property, Confidential Information, Proprietary Information of any nature whatsoever provided by it to MSRx under this Agreement or otherwise relating to the development and/or Commercialization of KP415, and it owns or has licenses to such Intellectual Property free and clear of all liens, Claims and encumbrances and free of all royalty or similar payment obligations to any Third Party, except such liens, Claims, encumbrances and obligations as will not have a material adverse effect on the other Party's rights under this Agreement.

6.6 Shire LOI. As of the Effective Date, none of KemPharm or any of KemPharm's Affiliates, Mickle or any equity holders, employees, officers, or directors of KemPhann or any of KemPharm's Affiliates (i) are party to any agreements with Shire or any of Shire's Affiliates other than the Shire LOI; (ii) are negotiating any agreements with Shire or any of Shire's Affiliates other than the Shire Definitive Settlement Documents; or (iii) shall receive at any time for the transfer of the "Acquired Assets" (as defined in the Shire LOI) or the settlement of any Claim between Shire and any of them any consideration or Value other than KemPharm's share of the Shire Payment in accordance with Section 2.3 above and the express non-monetary consideration covered under the covenants, terms and conditions set forth in the Shire LOI (except for reasonable consulting fees payable to Mickle, not in excess of industry standards, for consulting services described in Section 12 of the Shire LOI). If KemPharm or any of KemPharm's Affiliates, Mickle or any equity holders, employees, officers, or directors of KemPharm or any of KemPharm's Affiliates enters into any agreement or similar transaction, directly or indirectly, with Shire or any of Shire's Affiliates after the Effective Date (other than the Shire LOI or the Shire Definitive Settlement Documents, if applicable) involving the exchange or issuance of consideration to KemPharm or any of KemPharm's Affiliates, Mickle or any equity holders, employees, officers, or directors of KemPhann or any of KemPharm's Affiliates for any securities, assets, property or rights in any IP of KemPharm or its Affiliates which includes Value which should have been paid to MSRx under the CLA (with the defined term "Value" having such meaning under the CLA as it relates to KP106) or under this Agreement, MSRx shall be entitled to receive its share of such Value directly from Shire and/or its Affiliates which are a party to such agreement or transaction, and MSRx shall have such additional rights and remedies under this Agreement and available to MSRx at law or in equity. For the sake of clarity and not in limitation of the generality of the foregoing, if such agreement or transaction relates in any way to KP106, MSRx shall receive [*] of the aggregate of such Value and, if such agreement or transaction relates in any way to KP415, MSRx shall receive ten percent (10.0%) of the aggregate of such Value. The manner of payment of such Value to MSRx under this Section 6.6 shall be as set forth in Article 4 of this Agreement. In furtherance of the foregoing rights of MSRx, during the [*] period after the Effective Date, KemPhann shall provide to MSRx written notice of its or any of its Affiliates' intent to enter into any agreement or transaction, directly or indirectly, with Shire or any of its Affiliates after the Effective Date (other than the Shire LOI and the Shire Definitive Settlement Documents, if applicable) as soon as practicable but in no event later than five (5) Business Days after the execution of any agreement or letter of intent or similar document and no later than

ninety (90) days prior to the consummation of the transactions contemplated thereunder. Such notice shall contain the purchase price and other consideration being paid and the other written terms and conditions of the agreement or transaction. The agreement contemplating such transaction shall expressly acknowledge the rights of MSRx under this Agreement including, without limitation, the right to receive its share of the Value as set forth above out of the proceeds or other amounts due to KemPharm under such agreement.

6.7 Disclaimer of Warranty. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A WARRANTY OR REPRESENTATION BY KEMPHARM (I) REGARDING THE EFFECTIVENESS, VALUE, SAFETY, NON TOXICITY, OR PATENTABILITY OF KP415 AND/OR U.S. PROVISION PATENT APPLICATION NO. [*] OR (II) THAT KP415 WILL BE APPROVED OR OTHERWISE DEVELOPED OR COMMERCIALIZED. KEMPHARM MAKES NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO KP415.

ARTICLE 7
REPRESENTATIONS AND WARRANTIES OF MSRX

MSRx represents, warrants and covenants to MSRx as of the Effective Date that:

7.1 Existence. MSRx (a) is a company duly organized, validly existing, and in good standing under the laws of the State of Delaware; (b) is duly qualified as an entity and in good standing under the laws of each jurisdiction where its ownership or lease of property or the conduct of its business requires such qualification, where the failure to be so qualified would have a material adverse effect on its financial condition or its ability to perform its obligations under this Agreement; (c) has the requisite power and authority to execute, deliver, grant and perform the covenants and transactions contemplated in this Agreement.

7.2 Authority. The execution, delivery and performance of this Agreement by MSRx and all instruments and documents to be delivered by MSRx hereunder (a) have been duly authorized by all necessary or proper action; (b) do not conflict with any provision of the charter documents of MSRx; (c) will not violate any applicable law or regulation or any order or decree of any court or governmental authority having jurisdiction over MSRx where such violation would have a material adverse effect on its ability to perform its obligations under this Agreement; and (d) will not violate or conflict with any terms of any indenture, mortgage, deed of trust, lease, agreement, or other instrument to which MSRx is a party, or by which MSRx or any of its property is bound, which violation or conflict would have a material adverse effect on its financial condition or on its ability to perform its obligations under this Agreement.

7.3 Binding Effect. This Agreement has been duly executed and delivered by MSRx and constitutes a legal, valid and binding obligation of MSRx, enforceable against it in accordance with its terms, except as such enforceability may be limited by (a) [*]; and (b) [*].

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

ARTICLE 8
INDEMNIFICATION

8.1 Mutual Indemnification. Each Party shall defend indemnify and hold harmless the other Party, including Affiliates and each of their respective officers, directors, shareholders, employees, representatives, agents, successors and assigns from and against all Claims of Third Parties, and all associated Losses, to the extent arising out of (a) a Party's gross negligence or willful misconduct in performing any of its obligations under this Agreement, or (b) a material breach by a Party of any of its representations, warranties, covenants or agreements under this Agreement.

8.2 KemPharm Indemnification of Shire Complaint. In the event that Shire brings any Claim against MSRx in connection with the Acquired Assets other than solely as a result of a breach by MSRx of any obligation under this Agreement or in breach of the Shire Release, KemPharm shall indemnify, defend, and hold harmless, at KemPharm's cost and expense, MSRx and MSRx's Affiliates, and each of their respective officers, directors, shareholders, employees, representatives, agents, successors and assigns who are named therein (collectively, the "MSRx Parties"), in such Claim by Shire (a "Shire Claim").

8.3 Procedure for Indemnification.

(A) Notice. In the case of a Claim made by a Third Party (a "Third Party Claim") as to which a Party (the "Indemnitor") may be obligated to provide indemnification pursuant to this Agreement (including a Shire Claim), such Party seeking indemnification hereunder ("Indemnitee") shall notify the Indemnitor in writing of the Third Party Claim (and specifying in reasonable detail the factual basis for the Third Party Claim and to the extent known, the amount of the Third Party Claim) reasonably promptly after becoming aware of such Third Party Claim; provided, however, that failure to give such notification will not affect the indemnification provided hereunder except to the extent the Indemnitor shall have been actually materially prejudiced as a result of such failure.

(B) Defense of Claim. If the Indemnitor acknowledges in writing its obligation to indemnify the Indemnitee for a Third Party Claim, then the Indemnitor may elect to assume the defense of any such Third Party Claim and any litigation resulting from such Claim. Both Parties agree to cooperate with the Party providing the defense in all material respects including the timing of requests for information and access to material necessary to the defense.

(C) Assumption of Defense in the event of Default of Indemnitee. In the event the Indemnitor is not able to provide a defense, or elects not to provide a defense against any Third Party Claim, under this Section 8.3, notwithstanding anything to the contrary contained in this Agreement, an Indemnitee shall be entitled to assume the defense of any Third Party Claim and at its sole option provide the defense against the Third Party Claim. In such case of the Indemnitee providing the defense, the Indemnitor will be required, within thirty (30) days after receipt of written notice from the Indemnitee of the commencement or assertion of any such Third Party Claim, to provide to the Indemnitee all materials, correspondence, documents and information which may be useful in mounting a defense.

(D) Settlement of Claims. If the Indemnitor acknowledges in writing its obligation to indemnify the Indemnitee for a Third Party Claim, the Indemnitee will agree to a reasonable settlement, compromise or discharge of such Third Party Claim that the Indemnitor may

recommend that by its terms obligates the Indemnitor to pay the full amount of Losses (whether through settlement or otherwise) in connection with such Third Party Claim and unconditionally and irrevocably releases the Indemnitee completely from all Losses in connection with such Third Party Claim; provided, however, that, without the Indemnitee's prior written consent, the Indemnitor shall not consent to any settlement, compromise or discharge (including, without limitation, the consent to entry of any judgment), and the Indemnitee may refuse to agree to any such settlement, compromise or discharge, that provides for injunctive or other non-monetary relief materially and adversely affecting the Indemnitee. If the Indemnitor acknowledges in writing its obligation to indemnify the Indemnitee against a Third Party Claim, the Indemnitee shall not (unless required by applicable law) admit any liability with respect to, or settle, compromise or discharge, such Third Party Claim without the Indemnitor's prior written consent (which consent shall not be unreasonably withheld, delayed or conditioned).

(E) Other Assumption of Defense. Notwithstanding anything to the contrary contained in this Agreement, an Indemnitee shall be entitled to assume the defense of any Third Party Claim with respect to the Indemnitee upon written notice to the Indemnitor in which case, the Indemnitor shall be relieved of liability under Section 8.1 solely for such Third Party Claim and related Losses.

(F) Direct Claims. Any Claim on account of any and all damages, deficiencies, defaults, assessments, fines, dues, penalties, costs, fees, liabilities, obligations, taxes, liens, losses, and expenses (including, without limitation, court costs, interest and reasonable fees of attorneys, accountants and other experts) incurred by or suffered by a Party which does not involve a Third Party Claim (a "Direct Claim") shall be asserted by reasonably prompt written notice (stating in reasonable detail, the basis of such Claim and a reasonable estimate of the amount thereof) given by the Indemnitee to the Indemnitor. Except as otherwise stated in this Agreement, for a period of sixty (60) days from and after the receipt of the written notice (or such shorter period of time as otherwise set forth in this Agreement with respect to a specific Claim) the Parties shall attempt in good faith to resolve such Direct Claim. If the Parties are unable to resolve such Direct Claim, the Party seeking recourse may thereafter pursue any and all legal and equitable remedies at its disposal to enforce said Direct Claim.

ARTICLE 9
TERM AND TERMINATION

9.1 Term. This Agreement shall be deemed to commence on the Effective Date and, unless terminated earlier in accordance with the terms of this Agreement, shall continue until the completion or termination of all payments to MSRx of Value pursuant to Article 4 and Section 6.6 (the "Term").

9.2 Accrued Rights; Surviving Obligations. Termination, relinquishment or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination, relinquishment or expiration. Such termination, relinquishment or expiration shall not relieve any Party from obligations which are expressly or by implication intended to survive termination, relinquishment or expiration of this Agreement and shall not affect or prejudice any provision of this Agreement which is expressly or by implication provided to come into effect on, or continue in effect after, such termination, relinquishment or expiration.

9.3 Survival. The following provisions shall survive the termination of this Agreement: [*], [*], [*], [*] and [*], as well as any applicable definitions and general provisions. Remedies for breaches will also survive termination of this Agreement.

ARTICLE 10
MISCELLANEOUS

10.1 Relationship of the Parties. Unless as otherwise agreed in writing, each Party shall bear its own costs incurred in the performance of its obligations under this Agreement without charge or expense to the other except as expressly provided in this Agreement. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, each of the Parties' legal relationship under this Agreement to the other Party shall be that of independent contractor.

10.2 Registration and Filing of this Agreement. To the extent, if any, that either Party concludes in good faith that it or the other Party is required to file or register this Agreement or a notification thereof with any Governmental Authority including, without limitation, the U.S. Securities and Exchange Commission or the U.S. Federal Trade Commission, in accordance with law, such Party shall inform the other Party thereof. Should both Parties jointly agree that either of them is required to submit or obtain any such filing, registration or notification, they shall cooperate, each at its own expense, in such filing, registration or notification and shall execute all documents reasonably required in connection therewith. In such filing, registration or notification, the Parties shall request confidential treatment of sensitive provisions of this Agreement, to the extent permitted by applicable law. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to this Agreement, and shall reasonably cooperate to respond to any request for further information therefrom on a timely basis.

10.3 Governing Law/Disputes. This Agreement and all other disputes, difference and Claims arising out of or in connection with this Agreement or the respective rights of the Parties under this Agreement shall be construed and governed in all respects, and the respective rights of the Parties determined, according to the prevailing substantive laws of the State of [*], without regard to its conflict of laws principles. The Parties agree that, differences and Claims of any kind whatsoever arising out of or in connection with this Agreement or the respective rights of the Parties under this Agreement (other than disputes under Section 4.2, which shall be resolved in accordance with the procedures set forth under Section 4.2), either Party shall have the right to seek recourse and to pursue any and all legal and equitable remedies at its disposal with respect to such disputes, differences or claims. In the event any such action shall be brought to enforce or interpret the terms of this Agreement in accordance with this Section 10.3, the Parties agree that such action will be brought in the State or Federal courts located in [*]. Each of MSRx and KemPharm hereby irrevocably submits with regard to any action or proceeding for itself and in respect to its property, generally and unconditionally, to the exclusive jurisdiction of the

aforesaid courts. Each of MSRx and KemPharm hereby irrevocably waives, and agrees not to assert, by way of motion, as a defense, counterclaim or otherwise, in any action or proceeding with respect to this Agreement, (a) any claim that it is not personally subject to the jurisdiction of the above-named courts for any reason other than the failure to lawfully serve process, (b) that it or its property is exempt or immune from jurisdiction of any such court or from any legal process commenced in such courts (whether through service of notice, attachment prior to judgment, attachment in aid of execution of judgment, execution of judgment or otherwise), and (c) to the fullest extent permitted by applicable law, that (i) the suit, action or proceeding in any such court is brought in an inconvenient forum, (ii) the venue of such suit, action or proceeding is improper, and (iii) this Agreement, or the subject matter hereof, may not be enforced in or by such courts.

10.4 Assignment. Except as provided in this Section 10.4, this Agreement may not be assigned to any Third Party by either Party, whether by operation of law or otherwise, without the prior written consent of the other Party; provided, however, that either Party may assign its rights under this Agreement, in whole or in part, without the prior written consent of the other Party to any of its Affiliates, KemPharm may assign its obligations under this Agreement to a wholly-owned subsidiary pursuant to a 355 Spin-off Transaction, and either Party may assign its rights and obligations under this Agreement, in whole, to any purchaser of all or a substantial part of its assets or business, whether by merger, consolidation, reorganization, or sale of stock, subject to the provisions of Sections 4.2. The assignment of a Party's rights under this Agreement in accordance with this Section 10.4 shall be contingent on the delivery of the assigning Party and its Affiliate or Third Party to the other Party of a guarantee of the performance of this Agreement in a form reasonably satisfactory to the other Party. Any purported assignment or transfer in violation of this Section 10.4 shall be void ab initio and of no force or effect. This Agreement shall be binding upon, and subject to the terms of the foregoing sentence, inure to the benefit of the Parties hereto, their permitted successors, legal representatives and assigns.

10.5 Notices. All demands, notices, consents, approvals, reports, requests and other communications hereunder must be in writing and shall be deemed to have been duly given only if delivered personally, by facsimile or email transmission with confirmation of receipt, by mail (first class, postage prepaid), or by overnight delivery using a globally-recognized carrier, to the Parties at the following addresses:

MSRx: MonoSol Rx, LLC
30 Technology Drive
Warren, New Jersey 07059
Attn: President
Telephone: 908-941-1900
Facsimile: 908-561-1209
[*]

KemPhann: KemPharm, Inc.
7 Hawkeye Drive
Suite 103
North Liberty, Iowa 52317
Attn: President
Telephone: 319-665-2575
Facsimile: 319-665-2577
Email: tcmickle@kempharm.com

or to such other address as the addressee shall have last furnished in writing in accord with this provision to the addressor. If a demand, notice, consent, approval, report, request and other communication has been properly sent or delivered in accordance with this clause, it will be

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

deemed to have been received as follows: if delivered personally, at the time of delivery; or if sent by fax, at the time of transmission; or if sent by e-mail, at the time of transmission; if sent by mail, 9:00 am on the fourth Business Day after posting; or if delivered by commercial courier, on the date and at the time of signature of the courier's receipt; or if delivered by overnight delivery using a globally-recognized carrier, 9:00 am on the second working day after posting.

For the purposes of this clause all times are to be read as local time in the place of deemed receipt; and if deemed receipt under this clause is not within business hours (meaning 9:00 am to 5:30 pm Monday to Friday on a day that is not a public holiday in the place of receipt), the demand, notice, consent, approval, report, request and other communication is deemed to have been received when business next starts in the place of receipt.

10.6 Severability. In the event of the invalidity of any provisions of this Agreement or if this Agreement contains any inconsistencies, the Parties agree that such invalidity or inconsistency shall not affect the validity of the remaining provisions of this Agreement. The Parties will replace an invalid provision or correct any inconsistency with valid provisions which most closely approximate the purpose and economic effect of the invalid provision or, in case of an inconsistency, the Parties' presumed intentions. In the event that the terms and conditions of this Agreement are materially altered as a result of the preceding sentences, the Parties shall renegotiate the terms and conditions of this Agreement in order to resolve any inequities. Nothing in this Agreement shall be interpreted so as to require either Party to violate any laws.

10.7 Headings. The headings used in this Agreement have been inserted for convenience of reference only and do not define or limit the provisions hereof.

10.8 Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by any Party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by law or otherwise, will be cumulative and not in the alternative to any other rights or remedies that may be available to such Party.

10.9 Entire Agreement. This Agreement (including the exhibits hereto, which by this reference are incorporated herein and made a part hereof as if set forth verbatim) constitutes the entire agreement between the Parties hereto with respect to the within subject matter and supersedes all previous agreements and understandings between the Parties, whether written or oral, including, without limitation but subject to the rights of MSRx under Section 2.4 above, the CLA. Any and all confidential or proprietary information exchanged between the Parties pursuant to the CLA, the Confidentiality Agreement executed and delivered as of [*], and that certain agreement between the Parties dated [*] and amended on [*], shall be deemed Confidential Information for purposes of and covered by the terms of this Agreement. This Agreement may be altered, amended or changed only by a writing making specific reference to this Agreement and signed by duly authorized representatives of the Parties.

10.10 Third Party Beneficiaries. With the exception of either Party's Affiliates, and with the additional exception of Shire's rights with respect to the Shire Release, none of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including without limitation any creditor of either Party hereto. No such Third Party shall obtain any right under any provision of this Agreement or shall by reasons of any such provision make any Claim in respect of any debt, liability or obligation against either Party hereto. The rights of the Parties to terminate, rescind or agree any variation, waiver or settlement under this Agreement is not subject to the consent of any Third Party that is not a party to this Agreement.

10.11 Counterparts; Facsimile Signatures. This Agreement may be executed in multiple counterparts, all of which, when executed, shall be deemed to be an original and all of which together shall constitute one and the same document. Signatures provided by facsimile transmission shall be deemed to be original signatures.

[Signature Page Follows]

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

IN WITNESS WHEREOF, the Parties have entered into this Agreement as of the Effective Date.

MONOSOL RX, LLC	KEMPHARM, INC.
By: /s/ Alexander M. Schobel	By: /s/ Travis Mickle Travis Mickle, President and CEO

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

EXHIBIT A

Shire Release

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[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

Shire LLC
9200 Brookfield Court
Florence, Kentucky
Telephone 800-828-2088

EXECUTION COPY

March 20, 2012

A. Mark Schobel, President and Chief Executive Officer
MonoSol Rx, LLC
30 Technology Drive
Warren, New Jersey 07059

Re: Collaboration and License Agreement with KemPharm, Inc.

Dear Mr. Schobel:

[* 4 pages of text omitted]

Very truly yours,
Shire LLC

By: _____
Name: Mike Chapman, President
Title: _____
Date: _____

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

ACKNOWLEDGED AND AGREED:
MonoSol Rx, LLC

By: _____
A. Mark Schobel, President and Chief Executive Officer

Date: _____

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

EXHIBIT B

VALUATION TERMS

Any valuation conducted pursuant to Section 4.2 shall be in accordance with the following:

1. Any valuation expert utilized for the purposes of assessing and/or determining Value associated with KP415 pursuant to Section 4.2 shall be at least a credentialed partner or director from a certified public accounting firm or investment bank with which neither Party (nor their Affiliates) has had any past, material relationship. The Parties agree that any determination of the Value reasonably attributable to the KemPharm Sale Price by such independent valuation experts shall be conducted as a valuation engagement as defined by the Statement on Standards for Valuation Services (SSVS) of the American Institute of Certified Public Accountants and in accordance with SSVS. The determination of Value resulting from the valuation engagement shall be expressed as a conclusion of value as defined by SSVS and, as it relates to the all of the valuation experts performing such valuation, communicated in a detailed report as defined by SSVS.

2. Notwithstanding the requirements of SSVS, the valuation expert, at a minimum, shall consider the following with respect to KP415:

[*]

3. Notwithstanding the requirements of SSVS, the valuation expert, at a minimum, shall consider criteria substantially similar to the above paragraphs 2.A-I, with respect to each of the other assets included in the KemPharm Sale Transaction.

4. The valuation expert shall assign a valuation of the overall portfolio of tangible and intangible assets that are included the KemPharm Sale Transaction as a going concern, taking into consideration the individual value of each of such tangible and intangible assets.

5. Each of the Parties agree that it shall provide to the valuation expert a copy of this provision for instruction in connection with such independent valuation expert's determination of the Value.

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

EXHIBIT 31.1

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.

November 14, 2019

/s/ Travis C. Mickle

Name: Travis C. Mickle, Ph.D.

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

EXHIBIT 31.2

CERTIFICATIONS

I, R. LaDuane Clifton, certify that:

1. I have reviewed this 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.

November 14, 2019

/s/ R. LaDuane Clifton

Name: R. LaDuane Clifton, CPA

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

EXHIBIT 32.1

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

In connection with the Quarterly Report on Form 10-Q of KemPharm, Inc., (the "Company") for the quarterly period ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Travis C. Mickle, Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

November 14, 2019

/s/ Travis C. Mickle

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

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

EXHIBIT 32.2

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

In connection with the Quarterly Report on Form 10-Q of KemPharm, Inc., (the "Company") for the quarterly period ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, R. LaDuane Clifton, Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

November 14, 2019

/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.