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, 2015

OR

o **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.)**
2656 Crosspark Road, Suite 100, Coralville, IA	**52241**
(Address of principal executive offices)	**(Zip Code)**

(319) 665-2575

(Registrant's telephone number, including area code)

(Former name, former address, and former fiscal year if changed since last report)

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 o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No o

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

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	☒ (Do not check if a smaller reporting company)	Smaller reporting company	o

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

Total shares of common stock outstanding as of November 11, 2015: 14,448,826

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KEMPHARM, INC.

PART I

FINANCIAL INFORMATION

Item 1. Financial Statements.

KEMPHARM, INC.
UNAUDITED CONDENSED BALANCE SHEETS
(In Thousands, Except Share and Par Value Amounts)

	As of September 30, 2015 (unaudited)	As of December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 59,009	$ 10,255
Prepaid expenses and other current assets	607	23
Total current assets	59,616	10,278
Debt issuance costs, net	1,215	1,468
Property and equipment, net	386	352
Other long-term assets	199	1,616
Total assets	$ 61,416	$ 13,714
Liabilities, redeemable convertible preferred stock, and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,031	$ 3,711
Current portion of convertible notes	1,097	77
Current portion of term notes	1,632	115
Current portion of capital lease obligation	32	32
Total current liabilities	6,792	3,935
Convertible notes, net	7,708	7,235
Term notes, net	11,562	10,853
Derivative and warrant liability	41,097	15,966
Capital lease obligation, net	3	26
Total liabilities	67,162	38,015
Commitments and contingencies (Note D)		
Redeemable convertible preferred stock:		
Series A redeemable convertible preferred stock, $0.0001 par value; no shares authorized, issued or outstanding as of September 30, 2015 (unaudited); 9,705,000 authorized, 9,704,215 shares issued and outstanding as of December 31, 2014	—	3,343
Series B redeemable convertible preferred stock, $0.0001 par value; no shares authorized, issued or outstanding as of September 30, 2015 (unaudited); 6,220,000 shares authorized, issued and outstanding as of December 31, 2014	—	3,313
Series C redeemable convertible preferred stock, $0.0001 par value; no shares authorized, issued or outstanding as of September 30, 2015 (unaudited); 18,558,000 shares authorized, 18,557,408 shares issued and outstanding as of December 31, 2014	—	11,892
Series D redeemable convertible preferred stock, $0.0001 par value; no shares authorized, issued or outstanding as of September 30, 2015 (unaudited); 75,000,000 shares authorized, 7,255,425 shares issued and outstanding as of December 31, 2014	—	5,659
Series D-1 redeemable convertible preferred stock, $0.0001 par value, no shares authorized, issued or outstanding as of September 30, 2015 (unaudited) or December 31, 2014, respectively	—	—
Total redeemable convertible preferred stock	—	24,207
Stockholders' deficit:		
Common stock, $0.0001 par value, 250,000,000 shares authorized, 14,241,562 shares issued and outstanding as of September 30, 2015 (unaudited); $0.0001 par value, 140,000,000 shares authorized, 2,381,041 shares issued and outstanding as of December 31, 2014	3	2
Additional paid-in capital	89,873	1,650
Preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of September 30, 2015 (unaudited) or December 31, 2014, respectively	—	—
Accumulated deficit	(95,622)	(50,160)
Total stockholders' deficit	(5,746)	(48,508)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	$ 61,416	$ 13,714

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,	
	2015	2014	2015	2014
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	4,328	3,253	9,215	6,006
General and administrative	2,152	1,086	6,317	2,949
Total operating expenses	6,480	4,339	15,532	8,955
Loss from operations	(6,480)	(4,339)	(15,532)	(8,955)
Other income (expenses):				
Gain on extinguishment of debt	—	—	—	1,900
Amortization of debt discount	(479)	(477)	(1,434)	(636)
Interest expense	(687)	(173)	(1,973)	(974)
Fair value adjustment	(2,089)	(2,189)	(26,512)	(4,002)
Interest and other income	11	3	17	3
Total other expenses	(3,244)	(2,836)	(29,902)	(3,709)
Loss before income taxes	(9,724)	(7,175)	(45,434)	(12,664)
Income tax (expense) benefit	(20)	38	(27)	49
Net loss	$ (9,744)	$ (7,137)	$ (45,461)	$ (12,615)
Net loss per share:				
Basic and diluted	$ (0.68)	$ (3.00)	$ (4.71)	$ (5.30)
Weighted average common shares outstanding:				
Basic and diluted	14,232,133	2,381,041	9,643,231	2,381,041

See Accompanying Notes to Unaudited Condensed Financial Statements.

KEMPHARM, INC.
UNAUDITED CONDENSED STATEMENTS OF CASH FLOWS
(In Thousands)

	Nine Months Ended September 30,	
	2015	**2014**
Cash flows from operating activities:		
Net loss	$ (45,461)	$ (12,615)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on extinguishment of debt	—	(1,900)
Stock-based compensation expense	1,456	169
Non-cash interest expense	1,956	972
Amortization of debt issuance costs and debt discount	1,434	636
Depreciation and amortization expense	61	56
Fair value adjustment	26,512	4,002
Change in assets and liabilities:		
Prepaid expenses and other assets	(576)	(536)
Accounts payable and accrued expenses	(1,784)	1,316
Current portion of convertible notes	1,020	77
Current portion of term notes	1,517	115
Net cash used in operating activities	(13,865)	(7,708)
Cash flows from investing activities:		
Proceeds from sale of asset	—	2
Purchases of property and equipment	(95)	(19)
Net cash used in investing activities	(95)	(17)
Cash flows from financing activities:		
Proceeds from initial public offering, net of underwriting discounts and commissions	59,892	—
Proceeds from issuance of Series D-1 Preferred Stock	4,000	—
Payment of deferred offering costs	(1,244)	—
Proceeds from issuance of debt	—	25,000
Repayment of line of credit	—	(35)
Payment of debt and stock issuance costs	—	(163)
Repayment of obligations under capital lease	(24)	(24)
Proceeds from exercise of Series D Preferred Stock warrants	2	—
Proceeds from exercise of common stock options and warrants	88	—
Net cash provided by financing activities	62,714	24,778
Net increase in cash and cash equivalents	48,754	17,053
Cash and equivalents, beginning of period	10,255	1,969
Cash and equivalents, end of period	$ 59,009	$ 19,022
Supplemental cash flow information:		
Cash paid for interest	$ —	$ 1
Conversion of preferred stock into common stock upon initial public offering	28,209	—
Offering expense charged to equity	2,812	—
Reclassification of 2013 warrants to equity	1,110	—
Transfer of warrants to equity upon exercise	281	—
Capitalization of patents	162	—
Conversion of 2013 Convertible Notes into Series D Preferred Stock	—	4,160
Issuance of Deerfield warrant allocated to debt discount	—	7,610
Embedded Deerfield put option allocated to debt discount	—	220
Issuance of Series D Preferred Stock as transaction fee	—	1,500
Deferred offering costs included in accounts payable and accrued expense	—	313

See Accompanying Notes to Unaudited Condensed Financial Statements.

A. Description of Business and Basis of Presentation

Organization

KemPharm, Inc. (the "Company") is a clinical-stage specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs. The Company was formed on October 30, 2006, and incorporated in Iowa, and reorganized in Delaware on May 30, 2014. Through the use of its Ligand Activated Therapy ("LAT") platform technology, the Company is able to initiate and pursue the development of improved versions of widely prescribed, approved drugs.

The Company has experienced recurring losses from operations and negative operating cash flows due to its ongoing research and development of its potential product candidates. Various internal and external factors will affect whether and when the candidates become approved drugs and how significant their market share will be. The length of time and cost of developing and commercializing these candidates and/or failure of them at any stage of the drug approval process will materially affect the Company's financial condition and future operations.

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America 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 accounting principles generally accepted in the United States of America 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, 2015, are not necessarily indicative of the results that may be expected for the full year ending December 31, 2015.

This interim information should be read in conjunction with the audited financial statements included in the Company's prospectus dated April 15, 2015, and filed with the Securities and Exchange Commission ("SEC") pursuant to Rule 424 promulgated under the Securities Act of 1933, as amended.

Reverse Stock Split

In April 2015, the Company effected a 1-for-7.5 reverse stock split of its issued common stock. All applicable share data, per share amounts and related information in the unaudited condensed financial statements and notes thereto have been adjusted retroactively to give effect to the 1-for-7.5 reverse stock split.

Initial Public Offering

In April 2015, the Company completed an initial public offering ("IPO") of its common stock. In connection with the initial closing of the IPO, the Company sold an aggregate of 5,090,909 shares of common stock at a price to the public of $11.00 per share. In May 2015, the underwriters in the IPO exercised their option to purchase additional shares pursuant to which the Company sold an additional 763,636 shares of common stock at a price equal to the public price of $11.00 per share. In the aggregate, net proceeds from the IPO including net proceeds from the underwriters' exercise of their option to purchase additional shares, were $59.9 million, after deducting underwriting discounts and commissions of $4.5 million. In addition, offering expenses totaled $2.8 million. Upon completion of the IPO, all outstanding shares of the Company's redeemable convertible preferred stock were converted or reclassified into 5,980,564 shares of common stock and all outstanding warrants to acquire shares of the Company's redeemable convertible preferred stock became warrants to acquire the Company's common stock. In connection with the IPO, the Company amended and restated its Amended and Restated Certificate of Incorporation to change the authorized capital stock to 250,000,000 shares, designated as common stock, and 10,000,000 shares, designated as preferred stock, each with a par value of $0.0001 per share.

Reclassifications

Certain prior year amounts have been reclassified to conform to the current year presentation. These reclassifications had no effect on previously reported net loss.

B. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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, including those related to the useful lives of property and equipment, the fair value of the Company's common stock prior to the IPO 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 judgements about the carrying value of assets and liabilities.

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.

On April 5, 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 may elect 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 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 July 2013, the FASB issued Accounting Standards Update ("ASU") No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exist* ("ASU 2013-11"). ASU 2013-11 amends the presentation requirements of Accounting Standards Codification ("ASC") Topic 740 Income Taxes and requires an unrecognized tax benefit to be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, similar tax loss, or a tax credit carryforward. To the extent the tax benefit is not available at the reporting date under the governing tax law or if the entity does not intend to use the deferred tax asset for such purpose, the unrecognized tax benefit should be presented as a liability and not combined with deferred tax assets. ASU 2013-11 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The amendments are to be applied to all unrecognized tax benefits that exist as of the effective date and may be applied retrospectively to each prior reporting period presented. The Company adopted the new standard effective January 1, 2014. The adoption of ASU 2013-11 did not have a material impact on the Company's financial statements as no uncertain tax positions existed as of December 31, 2014 and September 30, 2015.

In June 2014, the FASB issued ASU No. 2014-10, *Development Stage Entities* (Topic 915): *Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation* ("ASU 2014-10"). This ASU removes all incremental financial reporting requirements for development stage entities, including the removal of ASC Topic 915. The amendments in this ASU eliminate certain disclosure requirements to (1) present inception-to-date information in the statements of operations, cash flows and stockholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. The ASU clarifies that disclosures about risks and uncertainties required by ASC Topic 275 also apply to entities that have not commenced planned principal operations.

The Company early adopted ASU 2014-10. The amendments primarily relate to disclosure matters and, therefore, had no impact on the Company's financial statements, other than the elimination of previously required disclosures including inception-to-date financial information.

Application of New or Revised Accounting Standards—Not Yet Adopted

In June 2014, the FASB issued ASU 2014-12, *Compensation-Stock Compensation (ASC Topic 718): Accounting for Share-Based Payments when the Terms of an Award Provide that a Performance Target Could Be Achieved After the Requisite Service Period* ("ASU 2014-12"). The amendments require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. ASU 2014-12 is effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Earlier adoption is permitted. Entities may apply ASU 2014-12 either (a) prospectively to all awards granted or modified after the effective date or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified

awards thereafter. If retrospective transition is adopted, the cumulative effect of applying this ASU as of the beginning of the earliest annual period presented in the financial statements should be recognized as an adjustment to the opening retained earnings balance at that date. Additionally, if retrospective transition is adopted, an entity may use hindsight in measuring and recognizing the compensation cost. The Company currently is evaluating the impact of the adoption of ASU 2014-12 on its financial statements and disclosures.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15"), which amends ASC Subtopic 205-40 to provide guidance about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related disclosures. Specifically, the amendments (1) provide a definition of the term "substantial doubt," (2) require an evaluation every reporting period, (3) provide principles for considering the mitigating effect of management's plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated and (6) require an assessment for a period of one year after the date that financial statements are issued. ASU 2014-15 is effective for fiscal years ending after December 15, 2016, and for annual periods and interim periods thereafter. The Company is currently evaluating the impact of the adoption of ASU 2014-15 on its financial statements and disclosures.

In May 2014, the FASB issued ASU No. 2014-09, amending revenue guidance to clarify the principles for recognizing revenue from contracts with customers. The guidance requires an entity to recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which an entity expects to be entitled in exchange for those goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. In August 2015, the FASB issued ASU No. 2015-14, which makes the guidance effective for the Company's interim and annual periods beginning January 1, 2018. The Company is currently evaluating the impact of this guidance on its financial statements and disclosures.

In April 2015, the FASB issued ASU 2015-03, *Interest—Imputation of Interest (Subtopic 835-30)* ("ASU 2015-03"), which requires the debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with the presentation of debt discounts. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Adoption of this ASU will reduce assets and liabilities by the amount of the debt issuance costs, which are $1.2 million and $1.5 million at September 30, 2015 and December 31, 2014, respectively.

C. Debt Obligations

Deerfield Facility Agreement

On June 2, 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 Notes") and a senior secured loan of $10 million (the "Deerfield Convertible Notes"). All loans issued under the Deerfield Facility Agreement bear interest at 9.75% per annum. Deerfield may convert any portion of the outstanding principal and any accrued but unpaid interest on the Deerfield Convertible Notes into shares of the Company's common stock at an initial conversion price of $5.85 per share. At its option, the Company may convert the outstanding principal and accrued interest under the Deerfield Convertible Notes into shares of the Company's common stock at an initial conversion price of $5.85 per share if either of the following occurs prior to June 30, 2016: (i) the FDA has approved, without requiring the performance of an efficacy study, a new drug application ("NDA") for the Company's product candidate, KP201/APAP, which consists of KP201, the Company's prodrug of hydrocodone, formulated in combination with acetaminophen ("APAP") for the treatment of acute pain; or (ii) the FDA has accepted the NDA for KP201/APAP for review and a qualified initial public offering, as defined in the Deerfield Facility Agreement, has occurred.

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 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. In the event that a Major Transaction occurs, as defined below, Deerfield may require the Company 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 "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 of $7.6 million and the fair value of the embedded Put Option of $220,000 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 in the statements of operations.

The Company must 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. The Company is then obligated to repay the balance of the outstanding principal amount on February 14, 2020.

Interest accrued on outstanding debt under the Deerfield Facility Agreement is due quarterly in arrears. Upon notice to Deerfield, the Company may choose 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 will be due on July 1, 2016. The Company has elected this option on all five of the scheduled interest payments to date. The accrued interest added to outstanding principal is reflected in the condensed balance sheets as current portion of convertible notes and current portion of term notes.

Deerfield is obligated to provide three additional tranches upon the Company's request and after the satisfaction of specified conditions, including the FDA's acceptance of an NDA for KP201/APAP, and, for the final two tranches, the subsequent approval for commercial sale thereof.

As of September 30, 2015, borrowings available to the Company under the Deerfield Facility Agreement were $35 million. Under the terms of the Deerfield Facility Agreement, future tranches to the Company are as follows:

- The second tranche consists of a $10.0 million term loan that bears interest at 9.75% and a warrant to purchase 1,282,052 shares of the Company's common stock at an exercise price of $5.85 per share.
- The third and fourth tranches each consist of a $12.5 million term loan that bears interest at 9.75% and a warrant exercisable for the number of shares equal to 60% of the principal amount of such disbursement divided by 115% of the volume weighted average sales price of the Company's common stock for the 20 consecutive trading days immediately prior to the date of such disbursement with an exercise price per share equal to such weighted average sales price.

Conversion of 2013 Convertible Notes into Series D Preferred

From June 2013 through October 2013, the Company issued 10.0% unsecured convertible promissory notes (the "2013 Convertible Notes") for gross proceeds of $3.8 million. The 2013 Convertible Notes accrued interest from the date of issuance through the maturity date, with such interest payable in cash upon maturity. The 2013 Convertible Notes did not have a stated maturity date and instead matured under various scenarios, such as the sale of substantially all of the assets of the Company, dissolution of the Company, failure to observe covenants, and voluntary or involuntary bankruptcy. In accordance with the terms of the 2013 Convertible Notes, and effected by the written consent of the holders of a majority of the outstanding principal of such notes, on June 2, 2014, the principal amount of the 2013 Convertible Notes of $3.8 million and all accrued interest of $0.3 million converted into 5,332,348 shares of Series D Preferred at $0.78 per share. Upon the conversion of the 2013 Convertible Notes, the embedded conversion feature of the 2013 Convertible Notes and Put Option was marked to fair value and the balance of $1.9 million was recorded as a gain on extinguishment of debt.

Line of Credit

The Company has a $50,000 credit agreement with a financial institution (the "Line of Credit Agreement"). As of September 30, 2015 and December 31, 2014, the Company had $50,000 available under the Line of Credit Agreement. The Line of Credit Agreement is collateralized by all of the Company's business assets as well as the personal guarantees of the Company's officers. The Line of Credit Agreement contains no financial covenants. Borrowings under the Line of Credit Agreement carry interest at a rate equal to the prime rate plus 1.75% per annum. The Company is required to make interest only payments on any draws under the Line of Credit Agreement. The interest rate under the Line of Credit Agreement was 5% for the three and nine months ended September 30, 2015, and September 30, 2014.

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.

In 2014, a former financial advisor of the Company filed a request with the Iowa District Court to declare valid a purported right of first refusal to serve as the Company's exclusive financial advisor for specified strategic transactions and to receive fees for the specified strategic transactions irrespective of whether any such specified transaction occurred during or after the term of the financial advisor's service agreement. This filing by the former financial advisor was made in response to an action initiated by the Company in 2013 seeking a declaratory judgement finding that such purported right was invalid and unenforceable. Two former members of the Company's board of directors (the "Board") joined the lawsuit as intervenors based on the former financial advisor's purported assignment of its rights, or a portion thereof, under the agreement to the intervenors. In September 2015, the court granted summary judgement in favor of the Company with respect to the Company's declaratory judgement action and the former financial advisor's counterclaims and the Company separately entered into settlement agreements with each of the intervenors. The settlements reached with the intervenors did not differ from the accrual previously recorded by the Company by a material amount. The former financial advisor subsequently filed a notice of appeal of the court's ruling with the Supreme Court of Iowa and the appeal is pending. The Company is unable to predict the timing or ultimate outcome of this litigation as of the date of this report. However, if it is determined that such purported right of first refusal and right to receive a cash fee related to any such specified strategic transactions are valid, then the Company could be required to pay the counterparty a portion of the consideration or proceeds received in any such specified strategic transaction, potentially including the Deerfield Facility Agreement, the IPO, the sale of the Company's Series D-1 redeemable convertible preferred stock ("Series D-1 Preferred") to Cowen KP Investment LLC ("Cowen"), and future capital raising and other strategic transactions.

E. Redeemable Convertible Preferred Stock and Warrants

Authorized, Issued, and Outstanding Redeemable Convertible Preferred Stock

In April 2015, the Company amended and restated its Certificate of Incorporation to decrease the number of its authorized shares of preferred stock to 10,000,000 shares with a par value of $0.0001 per share. As described in Note A, in April 2015, the Company completed an IPO of its common stock. Upon completion of the IPO, all outstanding shares of the Company's redeemable convertible preferred stock were automatically converted or reclassified into an aggregate of 5,980,564 shares of the Company's common stock. As of September 30, 2015, the Company had 10,000,000 shares of authorized and undesignated preferred stock, and did not have any preferred stock outstanding.

Preferred Stock Activity

The following table summarizes redeemable convertible preferred stock activity for the nine months ended September 30, 2015:

	Shares of					
	Series A Preferred	Series B Preferred	Series C Preferred	Series D Preferred	Series D-1 Preferred	Total
Balance, December 31, 2014	9,704,215	6,220,000	18,557,408	7,255,425	—	41,737,048
Issuance of Series D-1 Preferred Stock	—	—	—	—	3,200,000	3,200,000
Exercise of Series D Preferred Warrants	—	—	—	3,205	—	3,205
Less: Conversion of Preferred Stock into Common Stock upon IPO	(9,704,215)	(6,220,000)	(18,557,408)	(7,258,630)	(3,200,000)	(44,940,253)
Balance, September 30, 2015	—	—	—	—	—	—

Series D-1 Redeemable Convertible Preferred Stock

In February 2015, the Company entered into a stock purchase agreement with Cowen in which Cowen agreed to purchase and the Company agreed to sell 3,200,000 shares of the Company's Series D-1 Preferred for $1.25 per share, or an aggregate of $4 million. Upon completion of the IPO, these shares automatically converted into 415,584 shares of the Company's common stock.

Warrants

As described in Note A, in April 2015, the Company completed an IPO of its common stock. Upon completion of the IPO, and as of September 30, 2015, warrants to purchase 15,499,324 shares of Series D Preferred were reclassified into warrants to purchase 2,066,543 shares of the Company's common stock. As of December 31, 2014, the Company had outstanding warrants to purchase 15,502,529 shares of Series D Preferred at an exercise price of $0.78 per share. During the nine months ended September 30, 2015, warrants to purchase 3,205 shares of Series D Preferred were exercised.

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 criteria (a "Qualified Financing") (Note C). 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, if unexercised, expire on the earlier of June 2, 2019, or upon a liquidation event.

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 to interest expense over the term of the Term Notes and the Deerfield Convertible Notes.

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 determined that the 2013 Warrants should be marked to fair value and reclassified 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 statements of operations as a fair value adjustment (Note H).

F. Common Stock and Warrants

Authorized, Issued, and Outstanding Common Shares

In April 2015, the Company amended and restated its Certificate of Incorporation to increase the number of its authorized shares of common stock to 250,000,000 shares. Of the authorized shares, 14,241,562 and 2,381,041 shares of common stock were issued and outstanding at September 30, 2015 and December 31, 2014, respectively.

At September 30, 2015 and December 31, 2014, the Company had reserved authorized shares of common stock for future issuance as follows:

	September 30, 2015	December 31, 2014
Conversion of Series A Preferred	—	1,293,838
Conversion of Series B Preferred	—	829,234
Conversion of Series C Preferred	—	2,474,121
Conversion of Series D Preferred	—	967,359
Conversion of Series D-1 Preferred	—	—
Conversion of Deerfield Convertible Notes	1,943,458	1,808,353
Outstanding awards under equity incentive plans	1,390,438	395,185
Outstanding common stock warrants	2,636,180	595,920
Outstanding Series D Preferred warrants	—	2,066,970
Possible future issuances under equity incentive plans	1,422,498	365,706
Total common shares reserved for future issuance	7,392,574	10,796,686

Common Stock Activity

The following table summarizes common stock activity for the nine months ended September 30, 2015:

	Shares of Common Stock
Beginning balance at December 31, 2014	2,381,041
Issuance of common stock in connection with initial public offering	5,854,545
Conversion of preferred stock to common stock in connection with initial public offering	5,980,564
Common stock warrants exercised	24,746
Common stock options exercised	666
Ending balance at September 30, 2015	14,241,562

The Company calculates the fair value of common stock warrants using a Monte Carlo simulation. There were warrants exercised for an aggregate of 24,746 shares of common stock during the nine months ended September 30, 2015, and there were no warrants exercised in the nine months ended September 30, 2014. From 2008 through 2012, the Company issued warrants to purchase 595,920 shares of common stock in its private placement offerings of Series A Preferred, Series B Preferred and Series C Preferred (the "Underwriter Warrants") and for leasing laboratory space. The Company accounted for the Underwriter Warrants as a derivative liability, which is adjusted to fair value at each reporting period, with the change in fair value recorded within other expenses in the statements of operations.

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, 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 and, effective as of such time the Company determined not to make any further grants under the Incentive Stock Plan. 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 2,266,666. In addition, 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.

During the three and nine months ended September 30, 2015, stock options to acquire 666 shares of common stock were exercised. No stock options were exercised during the three and nine months ended September 30, 2014.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Research and development	$ 83	$ 21	$ 308	$ 37
General and administrative	409	31	1,148	132
	$ 492	$ 52	$ 1,456	$ 169

During the nine months ended September 30, 2015, the Company recognized $0.7 million of stock-based compensation expense related to performance-based awards included in general and administrative expenses and $0.1 million of stock-based compensation expense related to performance-based awards included in research and development expenses. These awards were in connection with the grant of fully vested stock options exercisable for an aggregate of 134,665 shares of common stock during the first quarter of 2015 and upon completion of the IPO during the second quarter of 2015. During the three months ended September 30, 2015, no stock-based compensation expense related to performance-based awards was included in general and administrative expenses or research and development expenses. The Company did not recognize any stock-based compensation expense related to performance-based incentive awards during the three and nine months ended September 30, 2014, since the strategic initiatives set for the awards were not achieved or probable of achievement.

H. Fair Value of Financial Instruments

The carrying amounts of certain financial instruments, including cash and cash equivalents and accounts payable, approximate their respective fair values due to the short-term nature of such instruments. The carrying amount of the line of credit approximates fair value due to the variable interest rate in that instrument.

The fair value of the Deerfield Convertible Notes and the Term Notes was $41.4 million and $13.5 million, respectively, at September 30, 2015. Both the Deerfield Convertible Notes and the Term 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.

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 judgements to be made. The following table summarizes the conclusions reached regarding fair value measurements as of September 30, 2015, and December 31, 2014 (in thousands):

	Balance at September 30, 2015	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Underwriter Warrant liability	$ 7,674	$ —	$ —	$ 7,674
Deerfield Warrant liability	32,615			32,615
Embedded Put Option	808	—	—	808
	$ 41,097	$ —	$ —	$ 41,097

	Balance at December 31, 2014	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Underwriter Warrant liability	$ 2,746	$ —	$ —	$ 2,746
2013 Warrant liability	520	—	—	520
Deerfield Warrant liability	12,560	—	—	12,560
Embedded Put Option	140	—	—	140
	$ 15,966	$ —	$ —	$ 15,966

The Company's Underwriter Warrant liability, Deerfield Warrant liability, and the embedded Put Option on the Deerfield Warrant are measured at fair value on a recurring basis. The 2013 Warrant liability was recorded at fair value on a recurring basis through the completion of the IPO. As of September 30, 2015 and December 31, 2014, the Underwriter Warrant liability, the Deerfield Warrant liability and the embedded Put Option are reported on the balance sheet in derivative and warrant liability. As of December 31, 2014, the 2013 Warrant liability was reported on the balance sheet in derivative and warrant liability. Upon closing of the IPO in April 2015, the 2013 Warrant liability was marked to fair value and then reclassified to equity. The Company used a Monte Carlo simulation to value the Underwriter Warrant liability and the embedded Put Option at September 30, 2015 and December 31, 2014. The Company used a Monte Carlo simulation to value the 2013 Warrant liability as of December 31, 2014, and the closing date of the IPO. 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 event, a present value discount rate and an estimate of the Company's stock volatility using the volatilities of guideline peer companies. Changes in the fair value of the Underwriter Warrant liability, the 2013 Warrant liability, the Deerfield Warrant liability and the embedded Put Option are reflected in the statements of operations as a fair value adjustment. A 10% increase in the enterprise value would result in an increase of $1.0 million in the estimated fair value of the Underwriter Warrant liability, an increase of $3.6 million in the estimated fair value of the Deerfield Warrant liability, and no change in the estimated fair value of the embedded Put Option at September 30, 2015.

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,	
	2015	2014	2015	2014
Balance at beginning of period	$ 39,279	$ 10,555	$ 15,966	$ 2,812
Issuance of Deerfield Warrant	—	—	—	7,610
Embedded Put Option	—	—	—	220
Conversion of 2013 Convertible Notes	—	—	—	(1,900)
Reclassification of 2013 Warrants to equity	—	—	(1,110)	—
Exercise of warrants	(271)	—	(271)	—
Adjustment to fair value	2,089	2,189	26,512	4,002
Balance at end of period	$ 41,097	$ 12,744	$ 41,097	$ 12,744

I. Net Loss Per Share

Under the two-class method, for periods with net income, basic net income per common share is computed by dividing the net income attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Net income attributable to common stockholders is computed by subtracting from net income the portion of current year earnings that participating securities would have been entitled to receive pursuant to their dividend rights had all of the year's earnings been distributed. No such adjustment to earnings is made during periods with a net loss as the holders of the participating securities have no obligation to fund losses. Diluted net loss per common share is computed under the two-class method by using the weighted average number of shares of common stock outstanding plus, for periods with net income attributable to common stockholders, the potential dilutive effects of stock options and warrants. In addition, the Company analyzes the potential dilutive effect of the outstanding participating securities under the if-converted method when calculating diluted earnings per share in which it is assumed that the outstanding participating securities convert or reclassified into common stock at the beginning of the period. The Company reports the more dilutive of the approaches (two-class or if-converted) as its diluted net income per share during the period. Due to the existence of net losses for the three and nine month periods ended September 30, 2015 and 2014, basic and diluted loss per share were the same, as the effect of potentially dilutive securities would have been anti-dilutive.

The following securities, presented on a common stock equivalent basis, have been excluded from the calculation of weighted average common shares outstanding because their effect is anti-dilutive:

	Three and Nine Months Ended September 30,	
	2015	2014
Redeemable convertible preferred stock:		
Series A	—	1,293,895
Series B	—	829,333
Series C	—	2,474,322
Series D	—	967,390
Series D-1	—	—
Total redeemable convertible preferred stock	—	5,564,940
Warrants to purchase common stock	2,636,180	596,104
Deerfield warrant to purchase Series D Preferred Stock	—	1,923,077
Warrants to purchase Series D Preferred Stock	—	1,823,827
Awards under equity incentive plans	1,390,438	395,200
Deerfield Convertible Notes	1,943,458	1,764,518
Total	5,970,076	12,067,666

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 in conjunction with our unaudited condensed financial statements and related notes included in Part I, Item 1 of this report. This discussion and other parts of this report contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report entitled "Risk factors."

Unless the context otherwise requires, we use the terms "KemPharm," "company," "we," "us" and "our" in this report to refer to KemPharm, Inc.

Forward-Looking Statements

This discussion contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are identified by words such as "believe," "will," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms or similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part II, Item 1A — "Risk Factors," and elsewhere in this report. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Overview

We are a clinical-stage specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs that we believe will be improved versions of widely prescribed, approved drugs. We employ our Ligand Activated Therapy, or LAT, platform technology to create our prodrugs, which in some cases may be eligible for composition-of-matter patent protection. Our most advanced product candidate is KP201/APAP, which consists of KP201, the company's prodrug of hydrocodone, formulated in combination with acetaminophen, or APAP. We are developing KP201/APAP as an immediate release, or IR, Hydrocodone product candidate for the treatment of acute moderate to moderately severe pain. We intend to submit a new drug application, or NDA, under 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or Section 505(b)(2), for KP201/APAP to the U.S. Food and Drug Administration, or the FDA, as early as the end of 2015. We are also building a pipeline of additional prodrug product candidates that target large market opportunities in pain, attention deficit hyperactivity disorder, or ADHD, and other central nervous system indications. We own worldwide commercial rights for all of our product candidates, including KP201/APAP, except that Shire Pharmaceuticals, LLC, or Shire, has a right of first refusal to acquire, license or commercialize our prodrug of methylphenidate or KP415, which we are developing for the treatment of ADHD.

We are a development stage company and have not generated any revenue. We have incurred losses since our inception and, as of September 30, 2015, had an accumulated deficit of $95.6 million. Our net losses for the nine months ended September 30, 2015 and 2014 were $45.5 million and $12.6 million, respectively. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, which may fluctuate significantly from quarter-to-quarter and year-to-year.

Our commercial revenue, if any, will be derived from sales of prodrug products that we do not expect to be commercially available for several years, if at all. 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 convertible debt securities, or exercise our right to borrow additional tranches under our $60 million facility agreement, dated as of June 2, 2014, or the Deerfield Facility Agreement, with Deerfield Private Design Fund III, LP, or Deerfield, the terms of these securities or this debt may restrict our ability to operate. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

Third-Party Agreements

In November 2009, we entered into a supply agreement with Johnson Matthey Inc., or JMI, pursuant to which JMI has agreed to supply us with all of the KP201 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 KP201. In exchange, we issued shares of our common stock to JMI, provided that the commercial supply arrangement for KP201 would be exclusive to JMI in the United States and agreed to pay JMI royalties on the net sales of KP201/APAP, if approved by the FDA. The percentage royalty rate ranges from the high teens at low volumes to the mid-single digits at higher volumes.

We are responsible for all costs of any KP201 manufactured during a specified validation process for KP201. After completion of the validation process, but prior to the commercial launch of KP201, JMI will manufacture the registration batches of KP201 at a price to be negotiated. Failure to agree upon this pricing would result in JMI supplying the registration 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. After the commercial launch of KP201/APAP, JMI will manufacture and supply KP201 at a price equal to JMI's fully allocated manufacturing cost.

We must purchase all of our U.S. KP201 needs from JMI and JMI cannot supply KP201 to other companies. After the commercial launch of KP201, JMI is required to identify a secondary manufacturing site and qualify and validate that site for the production of KP201.

The term of the supply agreement extends as long as we hold a valid and enforceable patent for KP201 or until the tenth anniversary of KP201's commercial launch, whichever date is later. Upon the expiration of such term, the agreement will automatically renew for a period of two years unless either party provides 12 months prior notice of its intent not to renew.

Under our March 2012 asset purchase agreement with Shire, Shire has a right of first refusal to acquire, license or commercialize KP415.

Under our March 2012 termination agreement with MonoSol Rx, LLC, or MonoSol, MonoSol has the right to receive an amount equal to a percentage in the low teens of any value generated by KP415, and any product candidates arising therefrom, including royalty payments on any license of KP415, the sale of KP415 to a third party, the commercialization of KP415 and the portion of any consideration that is attributable to the value of KP415 and paid to us or our stockholders in a change of control transaction.

We plan to increase our research and development expenses for the foreseeable future as we continue our effort to develop KP201/APAP and to further advance the development of our other product candidates, subject to the availability of additional funding.

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

Results of Operations

Comparison of the Three Months Ended September 30, 2015 and 2014 (in thousands):

	Three Months Ended September 30, 2015	2014	Period-to-Period Change
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	4,328	3,253	1,075
General and administrative	2,152	1,086	1,066
Total operating expenses	6,480	4,339	2,141
Loss from operations	(6,480)	(4,339)	(2,141)
Other income (expenses):			
Gain on extinguishment of debt	—	—	—
Amortization of debt discount	(479)	(477)	(2)
Interest expense	(687)	(173)	(514)
Fair value adjustment	(2,089)	(2,189)	100
Interest and other income	11	3	8
Total other expenses	(3,244)	(2,836)	(408)
Loss before income taxes	(9,724)	(7,175)	(2,549)
Income tax (expense) benefit	(20)	38	(58)
Net loss	$ (9,744)	$ (7,137)	$ (2,607)

Research and Development

Research and development expenses increased by $1.0 million, from $3.3 million for the three months ended September 30, 2014 to $4.3 million for the three months ended September 30, 2015. This increase was primarily attributable to a $0.3 million increase in salaries and personnel-related costs due to increased headcount, a $0.4 million increase in contracted third-party research and development spending on KP201/APAP, a $0.2 million increase in contracted third-party research and development spending on KP511 and KP415, and a $0.1 million increase in stock-based compensation expense related to the vesting of stock awards during the three months ended September 30, 2015.

General and Administrative

General and administrative expenses increased by $1.1 million, from $1.1 million for the three months ended September 30, 2014, to $2.2 million for the three months ended September 30, 2015. This increase was primarily attributable to a $0.4 million increase in salaries and personnel-related costs due to increased headcount, a $0.4 million increase in stock-based compensation expense related to the vesting of stock awards, and a $0.3 million increase in accounting expenses, professional fees and legal fees.

Other Expenses

Other expenses increased by $0.4 million, from $2.8 million for the three months ended September 30, 2014, to $3.2 million for the three months ended September 30, 2015. This change was primarily attributable to a $0.1 million decrease in the fair value adjustment related to our derivative and warrant liability offset by a $0.5 million increase in interest expense related to the Deerfield Facility Agreement during the three months ended September 30, 2015.

Comparison of the Nine Months Ended September 30, 2015 and 2014 (in thousands):

	Nine Months Ended September 30, 2015	2014	Period-to-Period Change
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	9,215	6,006	3,209
General and administrative	6,317	2,949	3,368
Total operating expenses	15,532	8,955	6,577
Loss from operations	(15,532)	(8,955)	(6,577)
Other income (expenses):			
Gain on extinguishment of debt	—	1,900	(1,900)
Amortization of debt discount	(1,434)	(636)	(798)
Interest expense	(1,973)	(974)	(999)
Fair value adjustment	(26,512)	(4,002)	(22,510)
Interest and other income	17	3	14
Total other expenses	(29,902)	(3,709)	(26,193)
Loss before income taxes	(45,434)	(12,664)	(32,770)
Income tax (expense) benefit	(27)	49	(76)
Net loss	$ (45,461)	$ (12,615)	$ (32,846)

Research and Development

Research and development expenses increased by $3.2 million, from $6.0 million for the nine months ended September 30, 2014, to $9.2 million for the nine months ended September 30, 2015. This increase was primarily attributable to a $1.1 million increase in contracted third-party research and development spending on KP201/APAP, a $0.8 million increase in contracted third-party research and development spending on KP511 and KP415, a $0.7 million increase in salaries and personnel-related costs due to increased headcount, a $0.3 million increase in miscellaneous research and development costs related to overhead and a $0.3 million increase in stock-based compensation expense related to the vesting of stock awards during the nine months ended September 30, 2015.

General and Administrative

General and administrative expenses increased by $3.4 million, from $2.9 million for the nine months ended September 30, 2014, to $6.3 million for the nine months ended September 30, 2015. This increase was primarily attributable to a $1.4 million increase in salaries and personnel-related costs due to increased headcount, a $1.1 million increase in stock-based compensation expense related to the vesting of stock awards, and a $0.9 million increase in accounting expenses and professional fees.

Other Expenses

Other expenses increased by $26.2 million, from $3.7 million for the nine months ended September 30, 2014, to $29.9 million for the nine months ended September 30, 2015. This change was primarily attributable to the $22.5 million increase in the fair value adjustment related to our derivative and warrant liability, and a $1.9 million decrease in the gain on extinguishment of debt recognized in the second quarter of 2014 related to the conversion of the 2013 Convertible Notes. In addition, there was an increase of $0.8 million in the amortization of the debt issuance costs and debt discount and an increase of $1.0 million in interest expense related to the Deerfield Facility Agreement during the nine months ended September 30, 2015.

Liquidity and Capital Resources

Sources of Liquidity

Through September 30, 2015, we have funded our research and development and operating activities primarily through the issuance of $29.6 million of debt, $27.0 million of private placements of redeemable convertible preferred stock, and the sale of common stock in our initial public offering. As of September 30, 2015, we had cash and cash equivalents of $59.0 million. We completed the initial closing of our IPO in April 2015 and with a subsequent closing in May 2015, pursuant to which we received net proceeds, including net proceeds from the underwriters' exercise of their option to purchase additional shares, of $59.9 million, after deducting underwriting discounts and commissions of $4.5 million. In addition, we incurred offering expenses totaling $2.8 million.

We have incurred losses since our inception and, as of September 30, 2015, had an accumulated deficit of $95.6 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and

general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may obtain through one or more equity offerings, debt financings or other third-party funding, including potential strategic alliances and licensing or collaboration arrangements.

Deerfield Facility

In June 2014, we entered into the $60.0 million multi-tranche credit facility with Deerfield. At the time we entered into the Deerfield facility, we borrowed the first tranche, which consisted of a $15.0 million term note and a $10.0 million senior secured convertible note. Under the terms of the Deerfield facility, Deerfield is obligated to provide three additional tranches in the principal amounts of $10.0 million, $12.5 million and $12.5 million, respectively, upon our request and after the satisfaction of specified conditions, including the FDA's acceptance of an NDA for KP201/APAP and, for the final two tranches, the subsequent approval for the commercial sale thereof. Deerfield's obligation to provide such disbursements terminates on June 30, 2016. All loans issued under the Deerfield facility bear interest at 9.75% per annum. Interest accrued on outstanding debt under the Deerfield facility is due quarterly in arrears. Upon notice to Deerfield, we may choose 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, provided that all such interest will be due on July 1, 2016. We must repay one third of the outstanding principal amount of all debt issued under the Deerfield facility on the fourth and fifth anniversaries of the Deerfield facility. We are then obligated to repay the balance of the outstanding principal amount on February 14, 2020.

Prepayment of the outstanding balance is not allowed without written consent of Deerfield.

Pursuant to the Deerfield facility, we issued to Deerfield 1,923,077 shares of our Series D redeemable convertible preferred stock as consideration for the loans provided to us thereunder. Upon closing of our IPO, these shares of Series D redeemable convertible preferred stock 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 redeemable convertible preferred stock at an initial exercise price of $0.78 per share. Upon closing of our IPO, this warrant converted into a warrant exercisable for 1,923,077 shares of our common stock at a price per share of $5.85. If we exercise our option to borrow the second tranche, then we will issue to Deerfield a warrant to purchase 1,282,052 shares of our common stock at an initial exercise price of $5.85 per share. Similarly, if we borrow the third and fourth tranches, in each instance, we will issue to Deerfield a warrant exercisable for the number of shares equal to 60% of the principal amount of such disbursement divided by 115% of the volume weighted average sales price of our common stock for the 20 consecutive trading days immediately prior to the date of such disbursement with an exercise price per share equal to 115% of such weighted average sales price.

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, an underwritten public offering of our common stock, 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 any notes issued under the Deerfield facility. Under each warrant issued pursuant to the Deerfield Facility Agreement, Deerfield has the right to demand that we redeem the warrant for a cash amount equal to the Black-Scholes value of a portion of the warrant upon the occurrence of specified events, including a merger, an asset sale or any other change of control transaction.

The Deerfield Facility Agreement also includes high yield discount obligation protections which go into effect in June 2019. After this time, 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, as amended, or the Code, then we are obligated to prepay in cash on each such date the amount necessary to avoid such classification. As of September 30, 2015, the outstanding principal balance under the Deerfield Facility Agreement was $25 million.

Comparison of Cash Flows for the Nine Months Ended September 30, 2015 and 2014 (in thousands):

	Nine Months Ended September 30,	
	2015	2014
Net cash used in operating activities	$ (13,865)	$ (7,708)
Net cash used in investing activities	(95)	(17)
Net cash provided by financing activities	62,714	24,778
Net increase in cash and cash equivalents	$ 48,754	$ 17,053

Operating Activities

For the nine months ended September 30, 2015, net cash used in operating activities of $13.9 million consisted of a net loss of $45.5 million, primarily attributable to an increase in fair value adjustments to our warrant and derivative liabilities, offset by $31.4 million in adjustments for non-cash items and $0.2 million of cash provided from changes in working capital. Adjustments for non-cash items primarily consisted of changes in fair value of our derivative and warrant liabilities of $26.5 million, non-cash interest expense of $2.0 million, amortization of debt issuance costs and debt discount of $1.4 million, and stock-based compensation expense of $1.5 million.

For the nine months ended September 30, 2014, net cash used in operating activities of $7.7 million consisted of a net loss of $12.6 million, primarily attributable to our spending on research and development, offset by $3.9 million in adjustments for non-cash items and $1.0 million of cash provided by changes in working capital. Adjustments for non-cash items primarily consisted of gain on extinguishment of debt of $1.9 million, changes in fair value of our derivative and warrant liabilities of $4.0 million, non-cash interest expense of $1.0 million, stock-based compensation expense of $0.2 million, and amortization of debt issuance costs and debt discount of $0.6 million.

Investing Activities

For the nine months ended September 30, 2015, net cash used in investing activities was $95,000, which was primarily attributable to the purchase of property and equipment.

For the nine months ended September 30, 2014, net cash used in investing activities was $17,000, which was primarily attributable to the purchase of property and equipment.

Financing Activities

For the nine months ended September 30, 2015, net cash provided by financing activities of $62.7 million. Net cash consisted of (i) $59.9 million in proceeds, net of underwriter's discounts, from our initial public offering, in which we issued and sold 5,090,909 shares of our common stock at a public offering price of $11.00 per share on April 21, 2015, and subsequently, sold an additional 763,636 shares of our common stock pursuant to the underwriters' option to purchase additional shares on May 12, 2015, and (ii) proceeds of $4.0 million from the issuance of our Series D-1 convertible redeemable preferred stock, or Series D-1 Preferred, on February 19, 2015, offset by payment of deferred offering costs of $1.2 million.

For the nine months ended September 30, 2014, net cash provided by financing activities of $24.8 million consisted of $25.0 million of proceeds from the issuance of the Deerfield facility, offset by payment of debt and stock issuance costs of $0.2 million.

Future Funding Requirements

To date, we have not generated any revenue. We do not know when, or if, we will generate any revenue. We do not expect to generate significant revenue unless and until we obtain regulatory approval for and commercialize any of our product candidates. In addition, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, product candidates. We also expect to incur additional costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Based upon our current operating plan, we believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through at least the next 15 months. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of product candidates.

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

- the progress and results of our studies and clinical trials for KP201/APAP;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the ability to obtain abuse-deterrent claims in the labels for our product candidates, including KP201/APAP;
- 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 our product candidates for which we receive marketing approval, which may be affected by market conditions, including obtaining coverage and adequate reimbursement of our product candidates from third-party payers, including government programs and managed care organizations, and competition within the therapeutic class to which our product candidates are assigned;
- 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.

Our commercial revenue, if any, will be derived from sales of prodrug products that we do not expect to be commercially available for several years, if at all. 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 convertible debt securities, or exercise our right to borrow additional tranches under the Deerfield Facility Agreement, the terms of these securities or this debt may restrict our ability to operate. The Deerfield Facility Agreement includes, and any future debt financing and equity financing, if available, may involve agreements that include, covenants limiting and restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, entering into profit-sharing or other arrangements or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

Contractual Obligations, Commitments and Contingencies

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Contractual Obligations and Commitments” in our prospectus dated April 15, 2015, filed with the SEC on April 16, 2015, pursuant to Rule 424 promulgated under the Securities Act of 1933, as amended, or the “Securities Act”.

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 our prospectus dated April 15, 2015, filed with the SEC on April 16, 2015, pursuant to Rule 424 promulgated under the Securities Act.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Sensitivity

Our primary exposure to market risk for our cash and cash equivalents is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. As of September 30, 2015, we had cash and cash equivalents of $59.0 million. We currently do not hedge interest rate exposure. Because of the fixed rate of interest on our outstanding debt, an immediate 10% increase in interest rates would not have a material effect on our results of operations.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, the company's principal executive officer and principal financial officer evaluated the effectiveness of the company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based on their evaluation of the company's disclosure controls and procedures, the company's principal executive officer and principal financial officer, with the participation of the company's management, have concluded that the company's disclosure controls and procedures were effective as of September 30, 2015.

Changes in Internal Control Over Financial Reporting

During the fiscal quarter ended September 30, 2015, there were no changes in the company's internal control over financial reporting that materially affected, or are reasonably likely to materially affect, the company's internal control over financial reporting.

PART II

OTHER INFORMATION

Item 1. Legal Proceedings.

We are currently party to a lawsuit against DeWaay Financial Network, L.L.C., or DFN, a financial advisor. We instituted the lawsuit by filing a declaratory judgement action against DFN on September 13, 2013, in the Iowa District Court for Johnson County, Iowa. The lawsuit was subsequently transferred to the Iowa District Court for Polk County, Iowa.

On June 6, 2011, we entered into an agreement with DFN, or the DFN agreement, pursuant to which we granted to DFN a purported right of first refusal to serve as our exclusive financial advisor for specified strategic transactions, including a sale of our company, private and public capital raising transactions, and joint ventures, licenses or similar transactions with respect to our product candidates. Pursuant to the DFN Agreement we also granted a purported right to receive, subject to specified conditions including non-exercise of such right of first refusal, a cash fee equal to the greater of $250,000 and 1.5% of the total consideration received by us, our affiliates and our equity owners and related to any such strategic transaction, in each case, irrespective of whether any such strategic transaction occurred during or after the term of the DFN agreement.

In the lawsuit, we are seeking a declaratory judgment finding invalid and unenforceable such purported right of first refusal and right to receive a cash fee related to any such strategic transaction. DFN filed an answer requesting that the court declare that such rights are valid and survive termination of the DFN agreement and counterclaims requesting that the court award damages to DFN, including a fee based upon the total consideration that we have received and in the future will receive under the Deerfield Facility Agreement. Two former members of our board of directors joined the lawsuit as intervenors based on DFN's purported assignment of its rights, or a portion thereof, under the DFN Agreement to the intervenors. In September 2015, the court granted summary judgement in our favor with respect to our declaratory judgement action and DFN's counterclaims and we separately entered into settlement agreements with each of the intervenors. The settlements reached with the intervenors did not differ from the accrual previously recorded by the Company by a material amount. DFN subsequently filed a notice of appeal of the court's ruling with the Supreme Court of Iowa and the appeal is pending. We cannot predict the timing or ultimate outcome of this litigation. However, if it is determined that such purported right of first refusal and right to receive a cash fee related to any such strategic transaction are valid, then we could be required to pay DFN a portion of the consideration or proceeds received in any such specified strategic transaction, including potentially the Deerfield Facility Agreement, our IPO, the sale of our Series D-1 Preferred to Cowen KP Investment LLC, or Cowen, and future capital raising and other strategic transactions.

From time to time we are involved in legal proceedings arising in the ordinary course of business. We believe there is no other litigation pending that could have, individually or in the aggregate, a material adverse effect on our results of operations or financial condition.

Item 1A. Risk Factors.

You should carefully consider all of 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 combined and consolidated 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 as a result 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 have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

We have incurred losses since our inception and, as of September 30, 2015, had an accumulated deficit of $95.6 million. Our net losses for the nine months ended September 30, 2015 and 2014, were $45.5 million and $12.6 million, respectively. We have financed our operations to date with $52.7 million raised in private placements of redeemable convertible preferred stock, convertible promissory notes and term debt and $59.9 in aggregate net proceeds from our initial public offering.

We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials. We are still in the early stages of development of many of our product candidates, and we have not completed development of any of our product candidates. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase 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 KP201/APAP and for any other 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;
- potentially establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, manufacturing and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our prodrug development and potential future commercialization efforts; and
- incur additional legal, accounting and other expenses in operating as a public company.

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 any product candidates for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We are only in the preliminary stages of most of these activities. We may never succeed in these 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 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.

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.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next 15 months. However, we will need to obtain substantial additional funding in connection with our continuing operations. Our future capital requirements will depend on many factors, including:

- the progress and results of our preclinical studies, clinical trials and other product development and commercialization activities;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the ability to obtain abuse-deterrent claims in the labels for our product candidates, including KP201/APAP;
- 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, we receive from commercial sales of our product candidates for which we obtain marketing approval, which may be affected by market conditions, including obtaining coverage and adequate reimbursement of our product candidates from third-party payers, including government programs and managed care organizations, and competition within the therapeutic class to which our product candidates are assigned;
- 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.

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 never 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, our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of prodrug products that we do not expect to be commercially available for a number of years, if at all. 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 convertible debt securities, or exercise our right to borrow additional tranches under the Deerfield facility, the terms of these securities or this debt may restrict our ability to operate. The Deerfield facility includes, and any future debt financing and equity financing, if available, may involve agreements that include, covenants limiting and restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, entering into profit-sharing or other arrangements or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

Our 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. We have not yet demonstrated an ability to obtain regulatory approvals, 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 or enter into a collaboration for that purpose. 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.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements for the fiscal year ended December 31, 2014.

Our report from our independent registered public accounting firm for the year ended December 31, 2014, includes an explanatory paragraph stating that our recurring losses from operations and stockholders' deficit 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, and this report was issued prior to completion of our initial public offering, there can be no assurances that we will be successful in these efforts, or that the proceeds from our initial public offering will be able to resolve our liquidity issues or eliminate our operating losses. If we are unable to obtain sufficient funding, 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 consolidated financial statements, and it is likely that investors will lose all or a part of their investment. Future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. 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.

Risks Related to the Development of Our Product Candidates

Our research and development is 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 LAT platform 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. The scientific 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 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, including as a result of being shown to have harmful side effects, a lack of efficacy, or other characteristics that indicate that they are unlikely to be prodrugs that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our LAT platform 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.

We are very early in our development efforts and have only two product candidates, KP201/APAP and KP201 (APAP-free), that have commenced clinical trials. All of our other product candidates are still in preclinical development. If we are unable to commercialize our product candidates, including KP201/APAP and KP201 (APAP-free), or experience significant delays in doing so, our business will be harmed.

We are very early in our development efforts and have only two product candidates, KP201/APAP and KP201 (APAP-free), that have commenced clinical trials. All of our other product candidates are still in preclinical development. We have not completed the development of any product candidates, we generate no revenue from the sale of any prodrugs and we may never be able to develop a marketable prodrug product. We have invested substantially all of our efforts and financial resources in the development of our LAT platform technology, the identification of potential product candidates and the development of our product candidates. Our ability to generate revenue from our product candidates, which we do not expect will occur for at least 15 months, if ever, will depend heavily on their successful development and eventual commercialization. The success of 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 our product candidates are outweighed by the benefits;
- successful development of our manufacturing processes for our product candidates, including entering into and maintaining arrangements with third-party manufacturers;
- successful completion of an FDA preapproval inspection of the facilities used to manufacture our product candidates, as well as select clinical trial sites;
- receipt of timely marketing approvals from applicable regulatory authorities, including the determination by the U.S. Drug Enforcement Agency, or DEA, of the controlled substance schedule for a product candidate, taking into account the recommendation of the FDA;
- obtaining abuse-deterrent claims in the labels for our product candidates, including KP201/APAP;
- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for 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 product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our prodrug product candidates, if approved, by patients, the medical community and third-party payers;
- competing effectively with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement; and
- maintaining a continued acceptable safety and efficacy profile of the prodrug products following approval.

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

It is possible that none of our 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 an inability to successfully commercialize our product candidates, which would harm our business.

Our ability to market and promote our products in the United States by describing their abuse-deterrent features will be determined by the FDA-approved labeling for them.

The commercial success of KP201/APAP and most of our other product candidates will depend upon our ability to obtain FDA-approved labeling describing their abuse-deterrent features. Our failure to achieve FDA approval of product labeling containing such information will prevent our advertising and promotion of the abuse-deterrent features of our product candidates in order to differentiate them from other similar products. This would make our products less competitive in the market.

FDA approval is required in order to make claims that a product has an abuse-deterrent effect. In January 2013, the FDA published draft guidance with regard to the evaluation and labeling of abuse-deterrent opioids. This guidance was published in final form in April 2015. The FDA guidance provides direction as to the studies and data required for obtaining abuse-deterrent claims in a product label. The guidance describes four categories of label claims for abuse-deterrent products. Depending on product and study data, a combination of categories can be included in the label claims. The FDA guidance lists the following theoretical examples:

- Category 1–in vitro data demonstrate the product has physical and chemical properties that are expected to deter intravenous abuse. However, abuse is still possible by the oral and nasal routes.
- Category 1 and 2–in vitro data demonstrate that the product has physical and chemical properties that are expected to deter oral, nasal and intravenous abuse. However, abuse of intact product is still possible by the oral route.
- Category 2 and 3–pharmacokinetic and clinical abuse potential studies indicate that the product has properties that are expected to deter abuse via the oral, intranasal and intravenous routes. However, abuse of product by these routes is still possible.
- Category 4–data demonstrated a reduction in the abuse of the product in the community setting compared to the levels of abuse, overdose, and death that occurred when only formulations of the same opioid without abuse-deterrent properties were available. This reduction in abuse appears to be attributable to the product's formulation, which deters abuse by injection or snorting of the manipulated product. However, such abuse of this product is still possible, and the product's abuse deterrence properties do not deter abuse associated with swallowing the intact formulation.

If a product is approved by the FDA to include such claims in its label, the applicant may use information about the abuse-deterrent features of the product in its marketing efforts to physicians.

Although we conducted trials intended to support approval by the FDA of Category 1, 2 and 3 labeling claims for KP201/APAP, there can be no assurance that KP201/APAP or any of our other product candidates will receive FDA-approved labeling that describes the abuse-deterrent features of such products. The FDA may find that our trials do not support abuse-deterrent labeling or that our product candidates do not provide substantial abuse deterrence because, for example, their deterrence mechanisms do not address the way they are most likely to be abused. As with all claims, we will be required to provide adequate substantiation. For example, we will need to demonstrate that KP201/APAP has abuse-deterrent properties sufficient to achieve Category 1, 2 and 3 abuse-deterrent labeling. Further, the FDA is not required to follow its guidance and could change this guidance, which could require us to conduct additional trials. If the FDA does not approve abuse-deterrent labeling, we will not be able to promote such products based on their abuse-deterrent features and may not be able to differentiate such products from other similar products.

Even if we do receive FDA approval for abuse-deterrent claims, the claims may not be broad enough to demonstrate a substantial benefit to health care providers and patients. For instance, the claims may not encompass the more common forms of abuse for products like our product candidates. Moreover, continued investigation in Phase 4 studies following product approval, if required, may not support the continued use of abuse-deterrent claims.

If 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 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, including KP201/APAP, through the 505(b)(2) NDA pathway. 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. 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. 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.

To rely on the FDA's previous findings of safety and effectiveness for an approved product in a 505(b)(2) NDA, the approved product must be an NDA product. For KP201/APAP, because there are no approved NDAs for hydrocodone/APAP combination products, we are required to establish safety and efficacy of APAP and safety and efficacy of hydrocodone separately through other methods. We plan to reference published medical and scientific literature in our 505(b)(2) NDA to establish the safety and effectiveness of hydrocodone. If this literature is insufficient, we may need to conduct additional clinical trials and provide additional data and information regarding the safety and effectiveness of hydrocodone.

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 a number of 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 black box 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 may be required to conduct Phase 4 studies and to implement a REMS and will have a black box warning for at least some of our product candidates.

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 product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Interpretation of results from early, usually smaller, studies that suggest positive trends in some subjects, requires caution. Results from later stages of clinical trials enrolling more subjects may fail to show the desired safety and efficacy results or otherwise fail to be consistent with the results of earlier trials of the same product candidates. Later clinical trial results may not replicate earlier clinical trials for a variety of reasons, including differences in trial design, different trial endpoints, or lack of trial endpoints in exploratory studies, subject population, number of subjects, subject selection criteria, trial duration, drug dosage and formulation and lack of statistical power in the earlier studies. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

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

- regulators or institutional review boards 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 contract research organizations, or 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 institutional review boards 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 institutional review boards 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. 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 KP201/APAP and other product candidates under 505(b)(2) may increase the risk that patent infringement suits are filed against us, which would delay the FDA's approval of such product candidates.

In connection with any NDA that we file under 505(b)(2), 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 significant 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 KP201/APAP or our other product candidates and distract management from their normal responsibilities.

We anticipate that most of our product candidates, if approved by the FDA, may be subject to mandatory REMS programs, which could increase the cost, burden and liability associated with the commercialization of these product candidates.

The FDA has indicated that some opioid 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. The FDA has already approved a REMS for extended release, or ER, and long-acting opioids as part of a federal initiative to address inappropriate prescribing and prescription drug abuse and misuse. The REMS introduces new safety measures designed to reduce risks and improve the safe use of ER and long-acting opioids, while ensuring access to needed medications for patients in pain. The ER and long-acting opioid REMS affects more than 20 companies that manufacture these opioid analgesics. Under the new REMS, companies are required to make education programs available to prescribers. It is expected that companies will meet this obligation by taking specific steps to ensure that health care providers are aware of the availability of the training and by providing educational grants to continuing education providers, who will develop and deliver the training. The REMS 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.

We anticipate that most of our product candidates, including KP201/APAP, if approved by the FDA, may 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.

Our product candidates contain controlled substances, the manufacture, use, sale, importation, exportation, prescribing and distribution of which are subject to regulation by the United States Drug Enforcement Administration.

Before we can commercialize our product candidates, the United States Drug Enforcement Administration, or 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. Most of our product candidates, including KP201/APAP, KP201 (APAP-free), KP511/ER, KP415 and KP606/IR, if approved, will be regulated as "controlled substances" as defined in the Controlled Substances Act of 1970, or 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 product candidates will be listed by the DEA as Schedule II controlled substances under the CSA. Consequently, the manufacturing, shipping, storing, selling and using of the products will be subject to a high degree of regulation. Schedule II drugs are subject to the strictest requirements for registration, security, recordkeeping and reporting. Also, distribution, prescribing and dispensing of these drugs are highly regulated.

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.

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 are expected to be regulated as Schedule II controlled substances, they will 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 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. 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 effect 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 institutional review board 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.

Clinical trials of our most advanced product candidate KP201/APAP have thus far found adverse events, such as dizziness and nausea and other adverse events consistent with other opioid products.

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 our 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 our ability to commercialize our product candidates. Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of hydrocodone or other opioid drugs, 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 our 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 payers may not be willing to pay a premium for abuse-deterrent formulations 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 our product candidates. For example, in April 2014, the FDA approved class-wide labeling changes to the indications for use of all approved ER and long-acting opioids so that ER and long-acting 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. It is possible that such changes could reduce the number of prescriptions for opioids written by physicians and negatively impact the potential market for our product candidates. The FDA also held a public meeting in October 2014, on the development and regulation of abuse-deterrent formulations of opioid medications. It is possible that FDA will announce new regulatory initiatives at any time that may increase the regulatory burden or decrease the commercial opportunity for our product candidates.

We are party to non-competition restrictions that may prevent us from investigating, developing or commercializing specified amphetamine-based product candidates.

On March 21, 2012, we entered into an asset purchase agreement with Shire LLC, or Shire, pursuant to which we sold assets and intellectual property to Shire. As partial consideration for this sale, we and our chief executive officer, Travis C. Mickle, Ph.D., agreed not to compete with Shire in the development, commercialization, production or distribution of amphetamine amino acid conjugate products until March 21, 2017. As a result, we have not engaged in any development efforts for such product candidates and will not engage in any such development efforts until the expiration of this non-competition provision, if at all. Prior to such time, our competitors may make substantial development progress regarding similar product candidates and even obtain FDA or other regulatory approval for similar product candidates. This could result in our competitors establishing a strong market position before we are able to enter the market or begin our development process, which may prevent us from entering such market altogether.

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, principal 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, principal 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 principal investigators are also subject to scrutiny under other health care regulatory laws, such as the federal 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 a third party for the manufacture of KP201/APAP used in our clinical trials and with a sole source supplier for the manufacture of bulk quantities of KP201 used in KP201/APAP 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 KP201 or KP201/APAP 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 or personnel. We procure KP201 bulk drug substance from a sole source, third-party manufacturer and the KP201/APAP used in our clinical trials from another third party. 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 other product candidates, as well as for commercial manufacture if any of our product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of KP201, other bulk drug substances or our 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 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.

While we are ultimately responsible for the manufacture of our product candidates, we do not, other than through our contractual arrangements, control the manufacturing process of, and 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 manufacture of 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 our product candidates, if approved.

Further, if our product candidates are approved, our suppliers will be subject to regulatory requirements, covering manufacturing, testing, quality control and record keeping relating to our product candidates, 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 KP201 bulk drug substance. If our current contract manufacturer for KP201 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 may seek collaborations with third parties for the development or commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We may seek third-party collaborators for the development and commercialization of our product candidates, including for the commercialization of any of our product candidates that are approved for marketing outside the United States. Our likely collaborators include large and mid-size pharmaceutical companies, regional, national and international pharmaceutical companies and biotechnology companies. If we do enter into any 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 our 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.

Collaborations involving our product candidates would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on 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;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- 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;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or 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, we may have to alter our development and commercialization plans.

Our prodrug development programs and the potential commercialization of our product candidates will require substantial additional capital. For some of our product candidates, 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 or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. 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 them to market and generate product revenue.

Provisions in our agreements with Shire and MonoSol may inhibit our ability to enter into future collaborations with third parties.

Under our asset purchase agreement with Shire, we granted Shire a right of first refusal to acquire, license or commercialize KP415. The right of first refusal may be exercised by Shire for a period of 30 business days following Shire's receipt of written notice from us of the existence of a bona fide offer from a third party to acquire, license or commercialize KP415.

We are also party to a termination agreement with MonoSol that may limit the value of any sale, license or commercialization of KP415. Under this termination agreement, MonoSol has the right to receive an amount equal to a percentage in the low teens of any value generated by KP415, and any product candidates arising therefrom, including royalty payments on any license of KP415, the sale of KP415 to a third party or the commercialization of KP415.

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

Pursuant to the Deerfield Facility Agreement, we may not enter into specified transactions, including any joint venture, partnership or any other profit sharing arrangement, without the prior approval of 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.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain trade secret protection or patent protection for our technology and 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 and product candidates may be impaired.

Our success depends in large part on our ability to obtain and maintain trade secret protection of our LAT platform technology as well as patent protection in the United States and other countries with respect to our 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.

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 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 LAT platform 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 LAT platform 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.

Recent 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. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, 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. 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 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.

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 a third 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 any of our product candidates that are approved for marketing from the products of our competitors. We have not yet solicited trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our product candidates. 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. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

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

In addition to seeking patent and trademark protection for our product candidates, we also rely on trade secrets, including unpatented show-how, know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Monitoring unauthorized uses and disclosures of our intellectual property, including our trade secrets, is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

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

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

We cannot be certain that the patent or trademark offices of countries outside the United States will not implement new rules that increase costs for drafting, filing, prosecuting and maintaining patents, trademarks and patent and trademark applications or that any such new rules will not restrict our ability to file for patent protection. For example, we may elect not to seek patent protection in some jurisdictions or for some inventions in order 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 Product Candidates

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

We do not have a sales or 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. We have not yet determined our commercialization strategy for KP201/APAP or any of our other product candidates. 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 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. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us, including as a result of restrictions in the Deerfield facility. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. 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 our product candidates.

Even if any of our product candidates receives marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community necessary for commercial success.

If any of our product candidates receives marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payers and others in the medical community. If our product candidates do not achieve an adequate level of market acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of 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 abuse-deterrent claims in the labels for KP201/APAP and most of our other 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 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 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 be more successful than us in manufacturing and marketing their products.

If approved, our abuse-deterrent opioid product candidates will face competition from commercially available branded and generic opioid drugs including hydrocodone, hydromorphone and oxycodone, fentanyl, morphine, oxymorphone and methadone, as well as other marketed non-opioid products for the treatment of pain, and potential competition from opioid and non-opioid products for the treatment of pain that are currently in clinical development. In addition, our product candidates will face competition from approved and abuse-deterrent labeled opioid drugs and potential competition from abuse-deterrent opioid drugs that are currently in clinical development. We also indirectly compete with multiple companies that have developed and are developing abuse-deterrent technologies that may be applied to a variety of drugs, including those being developed for the treatment of acute moderate to moderately severe pain as well as for other indications that we are pursuing or may pursue in the future. If approved, our abuse-deterrent opioid product candidates may face competition from products or technologies from companies including Actavis plc, Acura Pharmaceuticals, Inc., Cara Therapeutics, Inc., Collegium Pharmaceutical, Inc., Depomed, Inc., DURECT Corporation, Egalet Corporation, Elite Pharmaceuticals, Inc., Endo International plc, Grünenthal Group, IntelliPharmaceutics International Inc., Mallinckrodt plc, Mylan Inc., Nektar Therapeutics, Pain Therapeutics, Inc., Pfizer Inc., Purdue Pharma L.P., Signature Pharmaceuticals, Teva Pharmaceutical Industries Ltd., Trevena Inc. and UCB S.A.

If approved, KP201/APAP will compete against currently marketed, branded and generic, IR hydrocodone/APAP combination products indicated for the treatment of acute moderate to moderately severe pain. Some of these currently marketed products include AbbVie's Vicodin, Actavis's Norco, Shionogi's Xodol and UCB Pharma's Lortab, in addition to multiple other branded and generic hydrocodone/APAP combination products marketed by companies including Endo International plc, Actavis plc and Mallinckrodt plc. In addition, if approved, KP201/APAP will face potential competition from any abuse-deterrent or other IR hydrocodone/APAP combination products for the treatment of acute moderate to moderately severe pain that are currently in or may enter into clinical development.

If approved, KP415 will compete against currently marketed, branded and generic methylphenidate products for the treatment of ADHD. Some of these currently marketed products include Johnson & Johnson's Concerta, Novartis AG's Ritalin, Ritalin LA, Focalin and Focalin XR, UCB S.A.'s Metadate CD, and Noven Pharmaceuticals' Daytrana, in addition to multiple other branded and generic methylphenidate products marketed by companies including Actavis plc and Mallinckrodt plc. In addition, if approved, KP415 will face potential competition from any abuse-deterrent or other methylphenidate products for the treatment of ADHD that are currently in or which may enter into clinical development.

If approved, our product candidate KP303 will compete against currently marketed, branded and generic quetiapine products for the treatment of CNS disorders such as schizophrenia, bipolar disorder and major depressive disorder. Some of these currently marketed products include Astrazeneca PLC's Seroquel and Seroquel XR, in addition to multiple other generic quetiapine products marketed by companies including Lupin Pharmaceuticals, Inc., Roxanne Laboratories, Inc. and Teva Pharmaceutical Industries Ltd. In addition, if approved, KP303 will face potential competition from any quetiapine products for the treatment of CNS disorders such as schizophrenia, bipolar disorder and major depressive disorder that are currently in or which may enter into clinical development.

If approved, our product candidate KP511/ER will compete against currently marketed, branded and generic, IR and ER hydromorphone products approved for use in opioid-tolerant patients 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. Some of these currently marketed products include Purdue Pharma L.P.'s Dilaudid and Mallinckrodt plc's Exalgo, in addition to multiple other branded and generic IR and ER hydromorphone products marketed by companies including Actavis plc, Mallinckrodt plc, Rhodes Pharmaceuticals L.P. and Roxanne Laboratories, Inc. In addition, if approved, KP511/ER will face potential competition from any abuse-deterrent and other IR and ER hydromorphone products for the treatment of pain that are currently in or which may enter into clinical development.

If approved, our product candidate KP606/IR will compete against currently marketed, branded and generic abuse-deterrent and other IR and ER oxycodone products approved for use in opioid-tolerant patients 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. Some of these currently marketed products include Purdue Pharma L.P.'s OxyContin and Mallinckrodt plc's Roxicodone, in addition to multiple other branded and generic, abuse-deterrent and other, IR and ER oxycodone products marketed by companies including Actavis plc, Endo International plc, and Mallinckrodt plc. In addition, if approved, KP606/IR will face potential competition from any abuse-deterrent or other IR and ER oxycodone products for treatment of pain that are currently in or which may enter into clinical development.

We believe the key competitive factors that will affect the development and commercial success of our product candidates include their potential degree of abuse deterrence, onset of action, bioavailability, therapeutic efficacy, convenience of dosing, safety, tolerability and cost. 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 abuse-deterrent or other products for the treatment of acute moderate to moderately severe pain, or for other 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 payers seeking to encourage the use of generic drugs. 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.

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. 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 abuse-deterrent or other products for the treatment of pain or ADHD 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 an NCE 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 KP415, and we may seek NCE or new molecular entity status for other 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. 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 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 KP415 or 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 abuse-deterrent mechanisms or may be able to obtain approval for similar products without an abuse-deterrent mechanism.

Even if we are able to commercialize any product candidates, they may be subject to unfavorable pricing regulations, third-party coverage and reimbursement policies or healthcare reform initiatives.

Our ability to commercialize any product candidates successfully will depend, in part, on the extent to which coverage and adequate reimbursement for our product candidates will be available from government payer programs at the federal and state levels, including Medicare and Medicaid, private health insurers, managed care plans and other third-party payers. Government authorities and other third-party payers 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 payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. Increasingly, third-party payers 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, 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 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 payers 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 payers 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 payers 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 payer to payer. 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 payer 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 payers 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 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 payers, that coverage or an adequate level of reimbursement will be available, or that third-party payers' reimbursement policies will not adversely affect our ability to sell 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 the abuse-deterrent 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, civil whistleblower or "qui tam" actions, operating restrictions or criminal penalties. 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 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 if we commercialize any prodrug products that we may develop. This includes the risk that our products may be misused. For example, we anticipate that, if approved, our products may carry boxed warnings regarding lethality if our oral tablets 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. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for 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 commercialize 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 if we commence commercialization of our product candidates. 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;
- 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

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, advertising, marketing, promotion, sale, distribution, import, export, and reporting of safety and other post-market information, are subject to comprehensive regulation by the FDA, DEA and other regulatory agencies in the United States and by the European Medicines Agency, and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. Through the prior experience of our management, we have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Prior to product launch, the DEA would then need to determine the controlled substance schedule of KP201/APAP, taking into account the recommendation of the FDA. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. If any of our product candidates receives marketing approval, the accompanying label may limit its approved use, which could limit sales of the product.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. We may not gain approval of our product candidates, or even if we obtain regulatory approval for a product candidate, product candidates may be subject to fewer or more limited indications, 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 black box warning, may grant approval contingent on the performance of costly post-marketing clinical trials or other post-market requirements, such as REMS, may require post-marketing surveillance 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. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. Regulatory authorities may further disagree with the study design, assessment tools or evaluations that we conducted. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be materially impaired.

Failure to obtain marketing approval in international jurisdictions would prevent 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 our product candidates internationally could affect our business.

We may seek regulatory approval for 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.

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

Any product candidate for which we obtain marketing approval will 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. 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.

Even if marketing approval of a product candidate is granted, the approval 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. If any of our product candidates receives marketing approval, the accompanying label may limit its 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 black box 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.

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. 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 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. 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 payers 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 payers 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 payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and patient privacy and security regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or arranging for the purchase, lease or order of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid;
- federal civil and criminal false claims laws, including the federal 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 civil False Claims Act, 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 federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new 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 payer 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, and its implementing regulations, which imposes new annual reporting requirements for certain 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.

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, 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 and commercialize our product candidates and affect the prices we may obtain.

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 our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payers 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 50% 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 beginning in 2014, 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.

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 will stay in effect through 2024 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. 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 continue to evaluate the effect that the ACA has on our business. Final regulations, guidance, and judicial orders are anticipated in the near future and we will continue to assess the ACA's impact on us as final regulations and guidance are issued.

We expect that the ACA, as well as other healthcare reform measures that 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 payers. 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 recently enacted Drug Supply Chain Security Act imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this new legislation, manufacturers will be 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 will also be required to verify that purchasers of products are appropriately licensed. Further, under this new legislation, manufacturers will 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 computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

Risks Related to Employee Matters and Managing Our Growth

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

We are highly dependent on the management, research and development, clinical, financial and business development expertise of Travis C. Mickle, Ph.D., our president and chief executive officer, R. LaDuane Clifton, our chief financial officer, Gordon K. Johnson, our chief business officer, Tracy Woody, our chief commercial officer, Christal M.M. Mickle, our vice president operations and product development, Sven Guenther, Ph.D., our executive vice president research and development, and Christopher M. Lauderback, our vice president commercial operations, 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. Additionally, Mr. Mickle has consulting obligations to Shire Pharmaceuticals, LLC in addition to his duties as our president and chief executive officer, which may limit his availability to us.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our product 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.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of September 30, 2015, we had 25 full-time employees. As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, drug development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue 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 anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The 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 develop and you may not be able to resell your shares of our common stock for a profit, if at all.

Prior to our initial public offering, there had been no public market for our common stock. An active trading market for our shares may never develop or be sustained. If an active market for our common stock does not develop or is not sustained, it may be difficult for investors 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. 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;
- 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.

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. Such litigation, if instituted against us, 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 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

We may incur substantial costs as a result of ongoing litigation.

We are currently party to a lawsuit against DeWaay Financial Network, L.L.C., or DFN, a financial advisor, in the Iowa District Court for Polk County, Iowa to resolve whether DFN has a valid (i) right of first refusal to serve as our exclusive financial advisor for specified strategic transactions, including a sale of our company, private and public capital raising transactions and joint ventures, licenses or similar transactions with respect to our product candidates or (ii) right to a cash fee equal to the greater of $250,000 or 1.5% of the total consideration received by us, our affiliates and our equity owners related to any such strategic transaction, including our initial public offering, future offerings and the Deerfield facility, under an engagement agreement between us and DFN.

In the lawsuit, we are seeking a declaratory judgement finding invalid and unenforceable such purported right of first refusal and right to receive a cash fee related to any such strategic transaction. DFN filed an answer requesting that the court declare that such rights are valid and survive termination of the DFN Agreement and counterclaims requesting that the court award damages to DFN, including a fee based upon the total consideration that we have received and in the future will receive pursuant to the Deerfield facility. Two former members of our board of directors joined the lawsuit as intervenors based on DFN's purported assignment of its rights, or a portion thereof, under the DFN Agreement to the intervenors. In September 2015, the court granted summary judgement in our favor with respect to our declaratory judgement action and DFN's counterclaims and we separately entered into settlement agreements with each of the intervenors. The settlements reached with the intervenors did not differ from the accrual previously recorded by the Company by a material amount. DFN subsequently filed a notice of appeal of the court's ruling with the Supreme Court of Iowa and the appeal is pending.

If it is finally determined that such purported right of first refusal and right to receive a cash fee related to any such specified strategic transactions are valid, then we could be required to pay to DFN a portion of the consideration or proceeds received in any such specified strategic transaction, including potentially the Deerfield Facility Agreement, our IPO, the sale of our Series D-1 Preferred to Cowen, and future capital raising and other strategic transactions. Such an outcome would increase our costs in entering into any such transaction and might prevent us from doing so altogether. Further, we cannot predict the timing or outcome of this litigation and irrespective of its outcome, this litigation may cause us to incur substantial costs in related legal fees and divert management's attention and resources from our business.

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

As of September 30, 2015, we had outstanding immediately exercisable warrants to purchase 529,451 shares of our common stock at a weighted average exercise price of $5.34 per share that include anti-dilution provisions pursuant to which the exercise price of such warrants will be adjusted downward if we issue any shares of our common stock or any securities convertible into our common stock at a price per share or with an exercise or conversion price less than the exercise price of such warrants. Upon such an event, the exercise price of these warrants will be automatically adjusted to equal the price per share paid for, the conversion price of or the exercise price of such securities, as applicable, and the number of shares of common stock issuable upon exercise of each warrant will be proportionately increased.

Additionally, in June 2014, we issued to Deerfield a warrant to purchase 14,423,076 shares of Series D Preferred at an exercise price of $0.78 per share, which is exercisable until June 2, 2024, or the Deerfield Warrant. Upon completion of our IPO, the Deerfield Warrant automatically converted into a warrant to purchase 1,923,077 shares of our common stock at an exercise price of $5.85 per share. The Deerfield Warrant includes an exercise price protection provision, pursuant to which the exercise price of the warrant will be adjusted downward on a broad-based weighted-average basis if we issue or sell any shares of common stock, convertible securities, warrants or options at a sale or exercise price per share less than the greater of the warrant's exercise price or the closing sale price of

our common stock on The NASDAQ Global Market on the last trading date immediately prior to such issuance. Each time we borrow a tranche under the Deerfield facility, we are obligated to issue to Deerfield a warrant with substantially the same terms and conditions.

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

We expect that we will need significant additional capital in the future to fund our planned 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. We may also borrow additional tranches under the Deerfield Facility Agreement if the necessary conditions are satisfied. Each time we borrow a tranche under the Deerfield facility, we will simultaneously issue to Deerfield a warrant exercisable for a specified number of shares of our common stock. If we exercise our option to borrow the second tranche under the Deerfield Facility Agreement, we will issue to Deerfield a warrant to purchase 1,282,052 shares of our common stock at an initial exercise price of $5.85 per share. Similarly, if we exercise our option to borrow the third and fourth tranches, in each instance, we will issue to Deerfield a warrant exercisable for the number of shares of our common stock equal to 60% of the principal amount of such disbursement divided by 115% of the volume weighted average sales price of our common stock for the 20 consecutive trading days immediately prior to the date of such disbursement with an exercise price per share equal to 115% of such weighted average sales price. Each of these future Deerfield warrants, if issued, will be dilutive to your ownership interest.

Additionally, we previously issued to Deerfield a secured convertible note, or the Deerfield Note, in the principal amount of $10.0 million. The Deerfield Note bears interest at 9.75% per annum. Deerfield may convert all or any portion of the outstanding principal and any accrued but unpaid interest on the Deerfield Note into shares of our common stock at a conversion price of $5.85 per share. According to the terms of the Deerfield Note, in no event may Deerfield convert the Deerfield Note to the extent such conversion would result in Deerfield beneficially owning more than 9.985% of the then issued and outstanding shares of our common stock. This conversion limitation may not be waived and any purported conversion that is inconsistent with this conversion limitation 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 Note into a limited number of shares due to this conversion limitation, the Deerfield 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 Note is convertible into 1,943,458 shares of our common stock, assuming a conversion date of September 30, 2015. At our option, the Deerfield Note will convert into shares of our common stock upon the occurrence prior to June 30, 2016, of either (i) the FDA's approval of an NDA for KP201 for the treatment of acute pain without requiring the performance of an efficacy study or (ii) the FDA's acceptance of an NDA for KP201 for review. The conversion price of the Deerfield 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 Note's conversion price or the closing sale price of our common stock on The NASDAQ Global Market on the last trading date immediately prior to such issuance.

If Deerfield elects to convert the Deerfield Note, or in the event that the Deerfield Note automatically converts pursuant to its terms into shares of our common stock, your ownership interest will be diluted.

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 these plans 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.

Our substantial indebtedness, and the conditions we must satisfy in order to make further draws on our credit facility, may limit cash flow available to invest in the ongoing needs of our business.

In June 2014, we entered into the Deerfield Facility Agreement, pursuant to which Deerfield agreed to loan to us up to $60.0 million, subject to specified conditions. In June 2014, we drew down $25.0 million against the facility. Under the terms of the Deerfield Facility Agreement, Deerfield is obligated to provide three additional tranches in the principal amounts of $10.0 million, $12.5 million and $12.5 million, respectively, upon our request and after the satisfaction of specified conditions, including the FDA's acceptance of an NDA for KP201/APAP and, for the final two tranches, the subsequent approval for the commercial sale thereof. If these conditions do not occur, we may not be able to borrow any further tranches under the Deerfield Facility Agreement, which would limit our cash flow and our ability to invest in the ongoing needs of our business.

All loans issued under the Deerfield facility bear interest at 9.75% per annum. Interest accrued on outstanding debt under the Deerfield Facility Agreement is due quarterly in arrears. Upon notice to Deerfield, we may choose 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 will be due on July 1, 2016. We must 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. We are then obligated to repay the balance of the outstanding principal amount on February 14, 2020. If we are required to pay outstanding amounts due under the Deerfield facility prior to maturity or otherwise incur unanticipated monetary obligations under the Deerfield Facility Agreement, our cash flow available to invest in the ongoing needs of our business may be limited.

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.

Certain holders of shares of our common stock and shares of our common stock issuable upon the exercise of outstanding warrants, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their 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 MonoSol and our agreements with Deerfield 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 MonoSol will be entitled to a percentage in the low teens of the price being paid to us and our stockholders in such transaction which is attributable to the value of KP415. Pursuant to the Deerfield facility, 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 Deerfield has the option to demand repayment of all outstanding principal, and any unpaid interest accrued thereon, of all notes previously issued under the Deerfield facility immediately prior to consummation of such event. Further, under each warrant issued pursuant to the Deerfield facility, Deerfield has the right to demand that we 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.

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 any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, 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 any action asserting a claim against us that is governed by the internal affairs doctrine. 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 JOBS Act and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.0 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 $1.0 billion in non-convertible debt during the prior three-year period.

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

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

As of December 31, 2014, we had federal net operating loss carryforwards of $38.4 million, due to prior period losses, 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. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, 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 have not determined if we have experienced

Section 382 ownership changes in the past and if a portion of our net operating loss carryforwards are subject to an annual limitation under Section 382. 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 our initial public offering. 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.

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 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 control over financial reporting. Commencing with our fiscal year ending December 31, 2016, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We have never been required to test our internal controls within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

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 control 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 in a timely manner, 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 Securities and Exchange Commission, or 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, 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Unregistered Sales of Equity Securities

Not applicable.

Use of Proceeds

On April 21, 2015, we closed our initial public offering, in which we issued and sold 5,090,909 shares of common stock at a public offering price of $11.00 per share. Subsequently, on May 12, 2015, we sold an additional 763,636 shares of our common stock pursuant to the underwriters' option to purchase additional shares. In the aggregate, the gross proceeds of our initial public offering, including gross proceeds from the underwriters' exercise of their option to purchase additional shares, were $64.4 million. All of the shares issued and sold in our initial public offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-202660), which was declared effective by the SEC on April 15, 2015. Cowen and Company, LLC, RBC Capital Markets, LLC, Canaccord Genuity Inc. and Oppenheimer & Co. Inc. acted as the underwriters. The offering commenced on April 15, 2015, and did not terminate before all of the securities registered in the registration statement were sold.

The net offering proceeds to us were $59.9 million, after deducting underwriting discounts and commissions totaling $4.5 million. In addition, offering expenses totaled $2.8 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. There has been no material change in the planned use of proceeds from our initial public offering as described in our prospectus dated April 15, 2015, and filed with the SEC on April 16, 2015, pursuant to Rule 424(b) of the Securities Act. Through September 30, 2015, $0.9 million of the net proceeds had been used to fund the development of KP201/APAP and our other product candidates and for working capital and other general corporate purposes.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

The following is a list of exhibits filed as part of this Form 10-Q:

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of KemPharm, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 21, 2015).
3.2	Amended and Restated Bylaws, as currently in effect, of KemPharm, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the SEC on April 21, 2015).
10.1*#	Amendment to Employment Agreement by and between the Registrant and Christal M.M. Mickle, dated as of October 13, 2015.
10.2*#	Amendment to Amended and Restated Employment Agreement by and between the Registrant and R. LaDuane Clifton, dated as of October 13, 2015.
10.3*#	Amendment to Amended and Restated Employment Agreement by and between the Registrant and Gordon K. Johnson, dated as of October 13, 2015.
10.4*#	Amendment to Employment Agreement by and between the Registrant and Travis C. Mickle, Ph.D., dated as of October 13, 2015.
10.5*#	Amendment to Employment Agreement by and between the Registrant and Tracy M. Woody, dated as of September 4, 2015.
10.6*#	Acceleration Provisions of Stock Options Letter by and between the Registrant and Sven Guenther, Ph.D., dated as of October 13, 2015.
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 Pursuant to 18. U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (1)
32.2*	Certification Pursuant to 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, 2015, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Balance Sheets, (ii) Condensed Statements of Operations, (iii) Condensed Statements of Comprehensive Income (Loss), (iv) Condensed Statements of Cash Flows, and (v) Notes to Financial Statements, tagged as blocks of text and including detailed tags.

# Indicates management contract or compensatory plan.

(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 13, 2015

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

Date: November 13, 2015

By: /s/ R. LaDuane Clifton
R. LaDuane Clifton
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Index to Exhibits

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10.3*#	Amendment to Amended and Restated Employment Agreement by and between the Registrant and Gordon K. Johnson, dated as of October 13, 2015.
10.4*#	Amendment to Employment Agreement by and between the Registrant and Travis C. Mickle, Ph.D., dated as of October 13, 2015.
10.5*#	Amendment to Employment Agreement by and between the Registrant and Tracy M. Woody, dated as of September 4, 2015.
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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.
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32.1*	Certification Pursuant to 18. U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (1)
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* Filed herewith

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# 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.

EXHIBIT 10.1

AMENDMENT TO
EMPLOYMENT AGREEMENT

THIS AMENDMENT TO EMPLOYMENT AGREEMENT is made and entered into as of October 13, 2015 (this "***Amendment***") by and among **KEMPHARM, INC.**, a Delaware corporation (the "***Company***"), and Christal Mickle (the "***Executive***").

BACKGROUND

A. The Company and Executive previously entered into that certain Employment Agreement dated as of May 30, 2014 (the "***Employment Agreement***");

B. Pursuant to Section 17.F of the Employment Agreement, the Employment Agreement may be amended by a written instrument between the Company and the Executive; and

C. The Company and the Executive desire to amend the Employment Agreement as provided herein.

AMENDMENT

For and in consideration of the mutual promises and covenants set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties to this Amendment hereby agree as follows:

1. **Amendment to Section 2.** Section 2 of the Employment Agreement is hereby amended to include the following Subsection 2.E immediately following Subsection 2.D thereof:

> "E. Equity Compensation. All options granted pursuant to this Agreement, and each other outstanding equity award granted to Executive, shall accelerate so as to be fully vested and immediately exercisable immediately prior to any Change in Control (as defined in the Plan) of the Company."

2. This Amendment shall become effective immediately upon execution by the Company and the Executive.

3. Other than as set forth in this Amendment, all of the terms and conditions of the Employment Agreement shall continue in full force and effect.

[SIGNATURE PAGE FOLLOWS]

In Witness Whereof, the parties have executed this **Amendment to Employment Agreement** as of the date first written above.

COMPANY:

KemPharm, Inc.

By: /s/ R. LaDuane Clifton
Name: R. LaDuane Clifton
Title: Chief Financial Officer

In Witness Whereof, the parties have executed this **Amendment to Employment Agreement** as of the date first written above.

EXECUTIVE:

/s/ Christal Mickle
Christal Mickle

EXHIBIT 10.2

AMENDMENT TO
AMENDED AND RESTATED EMPLOYMENT AGREEMENT

THIS AMENDMENT TO AMENDED AND RESTATED EMPLOYMENT AGREEMENT is made and entered into as of October 13, 2015 (this "***Amendment***") by and among **KEMPHARM, INC.**, a Delaware corporation (the "***Company***"), and R. LaDuane Clifton (the "***Executive***").

BACKGROUND

A. The Company and Executive previously entered into that certain Amended and Restated Employment Agreement dated as of June 25, 2015 (the "***Employment Agreement***")

B. Pursuant to Section 16.F of the Employment Agreement, the Employment Agreement may be amended by a written instrument between the Company and the Executive; and

C. The Company and the Executive desire to amend the Employment Agreement as provided herein.

AMENDMENT

For and in consideration of the mutual promises and covenants set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties to this Amendment hereby agree as follows:

1. **Amendment to Section 2.C.** Section 2.C of the Employment Agreement is hereby deleted and replaced in its entirety by the following:

> "C. Equity Compensation. Upon the terms and conditions set forth in the following subsection, Company shall grant to Executive an option to purchase shares of Company's common stock ("Common Stock") pursuant to and in accordance with the terms and conditions of Company's 2014 Equity Incentive Plan, or a successor plan (the "Plan") and Company's form of option or stock grant agreement, as applicable. On or after the Effective Date, Company shall grant Executive stock options to purchase 45,000 shares of Common Stock (the "Option"). The Option shall have an exercise price equal to the fair market value of the Common Stock as of the grant date of the Option. The Option shall vest in equal shares over a four-year period commencing from the date of grant and, with 25% of the options vesting on the one-year anniversary of the Effective Date, and then the remainder of unvested options vesting on an annual basis thereafter until such time that all such shares are fully vested and exercisable, *provided*, that all options granted pursuant to this Section 2.C, and each other outstanding equity award granted to Executive, shall accelerate so as to be fully vested and immediately exercisable immediately prior to any Change in Control (as defined in the Plan) of the Company."

2. This Amendment shall become effective immediately upon execution by the Company and the Executive.

3. Other than as set forth in this Amendment, all of the terms and conditions of the Employment Agreement shall continue in full force and effect.

[SIGNATURE PAGE FOLLOWS]

In Witness Whereof, the parties have executed this **Amendment to Employment Agreement** as of the date first written above.

COMPANY:

KemPharm, Inc.

By: /s/ Travis Mickle
Name: Travis Mickle
Title: President and CEO

In Witness Whereof, the parties have executed this **Amendment to Employment Agreement** as of the date first written above.

EXECUTIVE:

/s/ R. LaDuane Clifton
R. LaDuane Clifton

AMENDMENT TO
AMENDED AND RESTATED EMPLOYMENT AGREEMENT

THIS AMENDMENT TO AMENDED AND RESTATED EMPLOYMENT AGREEMENT is made and entered into as of October 13, 2015 (this "***Amendment***") by and among **KEMPHARM, INC.**, a Delaware corporation (the "***Company***"), and Gordon K. Johnson (the "***Executive***").

BACKGROUND

A. The Company and Executive previously entered into that certain Amended and Restated Employment Agreement dated as of June 25, 2015 (the "***Employment Agreement***")

B. Pursuant to Section 17.F of the Employment Agreement, the Employment Agreement may be amended by a written instrument between the Company and the Executive; and

C. The Company and the Executive desire to amend the Employment Agreement as provided herein.

AMENDMENT

For and in consideration of the mutual promises and covenants set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties to this Amendment hereby agree as follows:

1. **Amendment to Section 2.C.** Section 2.C of the Employment Agreement is hereby deleted and replaced in its entirety by the following:

> "C. Equity Compensation. Upon the terms and conditions set forth in the following subsections on the Effective Date, Company shall grant to Executive an option (the "Option") to purchase 160,000 shares of Company's common stock ("Common Stock") pursuant to and in accordance with the terms and conditions of Company's 2014 Equity Incentive Plan, or a successor plan (the "Plan"), and the Company's form of option or stock grant agreement. The exercise price of the Option will be equal to the fair market value of the Common Stock on the date of such grant. The Option will vest on an annual basis over a period of four years with 25% of the shares of Common Stock subject to the Option vesting on the first anniversary of the date of grant and with an additional 25% of the shares of Common Stock subject to the Option vesting at each subsequent anniversary of the date of grant until such time that the Option is fully vested and exercisable, *provided*, that all options granted pursuant to this Section 2.C, and each other outstanding equity award granted to Executive, shall accelerate so as to be fully vested and immediately exercisable immediately prior to any Change in Control (as defined in the Plan) of the Company."

2. This Amendment shall become effective immediately upon execution by the Company and the Executive.

3. Other than as set forth in this Amendment, all of the terms and conditions of the Employment Agreement shall continue in full force and effect.

[SIGNATURE PAGE FOLLOWS]

In Witness Whereof, the parties have executed this **Amendment to Employment Agreement** as of the date first written above.

COMPANY:

KemPharm, Inc.

By: /s/ Travis Mickle
Name: Travis Mickle
Title: President and CEO

In Witness Whereof, the parties have executed this **Amendment to Employment Agreement** as of the date first written above.

EXECUTIVE:

/s/ Gordon K. Johnson
Gordon K. Johnson

EXHIBIT 10.4

AMENDMENT TO
EMPLOYMENT AGREEMENT

THIS AMENDMENT TO EMPLOYMENT AGREEMENT is made and entered into as of October 13, 2015 (this "***Amendment***") by and among **KEMPHARM, INC.**, a Delaware corporation (the "***Company***"), and Travis Mickle (the "***Executive***").

BACKGROUND

A. The Company and Executive previously entered into that certain Employment Agreement dated as of May 30, 2014 (the "***Employment Agreement***");

B. Pursuant to Section 17.F of the Employment Agreement, the Employment Agreement may be amended by a written instrument between the Company and the Executive; and

C. The Company and the Executive desire to amend the Employment Agreement as provided herein.

AMENDMENT

For and in consideration of the mutual promises and covenants set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties to this Amendment hereby agree as follows:

1. **Amendment to Section 2.** Section 2 of the Employment Agreement is hereby amended to include the following Subsection 2.E immediately following Subsection 2.D thereof:

> "E. Equity Compensation. All options granted pursuant to this Agreement, and each other outstanding equity award granted to Executive, shall accelerate so as to be fully vested and immediately exercisable immediately prior to any Change in Control (as defined in the Plan) of the Company."

2. This Amendment shall become effective immediately upon execution by the Company and the Executive.

3. Other than as set forth in this Amendment, all of the terms and conditions of the Employment Agreement shall continue in full force and effect.

[SIGNATURE PAGE FOLLOWS]

In Witness Whereof, the parties have executed this **Amendment to Employment Agreement** as of the date first written above.

COMPANY:

KemPharm, Inc.

By: /s/ R. LaDuane Clifton
Name: R. LaDuane Clifton
Title: Chief Financial Officer

In Witness Whereof, the parties have executed this **Amendment to Employment Agreement** as of the date first written above.

EXECUTIVE:

/s/ Travis Mickle
Travis Mickle

EXHIBIT 10.5

AMENDMENT TO
EMPLOYMENT AGREEMENT

THIS AMENDMENT TO EMPLOYMENT AGREEMENT is made and entered into as of September 4, 2015 (this "***Amendment***") by and among **KEMPHARM, INC.**, a Delaware corporation (the "***Company***"), and Tracy Woody (the "***Executive***").

BACKGROUND

A. The Company and Executive previously entered into that certain Employment Agreement dated as of March 30, 2015 (the "***Employment Agreement***")

B. Pursuant to Section 16.F of the Employment Agreement, the Employment Agreement may be amended by a written instrument between the Company and the Executive; and

C. The Company and the Executive desire to amend the Employment Agreement as provided herein.

AMENDMENT

For and in consideration of the mutual promises and covenants set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties to this Amendment hereby agree as follows:

1. **Amendment to Section 2.C.** Section 2.C of the Employment Agreement is hereby amended to include the following Subsection 2.C(4) immediately following Subsection 2.C(3) thereof:

> "(4) All options granted pursuant to this Section 2.C, and each other outstanding equity award granted to Executive, shall accelerate so as to be fully vested and immediately exercisable as of a Change in Control (as defined in the Company's 2014 Equity Incentive Plan)."

2. This Amendment shall become effective immediately upon execution by the Company and the Executive.

3. Other than as set forth in this Amendment, all of the terms and conditions of the Employment Agreement shall continue in full force and effect.

[SIGNATURE PAGE FOLLOWS]

In Witness Whereof, the parties have executed this **Amendment to Employment Agreement** as of the date first written above.

COMPANY:

KemPharm, Inc.

By: /s/ Travis Mickle
Name: Travis Mickle
Title: President and CEO

In Witness Whereof, the parties have executed this **Amendment to Employment Agreement** as of the date first written above.

EXECUTIVE:

/s/ Tracy Woody
Tracy Woody

1170 Celebration Blvd, Suite 103 | Celebration, Florida 34747 | Phone 321.939.3416 | www.kempharm.com

EXHIBIT 10.6

October 13, 2015

Mr. Sven Guenther

RE: Acceleration Provisions of Stock Options

I am pleased to announce that on September 4, 2015, the Compensation Committee of the Board of Directors of KemPharm, Inc. (the "***Company***") added the following acceleration provision (the "***Acceleration Provision***") to the vesting terms of all outstanding stock options (the "***Outstanding Options***") issued to you by the Company:

> "Notwithstanding anything to contrary, the vesting of this Option shall accelerate so as to be fully vested and immediately exercisable immediately prior to any Change in Control (as defined in the Plan) of the Company."

Other than the addition of the Acceleration Provision, the terms of your Outstanding Options shall remain unchanged, including without limitation the exercise price, number of shares, vesting schedule (including any non-Change in Control (as defined in the Company's 2014 Equity Incentive Plan) related acceleration provisions thereof) and the expiration date thereof.

Your Outstanding Options continue to be subject to the terms and conditions of your original option agreements and the Company's 2007 Stock Incentive Plan and 2014 Equity Incentive Plan, as applicable. No amended stock option agreements will be issued to you to reflect the Acceleration Provision. You should retain a copy of this letter with your original option agreements for your Outstanding Options. Except as expressly set forth in this letter agreement, no change or amendment is being made to your Outstanding Options and option agreements.

At your earliest convenience, please sign and return this letter agreement R. LaDuane Clifton, the Company's Chief Financial Officer, at lclifton@kempharm.com. Please contact R. LaDuane Clifton if you have any questions about the Acceleration Provision or your Outstanding Options.

Very truly yours,

/s/ Travis Mickle
Travis Mickle
President and Chief Executive Officer

By signing this letter agreement you hereby agree to the terms described herein, including without limitation to the addition of the Acceleration Provision to all of your Outstanding Options. You also acknowledge receipt of this letter agreement as of October 13, 2015, and agree that the amendment of your Outstanding Options to include the Acceleration Provision shall not be construed as an express or implied agreement of employment or other service-provider relationship with the Company other than on an at-will basis.

Agreed and acknowledged,

/s/ Sven Guenther
Sven Guenther

Exhibit 31.1

CERTIFICATIONS

I, Travis C. Mickle, certify that:

1. I have reviewed this quarterly report on Form 10-Q of KemPharm, Inc., for the quarterly period ended September 30, 2015;

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)) 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) 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

   (c) 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 13, 2015

/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. for the quarterly period ended September 30, 2015;

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)) 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) 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

   (c) 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 13, 2015

/s/ R. LaDuane Clifton

Name: R. LaDuane Clifton
Title: Chief Financial Officer
(Principal Financial Officer and Principal Accounting 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 of KemPharm, Inc., (the "Company") on Form 10-Q for the quarterly period ended September 30, 2015, 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 13, 2015

/s/ Travis C. Mickle

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

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 of KemPharm, Inc., (the "Company") on Form 10-Q for the quarterly period ended September 30, 2015, 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 13, 2015

/s/ R. LaDuane Clifton

Name: R. LaDuane Clifton
Title: Chief Financial Officer
(Principal Financial Officer and Principle Accounting Officer)