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 June 30, 2017

OR

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

For the Transition Period From _____ to

Commission File No. 001-36913

KEMPHARM, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**20-5894398**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
2500 Crosspark Road, Suite E126, 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 ☐

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 ☐

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

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

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

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

Total shares of common stock outstanding as of August 9, 2017: 14,657,430

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KEMPHARM, INC.

PART I
FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	As of June 30, 2017 (unaudited)	As of December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 12,386	$ 16,762
Restricted cash	1,100	1,100
Marketable securities	41,107	51,003
Trade date receivables	—	5,003
Prepaid expenses and other current assets	771	489
Total current assets	55,364	74,357
Property and equipment, net	2,148	1,970
Long-term investments	11,215	8,200
Other long-term assets	321	360
Total assets	$ 69,048	$ 84,887
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 6,303	$ 6,444
Current portion of capital lease obligation	177	157
Other current liabilities	112	41
Total current liabilities	6,592	6,642
Convertible notes, net	91,950	91,170
Derivative and warrant liability	8,311	4,618
Other long-term liabilities	1,472	1,153
Total liabilities	108,325	103,583
Commitments and contingencies (Note D)		
Stockholders’ deficit:		
Common stock, $0.0001 par value, 250,000,000 shares authorized, 14,657,430 shares issued and outstanding as of June 30, 2017 (unaudited); 14,646,982 shares issued and outstanding as of December 31, 2016	1	1
Additional paid-in capital	104,901	102,643
Preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of June 30, 2017 (unaudited) and December 31, 2016	—	—
Accumulated deficit	(144,179)	(121,340)
Total stockholders' deficit	(39,277)	(18,696)
Total liabilities and stockholders' deficit	$ 69,048	$ 84,887

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 June 30,		Six months ended June 30,	
	2017	2016	2017	2016
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	4,650	4,988	8,764	8,222
General and administrative	3,574	4,287	6,840	8,023
Total operating expenses	8,224	9,275	15,604	16,245
Loss from operations	(8,224)	(9,275)	(15,604)	(16,245)
Other (expense) income:				
Loss on extinguishment of debt	—	—	—	(4,740)
Interest expense related to amortization of debt issuance costs and discount	(390)	(393)	(780)	(835)
Interest expense on principal	(1,443)	(1,475)	(2,884)	(2,625)
Fair value adjustment	3,523	20,763	(3,693)	31,041
Interest and other income, net	13	144	114	246
Total other (expense) income	1,703	19,039	(7,243)	23,087
(Loss) income before income taxes	(6,521)	9,764	(22,847)	6,842
Income tax benefit (expense)	4	4	8	(8)
Net (loss) income	$ (6,517)	$ 9,768	$ (22,839)	$ 6,834
Net (loss) income per share:				
Basic	$ (0.44)	$ 0.59	$ (1.56)	$ 0.41
Diluted	$ (0.44)	$ (0.58)	$ (1.56)	$ (1.36)
Weighted average number of shares of common stock outstanding:				
Basic	14,649,586	14,597,449	14,648,291	14,546,576
Diluted	14,649,586	15,435,322	14,648,291	15,583,390

See Accompanying Notes to Unaudited Condensed Financial Statements

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

	Six Months Ended June 30,	
	2017	**2016**
Cash flows from operating activities:		
Net (loss) income	$ (22,839)	$ 6,834
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Loss on extinguishment of debt	—	4,740
Write-off of deferred offering costs	—	445
Stock-based compensation expense	2,254	2,279
Non-cash interest expense	2,220	2,443
Amortization of debt issuance costs and debt discount	780	835
Depreciation and amortization expense	164	55
Fair value adjustment	3,693	(31,041)
Loss on sublease	102	—
Change in assets and liabilities:		
Prepaid expenses and other assets	(151)	1,932
Accounts payable and accrued expenses	(2,318)	(693)
Other liabilities	101	32
Net cash used in operating activities	(15,994)	(12,139)
Cash flows from investing activities:		
Purchases of property and equipment	(143)	(219)
Purchases of marketable securities and long-term investments	(20,922)	(65,627)
Maturities of marketable securities	32,806	10,645
Net cash provided by (used in) investing activities	11,741	(55,201)
Cash flows from financing activities:		
Proceeds from issuance of debt, net of discounts and commissions	—	82,800
Repayment of term notes and related accrued interest	—	(18,621)
Payment of deferred offering costs	(50)	—
Payment of debt and stock issuance costs	—	(673)
Repayment of obligations under capital lease	(77)	(15)
Proceeds from exercise of common stock options and warrants	4	141
Net cash (used in) provided by financing activities	(123)	63,632
Net decrease in cash, cash equivalents and restricted cash	(4,376)	(3,708)
Cash, cash equivalents and restricted cash, beginning of period	17,862	32,318
Cash, cash equivalents and restricted cash, end of period	$ 13,486	$ 28,610
Supplemental cash flow information:		
Cash paid for interest	$ 2,857	$ 182
Transfer of warrants to equity upon exercise	—	755
Fixed assets included in accounts payable and accrued expenses	7	50
Deferred offering costs included in accounts payable and accrued expenses	60	—
Fixed assets financed under a lease agreement	284	548

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. 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 was formed and incorporated in Iowa on October 30, 2006 and reorganized in Delaware on May 30, 2014.

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. The Company also has an accumulated deficit at June 30, 2017. 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 ("GAAP") for interim financial information and with the instructions to Form 10-Q and Rule 8-03 of Regulation S-X. Accordingly, they do not include all of the information and related notes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included in the accompanying financial statements. Operating results for the three and six months ended June 30, 2017 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2017.

This interim information should be read in conjunction with the audited financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, filed with the Securities and Exchange Commission ("SEC") on March 10, 2017.

Initial Public Offering and Reverse Stock Split

In 2015, the Company completed an initial public offering ("IPO") of its common stock. Prior to the commencement of the IPO, the Company effected a 1-for-7.5 reverse stock split of its issued common stock. Upon completion of the IPO, all outstanding shares of the Company's redeemable convertible preferred stock were converted or reclassified into 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

During the second quarter of 2017, the Company early adopted Accounting Standards Update ("ASU") 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* ("ASU 2016-18"), which addresses the treatment of restricted cash and restricted cash equivalents in the statement of cash flows. The adoption of ASU 2016-18 reduced the Company's net cash used in investing activities and net decrease in cash and cash equivalents on the condensed statements of cash flows by $1.1 million for the six months ended June 30, 2016, as compared to the net cash used in investing activities and net decrease in cash and cash equivalents on the condensed statements of cash flows if the Company had not early adopted ASU 2016-18. This reclassification had no effect on the condensed balance sheets or statements of operations.

Entry into ATM Agreement

On October 3, 2016, the Company entered into a Common Stock Sales Agreement (the "ATM Agreement") with Cowen and Company, LLC ("Cowen") under which the Company may offer and sell, from time to time, in its sole discretion, shares of common stock having an aggregate offering price of up to $50,000,000 through Cowen as the Company's sales agent. The Company's registration statement on Form S-3 contemplated under the ATM Agreement was declared effective by the SEC on October 17, 2016. The registration statement on Form S-3 included a prospectus covering the offering up to $20,000,000 of shares of common stock in accordance with the ATM Agreement.

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

The Company is not obligated to make any sales of common stock under the ATM Agreement. The offering of shares of common stock pursuant to the ATM Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the ATM Agreement, or (ii) termination of the ATM Agreement in accordance with its terms. As of June 30, 2017, the Company has made no sales of its common stock pursuant to the terms of the ATM Agreement and had deferred offering costs related to the offering contemplated by the ATM Agreement recorded within prepaid and other current assets and other long-term assets in the amount of $0.2 million.

B. Summary of Significant Accounting Policies

Use of Estimates

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

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

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 could have elected to adopt new or revised accounting standards when they become effective for non-public companies, which typically is later than public companies must adopt the standards. The Company 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 November 2015, the FASB issued ASU 2015-17, *Income Taxes: Balance Sheet Classification of Deferred Taxes (Topic 740)* ("ASU 2015-17"), which requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. This update applies to all entities that present a classified statement of financial position. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. The adoption of ASU 2015-17 did not have a material impact on Company's financial statements and disclosures as the Company maintains a full valuation allowance.

In March 2016, the FASB issued ASU 2016-06, *Derivatives and Hedging (Topic 815), Contingent Put and Call Options in Debt Instruments* ("ASU 2016-06"), which clarifies the requirements for assessing whether contingent call and put options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts. ASU 2016-06 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted. The adoption of ASU 2016-06 did not have a material impact on Company's financial statements and disclosures.

In March 2016, the FASB issued ASU 2016-09, *Compensation–Stock Compensation (Topic 718), Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"), which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted. The adoption of ASU 2016-09 did not have a material impact on Company's financial statements and disclosures.

In November 2016, the FASB issued ASU 2016-18, which applies to all entities that have restricted cash or restricted cash equivalents and are required to present a statement of cash flows. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Company early adopted ASU 2016-18 in the current quarter. Refer to Note A for discussion regarding the impact the adoption of ASU 2016-18 had on the Company's financial statements and disclosures.

Application of New or Revised Accounting Standards—Not Yet Adopted

In May 2014, the FASB issued guidance codified in Accounting Standard Codification ("ASC") Topic 606, *Revenue Recognition—Revenue from Contracts with Customers* ("ASC 606"), which amends the guidance in former ASC 605, *Revenue Recognition*, and becomes effective beginning January 1, 2018. The Company does not currently expect this standard to have a material effect on its financial statements upon adoption since the Company is not generating revenue at this time.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments Overall – Recognition and Measurement of Financial Assets and Liabilities (Topic 825-10)* ("ASU 2016-01"), which provides several updates related to Topic 825-10. This update applies to all entities that hold financial assets or owe financial liabilities. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company is currently evaluating the impact of the adoption of ASU 2016-01 on its financial statements and disclosures.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which requires lessees to recognize assets and liabilities for operating leases with lease terms greater than twelve months in the balance sheet. The update also requires improved disclosures to help users of financial statements better understand the amount, timing and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the impact of the adoption of ASU 2016-02 on its financial statements and disclosures.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows – Classification of Certain Cash Receipts and Cash Payments (Topic 230)* ("ASU 2016-15"), which addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. This update applies to all entities that are required to present a statement of cash flows under Topic 230. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company is currently evaluating the impact of the adoption of ASU 2016-15 on its financial statements and disclosures.

In May 2017, the FASB issued ASU 2017-09, *Compensation – Stock Compensation (Topic 718) – Scope of Modification Accounting* ("ASU 2017-09"), which provides guidance about which changes to the terms or conditions of a stock-based payment award require an entity to apply modification accounting in Topic 718. This update applies to any entity that changes the terms or conditions of a stock-based payment award. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company is currently evaluating the impact of the adoption of ASU 2017-09 on its financial statements and disclosures.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) – I. Accounting for Certain Financial Instruments with Down Round Features and II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception* ("ASU 2017-11"), which addresses the complexity of accounting for certain financial instruments with down round features and addresses the difficulty of navigating Topic 480 because of the existence of extensive pending content in the ASC as a result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. This update applies to all entities that issue financial instruments that include down round features and entities that present earnings per share in accordance with Topic 260. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. The Company is currently evaluating the impact of the adoption of ASU 2017-11 on its financial statements and disclosures.

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”). As of June 30, 2016, Deerfield is no longer obligated to provide the Company any additional disbursements under the Deerfield Facility Agreement. 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 (the "Deerfield Note Put Option").

The Company also issued to Deerfield a warrant to purchase 14,423,076 shares of Series D redeemable convertible preferred stock (“Series D Preferred”) at an exercise price of $0.78 per share, which is exercisable until June 2, 2024 (the “Deerfield Warrant”). Upon completion of the IPO, the Deerfield Warrant automatically converted into a warrant to purchase 1,923,077 shares of the Company’s common stock at an exercise price of $5.85 per share. This warrant qualifies as a participating security under ASC Topic 260, *Earnings per Share*, and is treated as such in the earnings per share calculation (Note I). If a Major Transaction occurs, as defined below, Deerfield may require the Company to redeem the Deerfield Warrant for a cash amount equal to the Black-Scholes value of the portion of the Deerfield Warrant to be redeemed (the “Warrant Put Option”). A Major Transaction is (i) a consolidation, merger, exchange of shares, recapitalization, reorganization, business combination or other similar event; (ii) the sale or transfer in one transaction or a series of related transactions of all or substantially all of the assets of the Company; (iii) a third-party purchase, tender or exchange offer made to the holders of outstanding shares, such that following such purchase, tender or exchange offer a change of control has occurred; (iv) the liquidation, bankruptcy, insolvency, dissolution or winding-up affecting the Company; (v) the shares of the Company’s common stock cease to be listed on any eligible market; and (vi) at any time, the shares of the Company’s common stock cease to be registered under Section 12 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”).

In addition, the Company issued to Deerfield 1,923,077 shares of Series D Preferred as consideration for the loans provided to the Company under the Deerfield Facility Agreement. Upon completion of the IPO, these shares automatically reclassified into 256,410 shares of the Company’s common stock. The Company recorded the fair value of the shares of Series D Preferred of $1.5 million, to debt issuance costs on the date of issuance. The Company recorded the fair value of the Deerfield Warrant and the embedded Warrant Put Option to debt discount on the date of issuance. The debt issuance costs and debt discount are amortized over the term of the related debt and the expense is recorded as interest expense in the condensed statements of operations.

Pursuant to the Deerfield Facility Agreement, the Company may not enter into specified transactions, including a debt financing in the aggregate value of $750,000 or more, a merger, an asset sale or any other change of control transaction or any joint venture, partnership or other profit sharing arrangement, without the prior approval of Deerfield. Additionally, if the Company were to enter into a major transaction, including a merger, consolidation, sale of substantially all its assets or other change of control transaction, Deerfield would have the ability to demand that prior to consummation of such transaction the Company repay all outstanding principal and accrued interest of any notes issued under the Deerfield Facility Agreement. Under each warrant issued pursuant to the Deerfield Facility Agreement, Deerfield has the right to demand that the Company redeem the warrant for a cash amount equal to the Black-Scholes value of a portion of the warrant upon the occurrence of specified events, including a merger, an asset sale or any other change of control transaction.

The Company 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 also obligated to repay the balance of the outstanding principal amount on February 14, 2020. The Company prepaid all outstanding interest and principal on the Term Notes in February 2016.

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

Second Amendment to Senior Secured Convertible Note and Warrant

On January 6, 2016, the Company entered into a Second Amendment (the “Second Amendment”) to the Deerfield Convertible Notes and Deerfield Warrant, by and between the Company and Deerfield. The Second Amendment, among other things, clarified the calculation of an anti-dilution adjustment of the conversion price and exercise price of the Deerfield Convertible Notes and Deerfield Warrant, respectively, if the Company effects a firm commitment underwritten public offering of its securities. Except as modified by the Second Amendment, the Third Amendment (as described below) and the Fourth Amendment (as described below), all terms and conditions of the Deerfield Convertible Notes and Deerfield Warrant remain in full force and effect.

Issuance of 2021 Notes and Third Amendment to Senior Secured Convertible Note and Warrant

On February 9, 2016, the Company issued $86.3 million aggregate principal amount of its 5.50% Senior Convertible Notes due 2021 (the "2021 Notes") to Cowen and RBC Capital Markets, LLC., as representatives of the several initial purchasers (the "Initial Purchasers"), who subsequently resold the 2021 Notes to qualified institutional buyers (the "Note Offering") in reliance on the exemption from registration provided by Rule 144A under the Securities Act of 1933, as amended (the "Securities Act").

The net proceeds from the Note Offering were approximately $82.8 million, after deducting the Initial Purchasers' discount and estimated offering expenses. Concurrent with the Note Offering, the Company used approximately $18.6 million of the net proceeds from the Note Offering to repay in full the Term Notes, plus all accrued but unpaid interest, a make-whole interest payment and a prepayment premium on the Term Notes. This principal, accrued but unpaid interest, make-whole interest payment and prepayment premium on the Term Notes is reflected as a cash outflow from financing activity in the condensed statement of cash flows.

The 2021 Notes were issued pursuant to an Indenture, dated as of February 9, 2016 (the "Indenture"), between the Company and U.S. Bank National Association, as trustee. Interest on the 2021 Notes is payable semi-annually in cash in arrears on February 1 and August 1 of each year, beginning on August 1, 2016, at a rate of 5.50% per year. The 2021 Notes mature on February 1, 2021 unless earlier converted or repurchased. The 2021 Notes are not redeemable prior to the maturity date, and no sinking fund is provided for the 2021 Notes.

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

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

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

In connection with the Note Offering, on February 3, 2016, the Company entered into a Third Amendment (the "Third Amendment") to the Deerfield Facility Agreement, Deerfield Convertible Notes and Deerfield Warrant with Deerfield. The Third Amendment, among other things, eliminated the Company's ability to require Deerfield to convert the Deerfield Convertible Notes into Company common stock. In addition, pursuant to the Third Amendment, Deerfield consented to the prepayment of the Term Notes and the issuance of the 2021 Notes. Except as modified by the Third Amendment and the Fourth Amendment (as described below), all terms and conditions of the Deerfield Facility Agreement remain in full force and effect.

Fourth Amendment to Deerfield Convertible Notes and Deerfield Warrant

In connection with entering into the ATM Agreement, on October 3, 2016, the Company entered into a Fourth Amendment (the "Fourth Amendment") to the Deerfield Convertible Note and Deerfield Warrant with Deerfield. The Fourth Amendment, among other things, clarifies the calculation of an anti-dilution adjustment of the conversion price and exercise price of the Deerfield Convertible Note and Deerfield Warrant, respectively, if the Company effects an "at the market offering" as defined in Rule 415 of the Securities Act of its common stock.

Line of Credit

During the second quarter of 2016, the Company opened a line of credit with a total borrowing capacity of $1.1 million with City National Bank of Florida (the "Line of Credit Agreement") to support several irrevocable letters of credit issued by the bank on behalf of the Company. As of June 30, 2017, the Company had unused letters of credit totaling $0.4 million. The line of credit has a maturity date of January 31, 2018. As of June 30, 2017, the Company had no outstanding balance under the line of credit. The Line of Credit Agreement is collateralized by a restricted money market account, equal to the total amount of the borrowing capacity under the line of credit, held by the same bank institution. The money market account is reported as restricted cash on the condensed balance sheet. The line of credit contains no financial covenants. Borrowings under the Line of Credit Agreement carry interest at a rate equal to the 1-month London Interbank Offered Rate, or LIBOR, plus 2.00% per annum. The interest rate is updated at the beginning of each month for rate changes that occurred during the previous month. The interest rate under the Line of Credit Agreement was 3.06% as of June 30, 2017.

D. Commitments and Contingencies

From time to time, the Company is involved in various legal proceedings arising in the normal course of business. For some matters, a liability is not probable or the amount cannot be reasonably estimated and, therefore, an accrual has not been made. However, for such matters when it is probable that the Company has incurred a liability and can reasonably estimate the amount, the Company accrues and discloses such estimates. As of June 30, 2017 and December 31, 2016, no accruals have been made related to commitments and contingencies.

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. On January 6, 2016, the Company entered into a Settlement Agreement and Mutual Release (the "Settlement Agreement") with the former financial advisor and Donald DeWaay, Jr. pursuant to which, among other things, the former financial advisor agreed, in exchange for the consideration described therein, to dismiss with prejudice its pending appeal. The former financial advisor's appeal was subsequently dismissed by the Supreme Court of Iowa on January 7, 2016. The settlement amount was commensurate with the contingency recorded in the books and records of the Company. The consideration in the settlement agreement did not differ from the accrual previously recorded by the Company by a material amount.

In December 2016, a class action suit was filed against the Company in the Iowa District Court in Johnson County by a stockholder alleging that the Company, certain of its senior executives and directors who signed the registration statement in connection with its initial public offering, and each of the investment banks that acted as underwriters for the offering negligently, issued untrue statements of material facts and omitted to state material facts required to be stated in the registration statement and incorporated offering materials that the Company filed with the SEC in support of the offering. The plaintiff does not quantify any alleged damages in his complaint but, in addition to attorneys' fees and costs, the plaintiff seeks to recover damages and obtain other relief on behalf of himself and all other persons who purchased the Company's common stock pursuant or traceable to the offering and the registration statement and who were allegedly damaged thereby.

In January 2017, the class action suit was removed to the U.S. District Court for the Southern District of Iowa. The plaintiff subsequently filed a motion to remand the case to the Iowa District Court, and that motion was granted. The suit is still in a preliminary stage and has not yet been set for trial. Accordingly, the Company is unable to predict the timing or outcome of this litigation as of the date of this report.

North Carolina Sublease

During the second quarter of 2017, the Company subleased its office space in North Carolina under a non-cancelable operating lease to a third-party tenant. The sublease term with the third-party runs concurrent with the lease term the Company has with the landlord.

E. Preferred Stock and Warrants

Authorized, Issued, and Outstanding Preferred Stock

As of June 30, 2017, the Company had 10,000,000 shares of authorized and undesignated preferred stock, and did not have any preferred stock outstanding.

Warrants

During 2013, the Company issued $3.8 million of convertible notes and the warrants (the "2013 Warrants") to purchase 1,079,453 shares of equity securities in a future financing meeting specified criteria (a "Qualified Financing"). The 2013 Warrants allow the holders to purchase shares of the same class and series of equity securities issued in the Qualified Financing for an exercise price equal to the per share price paid by the purchasers of such equity securities in the Qualified Financing. When the Company entered into the Deerfield Facility Agreement, the 2013 Warrants became warrants to purchase 1,079,453 shares of Series D preferred stock. 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 stock (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 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 marked the 2013 Warrants to fair value and reclassified them to equity upon closing of the IPO. The Deerfield Warrant remains classified as a liability and is recorded at fair value at each reporting period since it can be settled in cash. Changes to the fair value of the warrant liability are recorded through the condensed statements of operations as a fair value adjustment (Note H).

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, 14,657,430 and 14,646,982 shares of common stock were issued and outstanding at June 30, 2017 and December 31, 2016, respectively.

At June 30, 2017 and December 31, 2016, the Company had reserved authorized shares of common stock for future issuance as follows:

	June 30, 2017	December 31, 2016
Conversion of Deerfield Convertible Notes	1,750,954	1,751,296
Conversion of 2021 Notes	5,040,914	5,040,914
Outstanding awards under equity incentive plans	2,873,344	1,990,260
Outstanding common stock warrants	2,027,763	2,087,477
Possible future issuances under equity incentive plans	928,800	1,244,671
Total common shares reserved for future issuance	12,621,775	12,114,618

Common Stock Activity

The following table summarizes common stock activity for the six months ended June 30, 2017:

	Shares of Common Stock
Balance at December 31, 2016	14,646,982
Common stock warrants exercised	698
Common stock options exercised	9,750
Balance at June 30, 2017	14,657,430

The Company calculates the fair value of common stock warrants using a Monte Carlo simulation. There were warrants exercised for an aggregate of 698 and 141,095 shares of common stock during the six months ended June 30, 2017 and 2016, respectively. From 2008 through 2012, the Company issued warrants to purchase 595,920 shares of common stock in its private placement offerings of Series A redeemable convertible preferred stock, Series B redeemable convertible preferred stock and Series C redeemable convertible preferred stock (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 (expense) income in the condensed 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. 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 3,432,183 as of June 30, 2017. The number of shares of common stock reserved for issuance under the 2014 Plan will automatically increase on January 1 of each year, beginning on January 1, 2016, and ending on and including January 1, 2024, by 4% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined, by the Board. Pursuant to the terms of the 2014 Plan, on January 1, 2017, the common stock reserved for issuance under the 2014 Plan automatically increased by 585,879 shares.

During the three and six months ended June 30, 2017 and 2016, stock options were exercised for a total of 9,250 and 14,933 shares of common stock, respectively.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Research and development	$ 340	$ 268	$ 631	$ 455
General and administrative	825	989	1,623	1,824
Total	1,165	$ 1,257	2,254	$ 2,279

There was no stock-based compensation expense related to performance-based awards recognized during the three or six months ended June 30, 2017. There was no stock-based compensation expense related to performance-based incentive awards recognized during the three months ended June 30, 2016. During the six months ended June 30, 2016, the Company recognized $29,000 of stock-based compensation expense related to performance-based awards included in research and development expenses in connection with the vesting of stock options exercisable for an aggregate of 13,333 shares of common stock as a result of the acceptance of the new drug application for Apadaz™, the Company's product candidate which consists of KP201, its prodrug of hydrocodone and acetaminophen, for priority review in February 2016.

H. Fair Value of Financial Instruments

The accounting standard for fair value measurements provides a framework for measuring fair value and requires disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, based on the Company's principal or, in absence of a principal, most advantageous market for the specific asset or liability.

The Company uses a three-tier fair value hierarchy to classify and disclose all assets and liabilities measured at fair value on a recurring basis, as well as assets and liabilities measured at fair value on a non-recurring basis, in periods subsequent to their initial measurement. The hierarchy requires the Company to use observable inputs when available, and to minimize the use of unobservable inputs, when determining fair value. The three tiers are defined as follows:

- Level 1—Observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets;
- Level 2—Observable inputs other than quoted prices in active markets that are observable either directly or indirectly in the marketplace for identical or similar assets and liabilities; and
- Level 3—Unobservable inputs that are supported by little or no market data, which require the Company to develop its own assumptions.

The carrying amounts of certain financial instruments, including cash and cash equivalents, restricted cash and accounts payable, approximate their respective fair values due to the short-term nature of such instruments.

The fair value of the Deerfield Convertible Notes was $11.0 million and $10.2 million, respectively, at June 30, 2017 and December 31, 2016. The fair value of the 2021 Notes was $50.0 million and $46.3 million, respectively, at June 30, 2017 and December 31, 2016. Both the Deerfield Convertible Notes and the 2021 Notes fall within Level 3 of the fair value hierarchy as their value is based on the credit worthiness of the Company, which is an unobservable input. The Company used a Tsiveriotis-Fernandes model to value the Deerfield Convertible Notes and 2021 Notes at June 30, 2017 and December 31, 2016.

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 June 30, 2017 and December 31, 2016 (in thousands):

	Balance at June 30, 2017	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Deerfield Warrant liability	5,212	—	—	5,212
Embedded Warrant Put Option	461	—	—	461
Fundamental change and make-whole interest provisions embedded in 2021 Notes	12	—	—	12
Embedded Deerfield Note Put Option	2,626			2,626
Total liabilities	$ 8,311	$ —	$ —	$ 8,311
Trading securities:				
Certificates of deposit	8,316	8,316	—	—
U.S. Treasury securities	38,504	38,504	—	—
U.S. government-sponsored agency securities	5,502	—	5,502	—
Total assets	$ 52,322	$ 46,820	$ 5,502	$ —

	Balance at December 31, 2016	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Underwriter Warrant liability	$ 16	$ —	$ —	$ 16
Deerfield Warrant liability	4,231	—	—	4,231
Embedded Warrant Put Option	365	—	—	365
Fundamental change and make-whole interest provisions embedded in 2021 Notes	6	—	—	6
Total liabilities	$ 4,618	$ —	$ —	$ 4,618
Trading securities:				
Certificates of deposit	7,788	7,788	—	—
U.S. Treasury securities	37,066	37,066	—	—
U.S. government-sponsored agency securities	14,349	—	14,349	—
Total assets	$ 59,203	$ 44,854	$ 14,349	$ —

The Company's Underwriter Warrant liability, Deerfield Warrant liability, embedded Warrant Put Option, the fundamental change and the make-whole interest provisions embedded in the 2021 Notes, and the embedded Deerfield Note Put Option, as well as the trading securities are measured at fair value on a recurring basis. As of June 30, 2017 and December 31, 2016, the Underwriter Warrant liability, Deerfield Warrant liability, embedded Warrant Put Option, and the fundamental change and make-whole interest provisions embedded in the 2021 Notes are reported on the condensed balance sheet in derivative and warrant liability, while the trading securities are reported on the condensed balance sheet in marketable securities and long-term investments. As of June 30, 2017, the embedded Deerfield Note Put Option is reported on the condensed balance sheet in derivative and warrant liability. The Company used a Monte Carlo simulation to value the Underwriter Warrant liability, Deerfield Warrant liability, embedded Warrant Put Option, and the fundamental change and make-whole interest provisions embedded in the 2021 Notes at June 30, 2017 and December 31, 2016. The Company also used a Monte Carlo simulation to value the embedded Deerfield Note Put Option at June 30, 2017. Significant unobservable inputs used in measuring the fair value of these financial instruments included the Company's estimated enterprise value, an estimate of the timing of a liquidity or fundamental change event, 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, Deerfield Warrant liability, embedded Warrant Put Option, the fundamental change and make-whole interest provisions embedded in the 2021 Notes and the embedded Deerfield Note Put Option are reflected in the condensed statements of operations as a fair value adjustment.

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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Balance at beginning of period	$ 11,834	$ 27,479	$ 4,618	$ 37,839
Exercise of warrants	—	(673)	—	(755)
Adjustment to fair value	(3,523)	(20,763)	3,693	(31,041)
Balance at end of period	$ 8,311	$ 6,043	$ 8,311	$ 6,043

I. Net (Loss) Income 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) income 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 net (loss) income per share in which it is assumed that the outstanding participating securities convert 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 (loss) income per share during the period.

Diluted net loss per share was the same as basic net loss per share for the three and six month periods ended June 30, 2017 because the effects of potentially dilutive items were anti-dilutive given the Company's net loss for the three and six month periods ended June 30, 2017.

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

	Three and Six Months Ended June 30,	
	2017	**2016**
Warrants to purchase common stock	2,027,763	164,400
Awards under equity incentive plans	2,873,344	2,238,153
Deerfield Convertible Notes	1,750,954	2,088,931
2021 Notes	5,040,914	5,040,914
Total	11,692,975	9,532,398

The following table reconciles basic net income per share of common stock to diluted net loss per share of common stock for the three and six month periods ended June 30, 2016 (in thousands, except per share data):

	Three Months Ended	Six Months Ended
	June 30, 2016	
Basic net income per share of common stock:		
Net income	$ 9,768	$ 6,834
Less: Net income allocable to participating securities	(1,137)	(798)
Net income allocable to shares of common stock	**8,631**	**6,036**
Less: Dividends declared or accumulated	—	—
Undistributed net income allocable to shares of common stock, basic	**$ 8,631**	**$ 6,036**
Weighted average number of shares of common stock outstanding	14,597	14,547
Basic net income per share of common stock	**$ 0.59**	**$ 0.41**
Diluted net loss per share of common stock:		
Net income	$ 9,768	$ 6,834
Less: Fair value adjustment for Deerfield stock warrants	(18,769)	(28,001)
Net loss allocable to shares of common stock, diluted	**$ (9,001)**	**$ (21,167)**
Weighted average number of shares of common stock outstanding	14,597	14,547
Dilutive effect of Deerfield stock warrants	838	1,037
Weighted average number of shares of common stock outstanding, diluted	**15,435**	**15,583**
Diluted net loss per share of common stock	**$ (0.58)**	**$ (1.36)**

J. Severance Expense

On September 15, 2016, the Company announced its intention to defer its commercial operations and realign its financial resources and operational priorities towards its product development pipeline. The activities related to the deferral and realignment were completed during the year ended December 31, 2016. As part of these activities, the Company reduced its workforce by three employees. Personnel and other related charges of approximately $1.1 million and stock compensation expense of approximately $1.9 million related to the acceleration of vesting on certain stock options, related to the workforce reduction, were presented as severance expense in the statements of operations for the year ended December 31, 2016. As of June 30, 2017, the Company had accrued severance expense recorded within accounts payable and accrued expenses in the amount of $0.2 million.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

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

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

Forward-Looking Statements

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

- *the progress of, timing of and amount of expenses associated with our research, development and commercialization activities;*
- *the timing, conduct and success of our clinical studies for our product candidates;*
- *our expectations regarding federal, state and foreign regulatory requirements;*
- *the therapeutic benefits and effectiveness of our product candidates;*
- *the size and characteristics of the markets that may be addressed by our product candidates;*
- *our intention to seek to establish strategic collaborations or partnerships for the development or sale of our product candidates;*
- *our expectations as to future financial performance, expense levels and liquidity sources; and*
- *the timing of commercializing our product candidates.*

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

Overview

We are a 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. We are building a pipeline of prodrug product candidates that target large market opportunities in pain, attention deficit hyperactivity disorder, or ADHD, and central nervous system, or CNS, disorders. Our lead product candidates include KP415 and KP484, our extended release, or ER, d-threo-methylphenidate product candidates for the treatment of ADHD, and KP201/IR, our acetaminophen, or APAP, free, single-entity, benzhydrocodone hydrochloride immediate-release, or IR, abuse-deterrent product candidate designed for the treatment of acute pain. We own worldwide commercial rights for all of our product candidates, except that Shire Pharmaceuticals, LLC, or Shire, has a right of first refusal to acquire, license or commercialize KP415 and KP484.

We previously submitted a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, for our product candidate Apadaz, which consists of KP201, our prodrug of hydrocodone, and APAP. In June 2016, the FDA issued a complete response letter, or CRL, for our Apadaz NDA. Generally, the FDA issues CRLs to indicate that the FDA considers the review cycle for an application complete and that the application is not ready for approval in its present form. In its CRL, the FDA advised us that it did not believe our proposed labeling included in the application accurately conveyed the outcome of our abuse deterrence studies of Apadaz. In August 2016, we completed our end-of-review meeting with the FDA. At the end-of-review meeting, we discussed with the FDA the issues identified by the FDA in the Apadaz NDA and what we believe is the potential to achieve a path forward for an Apadaz product label that could include abuse deterrence claims. The meeting also involved discussions pertaining to abuse deterrence in relation to the broader IR prescription opioid market, hydrocodone-APAP combination products, and published industry guidance from the FDA concerning the evaluation and labeling of abuse deterrent opioids. In November 2016, we elected to continue the regulatory review process for Apadaz with the submission of a Formal Dispute Resolution Request, or FDRR, to the FDA. We anticipate up to twelve months from the date of our FDRR may be required to complete all parts of the FDRR process.

We are a development stage company and have not generated any revenue. We have incurred operating losses since our inception and, as of June 30, 2017, had an accumulated deficit of $144.2 million. Our loss from operations for the three and six months ended June 30, 2017 and 2016 were $8.2 million and $9.3 million and $15.6 million and $16.2 million, respectively.

We expect to continue to incur significant expenses and operating losses for the foreseeable future, and those expenses and losses may fluctuate significantly from quarter-to-quarter and year-to-year. We anticipate that our expenses will 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 any product candidates that successfully complete clinical trials;
- continue research and preclinical development and initiate clinical trials of our other product candidates;
- seek to discover and develop additional product candidates either internally or in partnership with other pharmaceutical companies;
- 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; and
- incur additional legal, accounting and other expenses in operating as a public company.

Our commercial revenue, if any, will be derived from sales of prodrug products and we do not currently know when, if ever, any of our product candidates will be commercially available. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or debt, the terms of these securities 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.

Our Prodrug Product Candidates

We have employed our LAT platform technology to create a portfolio of product candidates that we believe will offer significant improvements over FDA-approved and widely prescribed drugs. In June 2017, we announced the development of KP484, our prodrug product candidate for the super-extended release of d-threo-methylphenidate, designed for the treatment of ADHD in patients that respond best with a long duration of therapy. KP484 was developed during a data analysis of the KP415 Phase 1 study, in which we observed that the prodrug molecule demonstrated an ability to produce a longer duration release of d-threo-methylphenidate relative to the comparator. As a result, we have initiated development of KP484 and anticipate filing an Investigational New Drug application for KP484 as early as the third quarter of 2017 and NDA submission as early as 2019.

Our pipeline of product candidates is summarized in the table below:

Selected KemPharm Prodrug Product Candidates

Indication / Parent Drug	Product Candidate	Development Status	Key Milestone
ADHD			
Methylphenidate (ER)	KP415	Clinical	NDA Submission - 2018 Pivotal Efficacy Trial Data - 2018
Methylphenidate (ER)	KP484	Clinical	NDA Submission - 2019 Pivotal Efficacy Trial Data - 2018
Pain			
Hydrocodone (IR)	KP201/IR (APAP-free)	"Fast Track" Designation December 2016	NDA Submission - 2018 Human POC Data - 2017
Hydromorphone (ER)	KP511/ER	“Fast Track” Designation May 2016	NDA Submission - 2019 Human POC Data - 2018
Hydromorphone (IR)	KP511/IR	Clinical	NDA Submission - 2019 Human POC Data - 2018
Oxycodone (IR)	KP606/IR	Preclinical	
Oxymorphone	KP746	Preclinical	
CNS			
Quetiapine	KP303	Preclinical	

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 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 any products that utilize KP201 as the active pharmaceutical ingredient, or API. The percentage royalty rate ranges from the high teens at low volumes to the mid-single digits at higher volumes.

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 any products that utilize KP201 as the API, JMI will manufacture batches of KP201 at a price to be negotiated. Failure to agree upon this pricing would result in JMI supplying these batches to us free of charge and we would pay JMI an additional royalty payment on such batches. The percentage royalty rate ranges from the low teens at low volumes to the low single digits at higher volumes and is additive to any minimum royalty we may owe JMI on such batch. JMI will manufacture and supply KP201 at a price equal to JMI’s fully allocated manufacturing cost after commercial launch should we obtain approval for marketing from the FDA.

We must purchase all our U.S. KP201 needs from JMI and JMI cannot supply KP201 to other companies. After the commercial launch of any product that utilizes KP201 as the API, JMI is required to identify a secondary manufacturing site and qualify and validate that site to produce 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 the commercial launch of any product that utilizes KP201 as the API, whichever date is later. Upon the expiration of such term, the agreement will automatically renew for a period of two years unless either party provides 12 months’ prior notice of its intent not to renew.

Under our March 2012 asset purchase agreement with Shire, Shire has a right of first refusal to acquire, license or commercialize KP415 and KP484.

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 or KP484, and any product candidates arising therefrom, including royalty payments on any license of KP415 or KP484, the sale of KP415 or KP484 to a third party, the commercialization of KP415 or KP484 and the portion of any consideration that is attributable to the value of KP415 or KP484 and paid to us or our stockholders in a change of control transaction.

Results of Operations

Comparison of the Three Months Ended June 30, 2017 and 2016 (in thousands):

	Three Months Ended June 30,		Period-to-Period Change
	2017	2016	
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	4,650	4,988	(338)
General and administrative	3,574	4,287	(713)
Total operating expenses	8,224	9,275	(1,051)
Loss from operations	(8,224)	(9,275)	1,051
Other (expense) income:			
Interest expense related to amortization of debt issuance costs and discount	(390)	(393)	3
Interest expense on debt principal	(1,443)	(1,475)	32
Fair value adjustment	3,523	20,763	(17,240)
Interest and other income, net	13	144	(131)
Total other (expense) income	1,703	19,039	(17,336)
(Loss) income before income taxes	(6,521)	9,764	(16,285)
Income tax benefit	4	4	—
Net (loss) income	$ (6,517)	$ 9,768	$ (16,285)

Net (Loss) Income

Net loss for the three months ended June 30, 2017 was $6.5 million, a change of $16.3 million compared to net income for the three months ended June 30, 2016 of $9.8 million. The change was primarily attributable to a period-over-period change of $17.2 million in fair value adjustment related to changes in the derivative and warrant liability for each period resulting in non-cash income of $3.5 million for the three months ended June 30, 2017 compared to non-cash income of $20.8 million for the three months ended June 30, 2016. Also contributing to the change in net (loss) income is an increase in net interest expense and other items of $0.1 million. These changes were partially offset by a decrease in loss from operations of $1.1 million.

Research and Development

Research and development expenses decreased by $0.3 million, from $5.0 million for the three months ended June 30, 2016, to $4.7 million for the three months ended June 30, 2017. This decrease was primarily attributable to a decrease in research and development costs related to overhead.

General and Administrative

General and administrative expenses decreased by $0.7 million, from $4.3 million for the three months ended June 30, 2016, to $3.6 million for the three months ended June 30, 2017. This decrease was primarily attributable to a decrease in personnel costs, including stock-based compensation, as well as other decreases in general and administrative costs related to overhead.

Other (Expense) Income

Other (expense) income decreased by $17.3 million, from income of $19.0 million for the three months ended June 30, 2016, to income of $1.7 million for the three months ended June 30, 2017. This period-to-period change was primarily attributable to the $17.2 million decrease in the fair value adjustment related to our derivative and warrant liability and an increase in net interest expense and other items of $0.1 million.

Comparison of the Six Months Ended June 30, 2017 and 2016 (in thousands):

	Six Months Ended June 30,		Period-to-Period Change
	2017	2016	
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	8,764	8,222	542
General and administrative	6,840	8,023	(1,183)
Total operating expenses	15,604	16,245	(641)
Loss from operations	(15,604)	(16,245)	641
Other (expense) income:			
Loss on extinguishment of debt	—	(4,740)	4,740
Interest expense related to amortization of debt issuance costs and discount	(780)	(835)	55
Interest expense on debt principal	(2,884)	(2,625)	(259)
Fair value adjustment	(3,693)	31,041	(34,734)
Interest and other income, net	114	246	(132)
Total other (expense) income	(7,243)	23,087	(30,330)
(Loss) income before income taxes	(22,847)	6,842	(29,689)
Income tax benefit (expense)	8	(8)	16
Net (loss) income	$ (22,839)	$ 6,834	$ (29,673)

Net (Loss) Income

Net loss for the six months ended June 30, 2017 was $22.8 million, a change of $29.7 million compared to net income for the six months ended June 30, 2016 of $6.8 million. The change was primarily attributable to a period-over-period change of $34.7 million in fair value adjustment related to changes in the derivative and warrant liability for each period resulting in non-cash expense of $3.7 million for the six months ended June 30, 2017 compared to non-cash income of $31.0 million for the six months ended June 30, 2016. Also contributing to the change in net (loss) income is an increase in net interest expense and other items of $0.3 million. These changes were partially offset by a decrease in loss from operations of $0.6 million and the non-recurrence in 2017 of a non-cash loss on extinguishment of debt of $4.7 million recognized during the six months ended June 30, 2016 related to the payment of the term note previously issued to Deerfield Private Design Fund III, L.P., or Deerfield.

Research and Development

Research and development expenses increased by $0.6 million, from $8.2 million for the six months ended June 30, 2016, to $8.8 million for the six months ended June 30, 2017. This increase was primarily attributable to increases in net third-party research and development costs and personnel costs, including stock-based compensation. These increases are partially offset by decreases in other research and development costs related to overhead.

General and Administrative

General and administrative expenses decreased by $1.2 million, from $8.0 million for the six months ended June 30, 2016, to $6.8 million for the six months ended June 30, 2017. This decrease was primarily attributable to a decrease in personnel costs, including stock-based compensation, as well as other decreases in general and administrative costs related to overhead.

Other (Expense) Income

Other (expense) income changed by $30.3 million, from income of $23.1 million for the six months ended June 30, 2016, to expense of $7.2 million for the six months ended June 30, 2017. This period-to-period change was primarily attributable to the $34.7 million change in the fair value adjustment related to our derivative and warrant liability and an increase in net interest expense and other items of $0.3 million. These changes were partially offset by the non-recurrence in 2017 of a non-cash loss on extinguishment of debt of $4.7 million recognized during the six months ended June 30, 2016 related to the payment of the term note previously issued to Deerfield.

Liquidity and Capital Resources

Sources of Liquidity

Through June 30, 2017, we have funded our research and development and operating activities primarily through the issuance of $115.9 million of debt, $25.3 million of private placements of redeemable convertible preferred stock and the sale of common stock in our initial public offering. As of June 30, 2017, we had cash and cash equivalents of $12.4 million, restricted cash of $1.1 million, marketable securities of $41.1 million and long-term investments of $11.2 million. We completed the initial closing of our initial public offering in April 2015, 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 filed a registration statement on Form S-3 covering the sale from time to time of up to $150.0 million of our common stock, preferred stock, debt and/or warrants, which was declared effective by the U.S. Securities and Exchange Commission, or the SEC, on October 17, 2016. We have not issued any of our securities under this registration statement.

On October 3, 2016, we entered into a Common Stock Sales Agreement, or the ATM Agreement, with Cowen and Company, LLC, or Cowen, under which we may offer and sell, from time to time, in our sole discretion, shares of common stock having an aggregate offering price of up to $50,000,000 through Cowen as our sales agent. The registration statement on Form S-3 included a prospectus covering the offering up to $20,000,000 of shares of common stock in accordance with the ATM Agreement. We have not sold any shares of our common stock under the ATM Agreement.

We have incurred operating losses since our inception and, as of June 30, 2017, had an accumulated deficit of $144.2 million. We anticipate that we will continue to incur operating losses for at least the next several years. We expect that our operating 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.

Convertible Debt

As of June 30, 2017, we had $96.3 million of convertible notes outstanding, consisting of a secured convertible note with Deerfield in the principal amount of $10.0 million, or the Deerfield Note, and $86.3 million principal amount of 5.50% senior convertible notes due 2021, or the 2021 Notes.

Deerfield Facility

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

All loans issued under the Deerfield facility, including the Deerfield Note, 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 was due on July 1, 2016. We elected this option on all eight of the scheduled interest payments through June 30, 2016 and paid all such interest 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. However, in connection with our offering of the 2021 Notes, on February 3, 2016, we entered into an amendment to the Deerfield facility in which Deerfield consented to the prepayment of its $15.0 million term note and the issuance of the 2021 Notes.

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 initial public offering, 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, or the Deerfield Warrant. Upon closing of our initial public offering, this warrant converted into a warrant exercisable for 1,923,077 shares of our common stock at an exercise price of $5.85 per share.

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

The Deerfield facility also includes high yield discount obligation protections that go into effect in June 2019. After this time, if at any interest payment date our outstanding indebtedness under the Deerfield facility 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.

2021 Notes

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

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

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

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

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

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

Cash Flows

Comparison of the Six Months Ended June 30, 2017 and 2016 (in thousands):

	Six Months Ended June 30,		Period-to Period Change
	2017	2016	
Net cash used in operating activities	$ (15,994)	$ (12,139)	$ (3,855)
Net cash provided by (used in) investing activities	11,741	(55,201)	66,942
Net cash (used in) provided by financing activities	(123)	63,632	(63,755)
Net decrease in cash, cash equivalents and restricted cash	$ (4,376)	$ (3,708)	$ (668)

Operating Activities

For the six months ended June 30, 2017, net cash used in operating activities of $16.0 million consisted of a net loss of $22.8 million primarily attributable to our spending on research and development programs and $2.4 million in changes in working capital, partially offset by $9.2 million in adjustments for non-cash items. The changes in working capital consisted of $2.3 million related to accounts payable and accrued expenses and $0.2 million related to prepaid expense and other assets, partially offset by $0.1 million related to other liabilities. The adjustments for non-cash items primarily consisted of a non-cash loss related to the change in the fair value of our derivative and warrant liabilities of $3.7 million, stock-based compensation expense of $2.3 million, non-cash interest expense of $2.2 million, amortization of debt issuance costs and debt discount of $0.8 million, loss on sublease of $0.1 million and $0.1 million related to depreciation and amortization.

For the six months ended June 30, 2016, net cash used in operating activities of $12.1 million consisted of net income of $6.8 million and $1.3 million provided by changes in working capital, which includes the impact of the refund of the $2.4 million user fee for the Apadaz NDA; offset by $20.2 million in adjustments for non-cash items. Adjustments for non-cash items primarily consisted of changes in fair value of our derivative and warrant liabilities of $31.0 million, partially offset by a loss on extinguishment of debt of $4.7 million primarily comprised of the write-off of debt issuance costs and debt discount and a make-whole interest payment related to the repayment of the term note issued under the Deerfield facility, non-cash interest expense of $2.5 million, stock-based compensation expense of $2.3 million, amortization of debt issuance costs and debt discount of $0.8 million and a $0.5 million write-off of deferred offering costs.

Investing Activities

For the six months ended June 30, 2017, net cash provided by investing activities was $11.7 million, which was primarily attributable to maturities of marketable securities of $32.8 million, partially offset by purchases of marketable securities and long-term investments of $20.9 million and purchases of property and equipment of $0.2 million.

For the six months ended June 30, 2016, net cash used in investing activities of $55.2 million consisted of purchases of marketable securities and long-term investments of $65.6 million and purchases of property and equipment of $0.2 million; partially offset by maturity of marketable securities of $10.6 million during the period.

Financing Activities

For the six months ended June 30, 2017, net cash used in financing activities was $123,000. Net cash consisted of a repayment of $77,000 of obligations under capital lease arrangements and payment of $50,000 of deferred offering costs; these payments were partially offset by proceeds from exercise of common stock warrants of $4,000.

For the six months ended June 30, 2016, net cash provided by financing activities was $63.6 million. Net cash consisted of (i) $82.8 million in proceeds, net of discounts and commissions, from the issuance of the 2021 Notes, of which we used approximately $18.6 million to repay in full the $15.0 million principal amount, accrued but unpaid interest, a make whole interest payment and a prepayment premium all related to the term note issued under the Deerfield facility and (ii) $0.1 million in proceeds from the exercise of common stock options and warrants; partially offset by payment of debt issuance costs of $0.7 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 of and commercialize one 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, restricted cash, marketable securities and long-term investments will enable us to fund our operating expenses and capital expenditure requirements through the second quarter of 2019. 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. To meet any additional cash requirements, we may seek to sell additional equity or convertible securities that may result in dilution to our stockholders. 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 any of our product candidates.

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;
- 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 and we do not currently know when, if ever, any of our product candidates will be commercially available. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or debt, the terms of these securities 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.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

Critical Accounting Policies and Significant Judgements and Estimates

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

Our critical accounting policies have not changed materially from those described in Note B of our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, filed with the SEC on March 10, 2017.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Our management, with the participation of our chief executive officer and our chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2017. Based on the evaluation of our disclosure controls and procedures as of June 30, 2017, our chief executive officer and our chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the most recent fiscal quarter that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II
OTHER INFORMATION

Item 1. Legal Proceedings

In December 2016, a class action suit was filed against us in the Iowa District Court in Johnson County by a stockholder alleging that we, certain of our senior executives and directors who signed the registration statement in connection with our initial public offering, and each of the investment banks that acted as underwriters for the offering negligently issued untrue statements of material facts and omitted to state material facts required to be stated in the registration statement and incorporated offering materials that we filed with the SEC in support of the offering. The plaintiff did not quantify any alleged damages in his complaint but, in addition to attorneys' fees and costs, the plaintiff seeks to recover damages and obtain other relief on behalf of himself and all other persons who purchased our common stock pursuant or traceable to the offering and the registration statement and who were allegedly damaged thereby.

In January 2017, the suit was removed to the U.S. District Court for the Southern District of Iowa. The plaintiff subsequently filed a motion to remand the case to the Iowa District Court, and that motion was granted. The suit is still in a preliminary stage and has not yet been set for trial. Accordingly, we are unable to predict the timing or outcome of this litigation as of the date of this report.

From time to time, we may be involved in routine legal proceedings, as well as demands, claims and threatened litigation, which arise in the normal course of our business. As of the date of this report we are unable to predict whether the pending litigation described above could have a material adverse effect on our results of operations or financial condition.

Item 1A. Risk Factors

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

Risks Related to Our Financial Position and Capital Needs

Considering our receipt of a CRL from the FDA regarding our NDA for Apadaz, the U.S. regulatory pathway for Apadaz and our other prodrugs is uncertain, and we may never obtain regulatory approval in the United States.

In December 2015, we submitted an NDA to the FDA for the marketing and sale of Apadaz. The NDA was accepted for filing by the FDA in February 2016. In June 2016, the FDA issued a CRL regarding the NDA, indicating that their review was complete and the NDA was not ready for approval in its present form. In its CRL, the FDA advised us that it did not believe our proposed labeling included in the application accurately conveyed the outcome of our abuse deterrent studies of Apadaz.

In August 2016, we completed our end-of-review meeting with the FDA. At the end-of-review meeting, we discussed with the FDA the issues identified by the FDA in the Apadaz NDA and what we believe is the potential to achieve a path forward for an Apadaz product label that could include abuse deterrence claims. Despite this end-of-review meeting with the FDA, we cannot guarantee when, or if, we will be successful in receiving approval for an Apadaz label that includes abuse deterrent claims.

In November 2016, we elected to continue the regulatory review process for Apadaz with the submission of a FDRR to the FDA. We anticipate up to twelve months from the date of our FDRR may be required to complete all parts of the FDRR process. We cannot guarantee that the FDRR or any other action will be resolved in our favor. As a result, the approval of our NDA for Apadaz has been substantially delayed and may never occur.

We cannot predict whether the FDA will have concerns regarding the abuse deterrent or other features of our product candidates for any future NDA we may submit. If the FDA were to raise similar concerns regarding the abuse deterrent or other features of our product candidates in the future, the FDA may not approve any such product candidates or we may not have sufficient capital resources to fully fund any new trials that the FDA may require as a condition to approval of our product candidates.

The U.S. regulatory pathway for Apadaz, and potentially our other product candidates, is highly uncertain at this time, and we may never obtain regulatory approval of any of our product candidates in the United States. If that were to occur, it would have a material adverse effect on our operations and financial condition.

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

We have incurred operating losses since our inception and, as of June 30, 2017, had an accumulated deficit of $144.2 million. Our loss from operations for the three and six months ended June 30, 2017 and 2016, were $8.2 and $9.3 million and $15.6 and $16.2 million, respectively. We have financed our operations to date with $25.3 million raised in private placements of redeemable convertible preferred stock, $115.9 million in convertible promissory notes and term debt and $59.9 million 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 product candidates that successfully complete clinical trials;
- continue research and preclinical development and initiate clinical trials of our other product candidates;
- seek to discover and develop additional product candidates either internally or in partnership with other pharmaceutical companies;
- 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; 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 of our clinical trials or the development of any of our product candidates, our expenses could increase.

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

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 through the second quarter of 2019. 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;
- 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 payors, 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 and we do not currently know when, if ever, any of our product candidates will be commercially available. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or debt, the terms of these securities 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. Additionally, in February 2016, we issued the 2021 Notes. We are required to make periodic interest payments to the holders of the 2021 Notes and to make payments of principal upon maturity. In this regard, if holders of the 2021 Notes do not convert their 2021 Notes prior to the maturity date, we will be required to repay the principal amount of all then outstanding 2021 Notes plus any accrued and unpaid interest. We may also be required to repurchase the 2021 Notes for cash upon the occurrence of a change of control or certain other fundamental changes involving us. If our capital resources are insufficient to satisfy our debt service obligations, we will be required to seek to sell additional equity or debt or to obtain debt financing. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

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.

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. For instance, in June 2016, we received a CRL from the FDA for our Apadaz NDA indicating that the FDA considers the review cycle for the Apadaz NDA complete and that the application is not ready for approval in its present form. In November 2016, we elected to continue the regulatory review process for Apadaz with the submission of a FDRR to the FDA. Despite this, we cannot guarantee when, or if, we will be successful in receiving approval for an Apadaz label that includes abuse deterrent claims. 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.

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

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

Even if regulatory approval is obtained, subsequent safety, efficacy, quality or other issues can result in a product approval being suspended or withdrawn. Other than the submission of our NDA for Apadaz to the FDA, as to which the FDA issued a CRL in June 2016, we have not yet submitted comparable applications to other regulatory authorities. If our development efforts for our product candidates, including regulatory approval, are not successful for their planned indications or are delayed, or if adequate demand for our product candidates that are approved for marketing, if any, is not generated, our business will be harmed.

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

- the FDA or comparable foreign regulatory authorities, institutional review boards, or IRBs, or ethics committees may disagree with the design or conduct of our clinical trials;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or other regulatory agencies for marketing approval or for us to receive approval for claims that are necessary for commercialization, for instance, in June 2016, the FDA issued a CRL for our Apadaz NDA;
- the dosing in a particular clinical trial may not be at an optimal level;
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our product candidates;
- the data collected from clinical trials may not be sufficient to support submissions to regulatory authorities or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies or may later suspend or withdraw such approval;
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and
- even if we obtain marketing approval in one or more countries, future safety or other issues could result in the suspension or withdrawal of regulatory approval in such countries.

We have only limited experience in filing the applications necessary to gain regulatory approvals and have relied, and expect to continue to rely, on consultants and third-party contract research organizations, or CROs, with expertise in this area to assist us in this process. Securing FDA approval requires the submission of extensive nonclinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA for each therapeutic indication to establish a product candidate's safety and efficacy for each indication and manufacturing quality. Additionally, we cannot guarantee that regulators will agree with our assessment of the results of the clinical trials we have conducted or that any future trials will be successful. For example, in May 2016, the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the FDA voted 16 to four for the approval of Apadaz, but voted 18 to two against inclusion of abuse deterrent labeling for Apadaz. Additionally, in June 2016, we received a CRL from the FDA for our Apadaz NDA indicating that the FDA considers the review cycle for the Apadaz NDA complete and that the application is not ready for approval in its present form. In November 2016, we elected to continue the regulatory review process for Apadaz with the submission of a FDRR to the FDA. Despite this, we cannot guarantee when, or if, we will be successful in receiving approval for an Apadaz label that includes abuse deterrent claims.

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

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

We are very early in our development efforts and only a limited number of our product candidates have entered clinical development. All our other active product candidates are still in preclinical development. If we are unable to commercialize our product candidates, or experience significant delays in doing so, our business will be harmed.

We are very early in our development efforts and only a limited number of our product candidates have entered clinical development. All of our other active 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 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 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, if applicable, the determination by the U.S. Drug Enforcement Administration, or DEA, of the controlled substance schedule for a product candidate, taking into account the recommendation of the FDA;
- obtaining abuse-deterrent claims in the labels for our product candidates;
- 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 payors;
- competing effectively with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement; and
- maintaining a continued acceptable safety and efficacy profile of the prodrug products following approval.

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

It is possible that none of our 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 most of our 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 to make claims that a product has an abuse-deterrent effect. In January 2013, the FDA published draft guidance regarding 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.

There can be no assurance that any of our 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. For instance, in May 2016, the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the FDA voted 18 to two against inclusion of abuse-deterrent labeling for Apadaz. Subsequently, in June 2016, the FDA issued a CRL for our Apadaz NDA indicating that the FDA considers the review cycle for the Apadaz NDA complete and that the application is not ready for approval in its present form. In its CRL, the FDA advised us that it did not believe our proposed labeling included in the application accurately conveyed the outcome of our abuse deterrent studies of Apadaz. In November 2016, we elected to continue the regulatory review process for Apadaz with the submission of a FDRR to the FDA. Despite this, we cannot guarantee when, or if, we will be successful in receiving approval for an Apadaz label that includes abuse deterrent claims.

As with all claims, we will be required to provide adequate substantiation. For example, we will need to demonstrate that our product candidates have abuse-deterrent properties sufficient to achieve 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 comparable 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 may not support the continued use of abuse-deterrent claims.

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

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

If the FDA does not allow us to pursue the 505(b)(2) NDA pathway as anticipated, or if we cannot demonstrate bioequivalence or comparable bioavailability of our product candidates to approved products, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. Moreover, even if the FDA does allow us to pursue the 505(b)(2) NDA pathway, depending on the product candidate, we may still need to conduct additional clinical trials, including clinical trials to assess product safety or efficacy. For instance, we currently plan on relying on the 505(b)(2) pathway for any NDA we submit for KP415 or KP484 and KP201/IR. However, we do not anticipate that the 505(b)(2) pathway will be available for every product candidate. For instance, it is possible we will only be permitted to utilize the 505(b)(2) NDA pathway for either KP415 or KP484, but not both. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates, and complications and risks associated with our product candidates, would likely substantially increase.

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

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

Even if our product candidates are approved under 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed, including more limited subject populations than we request, may require that contraindications, warnings or precautions be included in the product labeling, including a 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 will 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.

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

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

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

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

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

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

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

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

The risk of failure for our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Interpretation of results from early, usually smaller, studies that suggest positive trends in some subjects, requires caution. Results from later stages of clinical trials enrolling more subjects may fail to show the desired safety and efficacy results or otherwise fail to be consistent with the results of earlier trials of the same product candidates. Later clinical trial results may not replicate earlier clinical trials for a variety of reasons, including differences in trial design, different trial endpoints, or lack of trial endpoints in exploratory studies, subject population, number of subjects, subject selection criteria, trial duration, drug dosage and formulation and lack of statistical power in the earlier studies. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. For instance, in June 2016, the FDA issued a CRL for our Apadaz NDA indicating that the FDA considers the review cycle for the Apadaz NDA complete and that the application is not ready for approval in its present form. In its CRL, the FDA advised us that it did not believe our proposed labeling included in the application accurately conveyed the outcome of our abuse deterrent studies of Apadaz. In November 2016, we elected to continue the regulatory review process for Apadaz with the submission of a FDRR to the FDA. Despite this, we cannot guarantee when, or if, we will be successful in receiving approval for an Apadaz label that includes abuse deterrent claims.

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

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

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

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

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

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

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

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

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

We 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 ER, and long-acting opioids as part of a federal initiative to address inappropriate prescribing and prescription drug abuse and misuse, which the FDA continually updates. The Commissioner of the FDA recently announced his intention to expand the REMS program to include IR opioids in the near future. The REMS plan 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 25 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, if approved by the FDA, are likely to 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 DEA.

Before we can commercialize our product candidates, 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 KP415, KP484, KP201/IR (APAP-free), KP511/ER, KP511/IR, KP606/IR, KP746 and KP303, if approved, will be regulated as "controlled substances" as defined in the Controlled Substances Act, or the CSA, and the implementing regulations of the DEA, which establish registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA. These requirements are applicable to us, to our contract manufacturers and to distributors, prescribers and dispensers of our product candidates. The DEA regulates the handling of controlled substances through a closed chain of distribution. This control extends to the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce. A number of states and foreign countries also independently regulate these drugs as controlled substances.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Social issues around the abuse of opioids and stimulants, including law enforcement concerns over diversion and regulatory efforts to combat abuse, could decrease the potential market for 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 payors 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. Further, the Centers for Disease Control and Prevention recently issued draft guidelines for the prescribing of opioids for chronic pain, providing recommendations for primary care providers prescribing opioids for chronic pain on when to initiate or continue opioids, opioid selection and discontinuation, and the assessment of the risk and addressing harms of opioid use, among other areas. It is possible that FDA, or other regulatory bodies, will announce new regulatory initiatives at any time that may increase the regulatory burden or decrease the commercial opportunity for our product candidates.

Risks Related to Our Dependence on Third Parties

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

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

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

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

In addition, investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any NDA we submit by the FDA. Any such delay or rejection could prevent us from commercializing our product candidates. Further, our arrangements with investigators are also subject to scrutiny under other health care regulatory laws, such as the 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 third parties for the manufacture of our product candidates that utilize KP415, KP484, KP201 and KP511 as the API used in our clinical trials and with a sole source supplier for the manufacture of bulk quantities of KP415, KP484, KP201 and KP511 used in product candidates that utilize these moieties as the API and we expect to continue to do so. This reliance on third-party manufacturers increases the risk that we will not have sufficient quantities of KP415, KP484, KP201 or KP511, or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities. We procure the bulk drug substances for KP415, KP484, KP201 and KP511 from sole-source, third-party manufacturers and the product candidates that utilize these moieties as the API used in our clinical trials from other third parties. We anticipate we will continue to do so for the foreseeable future. We also expect to continue to rely on third parties as we proceed with preclinical and clinical testing of our 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 KP415, KP484, KP201, KP511, 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 KP415, KP484, KP201 or KP511 bulk drug substance. If our current contract manufacturer for KP415, KP484, KP201 or KP511 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 and KP484. 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 and KP484.

We are also party to a termination agreement with MonoSol that may limit the value of any sale, license or commercialization of KP415 or KP484. 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 or KP484, and any product candidates arising therefrom, including royalty payments on any license of KP415 or KP484, the sale of KP415 or KP484 to a third party or the commercialization of KP415 or KP484.

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

Pursuant to the Deerfield facility, 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 the USPTO, or its foreign counterparts, and may ultimately be declared invalid or unenforceable or narrowed in scope;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours that claims priority to an application filed prior to March 16, 2013, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions. In addition, changes enacted on March 16, 2013 to the U.S. patent laws under the Leahy-Smith Act resulted in the United States changing from a “first to invent” country to a “first to file” country. As a result, we may lose the ability to obtain a patent if 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 solicited and applied for trademarks for Apadaz and LAT. For all other product candidates, we have not yet solicited trademarks and have not yet begun the process of applying to register trademarks. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. If our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

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

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

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

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

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

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

Risks Related to the Commercialization of Our 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 have only a limited sales and marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product candidate for which we may obtain marketing approval in the United States, we will need to enter into collaborations with one or more parties or establish our own sales and marketing organization. We have not yet determined our commercialization strategy for any of our 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 adequate reimbursement levels;
- the inability of sales personnel to obtain access to physicians or achieve adequate numbers of physicians to prescribe any future prodrug products;
- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- liability for personnel, including sales personnel, failing to comply with applicable legal requirements; and
- costs associated with maintaining compliance with the FDA's marketing and promotional requirements, including ongoing training and monitoring, as well as unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we decide not to or are unable to establish our own sales, marketing and distribution capabilities and, instead, enter into arrangements with third parties to perform these services, our product revenue and our profitability, if any, are likely to be lower than if we were to sell, market and distribute any product candidates that we develop ourselves. 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. Further, we may be liable for conduct of third parties acting on our behalf, including failure to comply with legal requirements applicable to sales and marketing of our products. 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 payors 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 payors 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 most of our product candidates;
- our ability to offer our prodrug products for sale at competitive prices;
- the clinical indications for which our product candidates are approved;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the cost of treatment in relation to alternative treatments;
- the steps that prescribers and dispensers must take, since 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, KP415 and KP484 will compete against currently marketed, branded and generic methylphenidate products for the treatment of ADHD. Some of these currently marketed products include 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 Allergan plc and Mallinckrodt plc. In addition, if approved, KP415 and KP484 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 abuse-deterrent opioid product candidates will face competition from commercially available branded and generic opioid drugs, including hydrocodone, hydromorphone, 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 may 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 short-term management of acute 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 opioid products or abuse-deterrent technologies from companies including Allergan plc, Acura Pharmaceuticals, Inc., Cara Therapeutics, Inc., Collegium Pharmaceutical, Inc., Depomed, Inc., DURECT Corporation, Egalet Corporation, Elite Pharmaceuticals, Inc., Endo International plc, Grünenthal Group, Inspirion Delivery Technologies, LLC, 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/IR (APAP-free) will compete against currently marketed, branded and generic IR hydrocodone/APAP combination products indicated for the short-term management of acute pain. Some of these currently marketed products include AbbVie's Vicodin, Allergan'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 Allergan plc, Endo International plc and Mallinckrodt plc. In addition, if approved, KP201/IR (APAP-free) will face potential competition from any abuse-deterrent IR or hydrocodone/APAP combination or other APAP-free products for the short-term management of acute pain that are currently in or may enter into clinical development.

If approved, KP511 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 Allergan plc, Mallinckrodt plc, Rhodes Pharmaceuticals L.P. and Roxanne Laboratories, Inc. In addition, if approved, KP511/ER and KP511/IR will face potential competition from any abuse-deterrent or other IR and ER hydromorphone products for the treatment of pain that are currently in or which may enter into clinical development.

Many of our potential competitors have substantially greater financial, technical and human resources than we do, as well as more experience in the development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Consequently, our competitors may develop abuse-deterrent or other products for the short-term management of acute 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 payors seeking to encourage the use of generic drugs or giving abuse deterrence sufficient weight in a comparative clinical cost effectiveness analysis. For some of the indications that we are pursuing, drugs used off-label serve as cheaper alternatives to our product candidates. Their lower prices could result in significant pricing pressure, even if our product candidates are otherwise viewed as a preferable therapy. Additional drugs may become available on a generic basis over the coming years.

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 a new chemical entity or three-year FDA regulatory exclusivity.

The FDA provides periods of regulatory exclusivity following their approval of an NDA, which provide the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug. Five-year exclusivity precludes approval of 505(b)(2) applications or ANDAs by delaying the submission or approval of the application, while three-year exclusivity precludes the approval of the application. We intend to seek new chemical entity, or NCE, status for any of our prodrug product candidates as appropriate. Five years of exclusivity are available to NCEs following the approval of an NDA by the FDA. An NCE is a drug that contains no active moiety that has been approved by the FDA in any other NDA. If a product is not eligible for the NCE exclusivity, it may be eligible for three years of exclusivity. Three-year exclusivity is available to the holder of an NDA, including a 505(b)(2) NDA, for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials, other than bioavailability or bioequivalence trials, were essential to the approval of the application and were conducted or sponsored by the applicant.

There is a risk that the FDA may disagree with any claim that we may make that any of our prodrug product candidates are NCEs and therefore entitled to five-year exclusivity. The FDA may also take the view that the studies that we are conducting are not clinical trials, other than bioavailability and bioequivalence studies, that are essential to approval and therefore do not support three-year exclusivity. Further, to the extent that the basis for exclusivity is not clear, the FDA may determine to defer a decision until it receives an application which necessitates a decision.

If we do obtain either five or three years of exclusivity, such exclusivity will not block all potential competitors from the market. Competitors may be able to obtain approval for similar products with different forms of 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 payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers, managed care plans and other third-party payors. Government authorities and other third-party payors decide which medical products they will pay for and establish reimbursement levels, including co-payments. A trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs and products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Inadequate reimbursement levels may adversely affect the demand for, or the price of, 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 payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Private third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Except for certain government health care programs, such as the Department of Defense's TRICARE Uniform Formulary, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Even state Medicaid programs have their own preferred drug lists that may disadvantage non-preferred brand drugs. Therefore, coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained at all. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved prodrug products that we develop could significantly harm our operating results, our ability to raise capital needed to commercialize prodrugs and our overall financial condition.

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

There can be no assurance that our product candidates, if they are approved for sale in the United States or in other countries, will be considered medically reasonable and necessary for a specific indication, that they will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available, or that third-party payors' reimbursement policies will not adversely affect 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, operating restrictions or criminal penalties. We may also be subject to actions by other governmental entities or private parties, such as the False Claims Act, civil whistleblower or "qui tam" actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products could be impaired. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us and harm our reputation.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of 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

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. For instance, we expect that at least some of our product candidates would likely be required to carry black box warnings, including warnings regarding tampering, lethality if our oral tablets are prepared for injection and hepatotoxicity.

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

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

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

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

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

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

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

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the 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 violations of the Anti-Kickback Statute in connection with a claim for payment or for conduct constituting reckless disregard for the truth;

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

- the Health Insurance Portability and Accountability Act, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations, which impose obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, created under Section 6002 of the Affordable Care Act, or the ACA, and its implementing regulations, which imposes new annual reporting requirements for 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.

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

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws, or that our compliance systems are inadequate to detect and report such conduct or to report accurate pricing information to the government. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, 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 payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, President Obama signed into law the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

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

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

Since its enactment, there have been judicial and congressional challenges to numerous provisions of the ACA, and we expect there will be additional challenges and amendments in the future. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The U.S. House of Representatives passed legislation known as the American Health Care Act of 2017 in May, 2017, which would repeal and replace certain aspects of the ACA if ultimately enacted. More recently, the Senate Republicans introduced and then updated an ACA replacement bill known as the Better Care Reconciliation Act of 2017. The Senate Republicans also introduced legislation to repeal the ACA without companion legislation to replace it, and a "skinny" version of the Better Care Reconciliation Act of 2017. Each of these measures was rejected by the full Senate. Congress will likely consider other legislation to replace elements of the ACA. We continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013, and will stay in effect through 2025 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. These new laws may result in additional reductions in Medicare and other healthcare funding, which could negatively impact customers for our product candidates, if approved, and, accordingly, our financial operations.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Employee Matters and Managing Our Growth

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

We are highly dependent on the management, research and development, clinical, financial and business development expertise of Travis C. Mickle, Ph.D., our president and chief executive officer, Gordon K. Johnson, our chief business officer, R. LaDuane Clifton, CPA, our chief financial officer, Sven Guenther, Ph.D., our executive vice president research and development, and Daniel L. Cohen, our executive vice president government and public relations, as well as the other members of our scientific and clinical teams. Although we have employment agreements with each of our executive officers, these agreements do not obligate them to continue working for our company and they may terminate their employment with us at any time.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our product pipeline toward scaling up for commercialization, manufacturing and sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our prodrug product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Risks Related to Ownership of Our Common Stock and Our Status as a Public Company

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

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

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

Our stock price has been, and is likely to continue to be, volatile. Since shares of our common stock were sold in our initial public offering in April 2015 at a price of $11.00 per share, our stock price has ranged from $2.90 to $26.15 through August 9, 2017. In addition, the stock market in general and the market for pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

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

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

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. For instance, in December 2016, we received notice of a class action suit filed against us in the Iowa District Court in Johnson County by a stockholder alleging that we, certain of our senior executives and directors who signed the registration statement in connection with our initial public offering, and each of the investment banks that acted as underwriters for the offering negligently issued untrue statements of material facts and omitted to state material facts required to be stated in the registration statement and incorporated offering materials that we filed with the SEC in support of the offering. The plaintiff does not quantify any alleged damages in his complaint but, in addition to attorneys' fees and costs, the plaintiff seeks to recover damages and obtain other relief on behalf of himself and all other persons who purchased our common stock pursuant or traceable to the offering and the registration statement and who were allegedly damaged thereby. In January 2017, the suit was removed to the U.S. District Court for the Southern District of Iowa. The plaintiff subsequently filed a motion to remand the case to the Iowa District Court, and that motion was granted. The suit is still in a preliminary stage and has not yet been set for trial. As such, we are unable to predict the timing or outcome of this litigation as of the date of this report. Such litigation could cause us to incur substantial costs and divert management's attention and resources from our business. Further, companies listed on The NASDAQ Global Market, and biotechnology and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

If 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.

In December 2016, we received notice of a class action suit filed against us in the Iowa District Court in Johnson County by a stockholder alleging that we, certain of our senior executives and directors who signed the registration statement in connection with our initial public offering, and each of the investment banks that acted as underwriters for the offering negligently issued untrue statements of material facts and omitted to state material facts required to be stated in the registration statement and incorporated offering materials that we filed with the SEC in support of the offering. The plaintiff does not quantify any alleged damages in his complaint but, in addition to attorneys' fees and costs, the plaintiff seeks to recover damages and obtain other relief on behalf of himself and all other persons who purchased our common stock pursuant or traceable to the offering and the registration statement and who were allegedly damaged thereby. In January 2017, the suit was removed to the U.S. District Court for the Southern District of Iowa. The plaintiff subsequently filed a motion to remand the case to the Iowa District Court, and that motion was granted. The suit is still in a preliminary stage and has not yet been set for trial. 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 and convertible securities are entitled to certain anti-dilution protections which, if triggered, may cause substantial dilution to your investment.

In June 2014, we issued to Deerfield (i) the Deerfield Warrant to purchase 14,423,076 shares of Series D redeemable convertible preferred stock at an exercise price of $0.78 per share, which is exercisable until June 2, 2024, and (ii) the Deerfield Note, in the principal amount of $10.0 million, which bears interest at 9.75% per annum. Upon completion of our initial public offering, 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 and the outstanding principal and accrued interest under the Deerfield Note became convertible into shares of our common stock at a conversion price of $5.85 per share. The Deerfield Warrant and Deerfield Note each include an exercise or conversion, as applicable, price protection provision, pursuant to which the exercise or conversion, as applicable, price of the warrant or note will be adjusted downward on a broad-based weighted-average basis if we issue or sell any shares of common stock, convertible securities, warrants or options at a sale or exercise price per share less than the greater of the Deerfield Warrant’s exercise price or the Deerfield Note's conversion price, as applicable, or the closing sale price of our common stock as reported on The NASDAQ Global Market on the last trading date immediately prior to such issuance or, in the case of a firm commitment underwritten offering, on the date of execution of the underwriting agreement between us and the underwriters for such offering. Additionally, pursuant to the terms of our fourth amendment to the Deerfield Warrant and Deerfield Note, if we effect an “at the market offering” as defined in Rule 415 of the Securities Act, of our common stock, the exercise price of the Deerfield Warrant and conversion price of the Deerfield Note will be adjusted downward pursuant to this anti-dilution adjustment only if such sales are made at a price less than $5.85 per share.

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

We expect that we will need significant additional capital in the 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.

Additionally, we previously issued to Deerfield 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 1,750,954 shares of our common stock, assuming a conversion date of June 30, 2017. 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 as reported on The NASDAQ Global Market on the last trading date immediately prior to such issuance, or, in the case of a firm commitment underwritten offering, on the date of execution of the underwriting agreement between us and the underwriters for such offering. Although, if we effect an "at the market offering" as defined in Rule 415 of the Securities Act, of our common stock, the exercise price of the Deerfield Warrant and conversion price of the Deerfield Note will be adjusted downward pursuant to this anti-dilution adjustment only if such sales are made at a price less than $5.85 per share.

Additionally, in February 2016, we issued the 2021 Notes. The 2021 Notes are convertible at an initial conversion rate of 58.4454 shares of our common stock per $1,000 principal amount of the 2021 Notes, subject to adjustment under the indenture governing the 2021 Notes, which is equal to an initial conversion price of approximately $17.11 per share of our common stock. Upon conversion, the 2021 Notes will be settled in shares of our common stock, together with a cash payment in lieu of delivering any fractional shares. The conversion rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date, we will increase the conversion rate for a holder who elects to convert its 2021 Notes in connection with such a corporate event in certain circumstances. Holders who convert on or after the date that is one year after the last date of original issuance of the 2021 Notes may also be entitled to receive, under certain circumstances, an interest make-whole payment payable in shares of common stock. Without regard to this conversion, the 2021 Notes are convertible into 5,040,914 shares of our common stock, assuming a conversion date of June 30, 2017.

If Deerfield or the holders of the 2021 Notes elect to convert the Deerfield Note or the 2021 Notes, your ownership interest will be diluted and the market price of our common stock may be materially and adversely effected.

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

Additionally, in October 2016, we entered into the ATM Agreement with Cowen under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $50,000,000 through Cowen as our sales agent. Cowen may sell common stock under the ATM Agreement by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act, including without limitation sales made by means of ordinary brokers' transactions on The NASDAQ Global Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise directed by us. Cowen will use commercially reasonable efforts to sell the common stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). To the extent that we direct Cowen to make any sales of our common stock under the ATM Agreement, our stockholders may experience additional dilution, which could cause our stock price to fall.

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

As of June 30, 2017, we had $96.3 million of convertible notes outstanding, consisting of the $10 million Deerfield Note and $86.3 million of 2021 Notes.

The Deerfield Note bears interest at 9.75% per annum. Interest accrued on outstanding debt under the Deerfield Note 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 Note, provided that all such interest was due on July 1, 2016. We elected this option on all eight of the scheduled interest payments through June 30, 2016 and paid such interest on July 1, 2016. We must repay one-third of the outstanding principal amount of all debt issued under the Deerfield Note on the fourth and fifth anniversaries of the Deerfield Note. We are then obligated to repay the balance of the outstanding principal amount on February 14, 2020. If we are required to pay additional outstanding amounts due under the Deerfield Note prior to maturity or otherwise incur unanticipated monetary obligations under the Deerfield Note, our cash flow available to invest in the ongoing needs of our business may be limited.

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

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

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

The accounting method for the Deerfield Warrant and 2021 Notes could have a material effect on our reported financial results.

The Deerfield Warrant and 2021 Notes contain embedded derivatives, which require mark-to-market accounting treatment and could result in a gain or loss on a quarterly basis with regards to the mark-to-market value of that feature. Such accounting treatment could have a material impact on, and could potentially result in significant volatility in, our quarterly results of operations. Additionally, certain features of the 2021 Notes may result in the yield on the 2021 Notes not being deductible by us for tax purposes.

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

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

Certain holders of shares of our common stock and shares of our common stock issuable upon the exercise of outstanding warrants, including Deerfield, 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 and the holders of our 2021 Notes 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 or KP484. 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, pursuant to the Deerfield Note, Deerfield has the option to demand repayment of all outstanding principal, and any unpaid interest accrued thereon, of the Deerfield Note immediately prior to consummation of such event. Further, under the Deerfield Warrant, Deerfield has the right to demand that we redeem the Deerfield Warrant for a cash amount equal to the Black-Scholes value of a portion of the warrant upon the occurrence of specified events, including a merger, an asset sale or any other change of control transaction. Furthermore, the indenture governing the 2021 Notes requires us to repurchase the 2021 Notes for cash if we undergo certain fundamental changes. A takeover of us may trigger the requirement that we repurchase the 2021 Notes, which could make it more costly for a potential acquirer to engage in a business combination transaction with us.

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

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

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

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

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

As of June 30, 2017, we had federal net operating loss carryforwards of approximately $118.3 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, the conversion of our outstanding convertible debt or as a result of future changes in our stock ownership. If we determine that an ownership change has occurred and our ability to use our historical net operating loss carryforwards is materially limited, it would harm our future operating results by increasing our future tax obligations.

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 controls over financial reporting. Commencing with our fiscal year ending December 31, 2016, we performed system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K, as required by Section 404 of the Sarbanes-Oxley Act. We will be required to perform this evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting on an annual basis. This will require that we incur substantial additional professional fees and internal costs and that we expend significant management efforts on an annual basis. We have and will be required to test our internal controls within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements.

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

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

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

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

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

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

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

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

Recent Sales of Unregistered Securities

Between April 1, 2017 and June 30, 2017, we issued an aggregate of 698 shares of our common stock pursuant to the exercise of outstanding warrants for an aggregate cash purchase price of $4,083.30.

The offers, sales and issuances of the securities described above were exempt from registration under Section 4(a)(2) of the Securities Act. We believe that the recipients of these shares acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. We also believe that such recipients were accredited investors as defined in Rule 501 promulgated under the Securities Act.

Issuer Purchases 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, 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 June 30, 2017, $52.4 million of the net proceeds had been used to fund the development of Apadaz 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

Not applicable.

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 herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on April 21, 2015).
3.2	Amended and Restated Bylaws, as currently in effect, of KemPharm, Inc. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on April 21, 2015).
4.1	Reference is made to Exhibits 3.1 and 3.2 hereof.
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18. U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (1)
32.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18. U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (1)
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith

** Attached as Exhibit 101 to this Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Balance Sheets, (ii) Condensed Statements of Operations, (iii) Condensed Statements of Cash Flows, and (iv) Notes to Condensed Financial Statements, tagged as blocks of text and including detailed tags.

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

SIGNATURES

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

KemPharm, Inc.

Date: August 10, 2017

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

Date: August 10, 2017

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

EXHIBIT INDEX

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Exhibit 31.1

CERTIFICATIONS

I, Travis C. Mickle, certify that:

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

August 10, 2017

/s/ Travis C. Mickle

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

Exhibit 31.2

CERTIFICATIONS

I, R. LaDuane Clifton, certify that:

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

August 10, 2017

/s/ R. LaDuane Clifton

Name: R. LaDuane Clifton

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of KemPharm, Inc., (the "Company") for the quarterly period ended June 30, 2017, 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.

August 10, 2017

/s/ Travis C. Mickle

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

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

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of KemPharm, Inc., (the "Company") for the quarterly period ended June 30, 2017, 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.

August 10, 2017

/s/ R. LaDuane Clifton

Name: R. LaDuane Clifton
Title: Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer)

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