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

FORM 10-Q

☒ **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 number 001-38150

KALA PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**27-0604595**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
100 Beaver Street, Suite 201 Waltham, MA	**02453**
(Address of principal executive offices)	(Zip Code)

(781) 996-5252
(Registrant's telephone number, including area code)

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨☐	Accelerated filer ¨☐	Non-accelerated filer ☒ (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 ☒.

There were 24,227,050 shares of Common Stock, $0.001 par value per share, outstanding as of July 31, 2017.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "might," "plan," "predict," "project," "target," "potential," "would," "could," "should," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- our ongoing clinical trials, including our two Phase 3 clinical trials of KPI-121 0.25% in patients with dry eye disease;
- our plans to develop and commercialize KPI-121 1.0%, KPI-121 0.25% and any other product candidates, if they are approved;
- the timing of and our ability to submit applications for, obtain and maintain regulatory approvals for KPI-121 1.0%, KPI-121 0.25% and other product candidates;
- our expectations regarding our ability to fund our operating expenses and capital expenditure requirements with our cash on hand;
- the potential advantages of our product candidates;
- the rate and degree of market acceptance and clinical utility of our products;
- our estimates regarding the potential market opportunity for our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- our estimates regarding expenses, future revenue, timing of any future revenue, capital requirements and needs for additional financing;
- the impact of government laws and regulations;
- our competitive position;
- developments relating to our competitors and our industry;
- our ability to maintain and establish collaborations or obtain additional funding; and
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the “Risk Factors” section, 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.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and that we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on Form 10-Q, and we do not assume any obligation to update any forward-looking statements except as required by applicable law.

PART I – FINANCIAL INFORMATION

Item 1 Financial Statements

KALA PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

(UNAUDITED)

(In thousands, except share and per share amounts)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash	$ 26,350	$ 45,472
Prepaid expenses and other current assets	1,544	154
Total current assets	27,894	45,626
Property and equipment, net	563	594
Restricted cash	134	109
Total assets	$ 28,591	$ 46,329
Liabilities, Convertible Preferred Stock and Stockholders' (Deficit) Equity		
Current liabilities:		
Current portion of long-term debt	$ 2,222	$ 556
Accounts payable	1,325	997
Accrued expenses	4,303	3,993
Total current liabilities	7,850	5,546
Long-term liabilities:		
Long-term debt - less current portion	7,488	9,098
Warrant liability	2,260	1,039
Other long-term liabilities	21	17
Total long-term liabilities	9,769	10,154
Total liabilities	17,619	15,700
Commitments and Contingencies (Note 13)		
Convertible preferred stock, 170,336,260 shares authorized as of June 30, 2017 and December 31, 2016		
Series Seed convertible preferred stock, $0.001 par value - 11,323,209 shares designated as of June 30, 2017 and December 31, 2016; 11,243,209 shares issued and outstanding as of June 30, 2017 and December 31, 2016; liquidation value of $11,243 at June 30, 2017 and December 31, 2016	11,065	11,065
Series A convertible preferred stock, $0.001 par value - 9,583,432 shares designated as of June 30, 2017 and December 31, 2016; 9,583,432 shares issued and outstanding as of June 30, 2017 and December 31, 2016; liquidation value of $11,500 as of June 30, 2017 and December 31, 2016	10,736	10,736
Series B convertible preferred stock, $0.001 par value - 16,597,221 shares designated as of June 30, 2017 and December 31, 2016; 15,624,999 shares issued and outstanding as of June 30, 2017 and December 31, 2016; liquidation value of $22,500 as of June 30, 2017 and December 31, 2016	22,185	22,185
Series B-1 convertible preferred stock, $0.001 par value - 4,629,629 shares designated as of June 30, 2017 and December 31, 2016; 4,629,629 shares issued and outstanding as of June 30, 2017 and December 31, 2016; liquidation value of $7,000 as of June 30, 2017 and December 31, 2016	6,885	6,885
Series C convertible preferred stock, $0.001 par value - 43,034,639 shares designated as of June 30, 2017 and December 31, 2016; 42,782,688 shares issued and outstanding as of June 30, 2017 and December 31, 2016; liquidation value $67,922 as of June 30, 2017 and December 31, 2016	67,520	67,520
Stockholders' deficit:		
Common stock, $0.001 par value - 110,251,951 shares authorized as of June 30, 2017 and December 31, 2016; 1,181,429 shares issued and outstanding as of June 30, 2017 and December 31, 2016	1	1
Additional paid-in capital	5,485	4,374
Accumulated deficit	(112,905)	(92,137)
Total stockholders' deficit	(107,419)	(87,762)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 28,591	$ 46,329

See accompanying notes to these unaudited condensed financial statements.

KALA PHARMACEUTICALS, INC.

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
Operating expenses:				
Research and development	$ 8,071	$ 5,950	$ 16,110	$ 9,861
General and administrative	1,559	3,700	3,091	4,865
Total operating expenses	9,630	9,650	19,201	14,726
Loss from operations	(9,630)	(9,650)	(19,201)	(14,726)
Other income (expense):				
Interest income	37	30	83	30
Interest expense	(208)	(186)	(406)	(380)
Change in fair value of warrant liability	(1,185)	(47)	(1,221)	(29)
Total other income (expense)	(1,356)	(203)	(1,544)	(379)
Net loss attributable to common stockholders—basic and diluted	$ (10,986)	$ (9,853)	$ (20,745)	$ (15,105)
Net loss per share attributable to common stockholders—basic and diluted	$ (9.30)	$ (8.34)	$ (17.56)	$ (12.79)
Weighted average shares outstanding—basic and diluted	1,181,429	1,181,429	1,181,429	1,181,429

See accompanying notes to these unaudited condensed financial statements.

KALA PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(In thousands)

	Six Months Ended June 30,	
	2017	**2016**
Cash flows from operating activities:		
Net loss	$ (20,745)	$ (15,105)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	140	147
Change in fair value of warrant liability	1,221	29
Amortization of debt discount and debt issuance costs	56	52
Write-off of deferred offering costs	—	1,789
Stock-based compensation	1,089	1,193
Increase (decrease) in cash from:		
Prepaid expenses and other current assets	(148)	(48)
Accounts payable	192	951
Accrued expenses	(13)	(866)
Other long-term liabilities	4	(18)
Net cash used in operating activities	(18,204)	(11,876)
Cash flows from investing activities:		
Purchases of property and equipment	(109)	(46)
Restricted cash	(25)	—
Net cash used in investing activities	(134)	(46)
Cash flows from financing activities:		
Proceeds from issuance of Series C convertible preferred stock	—	67,922
Payment of Series C issuance costs	—	(401)
Payment of deferred offering costs	(784)	(283)
Net cash (used in) provided by financing activities	(784)	67,238
Net (decrease) increase in cash	(19,122)	55,316
Cash at beginning of period	45,472	5,759
Cash at end of period	$ 26,350	$ 61,075
Supplemental disclosure of non-cash investing and financing activities:		
Deferred offering costs included in accounts payable and accruals	$ 458	$ —
Cash paid for interest	$ 348	$ 329

See accompanying notes to these unaudited condensed financial statements.

KALA PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

1. NATURE OF BUSINESS AND BASIS OF PRESENTATION

Nature of Business—Kala Pharmaceuticals, Inc. (the "Company") was incorporated on July 7, 2009, and is a biopharmaceutical company focused on the development and commercialization of therapies using its proprietary nanoparticle-based Mucus Penetrating Particles, or MPP, technology, with an initial focus on the treatment of eye diseases. KPI-121, the Company's lead program, consists of topically applied MPP nanosuspensions of loteprednol etabonate, or LE, a corticosteroid designed for ocular applications. Under its KPI-121 program, the Company has two product candidates in Phase 3 development, one for the indications of the treatment of post-operative inflammation and pain following ocular surgery and one for the temporary relief of the signs and symptoms of dry eye disease. The Company is also evaluating compounds in its topically applied MPP receptor Tyrosine Kinase Inhibitor program, or rTKI program, that inhibit the vascular endothelial growth factor, or VEGF, pathway, for the potential treatment of a number of retinal diseases.

The Company is engaged in research and development activities, raising capital and recruiting skilled personnel. The Company is subject to a number of risks similar to those of other companies conducting high-risk, early-stage research and development of pharmaceutical product candidates. Principal among these risks are dependence on key individuals and intellectual property, competition from other products and companies and the technical risks associated with the successful research, development and marketing of its product candidates. The Company's success is dependent upon its ability to raise additional capital in order to fund ongoing research and development, obtain regulatory approval of its product candidates, successfully commercialize its products, generate revenue, meet its obligations, and, ultimately, attain profitable operations.

On July 19, 2017, the Company's registration statement on Form S-1 (File No. 333-218936) relating to the initial public offering ("IPO") of its common stock became effective and on July 25, 2017, the IPO closed. Pursuant to the IPO, the Company issued and sold 6,900,000 shares of common stock at a public offering price of $15.00 per share, which included 900,000 shares sold pursuant to the exercise of the underwriters' option to purchase additional shares. The Company received net proceeds of $94.9 million after deducting underwriting discounts and commissions of $7.2 million and offering costs incurred in 2017 of $1.4 million. The shares began trading on the NASDAQ Global Select Market on July 20, 2017. Upon the closing of the IPO, all of the Company's outstanding shares of convertible preferred stock automatically converted into 16,101,970 shares of common stock at the applicable conversion ratio then in effect and all of the Company's outstanding warrants to purchase preferred stock automatically converted into warrants to purchase 202,020 shares of common stock.

Unaudited Interim Financial Information

The condensed financial statements of the Company included herein have been prepared, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted from this report, as is permitted by such rules and regulations. The accompanying condensed financial statements reflect all adjustments consisting of normal, recurring adjustments, that are necessary for a fair presentation of the financial position, results of operations and cash flows for the interim periods presented. Interim results are not necessarily indicative of results for a full year. Accordingly, these financial statements should be read in conjunction with the financial statements as of and for the year ended December 31, 2016, and notes thereto, included in the Company's final prospectus for the IPO filed with the Securities and Exchange Commission pursuant to Rule 424(b)(4) on July 20, 2017 (the "Prospectus").

KALA PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

Reverse Stock Split—On July 7, 2017, the Company effected a one-for-5.2083 reverse stock split of the Company's issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for the Company's convertible preferred stock. The par value per share and authorized shares of common and convertible preferred stock were not adjusted as a result of the reverse stock split. All common stock and common stock per share amounts within the financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this reverse stock split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital.

Automatic Conversion of Preferred Stock – On July 7, 2017, the Company effected an amendment to its Amended and Restated Certificated of the Incorporation, as amended. This amendment eliminated the minimum price per share of Common Stock for an underwritten public offering that would result in the automatic conversion of all outstanding shares of the Company's Series Seed, Series A, Series B, Series B-1 and Series C Preferred Stock.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates—The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expense, and related disclosures. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. Estimates relied upon in preparing these financial statements relate to, but are not limited to, the fair value of common stock, preferred stock, warrants, stock compensation, accrued expenses and the recoverability of the Company's net deferred tax assets and related valuation allowance. Actual results may differ from these estimates under different assumptions or conditions.

Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies," in the Prospectus. There have been no material changes to the significant accounting policies during the period ended June 30, 2017.

Recently Adopted Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09" or "Topic 718"), which simplifies share-based payment accounting through a variety of amendments. The standard is effective for annual periods beginning after December 15, 2016 and for interim periods within those fiscal years. The changes resulting from the adoption of this standard impact the accounting for income taxes, accounting for forfeitures, statutory tax withholding and the presentation of statutory tax withholding on the statement of cash flows. The Company adopted this standard on January 1, 2017. Under guidance within ASU 2016-09, excess tax benefits and deficiencies are to be recognized as income tax expense or benefit in the statement of operations in the period in which they occur rather than as an increase or decrease in stockholders' equity (deficit). Since the Company maintains a full valuation allowance on its net deferred tax asset, there was no net impact to its accumulated deficit or its net loss resulting from the adoption of this standard. Also under the guidance in ASU 2016-09, an entity may elect to account for forfeitures as they occur or continue to estimate the total number of awards that are vested or expected to vest. The Company elected to account for forfeitures as they occur and applied the accounting change on a modified retrospective basis as a cumulative effect adjustment to accumulated deficit as of the date of adoption, January 1, 2017. The adoption of this standard did not have a material impact on the Company's financial position, results of operations or statement of cash flows.

KALA PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases today. ASU 2016-02 (ASC Topic 842) supersedes the previous leases standard, ASC 840, *Leases*. The standard is effective for public entities for annual periods beginning after December 15, 2018 and for interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-02 will have on its financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"), to address diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The standard is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. ASU 2016-15 should be applied restrospectively and early adoption is permitted, including adoption in an interim period. The Company is currently evaluating the impact that the adoption of ASU 2016-15, but believes its adoption will not have a material impact on its statement of cash flows.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows Restricted Cash* ("ASU 2016-18"). This new standard requires companies to include amounts generally described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This guidance is effective for annual and interim reporting periods beginning after December 15, 2017, and requires retrospective application. The Company does not believe that the adoption of ASU 2016-18 will have a material impact on its financial statements and related disclosures.

In May 2017, the FASB issued ASU Update No. 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 share-based payment award require an entity to apply modification accounting. The amendments in ASU 2017-09 are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017, with early adoption permitted. The Company is currently evaluating the impact that ASU 2017-09 will have on the Company's balance sheets, results of operations and statements of cash flows.

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815). The amendments in Part I of this Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. The amendments also clarify existing disclosure requirements for equity-classified instruments. The amendments in Part II of this Update recharacterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the Codification, to a scope exception. Those amendments do not have an accounting effect. For public business entities, the amendments in Part I of this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted for, including adoption in an interim period. The Company is currently evaluating the impact of adopting this standard on its financial statements and related disclosures.

KALA PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

3. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following (in thousands):

	June 30, 2017	December 31, 2016
Rent	$ 61	$ 58
Insurance	65	55
Deferred offering costs	1,242	—
Other	176	41
Prepaid expenses and other current assets	$ 1,544	$ 154

4. ACCRUED EXPENSES

Accrued expenses consist of the following (in thousands):

	June 30, 2017	December 31, 2016
Development costs	$ 2,948	$ 2,280
Compensation and benefits	950	1,480
Professional fees	33	171
Deferred offering costs	323	—
Other	49	62
Accrued expenses	$ 4,303	$ 3,993

5. DEBT

2014 Debt Facility

In November 2014, the Company entered into a venture debt facility (“2014 Debt Facility”) for a total loan commitment of $10.0 million. On October 13, 2016, the Company entered into the First Amendment. The First Amendment reaffirmed the initial commitment to a total of $10.0 million of funding (“Term Loan A”) and increased the Company’s total borrowing capacity by an additional $10.0 million (“Term Loan B” and together with Term Loan A, “Term Loans”). Under the terms of the facility, the borrowings accrued interest at an annual rate equal to the greater of (i) 3.00% above the Prime Rate then in effect, or (ii) 6.25%. The interest rate was 6.50% as of December 31, 2016 and 7.00% as of June 30, 2017. The unpaid principal balance under the 2014 Debt Facility was $10.0 million as of June 30, 2017 and December 31, 2016. The unamortized discount was $290,000 and $346,000 as of June 30, 2017 and December 31, 2016, respectively. During the three months ended June 30, 2017 and 2016, the Company recognized interest expense of $208,000 and $186,000, respectively, which consisted of amortization of the debt discount of $28,000 and $22,000 and the contractual coupon interest of $180,000 and $164,000, respectively. During the six months ended June 30, 2017 and 2016, the Company recognized interest expense of $406,000 and $380,000, respectively, which consisted of amortization of the debt discount of $56,000 and $52,000 and the contractual coupon interest of $350,000 and $328,000, respectively.

In connection with the 2014 Debt Facility and the initial borrowing of $5.0 million under Term Loan A, the Company issued warrants to the lender to purchase 138,889 shares of Series B Preferred Stock at an exercise price of $1.44 per share (the “2014 Warrants”). During 2015 the Company borrowed an additional $5.0 million under Term Loan

KALA PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

A and the number of exercisable shares underlying the 2014 Warrants increased to 277,778 shares. Upon executing the First Amendment, the Company issued warrants to purchase up to 251,951 shares of Series C Preferred Stock at an exercise price of $1.59 per share (the "2016 Warrants"). Consistent with the warrants issued under the original 2014 Debt Facility, the number of shares of Series C Preferred Stock that become exercisable increases in proportion to the amount of Term Loan B borrowings. The 2016 Warrants were not exercisable into shares as of the First Amendment date or June 30, 2017, as the Company had not borrowed under the Term B Loan during 2016 or the six months ended June 30, 2017.

Upon issuance of the 2014 Warrants and 2016 Warrants, the Company estimated the fair value of the warrants using the Black-Scholes option-pricing model (see Note 6), and recorded the estimated fair value of the warrants as a liability separate from the loan balance, resulting in additional debt discount included within long-term debt that is amortized to interest expense over the term of the loan using the effective interest method. The initial fair value of the 2014 Warrants and 2016 Warrants was $140,000 and $225,000, respectively. The warrants are subsequently re-measured to fair value at every reporting date with changes in fair value recorded in the statement of operations as a component of other income (expense), as the shares underlying the warrants are exercisable into contingently redeemable shares.

As of June 30, 2017 and December 31, 2016, the estimated fair value of the warrant liability associated with the original 2014 Debt Facility was $533,000 and $274,000, respectively, and the estimated fair value of the warrant liability associated with the First Amendment was $504,000 and $263,000, respectively.

The future annual principal payments due under the 2014 Debt Facility as of June 30, 2017 are as follows (in thousands):

Years Ending December 31,	
2017	$ 556
2018	3,333
2019	3,333
2020	2,778
Total	$ 10,000

6. PREFERRED STOCK WARRANTS

In addition to the warrants issued in connection with the 2014 Debt Facility and the First Amendment, the Company has issued warrants in connection with debt transactions that were completed prior to 2014, all of which are classified as liabilities and are remeasured at fair value at each reporting period, as the warrants are exercisable into contingently redeemable shares. The following table summarizes the warrants outstanding at each of the dates identified:

Issued	Exercisable for	Exercise Price	Expiration Date	Shares Exercisable at June 30, 2017	Shares Exercisable at December 31, 2016
2011 and 2012	Series Seed Preferred Stock	$ 1.00	July 2019	80,000	80,000
2013	Series B Preferred Stock	$ 1.44	April 2021	694,444	694,444
2014	Series B Preferred Stock	$ 1.44	November 2024	277,778	277,778
2016	Series C Preferred Stock	$ 1.59	October 2026	—	— (1)

(1) As of June 30, 2017 and as of December 31, 2016, warrants outstanding to acquire Series C Preferred Stock were not exercisable into shares of Series C Preferred Stock; however, only upon draw down of Term Loan B, the warrants will become exercisable into a maximum of 251,951 shares of Series C Preferred Stock.

KALA PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

7. FAIR VALUE OF FINANCIAL INSTRUMENTS

Certain assets and liabilities are carried at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value osf the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's preferred stock warrant liability is carried at fair value determined according to the fair value hierarchy and classified as a Level 3 measurement. The carrying value of accounts payable and accrued expenses approximate their fair value due to the short-term nature of these assets and liabilities. Management believes that the Company's long-term debt (See Note 5) bears interest at the prevailing market rate for instruments with similar characteristics and, accordingly, the carrying value of long-term debt, including the current portion, also approximates its fair value. The fair value of the outstanding debt was estimated using a discounted cash flow analysis based on current market interest rates for debt issuances with similar remaining years to maturity, adjusted for credit risk, which represents a Level 3 measurement.

KALA PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

The Company's preferred stock warrants associated with the issuances of the 2014 Debt Facility and the First Amendment, as well as debt transactions entered into prior to 2014, are recorded at fair value. The assets and liabilities measured at fair value on a recurring basis as of June 30, 2017 and December 31, 2016, and the input categories associated with those assets and liabilities are as follows (in thousands):

	Carrying Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
December 31, 2016				
2011 and 2012 Series Seed Warrants	$ 39	$ —	$ —	$ 39
2013 Series B Warrants	463	—	—	463
2014 Series B Warrants	274	—	—	274
2016 Series C Warrants	263	—	—	263
Total warrant liability	$ 1,039	$ —	$ —	$ 1,039
June 30, 2017				
2011 and 2012 Series Seed Warrants	$ 116	$ —	$ —	$ 116
2013 Series B Warrants	1,107	—	—	1,107
2014 Series B Warrants	533	—	—	533
2016 Series C Warrants	504	—	—	504
Total warrant liability	$ 2,260	$ —	$ —	$ 2,260

The Company has classified the value of the warrants as Level 3 measurements within the fair value hierarchy because the fair value is derived using significant unobservable inputs, which include the estimated volatility, the estimated fair value of the underlying preferred stock, and to the extent that the number of exercisable shares underlying the warrants are adjustable based on the amount of the Term Loans drawn down, the probability that the Company will draw down on the debt facility.

KALA PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

The following table provides a summary of changes in the fair value of the Company's derivative liability, which is included as a component of other (income) expense (in thousands):

	Three Months Ended June 30,	
	2017 Warrant Liability	2016 Warrant Liability
Fair value - March 31,	$ 1,075	$ 918
Change in fair value of warrant liability	1,185	47
Fair value - June 30,	$ 2,260	$ 965

	Six Months Ended June 30,	
	2017 Warrant Liability	2016 Warrant Liability
Fair value - December 31,	$ 1,039	$ 936
Change in fair value of warrant liability	1,221	29
Fair value - June 30,	$ 2,260	$ 965

The Company determined the fair values of the warrants, using the Black-Scholes option-pricing model using the following assumptions:

	2011 and 2012 Series Seed Warrants	2013 Series B Warrants	2014 Series B Warrants	Series C Warrants
December 31, 2016				
Volatility	100.00 %	87.00 %	114.00 %	58.30 %
Risk-free interest rate	1.30 %	1.80 %	2.30 %	2.40 %
Estimated fair value of underlying shares	$ 0.89	$ 1.11	$ 1.11	1.54
Remaining contractual term (years)	2.6	4.3	7.9	9.8
Expected dividend yield	— %	— %	— %	— %
June 30, 2017				
Volatility	63.20 %	84.20 %	87.40 %	88.30 %
Risk-free interest rate	1.40 %	1.70 %	2.20 %	2.30 %
Estimated fair value of underlying shares	$ 2.30	$ 2.30	$ 2.30	$ 2.30
Remaining contractual term (years)	2.1	3.8	7.4	9.3
Expected dividend yield	— %	— %	— %	— %

For purposes of determining the fair value of the warrants to purchase Series C Preferred Stock, the Company estimated that there is a 100% probability that it will draw down on the remaining $10.0 million available under the 2014 Debt Facility, and as such, assumed that the warrants will be exercisable into the maximum number of shares stipulated in the First Amendment. With respect to the aggregate warrant liabilities recorded as of June 30, 2017 and 2016, a

change in the assumptions regarding estimated volatility and/or the estimated fair value of the preferred stock could have a significant impact on the resulting fair values of the warrant liabilities.

8. CONVERTIBLE PREFERRED STOCK

Preferred stock consisted of the following as of June 30, 2017 and December 31, 2016 (in thousands, except share amounts):

	Designated Shares	Issuance Dates	Shares Issued and Outstanding	Liquidation Value	Carrying Value	Common Stock Issuable Upon Conversion (1)
Series Seed	11,323,209	December 2009	2,000,001			
		October 2010	2,000,003			
		February 2012	7,243,205			
			11,243,209	$ 11,243	$ 11,065	2,158,708
Series A	9,583,432	February 2013	4,791,716			
		July 2013	4,791,716			
			9,583,432	$ 11,500	$ 10,736	1,840,029
Series B	16,597,221	April 2014	15,624,999	$ 22,500	$ 22,185	3,000,017
Series B-1	4,629,629	August 2015	4,629,629	$ 7,000	$ 6,885	888,894
Series C	43,034,639	April 2016	42,782,688	$ 67,922	$ 67,520	8,214,322

(1) No fractional shares of Common Stock shall be issued upon conversion of the Preferred Stock. In lieu of any fractional shares to which the holder would otherwise be entitled, the Company shall pay cash equal to such fraction multiplied by the fair market value of a share of Common Stock as determined in good faith by the Board of Directors of the Company. Whether or not fractional shares would be issuable upon such conversion shall be determined on the basis of the total number of shares of Preferred Stock the holder is at the time converting into Common Stock and the aggregate number of shares of Common Stock issuable upon such conversion.

On July 25, 2017, upon the closing of the Company's IPO, all outstanding shares of the Convertible Preferred Stock converted into 16,101,970 shares of the Company's common stock.

Series Seed Convertible Preferred Stock

In December 2009, the Company issued an aggregate of 2,000,001 shares of Series Seed Preferred Stock for gross proceeds of $2.0 million or $1.00 per share. In October 2010, the Company issued an aggregate of 2,000,003 shares of Series Seed Preferred Stock to existing investors for gross proceeds of $2.0 million or $1.00 per share. In February 2012, the Company issued an aggregate of 7,243,205 shares of Series Seed Preferred Stock to existing and new investors, which included 6,150,000 shares for gross proceeds of $6.2 million and 1,093,205 shares converted from convertible debt of $1.0 million principal and $93,000 accrued interest. Costs incurred in connection with each of the individual issuances of Series Seed Preferred Stock were $124,000, $39,000 and $15,000 respectively, which have been recorded as a reduction to the carrying amount of the Series Seed Preferred Stock. On July 25, 2017, upon the closing of the Company's IPO, all outstanding shares of Series Seed Convertible Stock converted into 2,158,708 shares of the Company's common stock.

KALA PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

Series A Convertible Preferred Stock

In February 2013, the Company issued 4,791,716 shares of Series A Preferred Stock, at a purchase price of $1.20 per share for gross proceeds of $5.8 million.

Additionally, in accordance with the terms of the Series A Preferred Stock Purchase Agreement, investors were granted the right to purchase up to an additional 4,791,716 shares of Series A Preferred Stock, at a price of $1.20 per share, upon the Company meeting certain milestone criteria by December 31, 2013, approval of the Board and approval of the investors holding a majority of the outstanding shares of Series A Preferred Stock.

In June 2013, the Board approved waiving one of the milestone events provided for in the Series A Preferred Stock Purchase Agreement. Accordingly, the second tranche of Series A Preferred Stock closed on July 15, 2013 and the Company issued 4,791,716 shares of Series A Preferred Stock for gross proceeds of $5.8 million, or $1.20 per share. Costs incurred in connection with the issuance of the Series A Preferred Stock were $93,000, which have been recorded as a reduction in the carrying amount of the Series A Preferred Stock. On July 25, 2017, upon the closing of the Company's IPO, all outstanding shares of Series A Convertible Stock converted into 1,840,029 shares of the Company's common stock.

Series B Convertible Preferred Stock

In April 2014, the Company issued 15,624,999 shares of Series B Preferred Stock for gross proceeds of $22.5 million or $1.44 per share which included conversion of the outstanding principal and interest on the 2013 Notes (See Note 7) of $5.1 million, which converted into 3,562,785 shares of Series B Preferred Stock pursuant to the terms of the Notes. Costs incurred in connection with the issuance of the Series B Preferred Stock were $315,000, which have been recorded as a reduction in the carrying amount of the Series B Preferred Stock. On July 25, 2017, upon the closing of the Company's IPO, all outstanding shares of Series B Convertible Stock converted into 3,000,017 shares of the Company's common stock.

Series B-1 Convertible Preferred Stock

On August 17, 2015, the Company issued 4,629,629 shares of Series B-1 Senior Convertible Preferred Stock ("Series B-1 Preferred Stock") for gross proceeds of $7.0 million or $1.512 per share. Costs incurred in connection with the issuance of the Series B-1 Preferred Stock were $115,000, which have been recorded as a reduction in the carrying amount of the Series B-1 Preferred Stock. On July 25, 2017, upon the closing of the Company's IPO, all outstanding shares of Series B-1 Convertible Stock converted into 888,894 shares of the Company's common stock.

Series C Convertible Preferred Stock

On April 5, 2016, the Company issued 42,782,688 shares of Series C Preferred Stock for gross proceeds of $67.9 million or $1.5876 per share. Costs incurred in connection with the issuance of the Series C Preferred Stock were $402,000, which have been recorded as a reduction in the carrying amount of the Series C Preferred Stock. On July 25, 2017, upon the closing of the Company's IPO, all outstanding shares of Series C Convertible Stock converted into 8,214,322 shares of the Company's common stock.

Treatment of Preferred Stock Generally

The rights, preferences, and privileges of the Series Seed, Series A, Series B, Series B-1 and Series C (collectively the "Preferred Stock") are included in the Prospectus. There were no changes to the rights, preferences, and privileges of the Preferred Stock during the six months ended June 30, 2017.

KALA PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

As described in Note 1, on July 7, 2017, the Company effected an amendment to its Amended and Restated Certificated of the Incorporation, as amended. This amendment eliminated the minimum price per share of Common Stock for an underwritten public offering that would result in the automatic conversion of all outstanding shares of the Company's Series Seed, Series A, Series B, Series B-1 and Series C Preferred Stock.

As described in Note 1, on July 7, 2017, the Company effected a one-for-5.2083 reverse stock split of the Company's issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for the Company's convertible preferred stock.

9. COMMON STOCK

The Company was authorized to issue up to 110,251,951 shares of common stock with a $0.001 par value per share as of June 30, 2017 and December 31, 2016, respectively. As of June 30, 2017 and December 31, 2016, the Company had 1,181,429 shares of common stock issued and outstanding.

The rights, preferences, and privileges of the Company's common stock are included in the Prospectus. There were no changes to the rights, preferences, and privileges of the common stock during the six months ended June 30, 2017.

Reserved Shares—As of June 30, 2017 and December 31, 2016, the Company has reserved the following shares of common stock for potential conversion of the outstanding convertible preferred stock, convertible preferred stock issuable upon exercise of rights under warrants and exercise of stock options:

	June 30, 2017	December 31, 2016
Convertible preferred stock	16,101,970	16,101,970
2013 Warrant rights to acquire Series B Preferred Stock	133,327	133,327
2014 Warrant rights to acquire Series B Preferred Stock	53,333	53,333
2016 Warrant rights to acquire Series C Preferred Stock (1)	48,374	48,374
2011 Warrant rights to acquire Series Seed Preferred Stock	15,360	15,360
2009 stock option plan	3,533,726	3,533,726
Total	19,886,090	19,886,090

(1) As of June 30, 2017 and December 31, 2016, warrants outstanding to acquire Series C Preferred Stock were not exercisable into shares of Series C Preferred Stock; however, upon draw down of Term Loan B, the warrants will become exercisable into a maximum of 251,951 shares of Series C Preferred Stock, which represents a maximum of 48,374 potential common shares upon conversion of the Series C Preferred Stock into shares of common stock.

10. STOCK-BASED COMPENSATION

Stock Incentive Plan—On December 11, 2009, the Board adopted the 2009 Employee, Director and Consultant Equity Incentive Plan (the "2009 Plan") for the issuance of common stock and stock options to employees, officers, directors, consultants, and advisors. As of June 30, 2017 and December 31, 2016, the Board had authorized, 3,711,949 shares and 3,711,949 shares, respectively, of common stock to be issued under the 2009 Plan. Under the 2009 Plan, the Board determined the number of shares of common stock to be granted pursuant to the awards, as well as

the exercise price and terms of such awards. The exercise price of incentive stock options cannot be less than the fair value of the common stock on the date of grant.

Stock options awarded under the 2009 Plan expire 10 years after the grant date, unless the Board sets a shorter term. Options granted under the plan generally vest over a four-year period. As of June 30, 2017 and December 31, 2016, there were 241,548 shares and 338,256 shares, respectively, of common stock available for future grant under the 2009 Plan. On July 19, 2017, the Company's 2017 Equity Incentive Plan (the "2017 Plan") became effective and no further stock options or other awards will be made under the 2009 Plan. The 241,548 shares of common stock that remained available for grant under the 2009 Plan will be available for grant under the 2017 Plan. In addition, any shares of common stock subject to awards under the 2009 Plan that expire, terminate, or are otherwise surrendered, cancelled, forfeited or repurchased without having been fully exercised or resulting in any common stock being issued will become available for issuance under the 2017 Plan, up to a specified number of shares. Upon the exercise of stock options, the Company issues new shares of common stock. The Company does not hold any treasury shares.

Stock Options—In determining the exercise prices for options granted, the Board has considered the fair value of the common stock as of the measurement date. The fair value of the common stock has been determined by the Board based on a variety of factors, including the Company's financial position, the status of development efforts within the Company, the composition and ability of the current scientific and management teams, the current climate in the market place, the illiquid nature of the Company's common stock, arm's-length sale of the Company's preferred stock, the effect of the rights and preferences of the preferred stockholders, and the prospects of a liquidity event, among others.

The Company has granted 86,056 stock options which contain performance-based vesting criteria. These criteria are milestone events that are specific to the Company's corporate goals. Stock-based compensation expense associated with performance-based stock options are recognized if the achievement of the performance condition is considered probable using management's best estimates. These milestones have not been deemed probable as of June 30, 2017 and December 31, 2016. As of the six months ended June 30, 2017 and 2016, unrecognized compensation expense related to the performance-based awards was $25,000 and $35,000, respectively.

The Company granted 4,224 and 0 stock options to non-employees for the three months ended June 30, 2017 and 2016, respectively and 4,224 and 0 stock options for the six months ended June 30, 2017 and 2016, respectively. During the three months ended June 30, 2017 and 2016, the Company recognized $22,000 and $15,000, respectively, in stock compensation expense related to non-employees. During the six months ended June 30, 2017 and 2016, the Company recognized $37,000, and $28,000, respectively, in stock compensation expense related to non-employees.

A portion of the unvested stock options will vest upon the sale of all or substantially all of the stock or assets of the Company.

KALA PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

A summary of option activity for employee and non-employee awards under the 2009 Plan for the six months ended June 30, 2017 is as follows (in thousands, except share and per share amounts):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at January 1,2016	1,546,155	$ 3.17	8.7	$ 1,691
Granted	1,649,314	3.33		
Outstanding at December 31, 2016	3,195,469	$ 3.26	8.6	$ 1,200
Granted	103,013	3.86		
Forfeited	(6,305)	3.33		
Outstanding at June 30, 2017	3,292,177	$ 3.27	8.2	$ 28,676
Vested and expected to vest at December 31, 2016	2,899,032	$ 3.23	8.6	$ 1,141
Options exercisable at December 31, 2016	1,035,928	$ 2.89	8.0	$ 823
Vested and expected to vest at June 30, 2017	3,290,704	$ 3.27	8.2	$ 28,662
Options exercisable at June 30, 2017	1,507,793	$ 3.04	7.9	$ 13,480

The Company records stock-based compensation related to stock options granted at fair value. The Company utilizes the Black-Scholes option-pricing model to estimate the fair value of stock option grants and to determine the related compensation expense. The assumptions used in calculating the fair value of stock-based payment awards represent management's best estimates. The assumptions used in determining fair value of the stock options granted in the six months ended June 30, 2017 and 2016 are as follows:

	Six Months Ended June 30,	
	2017	2016
Expected volatility	103% - 122%	108% - 110%
Risk-free interest rate	1.81% - 2.29%	1.21% - 1.29%
Expected dividend yield	0%	0%
Expected term (in years)	5.04 - 9.82	5.62 - 6.18

The Company derived the risk-free interest rate assumption from the U.S. Treasury rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the awards being valued. The Company based the assumed dividend yield on its expectation of not paying dividends in the foreseeable future. The Company calculated the weighted-average expected term of options using the simplified method, as the Company lacks relevant historical data due to the Company's limited operating experience. The estimated volatility is based upon the historical volatility of comparable companies with publicly available share prices. The impact of forfeitures on compensation expense are recorded as they occur.

The weighted average grant-date fair value of options granted during the three and six months ended June 30, 2017 and 2016 was $3.86 and $3.34, respectively. There were 103,013 and 1,501,127 options granted during the six months ended June 30, 2017 and 2016, respectively. The fair value is being expensed over the vesting period of the options on a straight-line basis as the services are being provided. The Company has recorded aggregate stock-based compensation expense related to the issuance of stock option awards of $567,000 and $868,000, respectively, during the three months ended June 30, 2017 and 2016, and $1.1 million and $1.2 million during the six months ended June 30, 2017 and 2016, respectively. As of June 30, 2017, there was $5.0 million of unrecognized compensation cost related to

KALA PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

the stock options granted under the 2009 Plan, which is expected to be expensed over a weighted-average period of 2.38 years.

Stock-based Compensation Expenses—Stock-based compensation expense was classified in the statements of operations as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Research and development	$ 205	$ 74	$ 392	$ 129
General and administrative	362	794	697	1,064
Total	$ 567	$ 868	$ 1,089	$ 1,193

11. INCOME TAXES

The Company did not record a provision or benefit for income taxes during the three and six months ended June 30, 2017 and 2016. The Company continues to maintain a valuation allowance for its U.S. federal and state deferred tax assets.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Management reevaluates the positive and negative evidence at each reporting period.

Realization of the future tax benefits is dependent on many factors, including the Company's ability to generate taxable income within the net operating loss carryforward period. Under the provisions of Section 382 of the Internal Revenue Code of 1986, certain substantial changes in the Company's ownership, including a sale of the Company, or significant changes in ownership due to sales of equity, may have limited, or may limit in the future, the amount of net operating loss carryforwards, which could be used annually to offset future taxable income. The Company files its corporate income tax returns in the United States and Massachusetts, California, Kentucky, Pennsylvania, New York, Texas and New Hampshire. All tax years since the date of incorporation remain open to examination by the major taxing jurisdictions (state and federal) to which the Company is subject, as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service ("IRS") or other authorities if they have or will be used in a future period. The Company is not currently under examination by the IRS or any other jurisdictions for any tax year.

As of June 30, 2017 and 2016, the Company had no uncertain tax positions. The Company's policy is to recognize interest and penalties related to income tax matters as a component of income tax expense, of which no interest or penalties were recorded for the six months ended June 30, 2017 and 2016.

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NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

12. NET LOSS PER COMMON SHARE

Net Loss per Share—Basic and diluted net loss per share attributable to common stockholders were calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Numerator:				
Net loss attributable to common stockholders	$ (10,986)	$ (9,853)	$ (20,745)	$ (15,105)
Denominator:				
Weighted average shares outstanding—basic and diluted	1,181,429	1,181,429	1,181,429	1,181,429
Net loss per share attributable to common stockholders—basic and diluted	$ (9.30)	$ (8.34)	$ (17.56)	$ (12.79)

The Company's potential dilutive securities, which include stock options, warrants to purchase preferred stock and convertible preferred stock, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders are the same.

The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	June 30,	
	2017	2016
Convertible preferred stock (as converted to common stock)	16,101,970	16,101,970
Options to purchase common stock	3,292,177	3,047,285
Preferred stock warrants (1)	250,394	250,394
	19,644,541	19,399,649

(1) Warrants outstanding as of June 30, 2017 and 2016, respectively include warrants to purchase Series C Preferred Stock for which the underlying shares included above of 48,374 are only exercisable upon the Company's draw down of the full amount of Term Loan B of $10.0 million.

13. COMMITMENTS AND CONTINGENCIES

Leases—The Company entered into a three-year lease agreement for its new headquarters on September 30, 2013, with a commencement date of February 1, 2014. As part of the terms of the lease agreement, the landlord agreed to fund certain improvements to the Company's facility. The amount funded by the landlord was $78,000 and has been recorded as a liability which is being amortized as a reduction of rent expense over the term of the lease.

On June 30, 2016, the lease was amended to extend the term from January 31, 2017 to January 31, 2019. In connection with the lease agreement, the Company issued a letter of credit to the landlord for $84,000. The Company

secured the letter of credit using restricted cash for the full amount of the letter. The restricted cash as June 30, 2017 is included in other noncurrent assets in the accompanying balance sheets.

Total rent expense for the lease, which is recorded on a straight-line basis, for the three months ended June 30, 2017 and 2016 was $97,000 and $80,000, respectively and six months ended June 30, 2017 and 2016 was $193,000 and $159,000, respectively.

Future minimum commitments due under these non-cancelable operating lease agreements as of June 30, 2017 are as follows (in thousands):

Years Ending December 31,		
2017 (remaining six months)	$	198
2018		410
2019		34
Total minimum lease payments	$	642

License Agreement—In 2009, the Company entered into an exclusive license agreement with The Johns Hopkins University ("JHU"), as amended in November 2012, May 2014, August 2014 and October 2014, which licensed to the Company a portfolio of specified patent rights and remains in full force and effect. Pursuant to the terms of the agreement, as amended, the Company agreed to pay an initial license fee, minimum annual payments beginning in 2017, certain development and commercial milestone payments, royalties on product sales and reimburse all or a portion of the costs associated with the preparation, filing, prosecution and maintenance of the agreed-upon patents and patent applications to JHU ("Prosecution Costs").

After 2016 and until the first commercial sale of product, the minimum annual payment will be $38,000. If the Company achieves the first commercial sale of the product in the United States, European Union, or Japan, the annual minimum payment will increase to $113,000. The Company is obligated to pay JHU low single-digit running royalties based upon a percentage of net sales of the licensed products. The Company also has an obligation to pay JHU certain one-time development and commercial milestone payments.

The Company recorded research and development expenses related to the JHU agreement of $0 and $40,000, respectively, for the three months ended June 30, 2017 and 2016 and $10,000 and $49,000, respectively, for the six months ended June 30, 2017 and 2016.

In 2015, the Company entered into a non-exclusive license agreement with Massachusetts Eye and Ear Infirmary ("MEEI"), which licensed to the Company a certain questionnaire called "Symptom Assessment in Dry Eye" for use in clinical trials. Pursuant to the terms of the agreement, the Company agreed to pay an initial license fee of $10,000. Beginning in 2016, the Company was also obligated to pay an annual payment of $5,000. The agreement terminates in 2018.

Litigation—The Company is not currently subject to any material legal proceedings.

Guarantees and Indemnifications—The Company's Certificate of Incorporation authorizes the Company to indemnify and advance expenses to its officers and directors and agents to the fullest extent permitted by law. The Company leases office space under a non-cancelable operating lease. Under the lease the Company is required to indemnify the landlord against claims, actions, or damages incurred in connection with, among other items, the Company's occupancy and use of the premises.

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NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

The Company's equity agreements and certain other arrangements include standard indemnifications against claims, actions, or other matters that may arise in connection with these arrangements.

As of June 30, 2017, the Company had not experienced any losses related to these indemnification obligations, and no claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and has no amount accrued related to these contingencies. The Company does not expect these indemnifications to have a material adverse effect on these financial statements.

14. SUBSEQUENT EVENTS

Automatic Conversion of Preferred Stock

On July 1, 2017, the Board of Directors of the Company (the "Board") approved a further amendment to the Company's Amended and Restated Certificated of the Incorporation, as amended to eliminate the minimum price per share of Common Stock for an underwritten public offering that would result in the automatic conversion of all outstanding shares of the Company's Series Seed, Series A, Series B, Series B-1 and Series C Preferred Stock. This amendment became effective on July 7, 2017. On July 25, 2017, upon the closing of the Company's IPO, all outstanding shares of the Convertible Preferred Stock converted into 16,101,970 shares of the Company's common stock and all of the Company's outstanding warrants to purchase preferred stock automatically converted into warrants to purchase 202,020 shares of common stock.

Reverse Stock Split

On July 7, 2017, the Company effected a one-for-5.2083 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for the Company's Convertible Preferred Stock. The par value per share and authorized shares of common and convertible preferred stock were not adjusted as a result of the reverse stock split. Accordingly, all share and per share amounts within the financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this reverse stock split including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital.

2017 Equity Incentive Plan

On July 5, 2017, the Company's stockholders approved the 2017 Plan, which became effective on July 19, 2017. The 2017 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards for the purchase of that number of shares of Common Stock equal to the sum of (i) 1,786,883 shares of Common Stock, (ii) such additional number of shares of Common Stock (up to 3,533,757 as is equal to the sum of (x) 241,548, which was the number of shares of Common Stock reserved for issuance under the 2009 Plan that remained available for issuance under the 2009 Plan on July 19, 2017 and (y) the number of shares of Common Stock subject to awards granted under the 2009 Plan which awards expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right (subject, in the case of incentive stock options to any limitations of the Internal Revenue Code), and (iii) an annual increase to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2018 and continuing for each fiscal year until, and including, the fiscal year ending December 31, 2027, equal to the least of (a) 3,573,766 shares of Common Stock, (b) 4% of the number of outstanding shares of Common Stock on such date or (c) an amount determined by the Board.

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NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

2017 Employee Stock Purchase Plan

On July 5, 2017, the Company's stockholders approved the 2017 Employee Stock Purchase Plan (the "2017 ESPP"), which became effective on July 19, 2017. Under the 2017 ESPP the Company may issue up to an aggregate of (i) 223,341 shares of Common Stock, plus (ii) an annual increase to be added on the first day of each fiscal year, commencing on January 1, 20l9 and continuing for each fiscal year until, and including, the fiscal year ending December 31, 2029, equal to the least of (a) 893,441 shares of Common Stock, (b) 1% of the outstanding shares on such date and (c) an amount determined by the Board.

Initial Public Offering

On July 25, 2017, the Company completed its IPO in which it issued and sold 6,900,000 shares of its common stock at a price per share of $15.00, including 900,000 shares of common stock pursuant to the underwriters' option to purchase additional shares. The Company received net proceeds of $94.9 million after deducting underwriting discounts and commissions of $7.2 million and offering costs incurred in 2017 of $1.4 million. Upon the closing of the IPO, all the outstanding shares of convertible preferred stock converted by their terms into 16,101,970 shares of common stock.

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

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited condensed financial statements and related notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in our final prospectus for our initial public offering filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, or the Securities Act, with the Securities and Exchange Commission, or the SEC on July 20, 2017, or the Prospectus.

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. See "Special Note Regarding Forward-Looking Statements." Because 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.

Overview

We are a biopharmaceutical company focused on the development and commercialization of therapeutics using our proprietary nanoparticle-based Mucus Penetrating Particles, or MPP, technology, with an initial focus on the treatment of eye diseases. Our MPPs are selectively-sized nanoparticles and have proprietary coatings. We believe that these two key attributes enable even distribution of drug particles on mucosal surfaces and significantly increase drug delivery to target tissues by enhancing mobility of drug particles through mucus and preventing drug particles from becoming trapped and eliminated by mucus. We have applied the MPP technology to create nanosuspensions of loteprednol etabonate, or LE, a corticosteroid designed for ocular applications, resulting in two product candidates in Phase 3 development, KPI-121 1.0% for the treatment of inflammation and pain following ocular surgery and KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease.

We have completed two Phase 3 clinical trials of KPI-121 1.0%, our topical twice-a-day product candidate, in patients with inflammation and pain following cataract surgery, which is the most common type of ocular surgery in the United States. Commonly used topical ocular corticosteroid products for the treatment of post-operative inflammation and pain are approved for dosing four times a day. In May 2017, we announced topline results from the second, confirmatory Phase 3 clinical trial. In this second Phase 3 clinical trial, administration of KPI-121 1.0% two times a day achieved statistical significance for both primary efficacy endpoints of complete resolution of inflammation at day eight maintained through day 15 with no need for rescue medication compared to placebo and complete resolution of pain at day eight maintained through day 15 with no need for rescue medications compared to placebo and all secondary endpoints. In this trial, KPI-121 1.0% was well tolerated with no treatment-related significant adverse events observed during the course of the trial. Based on the results of our two completed Phase 3 trials of KPI-121 1.0%, we anticipate submitting a new drug application, or NDA, for the approval of KPI-121 1.0% for the treatment of post-operative inflammation and pain following ocular surgery by the end of 2017. KPI-121 0.25% is our product candidate for patients with dry eye disease utilizing a two-week course of therapy. After achieving positive results in a Phase 2 clinical trial, we initiated two parallel Phase 3 clinical trials of KPI-121 0.25% in June 2016. Each of these Phase 3 clinical trials has a target enrollment of at least 900 dry eye patients. We expect to receive topline results from these clinical trials by the end of 2017. Assuming positive results from these Phase 3 clinical trials, we anticipate submitting an NDA for KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease in the first half of 2018. We also are evaluating compounds in our topically applied MPP receptor Tyrosine Kinase Inhibitor program, or rTKI program, that inhibit the vascular endothelial growth factor, or VEGF, pathway, for the potential treatment of a number of retinal diseases.

For both KPI-121 1.0% and KPI-121 0.25% product candidates, we plan to rely on the potentially more expeditious pathway to U.S. Food and Drug Administration, or the FDA, approval under Section 505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act, or the FDCA. Based on our discussions with European Union, or EU, regulatory authorities, if the results of our ongoing Phase 3 dry eye disease trials are positive, we believe that we will be able to utilize the results from these trials to support a submission of a Marketing Authorization Application, or MAA, for KPI-121 0.25% for the short-term treatment of dry eye disease in the EU through the Article 10(3) submission pathway.

We are evaluating our current lead rTKI program compound, KPI-285, a topically applied MPP small molecule for the potential treatment of a number of retinal diseases. Prior to initiating IND-enabling studies, we may consider potential collaborative partnership opportunities to advance product candidates we develop through our rTKI program, including KPI-285. We are also evaluating opportunities for MPP nanosuspensions of LE with less frequent daily dosing regimens for the treatment of post-operative inflammation and pain, the temporary relief of the signs and symptoms of dry eye disease and for potential chronic treatment of dry eye disease. In addition, we also are evaluating additional product opportunities with significant unmet medical needs that we believe can be addressed by our proprietary MPP technology, including diseases of the lung, cervical/vaginal tract and gastrointestinal tract.

Recent Developments

On July 25, 2017, we completed our initial public offering of our common stock, or IPO, pursuant to which we issued 6,900,000 shares of our common stock at a price of $15.00 per share, which included 900,000 shares sold pursuant to the exercise of the underwriters' option to purchase additional shares. We received $94.9 million, net of underwriting discounts and commissions, and offering expenses.

Financial Operations Overview

Research and Development Expenses

Research and development expenses consist of costs associated with our research activities, including compensation and benefits for full-time research and development employees, an allocation of facilities expenses, overhead expenses, payments to universities under our license agreements and other outside expenses. Our research and development expenses include:

- employee-related expenses, including salaries, related benefits, travel and stock-based compensation;
- expenses incurred for the preclinical and clinical development of our product candidates and under agreements with contract research organizations, or CROs;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and supplies; and
- payments made under our third-party licensing agreements, including our license agreement with Johns Hopkins University, or JHU.

We expense research and development costs as they are incurred. Research and development costs that are paid in advance of performance are capitalized as a prepaid expense until incurred. We track outsourced development costs by development program but do not allocate personnel costs, payments made under our license agreements or other costs to specific product candidates or development programs. These costs are included in Employee-related costs and Other research and development costs in the tables below.

We expect our research and development expenses to increase for the foreseeable future as we advance our product candidates toward regulatory approval. The process of conducting preclinical studies and clinical trials necessary to obtain regulatory approval is costly and time-consuming. We may never succeed in obtaining marketing approval for any of our product candidates. The probability of success for each product candidate may be affected by numerous factors, including preclinical data, clinical data, competition, manufacturing capability and commercial viability.

Our research and development programs are at various stages of development. Successful development and completion of clinical trials is uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each future product candidate and are difficult to predict. We will continue to make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to our ability to enter into collaborations with respect to each product candidate, the scientific

and clinical success of each product candidate as well as ongoing assessments as to the commercial potential of product candidates. We will need to raise additional capital and may seek collaborations in the future to advance our various product candidates. Additional private or public financings may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a material adverse effect on our financial condition and our ability to pursue our business strategy.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, finance, legal, business development and support functions. Other general and administrative expenses include travel expenses, professional fees for auditing, tax, consultants and legal services and allocated facility-related costs not otherwise included in research and development expenses.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development activities and commercialization of our product candidates. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance costs as well as investor and public relations expenses associated with being a public company.

Interest Income

Interest income consists of interest earned on our cash balance held in a deposit account.

Interest Expense

Interest expense primarily consists of contractual coupon interest, amortization of debt discounts and debt issuance costs recognized on our debt facility.

Change in Fair Value of Warrant Liability

We recognize gains and losses on the change in the fair value of outstanding warrants to purchase our Series Seed, Series B and Series C preferred stock as a component of other income (expense). We have issued warrants for the purchase of our Series Seed, Series B and Series C preferred stock. These warrants are financial instruments that are issuable for contingently redeemable securities. Therefore, we have classified the warrants as liabilities that we remeasure to fair value at each reporting period, and we record the re-measurement as the change in fair value of warrant liability in the statement of operations. Upon the closing of our IPO, the underlying preferred stock was converted into common stock, the preferred stock warrants became exercisable for common stock instead of preferred stock, and the fair value of the warrant liability at that time was reclassified to additional paid-in capital.

Critical Accounting Policies and Significant Judgments and Estimates

Our 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 U.S. generally accepted accounting principles. We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as critical because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used. On an ongoing basis, we evaluate our estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that our most critical accounting policies are indicated in the Prospectus. There have been no significant changes to our accounting policies discussed in the Prospectus.

Results of Operations

Comparison of the Three Months Ended June 30, 2017 and 2016

The following table summarizes the results of our operations for the three months ended June 30, 2017 and 2016:

	Three Months Ended June 30,		
	2017	2016	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 8,071	$ 5,950	$ 2,121
General and administrative	1,559	3,700	(2,141)
Total costs and expenses	9,630	9,650	(20)
Loss from operations	(9,630)	(9,650)	20
Other income (expense)			
Interest income	37	30	7
Interest expense	(208)	(186)	(22)
Change in fair value of warranty liability	(1,185)	(47)	(1,138)
Net loss	$ (10,986)	$ (9,853)	$ (1,133)

Research and Development Expenses

The following table summarizes the research and development expenses incurred during the three months ended June 30, 2017 and 2016:

	Three Months Ended June 30,		
	2017	2016	Change
	(in thousands)		
KPI-121 development costs	$ 5,283	$ 4,092	$ 1,191
Employee-related costs	1,628	1,046	582
Other research and development costs	1,160	812	348
Total research and development	$ 8,071	$ 5,950	$ 2,121

Research and development expenses were $8.1 million for the three months ended June 30, 2017 compared to $6.0 million for the three months ended June 30, 2016, an increase of $2.1 million. This increase is primarily the result of a $1.2 million increase in KPI-121 development costs due to the increase in external costs associated with our two parallel Phase 3 clinical trials of KPI-121 0.25% for the treatment of dry eye disease, and Phase 3 clinical trial of KPI-121 1.0% for the treatment of inflammation and pain following cataract surgery; a $0.6 million increase in employee-related costs due to the additional hiring of clinical and regulatory personnel as a result of our progress on the Phase 3 trials, overall merit increases and an increase in stock compensation expense related to stock option grants; and a $0.3 million increase in other research and development costs related to clinical consulting support for our 3 Phase 3 trials and regulatory consulting support for our NDA preparation.

General and Administrative Expenses

The following table summarizes the general and administrative expenses incurred during the three months ended June 30, 2017 and 2016:

	Three Months Ended June 30,		
	2017	2016	Change
	(in thousands)		
Employee-related costs	$ 1,121	$ 1,340	$ (219)
External consulting costs	269	419	(150)
Write-off of deferred offering costs	—	1,789	(1,789)
External general and administrative costs	169	152	17
Total general and administrative	$ 1,559	$ 3,700	$ (2,141)

General and administrative expenses were $1.6 million for the three months ended June 30, 2017 compared to $3.7 million for the three months ended June 30, 2016, a decrease of $2.1 million. The decrease was primarily due to the write-off of $1.8 million in deferred offering costs resulting from our decision not to update our 2015 confidential S-1 filing, at which point in time our initial public offering was no longer considered to be probable of being consummated in 2016. In addition, we incurred a $0.2 million decrease in employee-related costs due to a decrease in stock compensation expenses of $0.4 million related to stock options granted during 2016 which was partially offset by increased salary and benefits costs due to the hiring of additional general and administrative employees and overall merit increases of $0.2 million. Also contributing to an overall decrease in general administrative expenses was the decrease in external consulting costs of $0.1 million due to the hiring of general and administrative personnel.

Interest Income

Interest income was $37,000 for the three months ended June 30, 2017 compared to $30,000 for the three months ended June 30 2016. Interest income consists of interest earned on our balance held in an interest-bearing deposit account.

Interest Expense

We incurred interest expense of $0.2 million for the three months ended June 30, 2017 and 2016, which was comprised of the contractual coupon interest and the amortization of debt discount associated with our venture debt facility.

Change in Fair Value of Warrant Liability

The change in the fair value of our preferred stock warrant liability consisted of a loss of $1.2 million for the three months ended June 30, 2017 compared with a loss of less than $0.1 million for the three months ended June 30, 2016, or an increase to the loss of $1.1 million. This increase was primarily the result of an increase in the fair value of the underlying preferred stock.

Comparison of the Six Months ended June 30, 2016 and 2017

The following table summarizes the results of our operations for the six months ended June 30, 2016 and 2017:

	Six Months Ended June 30,		
	2017	2016	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 16,110	$ 9,861	$ 6,249
General and administrative	3,091	4,865	(1,774)
Total costs and expenses	19,201	14,726	4,475
Loss from operations	(19,201)	(14,726)	(4,475)
Other income (expense)			
Interest income	83	30	53
Interest expense	(406)	(380)	(26)
Change in fair value of warranty liability	(1,221)	(29)	(1,192)
Net loss	$ (20,745)	$ (15,105)	$ (5,640)

Research and Development Expenses

The following table summarizes the research and development expenses incurred during the six months ended June 30, 2017 and 2016:

	Six Months Ended June 30,		
	2017	2016	Change
	(in thousands)		
KPI-121 development costs	$ 10,768	$ 6,502	$ 4,266
Employee-related costs	3,170	1,962	1,208
Other research and development costs	2,172	1,397	775
Total research and development	$ 16,110	$ 9,861	$ 6,249

Research and development expenses were $16.1 million for the six months ended June 30, 2017 compared to $9.9 million for the six months ended June 30, 2016, an increase of $6.2 million. This increase is primarily attributed to $4.3 million increase in KPI-121 development costs due to the increase in external costs associated with our second Phase 3 clinical trial of KPI-121 1.0% for the treatment of inflammation and pain following cataract surgery and our two parallel Phase 3 clinical trials of KPI-121 0.25% for the treatment of dry eye disease which began in June 2016; a $1.2 million increase in employee-related costs related to additional clinical and regulatory headcount and an increase in stock compensation from stock option grants; and a $0.7 million increase in other research and development costs primarily associated with clinical consulting services for our 3 Phase 3 trials and regulatory consulting support for our NDA preparation.

General and Administrative Expenses

The following table summarizes the general and administrative expenses incurred during the six months ended June 30, 2017 and 2016:

	Six Months Ended June 30,		
	2017	2016	Change
	(in thousands)		
Employee-related costs	$ 2,072	$ 2,133	$ (61)
External consulting costs	723	733	(10)
Write-off of deferred offering costs	—	1,789	(1,789)
External general and administrative costs	296	210	86
Total general and administrative	$ 3,091	$ 4,865	$ (1,774)

General and administrative expenses were $3.1 million for the six months ended June 30, 2017 compared to $4.9 million for the six months ended June 30, 2016, a decrease of $1.8 million. The decrease was primarily due to the write-off during the second quarter of 2016 of $1.8 million in deferred offering relating to our confidential submission of a draft registration statement on Form S-1 in 2015. Employee-related costs decreased by $0.1 million due to a $0.4 million decrease in stock compensation expense related to stock options granted during the six months ended June 30, 2016 which was partially offset by a $0.3 million increase in general and administrative salaries and benefits expenses due to the hiring of additional employees and overall merit increases.

Interest Income

Interest income was $83,000 for the six months ended June 30, 2017 compared to $30,000 for the six months ended June 30, 2016, an increase of $53,000. This increase was due to a higher average cash balance in our interest-bearing deposit account during the six months ended June 30, 2017 compared to the same period in 2016.

Interest Expense

Interest expense was $0.4 million for the six months ended June 30, 2017 and 2016, which was comprised of the contractual coupon interest and the amortization of the debt discount associated with our venture debt facility.

Change in Fair Value of Warrant Liability

The change in the fair value of our preferred stock warrant liability consisted of a loss of $1.2 million for the six months ended June 30, 2017 compared with a loss of less than $0.1 million for the six months ended June 30, 2016, or an increase to the loss of $1.2 million. This increase was the result of an increase in the fair value of the underlying preferred stock.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have derived limited revenue to date from feasibility studies with collaboration partners. We have not yet commercialized any of our product candidates, which are in various phases of clinical development, and we do not expect to generate revenue from sales of any product before 2019, if ever. We have funded our operations to date with proceeds from the sale of preferred stock, borrowings under venture debt facilities, the issuance of convertible promissory notes and warrants and to a lesser extent, payments received in connection with various feasibility studies.

In July 2017, we completed an IPO pursuant to which we issued and sold 6,900,000 shares of our common stock, which included 900,000 shares sold pursuant to the exercise of the underwriters' option to purchase additional shares, at a price of $15.00 per share. We received net proceeds of $94.9 million after deducting underwriting discounts and commission of $7.2 million and offering costs incurred in 2017 of $1.4 million.

Cash Flows

The following table summarizes our sources and uses of cash for the six months ended June 30, 2017 and 2016:

	Six Months Ended June 30,	
	2017	2016
	(in thousands)	
Net cash used in operating activities	$ (18,204)	$ (11,876)
Net cash used in investing activities	(134)	(46)
Net cash provided by financing activities	(784)	67,238
(Decrease) increase in cash	$ (19,122)	$ 55,316

Net Cash Used in Operating Activities

During the six months ended June 30, 2016, our cash used in operating activities was primarily due to our net loss of $15.1 million as we incurred increased external research and development costs associated with our clinical trials during the six months ended June 30, 2016 and increased general and administrative costs, partially offset by non-cash charges of $3.2 million, consisting primarily of $1.8 million in deferred offering costs relating to our confidential submission of a draft registration statement on Form S-1 in 2015 and $1.2 million in stock-based compensation. Net cash provided by changes in our operating assets and liabilities primarily consisted of an increase of $1.0 million increase in accounts payable and a decrease of $0.9 million in accrued expenses.

During the six months ended June 30, 2017, our cash used in operating activities was primarily due to our net loss of $20.7 million as we incurred increased external research and development costs associated with our clinical trials during the six months ended June 30, 2017 and increased general and administrative costs partially offset by non-cash charges of $2.5 million, consisting primarily of an $1.2 million increase in fair value of warrant liability and $1.1 million in stock-based compensation. Net cash provided by changes in our operating assets and liabilities primarily consisted of an increase of $0.2 million in accounts payable and an increase of $0.1 million in prepaid expenses and other current assets.

Net Cash Used in Investing Activities

Net cash used in investing activities was $46,000 for the six months ended June 30, 2016, consisting of purchases of property and equipment, primarily laboratory equipment

Net cash used in investing activities was $0.1 million for the six months ended June 30, 2017 consisting of purchases of property and equipment, primarily laboratory equipment, and an increase of $25,000 in restricted cash.

Net Cash (Used in)/Provided by Financing Activities

Net cash provided in financing activities was $67.2 million for the six months ended June 30, 2016, consisting of $67.5 million in net proceeds from the issuance of Series C preferred stock, partially offset by the payment of deferred offering costs of $0.3 million related to our confidential filing of a draft registration statement on Form S-1 in 2015.

Net cash used in financing activities was $0.8 million for the six months ended June 30, 2017, consisting of $0.8 million of deferred offering costs related to our IPO.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our preclinical activities and clinical trials. In addition, we expect to incur additional costs associated with operating as a public company.

Our expenses will also increase if and as we:

- seek marketing approvals for KPI-121 1.0% and KPI-121 0.25% and any other product candidates that successfully complete clinical development;
- pursue the clinical development of KPI-121 for the treatment of other additional indications or for use in other patient populations or, if approved, seek to broaden the label of KPI-121 1.0% or KPI-121 0.25%;
- pursue the preclinical and clinical development of product candidates derived from our rTKI program for use in the treatment of retinal diseases;
- establish sales, marketing and distribution capabilities for our product candidates for which we obtain marketing approval;
- scale up our manufacturing processes and capabilities to support our clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval;
- leverage our proprietary MPP technology to advance additional high-value therapeutics into preclinical and clinical development;
- in-license or acquire the rights to other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control, scientific, manufacturing, commercial and management personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company; and
- increase our product liability insurance coverage as we expand our commercialization efforts.

On July 25, 2017, we completed an IPO of our common stock pursuant to which we issued 6,900,000 shares of our common stock at a price of $15.00 per share, which included 900,000 shares sold pursuant to the exercise of the underwriters' option to purchase additional shares. We received net proceeds of $94.9 million after deducting underwriting discounts and commission of $7.2 million and offering costs incurred in 2017 of $1.4 million. We believe that the net proceeds from our IPO, together with our existing cash on hand as of June 30, 2017 and available borrowings under our 2014 Debt Facility, will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements through the second quarter of 2019. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical drugs, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the progress, costs and results of our ongoing Phase 3 clinical trials for KPI-121 0.25% and of any clinical activities for regulatory review of KPI-121 1.0% and KPI-121 0.25% outside of the United States;
- the costs and timing of process development and manufacturing scale-up activities associated with KPI-121 1.0% and KPI-121 0.25%;
- the costs, timing and outcome of regulatory review of KPI-121 1.0% and KPI-121 0.25%;

- the costs of commercialization activities for KPI-121 1.0% and KPI-121 0.25% if we receive, or expect to receive, marketing approval, including the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities;

- subject to receipt of marketing approval, revenue received from commercial sales of KPI-121 1.0% and KPI-121 0.25%;

- our ability to establish and maintain strategic collaborations, licensing or other agreements and the financial terms of such agreements;

- the scope, progress, results and costs of any product candidates that we may derive from our rTKI program or any other product candidates that we may develop;

- the extent to which we in-license or acquire rights to other products, product candidates or technologies; and

- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property-related claims.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaboration agreements, other third-party funding, strategic alliances, licensing arrangements and marketing and distribution arrangements.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through other third-party funding, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

During the six months ended June 30, 2017, there were no material changes to our contractual obligations and commitments as set forth under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Contractual Obligations” in the Prospectus.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We did not hold any cash equivalents or investments as of June 30, 2017. As of June 30, 2017, our exposure to the risk of changes in market interest rates related primarily to our borrowings under our 2014 Debt Facility, which are subject to a variable interest rate. We do not expect any material impact on our operating results from a reasonably possible change in market interest rates. A 50-basis point increase or decrease in interest rates would increase or decrease annual interest expense by $50,000 related to our borrowings under our 2014 Debt Facility.

Item 4. Controls and Procedures.

Evaluation of disclosure controls and procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2017. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2017, our Chief Executive Officer and 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 were no changes in our internal control over financial reporting during the three months ended June 30, 2017, that have materially affected, or are reasonably likely to materially affect, our internal control over financing reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

Careful consideration should be given to the following risk factors, in addition to the other information set forth in this Quarterly Report on Form 10-Q and in other documents that we file with the SEC, in evaluating the Company and our business. Investing in our common stock involves a high degree of risk. If any of the following risks actually occur, our business, prospects, operating results and financial condition could suffer materially. In such event, the trading price of our common stock could decline and you might lose all or part of your investment.

Risks Related to Our Financial Position and Need For Additional Capital

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

Since inception, we have incurred significant losses from operations and negative cash flows from operations. Our net losses were $16.7 million for the year ended December 31, 2015, $33.2 million for the year ended December 31, 2016 and $20.7 million for the six months ended June 30, 2017. As of June 30, 2017, we had an accumulated deficit of $112.9 million. We have not generated any revenues to date from product sales and have financed our operations primarily through private placements of our preferred stock, convertible debt financings and borrowings under credit facilities. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials. 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 compared to prior periods as we complete our Phase 3 trials of KPI-121 0.25% in patients with dry eye disease and prepare for commercialization of our product candidates, as a result of increased headcount, including management personnel to support our clinical, manufacturing and commercialization activities, expanded infrastructure, increased legal, compliance, accounting and investor and public relations expenses associated with being a public company and increased insurance premiums, among other factors. Our license agreement with The Johns Hopkins University, or JHU, under which we license certain of our patent rights and a significant portion of the technology for KPI-121 1.0% and KPI-121 0.25%, imposes royalty and other financial obligations on us, and we may enter into additional licensing and funding arrangements with third parties that may impose milestone payment, royalty, insurance and other obligations on us.

Our expenses will also increase if and as we:

- seek marketing approvals for KPI-121 1.0% and KPI-121 0.25% and any other product candidates that successfully complete clinical development;
- pursue the clinical development of KPI-121 for the treatment of other additional indications or for use in other patient populations or, if approved, seek to broaden the label of KPI-121 1.0% or KPI-121 0.25%;
- pursue the preclinical and clinical development of product candidates derived from our rTKI program for use in the treatment of retinal diseases;
- establish sales, marketing and distribution capabilities for our product candidates for which we obtain marketing approval;
- scale up our manufacturing processes and capabilities to support our clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval;
- leverage our proprietary MPP technology to advance additional high-value therapeutics into preclinical and clinical development;

- in-license or acquire the rights to other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control, scientific, manufacturing, commercial and management personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company; and
- increase our product liability insurance coverage as we expand our commercialization efforts.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses will increase if:

- we are required by the FDA or non-U.S. regulatory agencies to perform clinical trials or studies in addition to those currently expected;
- there are any delays in enrollment of patients in or completing our clinical trials or the development of our product candidates; or
- there are any third-party challenges to our intellectual property portfolio, or the need arises to defend against intellectual property-related claims.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate revenue that is sufficient to achieve profitability unless and until we obtain marketing approval for and commercialize one or more of our product candidates. We do not expect to commercialize any of our product candidates before 2019, if ever. This will require us to be successful in a range of challenging activities, including:

- completing and obtaining favorable results from our two ongoing Phase 3 clinical trials of KPI-121 0.25% in patients with dry eye disease;
- obtaining marketing approval for KPI-121 1.0%, KPI-121 0.25% or any other product candidates;
- manufacturing at commercial scale, marketing, selling and distributing those products for which we obtain marketing approval;
- achieving an adequate level of market acceptance of and obtaining and maintaining coverage and adequate reimbursement from third-party payors for our products; and
- obtaining, maintaining and protecting our intellectual property rights.

We may never succeed in these activities and may never generate revenue that is sufficient to achieve profitability. Even if we do 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 decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

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

We are an early-stage company. Our operations to date have been limited to organizing and staffing our company, acquiring rights to intellectual property, business planning, raising capital and developing KPI-121 and other product candidates. 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.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition 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 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.

We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we seek marketing approval for KPI-121 1.0%, conduct our multiple Phase 3 clinical trials and, assuming positive results from these trials, seek marketing approval for KPI-121 0.25%, and continue the development of and potentially seek marketing approval for other product candidates. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our preclinical activities and clinical trials. In addition, our expenses will further increase if we suffer any delays in our Phase 3 clinical programs for KPI-121 0.25%, including delays in enrollment of patients. We also expect to devote additional financial resources to conducting research and development, initiating clinical trials of, and potentially seeking regulatory approval for, other potential product candidates, including product candidates that we may develop using our rTKI program.

If we obtain marketing approval for KPI-121 1.0%, KPI-121 0.25% or any other product candidate that we develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Furthermore, we will incur additional costs associated with operating as a public company, hiring additional personnel and expanding our facilities. Accordingly, we may need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

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

- the progress, costs and results of our ongoing Phase 3 clinical trials for KPI-121 0.25% and of any clinical activities for regulatory review of KPI-121 1.0% and KPI-121 0.25% outside of the United States;
- the costs and timing of process development and manufacturing scale-up activities associated with KPI-121 1.0% and KPI-121 0.25%;
- the costs, timing and outcome of regulatory review of KPI-121 1.0% and KPI-121 0.25%;
- the costs of commercialization activities for KPI-121 1.0% and KPI-121 0.25% if we receive, or expect to receive, marketing approval, including the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities;
- subject to receipt of marketing approval, revenue received from commercial sales of KPI-121 1.0% and KPI-121 0.25%;

- our ability to establish and maintain strategic collaborations, licensing or other agreements and the financial terms of such agreements;
- the scope, progress, results and costs of any product candidates that we may derive from our rTKI program or any other product candidates that we may develop;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property-related claims.

On July 25, 2017, we completed an IPO of our common stock pursuant to which we issued 6,900,000 shares of our common stock at a price of $15.00 per share, which included 900,000 shares sold pursuant to the exercise of the underwriters' option to purchase additional shares. We received net proceeds of $94.9 million after deducting underwriting discounts and commissions of $7.2 million and offering costs incurred in 2017 of $1.4 million. We believe that the net proceeds from our IPO, together with our existing cash on hand as of June 30, 2017 and available borrowings under our 2014 Debt Facility, will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements through the second quarter of 2019. We have based these estimates on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. As a result, we could deplete our available capital resources sooner than we currently expect.

Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete. We may never generate the necessary data or results required to obtain regulatory approval of products with the market potential sufficient to enable us to achieve profitability. We do not expect to generate revenue from sales of any product candidates until at least 2019, if at all. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives. 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. Adequate additional financing may not be available to us on acceptable terms, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and marketing and distribution arrangements. Our only committed external source of funds is $10.0 million under our 2014 Debt Facility, which is available until October 13, 2017. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. If we draw down on the remaining $10.0 million of potentially available borrowings under our 2014 Debt Facility, the lenders thereunder will be entitled to exercise warrants for up to an additional 48,374 shares of our common stock. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our pledge of our assets as collateral to secure our obligations under our credit facility may limit our ability to obtain additional debt financing.

If we raise additional funds through collaborations, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or

terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

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

As of June 30, 2017, we had $10.0 million of outstanding borrowings under our 2014 Debt Facility, which we are required to begin repaying following the end of an interest-only period, in October 2017, in equal monthly installments until October 2020. We also are eligible to borrow an additional $10.0 million under the 2014 Debt Facility before October 13, 2017. Our obligations under this agreement are secured by substantially all of our assets other than our intellectual property. We could in the future incur additional indebtedness beyond our borrowings under the 2014 Debt Facility.

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

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

We intend to satisfy our current and future debt service obligations with our existing cash and funds from external sources. Nonetheless, we may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt. Funds from external sources may not be available on acceptable terms, if at all. In addition, a failure to comply with the covenants under our credit facility could result in an event of default and acceleration of amounts due. If an event of default occurs and the lender accelerates the amounts due under the 2014 Debt Facility, we may not be able to make accelerated payments, and the lender could seek to enforce security interests in the collateral securing such indebtedness.

Risks Related to Product Development

We are dependent on the success of our lead product candidates, KPI-121 1.0% and KPI-121 0.25%. If we are unable to successfully complete our Phase 3 clinical programs and obtain marketing approvals for either KPI-121 1.0% or KPI-121 0.25%, or experience significant delays in doing so, or if, after obtaining marketing approvals, we fail to commercialize these product candidates, our business will be materially harmed.

We have devoted a significant portion of our financial resources and business efforts to the development of KPI-121 1.0% for the post-operative treatment of inflammation and pain following ocular surgery and KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. There is a significant risk that we will fail to successfully develop KPI-121 1.0% and/or KPI-121 0.25%. We received topline results from our second Phase 3 clinical trial evaluating KPI-121 1.0% in 520 patients with inflammation and pain following cataract surgery in May 2017. Our Phase 3 clinical program for KPI-121 0.25% consists of two parallel Phase 3 clinical trials evaluating KPI-121 0.25%, each of which is expected to include approximately 900 dry eye patients. We expect to receive topline results from these parallel Phase 3 clinical trials by the end of 2017. The timing of the availability of such topline data and the completion of our Phase 3 clinical trials for KPI-121 0.25% is dependent, in part, on our ability to locate and enroll a sufficient

number of eligible patients in our Phase 3 clinical trials on a timely basis. We cannot accurately predict when or if either of these product candidates will be proven to be effective or safe in humans or whether either will receive marketing approval. Our ability to generate product revenues will depend on our obtaining marketing approval for, and commercializing one or both of, KPI-121 1.0% and KPI-121 0.25%.

The success of KPI-121 1.0% and KPI-121 0.25% and any other product candidates will depend on many factors, including the following:

- completing and obtaining favorable results from our two ongoing Phase 3 clinical trials of KPI-121 0.25%;
- applying for and receiving marketing approvals from applicable regulatory authorities for our product candidates;
- receiving regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities;
- expanding and maintaining a workforce of experienced scientists and others with experience in MPP technology to continue to develop our product candidates;
- establishing sales, marketing and distribution capabilities for KPI-121 1.0% and KPI-121 0.25% and successfully launching commercial sales of any other product candidates for which we obtain marketing approval, whether alone or in collaboration with others;
- acceptance of KPI-121 1.0% and KPI-121 0.25% and our other product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- maintaining an acceptable safety profile of our products following approval;
- obtaining and maintaining coverage, adequate pricing, and adequate reimbursement from third-party payors, including government payors, for our product candidates;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- protecting our rights in our intellectual property portfolio; and
- not infringing on others' intellectual property rights.

Successful development of KPI-121 1.0% or KPI-121 0.25% for additional indications, if any, or for use in broader patient populations and our ability, if it is approved, to broaden the label for KPI-121 1.0% or KPI-121 0.25% will depend on similar factors.

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 materially harm our business.

If clinical trials of KPI-121 1.0% and KPI-121 0.25% or any other product candidate that we develop fail to demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidate.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, including KPI-121 1.0% and KPI-121 0.25%, we must complete preclinical development and then conduct extensive 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 testing and early clinical trials may not be predictive of the success of later stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. 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 product candidates. Furthermore, the failure of any other product candidates to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of our other product candidates and/or cause the FDA or other regulatory authorities to require additional testing before approving any of our product candidates. For example, we previously conducted a Phase 2 clinical trial of KPI-121 0.25% for the treatment of meibomian gland dysfunction which did not achieve its primary endpoint. The failure of this trial may have an adverse impact on the perceived safety or efficacy of KPI-121 0.25% in treating dry eye disease or other indications or of KPI-121 1.0%. In addition, we have not conducted any Phase 2 clinical trial of KPI-121 1.0%. The lack of Phase 2 trial data may have an adverse impact on the perceived safety or efficacy of KPI-121 1.0% for the treatment of post-operative inflammation and pain following ocular surgery or other indications, and may adversely affect our ability to obtain marketing approval for KPI-121 1.0% from the FDA or outside the United States.

We reported topline results from our second Phase 3 clinical trial evaluating KPI-121 1.0% in patients with inflammation and pain following cataract surgery in May 2017, in which KPI-121 1.0% achieved statistical significance for both of its primary efficacy endpoints and all secondary endpoints. Further analyses of the data from the second Phase 3 clinical trial are ongoing. Clinical trial data are subject to differing interpretations, and the FDA, medical and scientific experts and others may not share our views of the Phase 3 data. Any such differing interpretations could adversely affect our ability to demonstrate the safety and efficacy of KPI-121 1.0% to the satisfaction of the FDA or other regulatory authorities.

We expect, based on our current development plan, that the FDA will require us to demonstrate effectiveness on both of our primary endpoints in our two Phase 3 clinical trials for market approval of an indication for the temporary relief of the signs and symptoms of dry eye disease. KPI-121 0.25% did not achieve statistical significance for the endpoint of ocular discomfort severity in our completed Phase 2 clinical trial. If KPI-121 0.25% does not achieve statistical significance in both primary endpoints in our Phase 3 clinical trials, the FDA may require us to conduct additional clinical trials to support approval of KPI-121 0.25% in this indication. Regulatory authorities outside the United States, in particular in the European Union, have not issued guidance on the requirements for approval of a dry eye drug. Our Phase 3 clinical trials of KPI-121 0.25% may not be sufficient to support an application for marketing approval outside the United States. Further, if regulatory authorities outside the United States do not accept the data from any trial we conduct in the United States, in particular if the European Union does not allow us to utilize the results from our ongoing Phase 3 clinical trials of KPI-121 0.25% pursuant to the Article 10(3) submission pathway or otherwise, we will likely need to conduct additional trials to obtain marketing approval in such jurisdiction, which would be costly and time-consuming and could delay or permanently halt our ability to commercialize the applicable product candidates in the applicable jurisdictions.

We performed post-hoc analyses on the results of our completed Phase 2 clinical trial for KPI-121 0.25% for purpose of designing our Phase 3 clinical trials for KPI-121 0.25%. We may also conduct post-hoc analyses on the results of clinical trials in the future. Post-hoc analyses performed after unmasking trial results can result in the introduction of bias and may not be predictive of success in our Phase 3 clinical trials.

If we are required to conduct additional clinical trials or other testing of KPI-121 0.25% or KPI-121 1.0% or any other product candidate that we develop beyond those that we currently expect, 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 with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

If we experience any of a number of possible unforeseen events in connection with our clinical trials, potential marketing approval or commercialization of our product candidates could be delayed or prevented.

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 KPI-121 1.0%, KPI-121 0.25% or any other product candidates that we may develop, including:

- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients 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 meet their obligations to us in a timely manner, or at all;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- we may decide, or regulators or institutional review boards may require us, to 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;
- regulators or institutional review boards may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post-marketing testing requirements to maintain regulatory approval;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- the cost of clinical trials of our product candidates may be greater than we anticipate;

- 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 or may be delayed;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate trials; and
- regulatory authorities may withdraw their approval of a product or impose restrictions on its distribution, such as in the form of a modified Risk Evaluation and Mitigation Strategy, or REMS.

Our product development costs will also increase if we experience delays in testing or 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 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.

If we experience delays or difficulties in the enrollment of patients 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 KPI-121 0.25% or any other product candidate we develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States.

Patient enrollment is affected by a variety of factors, including:

- the prevalence and severity of the ophthalmic disease or condition under investigation;
- the patient eligibility criteria for the trial in question;
- the perceived risks and benefits of the product candidate under study;
- the existence of existing treatments for the indications for which we are conducting clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of clinicians;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients;
- the conducting of clinical trials by competitors for product candidates that treat the same indications as our product candidates; and
- the lack of adequate compensation for prospective patients.

Our inability to locate and enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary regulatory approvals. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If the FDA does not conclude that KPI-121 1.0% and KPI-121 0.25% satisfy the requirements under Section 505(b)(2) of the Federal Food Drug and Cosmetics Act, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates may take longer, cost more and entail greater complications and risks than anticipated, and may not be successful.

We intend to seek FDA approval of KPI-121 1.0% and KPI-121 0.25% through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant, and for which the applicant has not received a right of reference, which could expedite the development program for KPI-121 1.0% and KPI-121 0.25% by potentially decreasing the amount of preclinical and clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for KPI-121 1.0% and KPI-121 0.25%, and complications and risks associated with approval of KPI-121 1.0% and KPI-121 0.25%, would likely substantially increase. Even if we are allowed to pursue the Section 505(b)(2) pathway to FDA approval, we cannot assure you that KPI-121 1.0% and KPI-121 0.25% will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain competitors and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and to mandatory delays in approval of our NDAs for up to 30 months, depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. Thus, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to faster product development or earlier approval of KPI-121 1.0% or KPI-121 0.25%.

Even if KPI-121 1.0% and KPI-121 0.25% are approved under Section 505(b)(2), their approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

If serious adverse or unacceptable side effects are identified during the development of KPI-121 1.0%, KPI-121 0.25% or any other product candidates that we may develop, we may need to abandon or limit our development of such product candidates.

If KPI-121 1.0%, KPI-121 0.25% or any other product candidates are associated with serious adverse events or undesirable 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 serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The most common adverse effects to date in trials evaluating the safety and efficacy of KPI-121 1.0% and KPI-121 0.25% have been eye pain, instillation site pain and photophobia, which is discomfort or pain due to exposure to light. There have been no serious adverse events related to the administration of KPI-121 reported in any of our clinical trials to date. Increases in intraocular pressure, or IOP, and cataract formation are additional adverse effects associated with the use of corticosteroids and in our Phase 2 trial of KPI-121 0.25%, one patient out of the 72 patients in the KPI-121 0.25% treatment arm had elevated IOP classified as an adverse event as of day 29. We have no clinical safety data on or patient exposure to either KPI-121 concentration for longer than 28 days. Our understanding of the relationship between our products and these adverse effects may change as we gather more information, and additional

unexpected adverse effects may occur. Many compounds that initially showed promise in clinical or earlier stage testing for treating ophthalmic disease have later been found to cause side effects that prevented further development of the compound. In addition, adverse events which had initially been considered unrelated to the study treatment may later be found to be caused by the study treatment. Moreover, incorrect or improper use of our product candidates (including use of KPI-121 0.25% more frequently than is prescribed) by patients could cause increases in IOP, and may result in additional unexpected side effects or adverse events. There can be no assurance that our product candidates will be used correctly, and if used incorrectly, such misuse could hamper commercial adoption of our product candidate, if approved, at the rate we currently expect.

We may not be successful in our efforts to develop product candidates based on our MPP technology or expand the use of our MPP technology for treating additional diseases and conditions.

We are currently directing all of our development efforts towards applying our MPP technology to develop product candidates that are designed to diffuse through the mucus layer and enable the active drug substance to reach cells in the underlying target tissue. We have product candidates at various stages of development for treatment of eye diseases and are exploring the potential use of our MPP technology in other diseases, including diseases of the lungs, cervical/vaginal tract and gastrointestinal tract. Our existing product candidates and any other potential product candidates that we identify may not be suitable for continued preclinical or clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize our product candidates that we develop based upon our MPP technology approach, we will not be able to obtain substantial product revenues in future periods.

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 managerial 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 products 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.

We may in the future conduct clinical trials for product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

We may in the future choose to conduct one or more of our clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and be performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with all applicable U.S. laws and regulations. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt our development of the applicable product candidates.

Risks Related to the Commercialization of Our Product Candidates

Even if KPI-121 1.0%, KPI-121 0.25% or any other product candidates receives marketing approval, they may fail to achieve market acceptance by clinicians and patients, or adequate formulary coverage, pricing or reimbursement by third-party payors and others in the medical community, and the market opportunity for these products may be smaller than we estimate.

If KPI-121 1.0%, KPI-121 0.25% or any other product candidate that we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by clinicians, patients, third-party payors and others in the medical community. Common treatments in the United States for inflammation and pain following ocular surgery include corticosteroids. While the most commonly used corticosteroids are approved for four-times-a-day dosing, and we plan to seek approval of KPI 1.0% with twice-a-day dosing, doctors may continue to rely on ocular steroids other than KPI-121 1.0% and other treatments rather than KPI-121 1.0%, if and when it is approved for marketing by the FDA. It is also possible that other therapeutics will be approved for treatment of inflammation and pain following ocular surgery with twice-a-day or less frequent dosing.

While there are no drugs currently approved in the United States for the temporary relief of the signs and symptoms of dry eye disease, current treatments that are used in the United States for dry eye disease include over-the-counter artificial tears, Restasis®, Xiidra® and off-label use of corticosteroids. It is possible that doctors may continue to rely on these treatments rather than KPI-121 0.25%, if and when it is approved for marketing by the FDA. In addition, if generic versions of any products that compete with any of our product candidates are approved for marketing by the FDA, they would likely be offered at a substantially lower price than we expect to offer for our product candidates, if approved. As a result, clinicians, patients and third-party payors may choose to rely on such products rather than our product candidates.

If KPI-121 1.0% or KPI-121 0.25% does not achieve an adequate level of acceptance, formulary coverage, pricing or reimbursement we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of KPI-121 1.0%, KPI-121 0.25% or any other product candidate that we develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages of our product candidates compared to alternative treatments, including the existing standard of care;
- our ability to offer our products for sale at competitive prices, particularly in light of the lower cost of alternative treatments;
- the clinical indications for which the product is approved;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of clinicians to prescribe these therapies;
- the strength of our marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of third-party formulary coverage and adequate reimbursement, particularly by Medicare in light of the prevalence of dry eye disease and cataracts in persons over age 55;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

Our assessment of the potential market opportunity for KPI-121 1.0%, KPI-121 0.25% and other product candidates is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties, some of which we commissioned. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. The potential market opportunity for the treatment of dry eye disease in particular is difficult to precisely estimate. In particular, we commissioned ClearView Healthcare Partners, a life science strategy consulting firm, to conduct a survey of 30 dry eye disease patients, which we refer to as the patient survey. As the patient survey involved a limited number of patients, the results from such survey may be less reflective of the dry eye disease population as a whole than a survey conducted with a larger sample size. Our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research and other surveys, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for KPI-121 1.0%, KPI-121 0.25% or any other product candidates may be smaller than we expect, and as a result our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

If we are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing KPI-121 1.0%, KPI-121 0.25% or any other product candidates that we may develop if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of therapeutic products. To achieve commercial success for any product for which we obtained marketing approval, we will need to establish sales, marketing and distribution capabilities, either ourselves or through collaborations or other arrangements with third parties.

Subject to successful results of our ongoing Phase 3 clinical trials and FDA approval of any of our product candidates, we plan to build a focused specialty sales and marketing infrastructure to market or co-promote KPI-121 1.0%, KPI-121 0.25% and possibly other product candidates that we develop in the United States, if and when they are approved, as well as distribution capabilities. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. Further, we may underestimate the size of the sales force required for a successful product launch and may need to expand our sales force earlier and at a higher cost than we anticipated. If the commercial launch of KPI-121 1.0%, KPI-121 0.25% or any other 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 KPI-121 1.0%, KPI-121 0.25% or any other product candidates on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to clinicians or persuade adequate numbers of clinicians to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales, marketing and distribution organization.

While we cannot be certain when, if ever, we will seek and/or receive marketing approval to commercialize any of our product candidates outside the United States, assuming positive results from our U.S. Phase 3 clinical trials of KPI-121 0.25% for the treatment of dry eye disease, we plan to seek marketing approval and explore commercialization of KPI-121 0.25% in certain markets outside the United States, including the EU, utilizing a variety of collaboration, distribution and other marketing arrangements with one or more third parties. Our product revenues and our profitability, if any, under any such third-party collaboration, distribution or other marketing arrangements are likely to be lower than if we were to market, sell and distribute KPI-121 0.25% ourselves. We may also consider seeking marketing approval outside the United States for other product candidates in future. If we decide to seek regulatory approval for any of our product candidates outside the United States, we may need to seek additional patent approvals, seek licenses to patents held by third parties and/or face claims of infringing third-party patent rights. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute KPI-121 1.0%, KPI-121 0.25% or any other product candidates or may be unable to do so on terms that are favorable to us. 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 KPI-121 1.0%, KPI-121 0.25% or other product candidates effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing KPI-121 1.0%, KPI-121 0.25% or any other product candidates that we may develop.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. Our product candidates will, if approved, also compete with existing branded, generic and off-label products.

The development and commercialization of new drug products is highly competitive. We face competition with respect to KPI-121 1.0%, KPI-121 0.25% and any other product candidates, and will face competition with respect to any other product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our product candidates will target markets that are already served by a variety of competing products. Many of these existing products have achieved widespread acceptance among clinicians, patients and payors. In addition, many of these products are available on a generic basis, and our product candidates may not demonstrate sufficient additional clinical benefits to clinicians, patients or payors to justify a higher price compared to generic products. In many cases, insurers or other third-party payors, particularly Medicare, seek to encourage the use of generic products. Given that we are developing products that utilize an FDA-approved corticosteroid, our product candidates, if approved, will face competition from generic and branded versions of existing drugs based on corticosteroids that are administered in a different manner.

Following ocular surgery, topical steroids are commonly used to manage and prevent complications from post-operative inflammation. The current market leaders for topical steroids in the United States, based on revenue, are Lotemax® products and Durezol®. There are also a number of companies in the United States developing products and therapies in preclinical research and clinical development for the treatment of inflammation and pain following ocular surgery, including the following: Valeant Pharmaceuticals International, Inc. is developing an LE gel, which is formulated for topical delivery and is currently in Phase 3 clinical development; Ocular Therapeutix, Inc. is developing Dextenza™, a punctal plug that is currently in Phase 3 clinical development and has filed an NDA for the treatment of ocular pain following ophthalmic surgery; and Icon Bioscience, Inc. has filed an NDA for IBI-10090, which is formulated as a drug delivery system, or DDS, to be injected into the eye following cataract surgery for the treatment of inflammation.

Current disease management approaches for dry eye disease in the United States include the following: over-the-counter artificial tear eye drops, which are used on an intermittent or chronic basis to provide short term symptomatic relief of dryness and irritation; off-label prescription drugs, including topical steroid drops and/or other similar products, which are prescribed on occasion for treatment of dry eye disease; on-label prescription drugs, including Restasis and Xiidra, which are the only prescription pharmaceutical products that are approved in the United

States for use in patients with dry eye disease. Restasis is approved for increasing tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation and Xiidra is approved for treatment of the signs and symptoms of dry eye disease. Both are typically used chronically as part of the dry eye management regimen, which also includes artificial tears and other palliative therapies, such as hot compresses for the eye and lid hygiene management; and devices, such as punctal plugs that are inserted into the tear ducts to inhibit tear drainage, resulting in more moisture on the surface of the eye.

We are developing KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease, which may include the management of dry eye disease flares. Any product that is developed for the temporary treatment of the signs and symptoms of dry eye disease could directly compete with KPI-121 0.25%. There are several product candidates in preclinical and clinical development in the United States for the treatment of dry eye disease. If any of these product candidates is approved and such product candidate either treats the signs and symptoms of dry eye disease or reduces the frequency of flares in dry eye patients, it could reduce the overall market opportunity for KPI-121 0.25%. These product candidates are being developed by pharmaceutical companies, biotechnology companies, and specialty pharmaceutical and generic drug companies of various sizes, such as Mimetogen Pharmaceuticals, Inc., or Mimetogen (MIM-D3), Sun Pharmaceuticals (Seciera™), ReGenTree (TGN-259) and Allergan plc, or Allergan (AGN-195263). There are also other product candidates for the treatment of dry eye disease in the United States in earlier stage development. Further, Oculeve, which was acquired by Allergan, is developing True Tear, a nasal neurostimulation medical device that is intended to increase tear production.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than our products. Our competitors also may obtain FDA or other regulatory approval for their products 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.

In addition, our ability to compete may be affected in many cases by insurers or other third-party payors, particularly Medicare, seeking to encourage the use of generic products. Generic products are currently being used for certain of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. 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. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If our contracted manufacturing facilities experience production issues for any reason, we may be unable to manufacture commercial quantities of our product candidates for a substantial amount of time, which could have a material adverse effect on our business.

We will rely on third-party contract manufacturers to manufacture commercial supplies of KPI-121 1.0% and KPI-121 0.25%. Specifically, we will rely on Catalent Pharma Solutions, LLC, or Catalent, to manufacture and supply to us a minimum amount of KPI-121 1.0% and KPI-121 0.25% for commercial use; Alliance Contract Pharma, LLC, or Alliance, for manufacturing bulk KPI-121 concentrates, and Chemo Iberica SA, or Chemo Iberica, to manufacture and supply to us a bulk supply of loteprednol, or LE. We expect to rely on third parties to manufacture clinical supplies of other product candidates and commercial supplies of all of our products, if and when approved for marketing by applicable regulatory authorities, as well as for packaging, serialization, storage, distribution and other production logistics. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or manufacture our product candidates in accordance with regulatory requirements, if there are disagreements between us

and such parties, or if such parties are unable to expand capacities to support commercialization of any of our product candidates for which we obtain marketing approval, we may not be able to complete, or may be delayed in producing sufficient product candidates to meet our supply requirements. These facilities may also be affected by natural disasters, such as floods or fire, or such facilities could face manufacturing issues, such as contamination or regulatory concerns following a regulatory inspection of such facility. In such instances, we may need to locate an appropriate replacement third-party relationship, which may not be readily available or on acceptable terms, which would cause additional delay and increased expense, including as a result of additional required FDA approvals, and may have a material adverse effect on our business.

Our third-party manufacturers are subject to inspection and approval by the FDA before we can commence the manufacture and sale of any of our product candidates, and thereafter subject to FDA inspection from time to time. Failure by our third-party manufacturers to pass such inspections and otherwise satisfactorily complete the FDA approval regimen with respect to our product candidates may result in regulatory actions such as the issuance of FDA Form 483 notices of observations, warning letters or injunctions or the loss of operating licenses. For example, one of our third-party testing laboratories recently received a FDA Form 483 containing two inspectional observations, relating to deficiencies in fully following responsibilities and procedures applicable to quality control units and in maintaining separate areas in the storage of drug products to prevent contamination or mix-ups. While the testing laboratory determined that the observations are non-critical and do not pose any risk or have any impact on its analytical programs, depending on the severity of any potential regulatory action, our clinical or commercial supply could be interrupted or limited, which could have a material adverse effect on our business.

We or our third-party manufacturers may also encounter shortages in the raw materials or active pharmaceutical ingredient necessary to produce our product candidates in the quantities needed for our clinical trials or, if our product candidates are approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials or active pharmaceutical ingredient, including shortages caused by the purchase of such raw materials or active pharmaceutical ingredient by our competitors or others. The failure of us or our third-party manufacturers to obtain the raw materials or active pharmaceutical ingredient necessary to manufacture sufficient quantities of our product candidates, may have a material adverse effect on our business.

Even if we are able to commercialize KPI-121 1.0%, KPI-121 0.25% or any other product candidate that we may develop, the products may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.

Our ability to commercialize KPI-121 1.0%, KPI-121 0.25% or any other product candidates that we may develop successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers, managed care plans and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for KPI-121 1.0%, KPI-121 0.25% or any other product that we commercialize and, even if they are available, the level of reimbursement may not be satisfactory.

Inadequate reimbursement 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 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. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize KPI-121 1.0%, KPI-121 0.25% or any other product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug 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 drugs, 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 drug 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 drugs 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. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop would compromise our ability to generate revenues and become profitable.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products 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 drug 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 our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. To obtain 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. 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, even 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 or cost-effective by third-party payors, or that coverage and 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.

Product liability lawsuits against us could divert our resources and could cause us to incur substantial liabilities and to limit commercialization of any products that we develop.

We face an inherent risk of product liability exposure related to the use of our product candidates that we develop in human clinical trials. We face an even greater risk if we commercially sell any products that we develop. 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 develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;

- reduced time and attention of our management to pursue our business strategy; and
- the inability to commercialize any products that we develop.

We currently hold $10 million in product liability insurance coverage in the aggregate, with a per incident limit of $10 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. We will need to further increase our insurance coverage if we commence commercialization of any of KPI-121 1.0%, KPI-121 0.25% or any product candidates for which we obtain marketing approval. 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.

Risks Related to Our Dependence on Third Parties

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

We relied on third-party clinical research organizations, or CROs, in conducting our completed Phase 3 clinical trials of KPI-121 1.0% for the treatment of inflammation and pain following cataract surgery, our completed Phase 2 clinical trial of KPI-121 0.25% in patients with dry eye disease, and our ongoing Phase 3 clinical trials of KPI-121 0.25%. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct clinical trials of any other product candidate that we develop. We or these third parties may terminate their engagements with us at any time for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that would delay our product development activities.

Our reliance on these third parties for clinical 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 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. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors.

We also rely on other third parties to store and distribute drug 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.

We contract with third parties for the manufacture of KPI-121 1.0% and KPI-121 0.25% for commercialization and for clinical trials and commercialization of any of our other existing and any future product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of KPI-121 1.0% and KPI-121 0.25% or any other product candidates. We will rely on Catalent to manufacture and supply to us a minimum amount of KPI-121 1.0% and KPI-121 0.25% for commercial use; Alliance for manufacturing bulk KPI-121 concentrates, and Chemo Iberica to manufacture and supply to us a bulk supply of LE. We expect to rely on

such third-party manufacturers to manufacture commercial supplies of all of our products and clinical supplies of any other product candidates if and when approved for marketing by applicable regulatory authorities. Our current and anticipated future dependence upon others for the manufacture of KPI-121 1.0% and KPI-121 0.25% and any other product candidate or product that we develop may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. In addition, any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval.

To date, we have obtained materials for KPI-121 for our clinical trials from third-party manufacturers, including Catalent and Alliance. We have supply agreements in place with these contract manufacturers to provide commercial supply. We obtain the active pharmaceutical ingredient for KPI-121 from Chemo Iberica, a third-party API manufacturer. While we have long-term commercial supply agreements with these third-party manufacturers, if these suppliers do not perform as we expect, we may be required to replace one or more suppliers. Although we believe that there are a number of potential long-term replacements to our suppliers, we may incur added costs and delays in identifying and qualifying any such replacements.

The FDA maintains strict requirements governing the manufacturing process. When a manufacturer seeks to modify or make even seemingly minor changes to that process, the FDA may require the applicant to conduct a comparability study that evaluates the potential differences in the product resulting from the change in the manufacturing process. The FDA has issued several guidances on this point. In connection with our application for approval to market KPI-121 1.0%, KPI-121 0.25% or other product candidates in the United States, we may be required to conduct a comparability study if the product we intend to market is supplied by a manufacturer different from the one who supplied the product evaluated in our clinical studies. Delays in designing and completing this study to the satisfaction of the FDA could delay or preclude our development and commercialization plans and thereby limit our revenues and growth.

Reliance on third-party manufacturers entails additional risks, including:

- KPI-121 1.0%, KPI-121 0.25% and any other product that we develop may compete with other product candidates and products for access to a limited number of suitable manufacturing facilities that operate under current good manufacturing practices, or cGMP, regulations;
- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with 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 clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and harm our business and results of operations.

Any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. We were previously required to change our third-party manufacturer when the manufacturer was purchased by a third party and exited the contract manufacturing business. The process of changing

manufacturers can cause substantial time delays, and if we are required to change our manufacturer again in the future, it may delay our planned clinical trials or development timeline.

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 for bulk drug substances. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any medicines that receive marketing approval on a timely and competitive basis.

We may enter into collaborations with third parties for the development or commercialization of our product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with third parties to develop and commercialize KPI-121 1.0%, KPI-121 0.25% or any other product candidates for which we obtain marketing approval in markets outside the United States. We also may enter into arrangements with third parties to perform these services in the United States if we do not establish our own sales, marketing and distribution capabilities in the United States for our product candidates or if we determine that such third-party arrangements are otherwise beneficial. We also may seek third-party collaborators for development and commercialization of other product candidates. For example, we may utilize a variety of collaboration, distribution and other marketing arrangements with one or more third parties to facilitate commercialization of KPI-121 0.25% outside the U.S. We may also consider potential collaborative partnership opportunities prior to initiating IND-enabling studies on KPI-285 or any other product candidates we develop through our rTKI program. Our likely collaborators for any sales, marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We are not currently party to any such arrangement. However, if we do enter into any such arrangements with any third parties in the future, 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 revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Collaborations that we enter into may pose a number of risks, including the following:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development of our product candidates or may elect not to continue or renew development programs based on results of clinical trials or other studies, 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 not pursue commercialization of our product candidates that receive marketing approval or may elect not to continue or renew commercialization programs based on 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 products or 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 product or 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 divert management attention and resources, be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our 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 any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described herein also apply to the activities of our collaborators.

Additionally, subject to its contractual obligations to us, if a collaborator of ours were to be involved in a business combination, it might de-emphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be harmed.

If we are not able to establish collaborations, we may have to alter our development and commercialization plans and our business could be adversely affected.

For some of our product candidates, we may decide to collaborate with pharmaceutical or 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. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. 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.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its 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 fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform.

Risks Related to Our Intellectual Property

We may be unable to obtain and maintain patent protection for our technology and product candidates, or the scope of the patent protection obtained may not be sufficiently broad or enforceable, such that our competitors could develop and commercialize technology and products 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 patent protection in the United States and other countries with respect to our proprietary technology and product candidates. We have sought to protect our proprietary position by filing in the United States and in certain foreign jurisdictions patent applications related to our novel technologies and product candidates.

The patent prosecution process is expensive and time-consuming, and we may not have filed, maintained or prosecuted and may not be able to file, maintain and prosecute all necessary or desirable patents or patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of pharmaceutical, biotechnology and medical device companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. 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 fail to result in issued patents in the United States or in other foreign countries which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and products. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and the standards applied by the U.S. Patent and Trademark Office and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, unlike patent law in the United States, European patent law precludes the patentability of methods of treatment of the human body and imposes substantial restrictions on the scope of claims it will grant if broader than specifically disclosed embodiments. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. Databases for patents and publications, and methods for searching them, are inherently limited so we may not know the full scope of all issued and pending patent applications. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are uncertain. Our pending and future patent

applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. In particular, during prosecution of any patent application, the issuance of any patents based on the application may depend upon our ability to generate additional preclinical or clinical data that support the patentability of our proposed claims. We may not be able to generate sufficient additional data on a timely basis, or at all. Moreover, 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.

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 for our proprietary technology and product candidates, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. In particular, a competitor may develop an approach to deliver drugs through the mucus layer to the underlying target tissue that uses a different approach than our MPP technology, and therefore may not infringe on our patent rights.

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 or patent offices 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 products, or limit the duration of the patent protection of our technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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, 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 United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. The first to file provisions limit the rights of an inventor to patent an invention if not the first to file an application for patenting that invention, even if such invention was the first invention. 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, which could have a material adverse effect on our business, financial condition, results of operations and prospects. For example, the Leahy-Smith Act provides a new administrative tribunal known as the Patent Trial and Appeals Board, or PTAB, that provides a venue for companies to challenge the validity of competitor patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long term impact the PTAB proceedings will have on the operation of our business, the initial results of patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U.S. patent claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could therefore increase the likelihood that our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining, defending and enforcing them.

If we are not able to obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one of the U.S. patents covering each of such product candidates or the use thereof may be eligible for up to five years of patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates. Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product may be shortened and our competitors may obtain approval of competing products following our patent expiration sooner, and our revenue could be reduced, possibly materially.

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering one of our product candidates even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for our licensed patents, we do not have the right to control prosecution, including filing with the U.S. Patent and Trademark Office, a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch-Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the U.S. Patent and Trademark Office.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any Abbreviated New Drug Application filed with the FDA to obtain permission to sell a generic version of such product candidate.

We also intend to seek pediatric exclusivity for certain of our product candidates, including KPI-121 1.0%. Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. We cannot provide any assurance that pediatric exclusivity will be obtained for any of our product candidates.

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 and other third parties may infringe, misappropriate or otherwise violate our owned and licensed patents, trade secrets, or other intellectual property. As a result, to counter infringement, misappropriation or unauthorized use, we may be required to file infringement or misappropriation claims or other intellectual property related proceedings, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our asserted

patents are invalid. In addition, in a patent infringement or other intellectual property related 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 in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly, and could put any of our patent applications at risk of not yielding an issued patent. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information or trade secrets could be compromised by disclosure during this type of litigation.

We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in other contested proceedings such as opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings in the United States or elsewhere, 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 product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products 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 license, develop or commercialize current or future product candidates.

In the United States, the FDA does not prohibit clinicians from prescribing an approved product for uses that are not described in the product's labeling. Although use of a product directed by off-label prescriptions may infringe our method-of-treatment patents, the practice is common across medical specialties, particularly in the United States, and such infringement is difficult to detect, prevent or prosecute.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell KPI-121 1.0%, KPI-121 0.25% and other product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. There is a considerable amount of intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, infringement litigation claims regarding our products and technology, including claims from competitors or from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. Moreover, we may become party to future adversarial proceedings or litigation regarding our patent portfolio or the patents of third parties. Such proceedings could also include contested post-grant proceedings such as oppositions, *inter partes* review, reexamination, interference or derivation proceedings before the U.S. Patent and Trademark Office or foreign patent offices. For example, we are aware of a third-party European patent that contains claims related to use of LE for the treatment of moderate to severe dry eye disease and the use of LE for reducing conjunctival redness associated with dry eye disease. This European patent will expire in early 2025, and is in force in Germany, the United Kingdom, Spain, Italy, and France. There is no United States counterpart patent or pending U.S. patent application. While we have obtained an opinion of European counsel that this patent is invalid, until this patent expires or a court of competent jurisdiction finally determines the patent is invalid in each country, the patent holder may be able to block our ability to develop and commercialize KPI-121 0.25% for the treatment of dry eye disease in Europe unless we obtain a license under this patent in each country where it is in force. Such a license may not be available on commercially reasonable terms or at all. If we are unable to invalidate the patent in each country or obtain a license on commercially reasonable terms, our ability to commercialize KPI-121 0.25% for the treatment of dry eye disease in Europe may be impaired, delayed or halted altogether.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase as our product candidates near commercialization and as we gain the

greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. We may not be aware of all such intellectual property rights potentially relating to our product candidates and their uses. Thus, we do not know with certainty that KPI-121 1.0%, KPI-121 0.25% or any other product candidates, or our development and commercialization thereof, do not and will not infringe or otherwise violate any third party's intellectual property.

If we are found to infringe, misappropriate or otherwise violate 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 products and technology. 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 and could require us to make substantial licensing and royalty payments. 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 and could be forced to indemnify our customers or collaborators. A finding of infringement could also result in an injunction that prevents us from commercializing our product candidates or forces us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign our product candidates, seek new regulatory approvals and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance, renewal and annuity fees on any issued patent must be paid to the U.S. Patent and Trademark Office and foreign patent agencies in several stages or annually over the lifetime of our owned and licensed patents and patent applications. The U.S. Patent and Trademark Office and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, it would have a material adverse effect on our business.

KPI-121 1.0%, KPI-121 0.25% and certain aspects of our MPP technology are protected by patents exclusively licensed from other companies or institutions. If these third parties terminate their agreements with us or fail to maintain or enforce the underlying patents, or we otherwise lose our rights to these patents, our competitive position and our market share in the markets for any of our approved products will be harmed.

A substantial portion of our patent portfolio is in-licensed. As such, we are a party to license agreements and certain aspects of our business depend on patents and/or patent applications owned by other companies or institutions. In particular, we hold exclusive licenses for patent families relating to KPI-121 1.0% and KPI-121 0.25%, other product candidates and some aspects of our MPP technology. While we control patent prosecution of the licensed patent families relating to KPI-121 1.0% and KPI-121 0.25%, for the remainder of the patent families subject to our exclusive license agreement with JHU that relate to our MPP technology, JHU retains control of patent prosecution. Our rights with respect to in-licensed patents and patent applications may be lost if the applicable license agreement expires or is terminated. We are likely to enter into additional license agreements to in-license patents and patent applications as part of the development of our business in the future, under which we may not retain control of the preparation, filing, prosecution, maintenance, enforcement and defense of such patents. If we are unable to maintain these patent rights for any reason, our ability to develop and commercialize our product candidates could be materially harmed.

Our licensors may not successfully prosecute certain patent applications, the prosecution of which they control, under which we are licensed and on which our business depends. Even if patents issue from these applications, our licensors may fail to maintain these patents, may decide not to pursue litigation against third-party infringers, may fail to prove infringement, or may fail to defend against counterclaims of patent invalidity or unenforceability.

Risks with respect to parties from whom we have obtained intellectual property rights may also arise out of circumstances beyond our control. In spite of our best efforts, our licensors might conclude that we have materially breached our intellectual property agreements and might therefore terminate the intellectual property agreements, thereby removing our ability to market products covered by these intellectual property agreements. If our intellectual property agreements are terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products similar or identical to ours. Moreover, if our intellectual property agreements are terminated, our former licensors and/or assignors may be able to prevent us from utilizing the technology covered by the licensed or assigned patents and patent applications. This could have a material adverse effect on our competitive business position and our business prospects

Some intellectual property which we own or have licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements, and a preference for United States industry. Compliance with such regulations may limit our exclusive rights, subject us to expenditure of resources with respect to reporting requirements, and limit our ability to contract with non-U.S. manufacturers.

Some of the intellectual property rights we own or have licensed have been generated through the use of United States government funding and may therefore be subject to certain federal regulations. For example, certain aspects of our MPP technology as well as certain aspects of our patents that use LE as an active ingredient were developed using United States government funds. As a result, the United States government may have certain rights to intellectual property embodied in our current or future products and product candidates based on our MPP technology or that use LE as an active ingredient pursuant to the Bayh-Dole Act of 1980. These United States government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the United States government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The United States government also has the right to take title to these inventions if we fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. In addition, the United States government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the United States government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for United States manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. Any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations and prospects.

If we 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.

Our license agreement with JHU, under which we license certain of our patent rights and a significant portion of the technology for KPI-121 1.0%, KPI-121 0.25% and other product candidates, imposes royalty and other financial obligations on us and other substantial performance obligations. We also may enter into additional licensing and funding arrangements with third parties that may impose diligence, development and commercialization timelines and milestone

payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under current or future license and collaboration agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could diminish the value of our product. 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.

In addition, it is possible that JHU may conclude that we have materially breached the JHU licensing agreement and might therefore terminate the agreement, thereby removing our ability to market products covered by our license agreement with JHU. If the JHU licensing agreement is terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products similar or identical to ours. Moreover, if our license agreement with JHU is terminated, JHU and/or its assignors may be able to prevent us from utilizing the technology covered by the licensed or assigned patents and patent applications. If we breach the agreement (including by failing to meet our payment obligations) and do not adequately cure such breach, the rights in the technology licensed to us under the JHU license agreement will revert to JHU at no cost to JHU. This could have a material adverse effect on our competitive business position and our business prospects.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

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

Many of our and our licensors' employees and contractors were previously employed at other biotechnology, medical device or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these 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. Furthermore, we are unable to control whether our licensors have obtained similar assignment agreements from their own employees and contractors. Our and their assignment agreements may not be self-executing or may be breached, and we or our licensors 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 or our licensors fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel which could have a material adverse effect on our competitive business position and prospects. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products, which may not be available on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property litigation or other legal proceedings relating to intellectual property 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 and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on 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 and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

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

In addition to seeking patents for our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these 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, and we may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and 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. 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 it, 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.

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

If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate significant revenue will be materially impaired. The marketing approval process is expensive, time-consuming and uncertain. As a result, we cannot predict when or if we, or any collaborators we may have in the future, will obtain marketing approval to commercialize our product candidates.

Our product candidates, including KPI-121 1.0% and KPI-121 0.25%, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries.

Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market KPI-121 1.0%, KPI-121 0.25% or any other product candidate from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party consultants and vendors to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA or other regulatory authorities may determine that KPI-121 1.0%, KPI-121 0.25% or any other product candidate that we develop is not effective, is only moderately effective or has undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of KPI-121 1.0%, KPI-121 0.25% or any other product candidate that we develop, the commercial prospects for such product candidate may be harmed and our ability to generate revenues will be materially impaired.

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

In order to market and sell KPI-121 1.0%, KPI-121 0.25% or other product candidates in the European Union and many other jurisdictions, we or our potential third-party collaborators, must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. Regulatory authorities outside the United States, in particular in the European Union, have not issued guidance on the requirements for approval of a dry eye drug. Our Phase 3 clinical trials of KPI-121 0.25% may not be sufficient to support an application for marketing approval outside the United States.

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 sold in that country. We or our potential collaborators 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, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. On March 29, 2017, the United Kingdom formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the withdrawal could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

The terms of approvals, ongoing regulations and post-marketing restrictions for our products may limit how we manufacture and market our products, which could materially impair our ability to generate revenue.

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any potential collaborators we may have in the future, must therefore comply with requirements concerning advertising and promotion for any of our products for which we or our collaborators obtain marketing approval. Promotional communications with respect to drug products and medical devices are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, if any of our product candidates receives marketing approval, the accompanying label may limit the approved use of our product, which could limit sales of the product.

The FDA may also impose requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product, including the adoption and implementation of risk evaluation and mitigation strategies. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling and regulatory requirements. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not restrict the marketing of our products only to 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 investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

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

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions and warnings in the labeling and marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

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

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs applicable to drug manufacturers or quality assurance standards applicable to medical device manufacturers, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, any contract manufacturers we may engage in the future, our future collaborators and their contract manufacturers will also be subject to other regulatory requirements, including submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to clinicians, recordkeeping, and costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product such as the requirement to implement a risk evaluation and mitigation strategy.

We may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products.

Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion or manufacturing of drug products or medical devices may lead to investigations by the FDA, Department of Justice and state Attorneys General alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. In

addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties.

Our relationships with customers and third-party payors may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, clinicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription and use of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing 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, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty 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 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 a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements 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 imposes obligations, including mandatory contractual terms, on covered healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers, state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to clinicians and other healthcare providers or marketing expenditures, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our 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 and regulations. 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 funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the clinicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government funded healthcare programs.

Recently enacted and future legislation may affect our ability to commercialize and the prices we obtain for any products that are approved in the United States or foreign jurisdictions.

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 affect our ability to profitably sell or commercialize KPI-121 1.0%, KPI-121 0.25% or any other product candidate for which we obtain marketing approval. The pharmaceutical industry has been a particular focus of these efforts and have been significantly affected by legislative initiatives. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any FDA approved product.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for clinician administered drugs. In addition, this legislation provided authority for limiting the

number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA. Among the provisions of the ACA of importance to our business, including, without limitation, our ability to commercialize and the prices we may obtain for any of our product candidates and that are approved for sale, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new Medicare Part D coverage gap discount program, in which participating manufacturers must agree to offer 50% point-of-sale discounts off negotiated drug prices during the coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, and the addition of new government investigative powers, and enhanced penalties for noncompliance;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs; and
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program.

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. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

With the new Administration and Congress, there may be additional legislative changes, including potentially repeal and replacement of certain provisions of the ACA. It remains to be seen, however, whether new legislation will be enacted and, if so, precisely what any new legislation could provide and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare. For example, it is possible that any repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. The timing and scope of any potential future legislation to repeal and replace ACA provisions is highly uncertain in many respects.

Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which any products we may develop are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

The costs of prescription pharmaceuticals in the United States has also been the subject of considerable discussion in the United States, and members of Congress and the Administration have stated that they will address such costs through new legislative and administrative measures. The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

If we or any third-party manufacturers we engage in the future fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur significant costs.

We and any third-party manufacturers we may engage in the future 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. From time to time and in the future, our operations may involve the use of hazardous materials, including chemicals and biological materials, and 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 general liability insurance as well as 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.

Further, with respect to the operations of any future third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, be precluded from developing manufacturing and selling certain products outside the United States or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010, or Bribery Act, the U.S. Foreign Corrupt Practices Act, or FCPA, and other anti-corruption laws that apply in countries where we do business and may do business in the future. The Bribery Act, FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

We may in the future operate in jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. If we expand our operations outside of the United States, we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The Securities and Exchange Commission also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by U.K., U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

Risks Related to Employee Matters and Managing 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 research and development, clinical and business development expertise of Mark Iwicki, our Chief Executive Officer, Kim Brazzell, Ph.D., our Chief Medical Officer, and Hongming Chen, Sc.D., our Chief Scientific Officer, as well as the other principal members of our management, scientific and clinical team.

Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, legal 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 products. 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 be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

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

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, clinical, regulatory affairs, manufacturing, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and our limited experience in managing such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Risks Related to Our Common Stock

Our executive officers, directors and principal stockholders, if they choose to act together, continue to have the ability to control all matters submitted to stockholders for approval.

As of July 31, 2017, our executive officers and directors and our stockholders who owned more than 5% of our outstanding common stock before our IPO, in the aggregate, own shares representing approximately 68% of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

This concentration of voting power may:

- delay, defer or prevent a change in control;
- entrench our management and our board of directors; or
- delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- provide for a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- provide for advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

An active trading market for our common stock may not be sustained.

Our shares of common stock began trading on the NASDAQ Global Select Market on July 20, 2017. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price for our common stock and thereby affect the ability of our stockholders to sell their shares. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price is likely to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- results of clinical trials of KPI-121 0.25% and any other product candidates;
- results of clinical trials of product candidates of our competitors;
- our success in commercializing KPI-121 1.0% and KPI-121 0.25%;
- the success of competitive products or technologies;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional products, product candidates or technologies for the treatment of ophthalmic diseases or conditions, the costs of commercializing any such products and the costs of development of any such product candidates or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

In the past, following periods of volatility in the market price of a company’s securities, securities class-action litigation has often been instituted against that company. We also may face securities class-action litigation if we cannot obtain regulatory approvals for or if we otherwise fail to commercialize KPI-121 1.0%, KPI-121 0.25% or other product candidates. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management’s attention and resources.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which 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, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of July 31, 2017, we had 24,227,050 shares of common stock outstanding. Of these shares, 17,283,399 shares

are currently restricted as a result of securities laws or lock-up agreements but will become eligible to be sold at various times after the expiration of the applicable lock-up period. Moreover, beginning 180 days after the completion our IPO, holders of an aggregate of 16,086,480 shares of our common stock will have rights, along with holders of an additional 1,504,470 shares of our common stock issuable upon exercise of outstanding warrants and options, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. In July 2014, we registered all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements entered into in connection with our IPO.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company for up to five years. As an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- 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; and
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Investors may find our common stock less attractive as a result of our reliance 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 have incurred and will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the NASDAQ Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We are evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

For as long as we remain an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies as described in the preceding risk factor. We may remain an emerging growth company until December 31, 2022, although if the market value of our common stock that is held by non-affiliates exceeds $700 million as of any June 30 before that time or if we have annual gross revenues of $1.07 billion or more in any fiscal year, we would cease to be an emerging growth company as of December 31 of the applicable year. We also would cease to be an emerging growth company if we issue more than $1 billion of non-convertible debt over a three-year period.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be our stockholders' sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of our 2014 Debt Facility preclude us from paying dividends without the lenders' consent, and any future debt agreements that we may enter into may preclude us from paying dividends without the lenders' consent or at all. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

Our certificate of incorporation designates the state courts in the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against the company and our directors, officers and employees.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or employees to our company or our stockholders, any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws or as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of Chancery of the State of Delaware, or any action asserting a claim against us governed by the internal affairs doctrine. This exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees.

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

Sales of Unregistered Securities

None.

Use of Proceeds from our Public Offering of Common Stock

On July 19, 2017, our registration statement on Form S-1 (File No. 333-218936) relating to the IPO of our common stock became effective. In the IPO, we issued 6,900,000 shares of our common stock at an initial offering price of $15.00 per share, including 900,000 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares of common stock. We received net proceeds of $94.9 million after deducting underwriting discounts and commission of $7.2 million and offering costs incurred in 2017 of $1.4 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to our affiliates. J.P. Morgan and BofA Merrill Lynch acted as joint book-running managers and Wells Fargo Securities and Wedbush PacGrow acted as co-managers for the offering. The offering commenced on July 19, 2017 and did not terminate until the sale of all of the shares offered.

Because the closing of our IPO occurred on July 25, 2017, as of June 30, 2017, we had not yet received the net proceeds from the sale of shares of common stock in our IPO and therefore had used none of the proceeds as of June 30, 2017.

There has been no material change in the planned use of proceeds from the IPO of our common stock from that described in the Prospectus.

Repurchase of Shares or of Company Equity Securities

None.

Item 6. Exhibits

Exhibit Index

EXHIBIT 31.1	-	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
EXHIBIT 31.2	-	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
EXHIBIT 32.1	-	Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002, by Mark Iwicki, President and Chief Executive Officer of the Company.
EXHIBIT 32.2	-	Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002, by Mary Reumuth, Chief Financial Officer of the Company.
EXHIBIT 101.INS	-	XBRL Instance Document.
EXHIBIT 101.SCH	-	XBRL Taxonomy Extension Schema Document.
EXHIBIT 101.CAL	-	XBRL Taxonomy Extension Calculation Linkbase Document.
EXHIBIT 101.DEF	-	XBRL Taxonomy Extension Definition Linkbase Document.
EXHIBIT 101.LAB	-	XBRL Taxonomy Extension Label Linkbase Document.
EXHIBIT 101.PRE	-	XBRL Taxonomy Extension Presentation Linkbase Document.

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.

KALA PHARMACEUTICALS, INC.

Dated: August 31, 2017

By: /s/ Mark Iwicki
Mark Iwicki
Chairman of the Board and Chief Executive Officer

Dated: August 31, 2017

By: /s/ Mary Reumuth
Mary Reumuth
Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATIONS

I, Mark Iwicki, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Kala Pharmaceuticals, 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)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 31, 2017

By: /s/ Mark Iwicki

Mark Iwicki
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Mary Reumuth, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Kala Pharmaceuticals, 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)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 31, 2017

By: /s/ Mary Reumuth

Mary Reumuth
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION 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 Kala Pharmaceuticals, Inc. (the "Company") for the period ended June 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(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.

Date: August 31, 2017

/s/ Mark Iwicki
Mark Iwicki
President and Chief Executive Officer

Exhibit 32.2

CERTIFICATION 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 Kala Pharmaceuticals, Inc. (the "Company") for the period ended June 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(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.

Date: August 31, 2017

/s/ Mary Reumuth
Mary Reumuth
Chief Financial Officer