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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

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

For the quarterly period ended September 30, 2018  
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

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**KALA PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**100 Beaver Street, Suite 201**  
**Waltham, MA**  
(Address of principal executive offices)

**27-0604595**  
(I.R.S. Employer  
Identification No.)

**02453**  
(Zip Code)

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

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

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

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

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

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

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

There were 33,795,656 shares of Common Stock, \$0.001 par value per share, outstanding as of November 6, 2018.

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**PART I – FINANCIAL INFORMATION****Item 1 Financial Statements**

**KALA PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(UNAUDITED)**

(In thousands, except share and per share amounts)

	September 30, 2018	December 31, 2017
<b>Assets</b>		
Current assets:		
Cash	\$ 74,910	\$ 114,565
Inventory	976	—
Prepaid expenses and other current assets	4,569	648
Total current assets	80,455	115,213
Noncurrent assets:		
Property and equipment, net	1,311	786
Right-of-use asset	131	413
Restricted cash	2,178	134
Total assets	\$ 84,075	\$ 116,546
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,283	\$ 1,202
Accrued expenses	7,968	6,606
Lease liabilities	101	397
Current portion of long-term debt	3,333	6,667
Total current liabilities	12,685	14,872
Long-term liabilities:		
Long-term debt - less current portion	16,456	11,987
Other long-term liabilities	—	8
Total long-term liabilities	16,456	11,995
Total liabilities	29,141	26,867
Commitments and Contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized as of September 30, 2018 and December 31, 2017; no shares issued or outstanding as of September 30, 2018 or December 31, 2017	—	—
Common stock, \$0.001 par value; 120,000,000 shares authorized as of September 30, 2018 and December 31, 2017; 24,645,542 and 24,538,309 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	25	25
Additional paid-in capital	230,799	224,025
Accumulated deficit	(175,890)	(134,371)
Total stockholders' equity	54,934	89,679
Total liabilities and stockholders' equity	\$ 84,075	\$ 116,546

See accompanying notes to these unaudited condensed consolidated financial statements.

**KALA PHARMACEUTICALS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(In thousands, except share and per share amounts)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	\$ 7,027	\$ 7,018	\$ 20,051	\$ 23,128
General and administrative	8,469	2,516	21,102	5,607
Total operating expenses	15,496	9,534	41,153	28,735
Loss from operations	(15,496)	(9,534)	(41,153)	(28,735)
Other income (expense):				
Interest income	325	194	848	276
Interest expense	(432)	(212)	(1,214)	(618)
Change in fair value of warrant liability	—	(623)	—	(1,844)
Total other income (expense)	(107)	(641)	(366)	(2,186)
Net loss	\$ (15,603)	\$ (10,175)	\$ (41,519)	\$ (30,921)
Net loss per share—basic and diluted	\$ (0.63)	\$ (0.56)	\$ (1.69)	\$ (4.51)
Weighted average shares outstanding—basic and diluted	24,600,080	18,034,278	24,570,081	6,860,777

See accompanying notes to these unaudited condensed consolidated financial statements.

**KALA PHARMACEUTICALS, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

	Nine Months Ended September 30,	
	2018	2017
	(unaudited)	
<b>Cash flows from operating activities:</b>		
Net loss	\$ (41,519)	\$ (30,921)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	243	213
Amortization of right-of-use asset	283	265
Change in fair value of warrant liability	—	1,844
Amortization of debt discount	75	86
Stock-based compensation	6,417	2,070
Loss on disposal of fixed asset	9	—
Change in operating assets and liabilities		
Prepaid expenses and other current assets	(3,350)	(732)
Inventory	(910)	—
Accounts payable	(220)	74
Accrued expenses	1,143	(163)
Lease liabilities	(295)	(268)
Other long-term liabilities	(8)	(2)
Net cash used in operating activities	<u>(38,132)</u>	<u>(27,534)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(668)	(198)
Net cash used in investing activities	<u>(668)</u>	<u>(198)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from common stock offering, net of underwriters discounts	—	96,255
Proceeds from venture debt, net of debt issuance costs of \$50 and \$0	2,728	10,000
Payment of principal on venture debt	(1,667)	—
Payment of common stock offering costs	—	(2,111)
Payment of deferred offering costs	(163)	—
Proceeds from exercise of stock options	291	189
Net cash provided by financing activities	<u>1,189</u>	<u>104,333</u>
<b>Net (decrease) increase in cash and restricted cash</b>	<b>(37,611)</b>	<b>76,601</b>
Cash and restricted cash at beginning of period	114,699	45,581
Cash and restricted cash at end of period	<u>77,088</u>	<u>122,182</u>
<b>Reconciliation of cash and restricted cash:</b>		
Cash and restricted cash at end of period	77,088	122,182
Less restricted cash	(2,178)	(133)
Cash at end of period	<u>\$ 74,910</u>	<u>\$ 122,049</u>
<b>Non-cash investing and financing activities:</b>		
Conversion of convertible preferred stock into common stock	\$ —	\$ 118,391
Reclassification of warrants to additional paid-in capital	—	2,883
Common stock offering cost included in accounts payable and accrual	—	131
Purchases of property and equipment in accounts payable	110	45
<b>Supplemental disclosure:</b>		
Cash paid for interest	\$ 1,138	\$ 532

See accompanying notes to these unaudited condensed consolidated financial statements.

**KALA PHARMACEUTICALS, INC.****NOTES TO UNAUDITED CONDENSED CONSOLIDATED 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 therapeutics using its AMPPLIFY™ mucus-penetrating particle (“MPP”) Drug Delivery Technology (“AMPPLIFY”), with an initial focus on the treatment of eye diseases. The Company has applied the AMPPLIFY technology to loteprednol etabonate, (“LE”), a corticosteroid designed for ocular applications, resulting in the U.S. Food and Drug Administration’s (the “FDA”), approval of INVELTYS™ (loteprednol etabonate ophthalmic suspension) 1% as a twice-daily ocular corticosteroid for treatment of post-operative inflammation and pain following ocular surgery on August 22, 2018, and its lead product candidate KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. On October 16, 2018, the Company submitted a New Drug Application (“NDA”) to the FDA for KPI-121 0.25%. In addition, based upon the recommendation of the FDA, the Company initiated an additional Phase 3 clinical trial (“STRIDE 3”) (STRIDE- Short Term Relief in Dry Eye), in the third quarter of 2018 evaluating KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. The Company expects to receive top-line results for STRIDE 3 in the fourth quarter of 2019. The Company is evaluating opportunities for MPP nanosuspensions of LE with less frequent daily dosing regimens for the treatment of inflammation and pain following ocular surgery, for the temporary relief of the signs and symptoms of dry eye disease and for potential chronic treatment 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 commercializing a product, 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 and launching a product for the first time. 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 and future research and development, obtain regulatory approval of its product candidates, successfully commercialize its products, generate revenue, meet its obligations, and, ultimately, attain profitable operations.

**Initial Public Offering**—On July 25, 2017, the Company completed its initial public offering (“IPO”) of common stock pursuant to its registration statement on Form S-1, as amended (File No. 333-218936), which was declared effective by the Securities Exchange Commission (the “SEC”) on July 19, 2017. Pursuant to the registration statement, the Company issued and sold 6,900,000 shares of \$0.001 par value common stock at an initial offering price of \$15.00 per share, which included 900,000 shares of common stock pursuant to the underwriters’ option to purchase additional shares. The Company’s shares began trading on the Nasdaq Global Select Market under the symbol “KALA” on July 20, 2017.

Proceeds from the Company’s IPO were approximately \$94.0 million after deducting underwriting discounts and commissions of \$7.3 million and offering costs of \$2.2 million. 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. All of the Company’s outstanding warrants to purchase preferred stock automatically converted into warrants to purchase 202,020 shares of common stock.

**October 2018 Financings**— On August 9, 2018, the Company filed a shelf registration statement on Form S-3 with the SEC, which was declared effective on August 27, 2018 (the “Shelf”). Under the Shelf, the Company may offer and sell up to \$250.0 million of a variety of securities including common stock, preferred stock, warrants, depositary shares, debt securities, purchase contracts, purchase units or any combination of such securities during the three-year period that commenced upon the Shelf becoming effective. Under the Shelf, the Company may periodically offer one or more types of securities in amounts, at prices and on terms announced, if and when the securities are ever offered. In

**KALA PHARMACEUTICALS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

connection with the filing of the Shelf, the Company entered into a sales agreement with Jefferies, LLC (the “Sales Agreement”) pursuant to which the Company may issue and sell, from time to time, up to an aggregate of \$50.0 million of its common stock in an at-the-market equity offering (“ATM Offering”) through Jefferies, LLC., as sales agent.

On October 1, 2018, the Company entered into a credit agreement (the “Athyrium Credit Facility”), with Athyrium Opportunities III Acquisition LP (“Athyrium”). The Athyrium Credit Facility provides for a term A loan in the aggregate principal amount of \$75.0 million (the “Term A Loan”), and a term B loan in the aggregate principal amount of \$35.0 million (the “Term B Loan”). On October 1, 2018, the Company borrowed the entire principal amount of the Term A Loan. The Company may draw down the Term B Loan upon either (i) FDA approval of KPI-121 0.25% for a dry eye disease indication or (ii) reaching certain net product revenues for INVELTYS, in each case on or prior to June 30, 2020.

On October 5, 2018, the Company sold 7,500,000 shares of the Company’s common stock (the “Shares”) in an underwritten offering pursuant to the Shelf at a public offering price of \$8.25 per share, before underwriting discounts and commissions. In addition, the underwriters were granted an overallotment option to purchase an additional 1,125,000 shares of the common stock at the same public offering price, less underwriting discounts and commissions (the “Overallotment Shares”). On October 11, 2018, the underwriters exercised in full their option to purchase the Overallotment Shares. The total number of Shares and Overallotment Shares sold by the Company in the offering was 8,625,000 shares, resulting in net proceeds to the Company, after underwriting discounts and offering expenses, of approximately \$66.4 million.

Between September 30, 2018 and November 8, 2018, the Company issued 518,135 shares of its common stock under the ATM Offering resulting in net proceeds to the Company of approximately \$4.7 million.

**Liquidity**— Since inception, we have incurred significant losses from operations and negative cash flows from operations. As of September 30, 2018, we had an accumulated deficit of \$175.9 million. The Company has not generated any revenues to date from product sales and has financed operations primarily through the IPO, private placements of preferred stock, convertible debt financings, borrowings under credit facilities, warrants and public common stock offerings and to a lesser extent, payments received in connection with various feasibility studies. The Company has devoted substantially all of its financial resources and efforts to research and development, including preclinical studies and clinical trials. The Company expects to continue to incur significant expenses and operating losses over the next several years. Net losses may fluctuate significantly from quarter-to-quarter and year-to-year.

The Company believes that its existing cash on hand as of September 30, 2018, together with the proceeds from the October 2018 Financings, will enable it to fund its planned operating expenses, debt service obligations and capital expenditure requirements for at least twelve months from the date these condensed consolidated financial statements were issued and through at least early 2020. This evaluation is based on relevant conditions and events that are known and reasonably knowable at the date that the condensed consolidated financial statements are issued. As a result, the Company could deplete its available capital resources sooner than it currently expects.

**Use of Estimates**—The preparation of condensed consolidated financial statements in conformity with accounting principles generally accepted in the United States of America (“U.S. 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 condensed consolidated financial statements relate to, but are not limited to, the present value of lease liabilities and the corresponding right-of-use assets, the fair value of 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.

**KALA PHARMACEUTICALS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Net Loss per Share**—Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the sum of the weighted average number of common shares outstanding during the period and, if dilutive, the weighted average number of potential shares of common stock, including the assumed exercise of stock options and warrants.

The Company applies the two-class method to calculate basic and diluted net loss per share attributable to common stockholders as its warrants to purchase common stock are participating securities.

The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. However, the two-class method does not impact the net loss per share of common stock as the Company has been in a net loss position and the warrant holders do not participate in losses.

Basic and diluted shares outstanding are the same for each period presented as all common stock equivalents would be antidilutive due to the net losses incurred.

**Unaudited Interim Financial Information**—The condensed consolidated financial statements of the Company included herein have been prepared, without audit, pursuant to the rules and regulations of 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 consolidated 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 condensed consolidated financial statements should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 (the "Annual Report").

The unaudited condensed consolidated financial statements include the accounts of Kala Pharmaceuticals, Inc. and its wholly owned subsidiary, Kala Pharmaceuticals Security Corporation, which was established in November 2017. All intercompany transactions and balances have been eliminated in consolidation.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

The Company's significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies," to the consolidated financial statements included in the Annual Report. There have been no material changes to the significant accounting policies during the period ended September 30, 2018 other than those noted below.

**Inventory**

Inventory is stated at the lower of cost or net realizable value, on a first-in, first-out ("FIFO") method. Costs include amounts related to third party manufacturing, transportation, internal labor and overhead. Capitalization of costs as inventory begins when the product has received regulatory approval in the U.S. We expense inventory costs related to product candidates as research and development expenses prior to regulatory approval in the respective territory, even if this inventory may later be sold. For INVELTYS, capitalization of costs as inventory began upon U.S. regulatory approval on August 22, 2018.

**Leases**

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Most leases with a term greater than one-year are recognized on the



**KALA PHARMACEUTICALS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. The Company has elected not to recognize on the balance sheet leases with terms of one-year or less. Lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes the appropriate incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received.

The components of a lease should be split into three categories: lease components (e.g., land, building, etc.), non-lease components (e.g., common area maintenance, maintenance, consumables, etc.), and non-components (e.g., property taxes, insurance, etc.). Then the fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on fair values to the lease components and non-lease components.

Although separation of lease and non-lease components is required, certain practical expedients are available to entities. Entities electing the practical expedient would not separate lease and non-lease components. Rather, they would account for each lease component and the related non-lease component together as a single component. The Company's facilities operating leases have lease and non-lease components which the Company has elected to account for as one single lease component. The lease component results in a right-of-use asset being recorded on the balance sheet and amortized as lease expense on a straight-line basis to the statements of operations.

**Recently Adopted Accounting Pronouncements**

In May 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 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 has prospectively adopted this new standard as of January 1, 2018. The adoption of this standard did not have a material impact on the Company's condensed consolidated 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 retrospectively and early adoption is permitted, including adoption in an interim period. The Company has adopted this new standard as of January 1, 2018. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which provides guidance to enhance the transparency and comparability of financial reporting related to leasing arrangements. Under this new lease standard, most leases are required to be recognized on the balance sheet as right-of-use assets and corresponding lease liabilities. Disclosure requirements have been enhanced with the objective of enabling financial statement users to assess the amount, timing, and uncertainty of cash flows arising from leases.

The Company elected to early adopt ASU 2016-02, effective January 1, 2018, as permitted in the guidance. The standard has been implemented using the required modified retrospective approach and the Company has also elected to utilize the available practical expedients. In using the modified retrospective approach, the Company was required to recognize and measure leases existing at, or entered into after, the beginning of the earliest comparative period presented. Prior period results have been restated resulting in adjustments to the condensed consolidated balance sheets

**KALA PHARMACEUTICALS, INC.****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

and the condensed consolidated statement of cash flows. The adoption of this standard did not have a material impact on the condensed consolidated statement of operations. The impact on the consolidated balance sheet as of December 31, 2017 and the condensed consolidated statement of cash flows for the nine months ended September 30, 2017 is shown below.

**Impact to Previously Reported Results**

From December 31, 2017 consolidated balance sheet (in thousands):

	<u>As Previously Reported</u>	<u>New Lease Standard Adjustment</u>	<u>As Restated</u>
Right-of-use asset	\$ —	\$ 413	\$ 413
Accrued expenses	\$ 6,589	\$ 17	\$ 6,606
Other current and long-term liabilities	\$ 9	\$ (1)	\$ 8
Lease liabilities	\$ —	\$ 397	\$ 397

For the nine months ended September 30, 2017 condensed consolidated statement of cash flows (in thousands):

	<u>As Previously Reported</u>	<u>New Lease Standard Adjustment</u>	<u>As Restated</u>
Amortization of right-of-use asset	\$ —	\$ 265	\$ 265
Accrued expenses	\$ (166)	\$ 3	\$ (163)
Lease liabilities	\$ —	\$ (268)	\$ (268)

**3. INVENTORY**

Inventory consists of the following (in thousands):

	<u>September 30, 2018</u>	<u>December 31, 2017</u>
Raw Materials	\$ —	\$ —
Work in Progress	976	—
Finished Goods	—	—
Inventory	<u>\$ 976</u>	<u>\$ —</u>

**KALA PHARMACEUTICALS, INC.****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****4. ACCRUED EXPENSES**

Accrued expenses consist of the following (in thousands):

	<u>September 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Development costs	\$ 2,803	\$ 3,054
Compensation and benefits	3,067	2,402
Professional fees	1,122	666
General and administrative consulting	642	229
Other	334	255
Accrued expenses	<u>\$ 7,968</u>	<u>\$ 6,606</u>

**5. LEASES**

The Company entered into a three-year lease agreement for its headquarters on September 30, 2013, with a commencement date of February 1, 2014. 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 for the full amount of the letter with cash on deposit, which is reported as restricted cash. With the adoption of ASU 2016-02, the Company has recorded a right-of-use asset and corresponding lease liability.

On February 28, 2018, the Company entered into a lease agreement with 480 Arsenal Group LLC (the "Arsenal Group") for the lease of a portion of the building located at 490 Arsenal Way Watertown, Massachusetts (the "Watertown Lease"). The initial term of the Watertown Lease is eight years with an option to extend for an additional five years. The Company expects to occupy the premises in early 2019. The Company plans to use the premises as its new corporate headquarters and for research and development. The Company has not yet occupied this space as it is being renovated for the Company's use. The Company has concluded that it does not control the space as defined in ASU 2016-02 during the construction period and does not expect to gain control of the space until on or near construction completion and, as such, a right-of-use asset and corresponding lease liability have not been recorded.

In connection with the Watertown Lease, the Company issued a letter of credit to the Arsenal Group for \$2.0 million. The Company secured the letter of credit for the full amount of the letter with cash on deposit, which is reported as restricted cash.

On March 15, 2018, the Company entered into a lease agreement with Duffy Associates, LLC for the lease of a portion of the building located at 465 Waverley Oaks Road, Suite 301, Waltham, Massachusetts (the "Waverley Oaks Lease"). The term of the Waverley Oaks Lease is one-year, and as such a right-of-use asset and corresponding lease liability has not been recorded. The Company plans to use this location for additional corporate offices before moving to its new corporate headquarters in Watertown, Massachusetts.

KALA PHARMACEUTICALS, INC.

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The components of lease expense and related cash flows were as follows (in thousands):

	<b>For the three months ended September 30,</b>	
	<b>2018</b>	<b>2017</b>
<b>Lease cost</b>		
Operating lease cost	\$ 99	\$ 99
Short-term lease cost	55	—
<b>Total lease cost</b>	<b>\$ 154</b>	<b>\$ 99</b>
Operating cash flows from operating leases	\$ 103	\$ 100
	<b>For the nine months ended September 30,</b>	
	<b>2018</b>	<b>2017</b>
<b>Lease cost</b>		
Operating lease cost	\$ 296	\$ 296
Short-term lease cost	117	—
<b>Total lease cost</b>	<b>\$ 413</b>	<b>\$ 296</b>
Operating cash flows from operating leases	\$ 307	\$ 296

As of September 30, 2018, and December 31, 2017, the remaining lease term on the operating lease was 0.33 years and 1.08 years, respectively. As of September 30, 2018, and December 31, 2017, the discount rate was 6.50%.

Future minimum commitments due under these lease agreements as of September 30, 2018 are as follows (in thousands):

<b>Years Ending December 31,</b>	<b>Operating Lease Obligation (1)</b>	<b>Other Lease Obligations (2)</b>	<b>Total</b>
2018 (remaining three months)	\$ 69	\$ 63	\$ 132
2019	34	52	86
2020	—	—	—
2021	—	—	—
2022	—	—	—
Present value adjustment	(2)	—	(2)
<b>Total minimum lease payments</b>	<b>\$ 101</b>	<b>\$ 115</b>	<b>\$ 216</b>

- (1) Future minimum lease payments under the Company's operating lease for its current corporate headquarters and lab space in Waltham, Massachusetts.
- (2) Future minimum lease payments under the Company's Waverley Oaks Lease. Excluded from the table above is the Watertown Lease because the Company has concluded that it does not control the space during the construction period and does not expect to gain control of the space until on or near construction completion.

**KALA PHARMACEUTICALS, INC.****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****6. 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 a First Amendment to the 2014 Debt Facility the (“First Amendment”), which 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”). On September 28, 2017, the Company drew the additional \$10.0 million available under Term Loan B. On November 22, 2017, the Company entered into a Second Amendment to the 2014 Debt Facility to account for the formation of the Company’s wholly-owned subsidiary. On March 29, 2018, the Company entered into a Third Amendment to the 2014 Debt Facility the (“Third Amendment”), which reaffirmed the initial commitment to a total of \$20.0 million of funding (“Term Loan A”), increased the Company’s total borrowing capacity by an additional \$5.0 million and extended the interest-only end date for 12 months following the execution of the Third Amendment. The maturity date of the 2014 Debt Facility was also extended from October 13, 2020 to March 29, 2022. Under the terms of the facility, the borrowings accrue interest at an annual rate equal to 3.00% above the Prime Rate then in effect. The interest rate was 8.25% as of September 30, 2018 and 7.50% as of December 31, 2017.

The unpaid principal balance under the 2014 Debt Facility was \$20.0 million and \$18.9 million as of September 30, 2018 and December 31, 2017, respectively. The unamortized discount was \$210,000 and \$235,000 as of September 30, 2018 and December 31, 2017, respectively. During the three months ended September 30, 2018 and 2017, the Company recognized interest expense of \$432,000 and \$212,000, respectively, which consisted of amortization of the debt discount of \$23,000 and \$29,000, respectively and the contractual coupon interest of \$409,000 and \$183,000, respectively. During the nine months ended September 30, 2018 and 2017, the Company recognized interest expense of \$1,214,000 and \$618,000, respectively, which consisted of amortization of the debt discount of \$74,000 and \$86,000, respectively, and the contractual coupon interest of \$1,138,000 and \$532,000, respectively.

The 2014 Debt Facility, as amended, is senior debt and is secured by substantially all of the assets of the Company other than intellectual property. The Company’s ability to pay cash dividends is currently restricted by the terms of the 2014 Debt Facility. In the event the Company is determined to be in default under the 2014 Debt Facility, the outstanding balance accrues interest at five percentage points above the interest rate applicable immediately prior to the occurrence of the event of default and the lender has the right to declare all outstanding principal and interest payable. Under the terms of the 2014 Debt Facility, certain events including but not limited to, the Company’s failure to pay obligations when due, failure to perform obligations under the agreement, insolvency or the occurrence of any circumstance that could reasonably be expected to have a material adverse effect on the Company, constitute events of default.

In connection with its borrowings under the 2014 Debt Facility, the Company issued preferred stock warrants. Upon each issuance of such preferred stock warrants, the Company estimated the fair value using the Black-Scholes option-pricing model, and recorded the estimated fair value as a liability separate from the loan balance, and an 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 all issuances of such preferred stock warrants on an aggregate basis was \$365,000. Upon the closing of the Company’s IPO on July 25, 2017, all of the underlying preferred stock warrants were converted into warrants for common stock (see Note 7), and the warrant liability was re-measured to fair value and reclassified to additional paid-in capital.

**KALA PHARMACEUTICALS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The future annual principal payments due under the 2014 Debt Facility as of September 30, 2018 were as follows (in thousands):

<b>Years Ending December 31,</b>	
2018 (remaining three months)	\$ —
2019	5,000
2020	6,667
2021	6,667
2022	1,666
Total	<u>\$ 20,000</u>

**Athyrium Credit Facility**

On October 1, 2018, the Company entered into the Athyrium Credit Facility. The Athyrium Credit Facility provides for a Term A loan in the aggregate principal amount of \$75.0 million, and a Term B loan in the aggregate principal amount of \$35.0 million. On October 1, 2018, the Company borrowed the entire principal amount of the Term A Loan. The Company may draw down the Term B Loan upon either (i) FDA approval of KPI-121 0.25% for a dry eye disease indication or (ii) reaching certain net product revenues for INVELTYS, in each case on or prior to June 30, 2020.

The Athyrium Credit Facility has a six-year term and bears interest at a rate of 9.875% per annum. A portion of the proceeds from the Term A Loan was used to replace and repay in full the 2014 Debt Facility scheduled to mature on March 29, 2022. In connection with the Company's repayment of the 2014 Debt Facility, the Company paid a prepayment fee of \$180,000.

**7. WARRANTS**

The Company has issued warrants in connection with debt transactions that were completed prior to 2017. Upon the completion of the IPO, the Company's outstanding warrants to purchase preferred stock converted into warrants to purchase common stock.

The following table summarizes the common stock warrants outstanding as of September 30, 2018 and December 31, 2017, each exercisable into the number of shares of common stock set forth below as of the specified dates:

<b>Issued</b>	<b>Exercise Price</b>	<b>Expiration Date</b>	<b>Exercisable From</b>	<b>Shares Exercisable at</b>	
				<b>September 30, 2018</b>	<b>December 31, 2017</b>
2013	\$ 7.50	April 2021	July 2017	82,816	82,816
2014	\$ 7.50	November 2024	July 2017	16,000	16,000
2016	\$ 8.27	October 2026	September 2017	14,512	14,512
				<u>113,328</u>	<u>113,328</u>

In connection with and in consideration for the commitment of the Athyrium Credit Facility, on October 1, 2018, the Company issued to Athyrium a warrant ("Warrant"), to purchase up to 270,835 shares of the Company's common stock, at an exercise price per share of \$12.18456. The Warrant is immediately exercisable as to 184,660 shares and will become exercisable as to the remaining 86,175 shares only upon the Company's draw of the Term B

**KALA PHARMACEUTICALS, INC.****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Loan. The Warrant expires and is no longer exercisable on October 1, 2025, the seven-year anniversary of the closing of the Athyrium Credit Facility.

**8. FAIR VALUE OF FINANCIAL INSTRUMENTS**

The Company classifies fair value based measurements using a three-level hierarchy that prioritizes the inputs used to measure fair value. This hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows: Level 1, quoted market prices in active markets for identical assets or liabilities; Level 2, observable inputs other than quoted market prices included in Level 1 such as quoted market prices for markets that are not active or other inputs that are observable or can be corroborated by observable market data; and Level 3, unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities, including estimates and assumptions developed by the Company, reflective of those that a market participant would use, as inputs to certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

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 6) 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. There were no transfers between fair value measurement levels during the nine months ended September 30, 2018 or September 30, 2017.

The Company has historically classified the value of the warrant liability as a Level 3 measurement within the fair value hierarchy because the fair value is derived using significant unobservable inputs, which included 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 were adjustable based on the amount of the 2014 Term Loans drawn down or the probability that the Company would draw down on the 2014 Debt facility. Upon the completion of the IPO, the Company's outstanding warrants to purchase preferred stock converted into warrants to purchase common stock and the Company reclassified the fair value of the warrant liability to additional paid-in capital. All warrants are currently classified as equity and their fair value is not recorded or re-measured.

The following table provides a summary of changes in the fair value of the Company's warrant liability, which is included as a component of other (income) expense (in thousands) which was subsequently remeasured to the fair value at the date of the IPO and reclassified to additional paid-in capital at that time:

	<b>Three Months Ended</b>	
	<b>September 30,</b>	
	<b>2018</b>	<b>2017</b>
	<b>Warrant</b>	<b>Warrant</b>
	<b>Liability</b>	<b>Liability</b>
Fair value -June 30,	\$ —	\$ 2,260
Change in fair value of warrant liability	—	623
Reclassification of preferred warrant liability	—	(2,883)
Fair value - September 30,	<u>\$ —</u>	<u>\$ —</u>

## KALA PHARMACEUTICALS, INC.

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

	Nine Months Ended September 30,	
	2018 Warrant Liability	2017 Warrant Liability
Fair value - December 31,	\$ —	\$ 1,039
Change in fair value of warrant liability	—	1,844
Reclassification of preferred warrant liability	—	(2,883)
Fair value - September 30,	<u>\$ —</u>	<u>\$ —</u>

**9. STOCK-BASED COMPENSATION**

**Stock Incentive Plans**—In December 2009, the Board of Directors (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.

In July 2017, the Company’s 2017 Equity Incentive Plan (the “2017 Plan”) became effective, as a result, and no further stock options or other awards will be made under the 2009 Plan. The 2017 Plan was established to provide equity based ownership opportunities for employees, officers, directors, consultants, and advisors. As of September 30, 2018, there were 1,050,649 shares of common stock available for grant under the 2017 Plan. In addition, any shares of common stock subject to awards under the 2009 Plan that expire, are forfeited, or are otherwise surrendered, without having been fully exercised or resulting in any common stock being issued will become available for issuance under the 2017 Plan, up to an additional 2,649,952 shares, which is the number of shares issuable pursuant to outstanding awards granted under the 2009 Plan.

Also approved under the 2017 Plan is an annual increase for each of the years through December 31, 2027, equal to the least of (i) 3,573,766 shares of common stock, (ii) 4% of the shares of common stock outstanding on December 31 of the prior year and (iii) an amount determined by the Board.

Under the plans, the Board determines 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 could not be less than the fair value of the common stock on the date of grant. Stock options awarded under the plans expire 10 years after the grant date, unless the Board sets a shorter term. Options granted under the plans generally vest over a four-year period. 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.

In the past, the Company had granted stock options which contain performance-based vesting criteria. These criteria were milestone events that were specific to the Company’s corporate goals. Stock-based compensation expense associated with performance-based stock options is recognized if the achievement of the performance condition is considered probable using management’s best estimates. As of September 30, 2018 there were no performance-based awards outstanding.

For the three months ended September 30, 2018 and 2017, the Company did not grant any stock options to non-employee consultants. For the nine months ended September 30, 2018 and 2017, the Company granted 0 and 4,224 stock options to non-employee consultants, respectively. During the three months ended September 30, 2018 and 2017, the Company recognized \$0 and \$46,000, respectively, in stock compensation expense related to non-employee consultants. During the nine months ended September 30, 2018 and 2017, the Company recognized \$11,000 and \$83,000, respectively, in stock compensation expense related to non-employee consultants.



**KALA PHARMACEUTICALS, INC.**
**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Inducement Stock Option Awards**—During the three months ended September 2018, the Company granted non-statutory stock options to purchase an aggregate of 69,500 shares of the Company’s common stock to seven new employees. During the nine months ended September 2018, the Company granted non-statutory stock options to purchase 219,500 shares of Company’s common stock to a total of eight new employees. These stock options will vest over a four-year period, with 25% of the shares underlying each option award vesting on the one-year anniversary of the applicable employees’ new hire date and the remaining 75% of the shares underlying each award vesting monthly thereafter for three-years. Vesting of each option is subject to such employee’s continued service with the Company through the applicable vesting dates. These stock options were granted outside of the 2017 Plan as an inducement material to each employee’s acceptance of employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4).

A summary of option activity for employee and non-employee awards under the 2009 Plan, the 2017 Plan and inducement grants for the nine months ended September 30, 2018 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, 2018	3,738,928	\$ 6.93	8.4	\$ 44,578
Granted	1,449,690	13.74		
Exercised	(107,233)	2.71		
Forfeited	(144,152)	5.85		
Outstanding at September 30, 2018	<u>4,937,233</u>	\$ 9.04	8.03	\$ 16,968
Vested or expected to vest at September 30, 2018	<u>4,937,233</u>	\$ 9.04	8.03	\$ 16,968
Options exercisable at September 30, 2018	<u>2,414,308</u>	\$ 5.29	7.14	\$ 13,198

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. There were 747,892 options granted during the nine months ended September 30, 2017. The assumptions used in determining fair value of the stock options granted in the nine months ended September 30, 2018 and 2017 are as follows:

	Nine Months Ended September 30,			
	2018		2017	
Expected volatility	80%	– 85%	103%	– 122%
Risk-free interest rate	2.63%	– 2.96%	1.81%	– 2.29%
Expected dividend yield	0%		0%	
Expected term (in years)	5.27	– 6.13	5.04	– 9.82

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 is recorded as they occur.

KALA PHARMACEUTICALS, INC.

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

During the three months ended September 30, 2018 and 2017, the weighted average grant-date fair value of options granted was \$8.83 and \$14.74, respectively. During the nine months ended September 30, 2018 and 2017, the weighted average grant-date fair value of options granted was \$9.99 and \$13.19, 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. As of September 30, 2018, there was \$22.7 million of unrecognized compensation cost related to the stock options granted, which is expected to be expensed over a weighted-average period of 2.98 years.

**Employee Stock Purchase Plan**—In 2017, the Company approved the 2017 Employee Stock Purchase Plan (the “ESPP”). Under the ESPP, participating employees can authorize the Company to withhold a portion of their base pay during consecutive six-month payment periods for the purchase of shares of the Company’s common stock. At the conclusion of the period, participating employees can purchase shares of the Company’s common stock at 85% of the lesser of the closing price of the common stock on (i) the first business day of the plan period or (ii) the exercise date. The initial six-month period will not commence until January 1, 2019.

**Reserved Shares**—As of September 30, 2018 and December 31, 2017, the Company had reserved the following shares of common stock issuable upon exercise of rights under equity compensation plans and inducement stock option awards:

	<u>September 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
ESPP	223,341	223,341
Shares reserved for outstanding inducement stock option award	219,500	—
2009 Plan	2,649,952	2,868,449
2017 Plan	3,118,430	2,025,633
Total	<u>6,211,223</u>	<u>5,117,423</u>

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

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Research and development	\$ 684	\$ 357	\$ 2,064	\$ 749
General and administrative	1,581	624	4,353	1,321
Total	<u>\$ 2,265</u>	<u>\$ 981</u>	<u>\$ 6,417</u>	<u>\$ 2,070</u>

For three and nine months ended September 30, 2018, stock-based compensation expense for the Company’s manufacturing employees related to INVELTYS manufactured since the FDA approval of \$66,000, has been capitalized into inventory as a component of overhead expense.

**10. INCOME TAXES**

The Company did not record a provision or benefit for income taxes during the three and nine months ended September 30, 2018 and 2017. The Company continues to maintain a full 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

**KALA PHARMACEUTICALS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 Hampshire, New York, North Carolina and Texas. 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 September 30, 2018 and 2017, 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 nine months ended September 30, 2018 and 2017.

**11. COMMITMENTS AND CONTINGENCIES**

**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, October 2014 and June 2018, 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.

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 \$100,000 and \$97,000, respectively, for the three months ended September 30, 2018 and 2017 and \$300,000 and \$108,000, respectively, for the nine months ended September 30, 2018 and 2017.

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

**12. SUBSEQUENT EVENTS**

**Underwritten Equity Offering**— On October 5, 2018, the Company sold 7,500,000 shares of the Company's Shares in an underwritten offering pursuant to the Shelf at an underwritten offering price of \$8.25 per share, before underwriting discounts and commissions. In addition, the underwriters were granted an Overallotment option to purchase an additional 1,125,000 shares of the common stock at the same public offering price, less underwriting discounts and commissions. On October 11, 2018, the underwriters exercised in full their option to purchase the

**KALA PHARMACEUTICALS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Overallotment shares. The total number of shares sold by the Company in the offering was 8,625,000 shares, resulting in net proceeds to the Company, after underwriting discounts and offering expenses, of approximately \$66.4 million.

**ATM OFFERING** - Between September 30, 2018 and November 8, 2018, the Company issued 518,135 shares of its common stock under the ATM Offering resulting in net proceeds to the Company of approximately \$4.7 million.

**Athyrium Credit Facility**— On October 1, 2018, the Company entered into the Athyrium Credit Facility. The Athyrium Credit Facility provides for a Term A loan in the aggregate principal amount of \$75.0 million, and a Term B loan in the aggregate principal amount of \$35.0 million. On October 1, 2018, the Company borrowed the entire principal amount of the Term A Loan. The Company may draw down the Term B Loan upon either (i) FDA approval of KPI-121 0.25% for a dry eye disease indication or (ii) reaching certain net product revenues for INVELTYS, in each case on or prior to June 30, 2020.

The Athyrium Credit Facility has a six-year term and bears interest at a rate of 9.875% per annum. A portion of the proceeds from the Term Loan A was used to replace and repay in full the 2014 Debt Facility scheduled to mature on March 29, 2022. In connection with the Company's repayment of the 2014 Debt Facility, the Company paid a prepayment fee of \$180,000.

**Warrants**— In connection with the Athyrium Credit Facility and in consideration for the commitment of the Athyrium Credit Facility, on October 1, 2018, the Company issued to Athyrium a Warrant to purchase up to 270,835 shares of the Company's common stock, at an exercise price per share of \$12.18456. The Warrant is immediately exercisable as to 184,660 shares and will become exercisable as to the remaining 86,175 shares only upon the Company's draw of the Term B Loan. The Warrant expires and is no longer exercisable on October 1, 2025, the seven-year anniversary of the closing of the Athyrium Credit Facility.

## 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 consolidated financial statements and related notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2017, which was filed with the Securities and Exchange Commission on April 2, 2018.*

*This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. 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. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. 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 section entitled "Risk Factors" in Part II, Item 1A that 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*

We are a biopharmaceutical company focused on the development and commercialization of therapeutics using our AMPPLIFY™ mucus-penetrating particle (MPP) Drug Delivery Technology, or AMPPLIFY, 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 AMPPLIFY technology to loteprednol etabonate, or LE, a corticosteroid designed for ocular applications, resulting in the U.S. Food and Drug Administration, or FDA, approved INVELTYS™ (loteprednol etabonate ophthalmic suspension) 1% for the treatment of inflammation and pain following ocular surgery, and our lead product candidate KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease.

In August 2018, the FDA approved our new drug application, or NDA, for INVELTYS, our topical twice-a-day product candidate, for the treatment of inflammation and pain following ocular surgery. INVELTYS is the first and only FDA-approved ocular corticosteroid product with a twice-a-day dosing regimen for the treatment of post-operative inflammation and pain. Other approved topical ocular corticosteroid products for this indication are dosed four times a day. INVELTYS is indicated for the treatment of post-operative inflammation and pain following ocular surgery, with an approved dosage of one to two drops twice daily beginning the day after surgery and continuing throughout the first two weeks of the post-operative period. As indicated on its approved label, the most common adverse drug reactions to INVELTYS in clinical trials were eye pain (1%) and posterior capsular opacification (1%). These reactions may have been the consequence of the surgical procedure.

We have retained worldwide commercial rights for INVELTYS. We expect to commercialize INVELTYS in the United States, and have started to build a commercial infrastructure to do so. We plan to hire a specialty sales force that will focus on eye care professionals in the United States. We expect to launch INVELTYS early in 2019. We further expect our commercial organization for INVELTYS will initially consist of approximately 75 sales and marketing personnel.

KPI-121 0.25% is our product candidate for patients with dry eye disease utilizing a two-week course of therapy. In January 2018, we announced topline results from two completed Phase 3 clinical trials of KPI-121 0.25%, which we refer to as STRIDE 1 and STRIDE 2 (STRIDE— S hort T erm R elief I n D ry E ye), evaluating the safety and efficacy of KPI-121 0.25% versus placebo (vehicle) in patients with dry eye disease. In STRIDE 1, statistical significance was achieved for the primary sign endpoint of conjunctival hyperemia at day 15 and the primary symptom endpoint of ocular discomfort severity change from baseline to day 15 in the intent to treat, or ITT, population; in addition, statistical significance was also achieved in STRIDE 1 for a second pre-specified primary symptom endpoint of

ocular discomfort severity change from baseline to day 15 in patients with more severe baseline ocular discomfort. In STRIDE 2, statistical significance was achieved for the primary sign endpoint of conjunctival hyperemia at day 15, but statistical significance was not achieved for the primary symptom endpoint of ocular discomfort severity change from baseline to day 15. KPI-121 0.25% was generally well tolerated in both STRIDE 1 and STRIDE 2, with no clinically significant treatment-related adverse events observed during the course of either trial, and with elevations in intraocular pressure, or IOP, in both trials similar to placebo.

In May 2018, we met with the FDA to discuss the results of our dry eye clinical trials and potential next steps for our dry eye disease program. On October 16, 2018 we submitted the NDA to the FDA for KPI-121 0.25%. The NDA included data from three clinical trials studying approximately 2,000 patients, including one Phase 2 trial and two Phase 3 efficacy and safety trials (STRIDE 1 and STRIDE 2).

In addition, based upon the recommendation of the FDA, we initiated an additional Phase 3 clinical trial, STRIDE 3, in the third quarter of 2018 evaluating KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. We expect to receive top-line results for STRIDE 3 in the fourth quarter of 2019. The STRIDE 3 trial is a multicenter, randomized, double-blind, placebo controlled, parallel-arm study comparing KPI-121 0.25% to placebo, each with four times a day dosing for 14 days, in approximately 900 patients with dry eye disease. The primary endpoint, day 15 ocular discomfort severity, is based upon a patient diary in which ocular discomfort is recorded daily over the entire course of the trial using a visual analog grading scale. We have conducted a comprehensive analysis of data generated in the previous three clinical trials and we believe we have identified key factors that contributed to the differences observed in the results from STRIDE 2 compared to those of STRIDE 1 and Phase 2. Based on this analysis, we have made changes to the inclusion/ exclusion criteria of STRIDE 3, which we believe will improve the probability of success for the trial.

If approved, KPI-121 0.25% could be the first FDA-approved product for the short-term treatment of dry eye disease.

For KPI-121 0.25%, we are seeking FDA approval under Section 505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act, or the FDCA, which is the same regulatory pathway we used for the approval of INVELTYS. We have retained worldwide commercial rights for KPI-121 0.25%. If KPI-121 0.25% receives marketing approval, we expect to further expand our sales force by up to approximately an additional 100 personnel. We also expect to commercialize in the United States any of our other product candidates that receive marketing approval. In anticipation of the potential to commercialize our product candidates in other global markets, we will continue evaluating a variety of collaboration, distribution and other marketing arrangements with one or more third parties.

We are evaluating opportunities for MPP nanosuspensions of LE with less frequent daily dosing regimens for the treatment of inflammation and pain following ocular surgery, for the temporary relief of the signs and symptoms of dry eye disease and for potential chronic treatment of dry eye disease. 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.

## **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 The 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 under “Results of Operations”.

We expect our research and development expenses to increase for the foreseeable future as we advance our product candidate, KPI-121 0.25%, toward regulatory approval, pursue other products candidates and conduct additional clinical trials. 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, commercial, 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 general and administrative expenses to increase for the foreseeable future as we increase our headcount to support our continued research and development activities for our product candidates and continue to build our commercial infrastructure to support the continued development and launch of INVELTYS or any other product candidates for which we obtain marketing approval. In addition, we anticipate increased expenses related to supporting a larger organization.

### ***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***

Prior to our IPO, we issued warrants for the purchase of preferred stock. These warrants were classified as liabilities as they were financial instruments that were issuable for contingently redeemable securities. We recognized gains and losses on the change in the fair value of outstanding warrants and these gains and losses are recorded as a component of other income (expense). Upon the closing of our IPO, the underlying preferred stock was converted into common stock, the preferred stock warrants were converted into warrants for common 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, or U.S. GAAP. 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.

There have been no material changes to our critical accounting policies from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K except for the adoption of ASU No. 2016-02, *Leases (Topic 842)*, or ASU 2016-02 on January 1, 2018 as discussed below.

We elected to early adopt ASU 2016-02, effective January 1, 2018, as permitted. Under this new lease standard, most leases are required to be recognized on the balance sheet as right-of-use assets and corresponding lease liabilities. The standard has been implemented using the required modified retrospective approach and we have also elected to utilize the available practical expedients. In using the modified retrospective approach, we were required to recognize and measure leases existing at, or entered into after, the beginning of the earliest comparative period presented. Prior period results have been restated resulting in a material impact on the condensed consolidated balance sheet and condensed consolidated statement of cash flows. The adoption of this standard did not have a material impact on our condensed consolidated statements of operations.



## Results of Operations

### Comparison of the Three Months Ended September 30, 2018 and 2017

The following table summarizes the results of our operations for the three months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		Change
	2018	2017	
	(in thousands)		
Operating expenses:			
Research and development	\$ 7,027	\$ 7,018	\$ 9
General and administrative	8,469	2,516	5,953
Total operating expenses	15,496	9,534	5,962
Loss from operations	(15,496)	(9,534)	(5,962)
Other income (expense)			
Interest income	325	194	131
Interest expense	(432)	(212)	(220)
Change in fair value of warranty liability	—	(623)	623
Net loss	<u>\$ (15,603)</u>	<u>\$ (10,175)</u>	<u>\$ (5,428)</u>

#### Research and Development Expenses

The following table summarizes the research and development expenses incurred during the three months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		Change
	2018	2017	
	(in thousands)		
KPI-121 development costs	\$ 3,402	\$ 4,438	\$ (1,036)
Employee-related costs	3,179	1,995	1,184
Other research and development costs	446	585	(139)
Total research and development	<u>\$ 7,027</u>	<u>\$ 7,018</u>	<u>\$ 9</u>

Research and development expenses were \$7.0 million for the three months ended September 30, 2018 compared to \$7.0 million for the three months ended September 30, 2017, representing a change of \$0. This was primarily the result of a \$1.7 million decrease in KPI-121 development costs due to the decrease in external costs associated with the completion of our Phase 3 clinical trials of INVELTYS for the treatment of inflammation and pain following cataract surgery and STRIDE 1 and STRIDE 2, our Phase 3 trials of KPI-121 0.25% for the treatment of dry eye disease offset by 0.6 million increase in STRIDE 3, our additional Phase 3 clinical trial of KPI-121 0.25% beginning during the three months ended September 30, 2018. An additional decrease of \$0.1 million in other research and development costs was offset by a \$1.2 million increase in employee-related costs due to the additional hiring of personnel, overall merit increases and an increase in stock compensation expense related to stock option grants.

We expect that our research and development costs will increase as we advance our product candidate, KPI-121 0.25%, pursue other product candidates and conduct additional clinical trials.

#### General and Administrative Expenses

General and administrative expenses were \$8.5 million for the three months ended September 30, 2018 compared to \$2.5 million for the three months ended September 30, 2017, an increase of \$6.0 million.

We incurred a \$3.2 million increase in employee-related costs primarily due to a \$2.2 million increase in general and administrative employee headcount and merit increases and a \$1.0 million increase in stock compensation expenses related to stock options granted during 2018. In addition, we incurred a \$0.5 million increase in costs associated with legal, accounting and finance activities, a \$2.0 million increase in costs associated with the building of our commercial organization in advance the potential launch of INVELTYS in early 2019 as well as a \$0.3 million increase in facilities costs made up additional leased space and a larger allocation of our overall facility-related costs.

Our general and administrative expenses are expected to increase for the foreseeable future as we continue to build out our corporate and commercial infrastructure to support the continued development and commercial launch of INVELTYS, which was approved by the FDA on August 22, 2018, or any other product candidate. We expect to incur material and ongoing increases in sales and marketing costs, a component of general and administrative expenses, related to our hiring of a field sales force to market INVELTYS in the United States. In addition, we anticipate increased expenses related to supporting a larger organization.

#### *Interest Income*

Interest income was \$0.3 million for the three months ended September 30, 2018 compared to \$0.2 million for the three months ended September 30, 2017. Interest income consists of interest earned on our cash balance held in an interest-bearing deposit account. The increase was attributable to a higher interest rate on the average cash balance during the three months ended September 30, 2018 due to the receipt of the proceeds from the IPO in July 2017.

#### *Interest Expense*

We incurred interest expense of \$0.4 million for the three months ended September 30, 2018 compared to \$0.2 million for the three months ended September 30, 2017. Interest expense is comprised of the contractual coupon interest and the amortization of debt discount associated with our \$20.0 million venture debt facility entered into in 2014 or the 2014 Debt Facility. The increase was due to an increase in our outstanding balance upon the September 2017 draw down of an additional \$10.0 million under the 2014 Debt Facility.

#### *Change in Fair Value of Warrant Liability*

The change in the fair value of our preferred stock warrant liability consisted of no gain or loss for the three months ended September 30, 2018 compared to a loss of \$0.6 million for the three months ended September 30, 2017. Upon the closing of our IPO, the underlying preferred stock was converted into common stock, the preferred stock warrants were converted into warrants for common stock, and the fair value of the warrant liability at that time was reclassified to additional paid-in capital.

### Comparison of the Nine Months Ended September 30, 2018 and 2017

The following table summarizes the results of our operations for the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,		Change
	2018	2017	
	(in thousands)		
Operating expenses:			
Research and development	\$ 20,051	\$ 23,128	\$ (3,077)
General and administrative	21,102	5,607	15,495
Total costs and expenses	<u>41,153</u>	<u>28,735</u>	<u>12,418</u>
Loss from operations	(41,153)	(28,735)	(12,418)
Other income (expense)			
Interest income	848	276	572
Interest expense	(1,214)	(618)	(596)
Change in fair value of warranty liability	—	(1,844)	1,844
Net loss	<u>\$ (41,519)</u>	<u>\$ (30,921)</u>	<u>\$ (10,598)</u>

#### Research and Development Expenses

The following table summarizes the research and development expenses incurred during the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,		Change
	2018	2017	
	(in thousands)		
KPI-121 development costs	\$ 10,020	\$ 16,304	\$ (6,284)
Employee-related costs	9,071	5,245	3,826
Other research and development costs	960	1,579	(619)
Total research and development	<u>\$ 20,051</u>	<u>\$ 23,128</u>	<u>\$ (3,077)</u>

Research and development expenses were \$20.0 million for the nine months ended September 30, 2018 compared to \$23.1 million for the nine months ended September 30, 2017, a decrease of \$3.1 million. This decrease is primarily the result of a \$6.3 million decrease in KPI-121 development costs due to the decrease in external costs associated with the completion of our Phase 3 clinical trials of INVELTYS for the treatment of inflammation and pain following cataract surgery and STRIDE 1 and STRIDE 2, our Phase 3 trial of KPI-121 0.25% for the treatment of dry eye disease, partially offset by STRIDE 3, our additional Phase 3 clinical trial of KPI-121 0.25% beginning during the nine month ended September 30, 2018. An additional decrease of \$0.6 million in other research and development costs primarily driven by decrease in the allocation of facility costs was offset by a \$3.8 million increase in employee-related costs due to the additional hiring of personnel, overall merit increases and an increase in stock compensation expense related to stock option grants.

#### General and Administrative Expenses

General and administrative expenses were \$21.1 million for the nine months ended September 30, 2018 compared to \$5.6 million for the nine months ended September 30, 2017, an increase of \$15.5 million.

We incurred a \$7.7 million increase in employee-related costs primarily due to a \$4.7 million increase in general and administrative employee headcount expense and overall merit increases and a \$3.0 million increase in stock compensation expenses related to stock options granted during 2018. In addition, we incurred a \$2.7 million increase in costs associated with legal, accounting and finance activities primarily as a result of operating as a public company, a \$1.4 million increase in facility costs made up additional leased space and a larger allocation of our overall facility-

related costs, and a \$3.7 million increase in costs associated with building of our commercial organization in advance of the potential launch of INVELTYS in early 2019.

#### *Interest Income*

Interest income was \$0.8 million for the nine months ended September 30, 2018 compared to \$0.3 million for the nine months ended September 30, 2017. Interest income consists of interest earned on our cash balance held in an interest-bearing deposit account. The increase was attributable to a higher interest rate and higher average cash balance during the nine months ended September 30, 2018 due to receipt of the proceeds from the IPO in July 2017.

#### *Interest Expense*

We incurred interest expense of \$1.2 million for the nine months ended September 30, 2018 compared to \$0.6 million for the nine months ended September 30, 2017. Interest expense is comprised of the contractual coupon interest and the amortization of debt discount associated with our 2014 Debt Facility. The increase was primarily due to an increase in the outstanding balance upon the September 2017 draw down of \$10.0 million under the 2014 Debt Facility.

#### *Change in Fair Value of Warrant Liability*

The change in the fair value of our preferred stock warrant liability consisted of no gain or loss for the nine months ended September 30, 2018 compared to a loss of \$1.8 million for the nine months ended September 30, 2017. Upon the closing of our IPO, the underlying preferred stock was converted into common stock, the preferred stock warrants were converted into warrants for common stock, and the fair value of the warrant liability at that time was reclassified to additional paid-in capital.

### **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 are in process of commercializing our FDA approved INVELTYS product, and we do not expect to generate revenue from sales of any product before 2019. We have funded our operations to date with proceeds from our IPO, private placements of preferred stock, convertible debt financings, borrowings under credit facilities, warrants and public common stock offerings 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 \$94.0 million after deducting underwriting discounts and commission of \$7.3 million and offering costs incurred in 2017 of \$2.2 million.

#### **Cash Flows**

As of September 30, 2018, we had \$74.9 million in cash on hand and \$20.0 million in indebtedness. The following table summarizes our sources and uses of cash for the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,	
	2018	2017
	(in thousands)	
Net cash used in operating activities	\$ (38,132)	\$ (27,534)
Net cash used in investing activities	(668)	(198)
Net cash provided by financing activities	1,189	104,333
Decrease in cash and restricted cash	<u>\$ (37,611)</u>	<u>\$ 76,601</u>

### *Net Cash Used in Operating Activities*

During the nine months ended September 30, 2017, our cash used in operating activities was primarily due to our net loss of \$30.9 million as we incurred external research and development costs associated with our clinical trials during the nine months ended September 30, 2017 and general and administrative costs, offset by non-cash charges of \$4.5 million, consisting primarily of \$2.1 million in stock-based compensation and \$1.8 million in fair value of warrant liability. Net cash used by changes in our operating assets and liabilities primarily consisted an increase of \$0.7 million in prepaid expenses and other current assets and a \$0.4 million decrease in accounts payable and accrued expenses.

During the nine months ended September 30, 2018, our cash used in operating activities was primarily due to our net loss of \$41.5 million primarily consisting of \$20.0 million of research and development costs and \$21.1 million of general and administrative costs partially offset by non-cash charges of \$7.0 million, consisting primarily of \$6.4 million in stock-based compensation, \$0.3 million in amortization of a right of use asset, \$ 0.2 million in depreciation and \$0.1 million in amortization of debt discount. Net cash used by changes in our operating assets and liabilities primarily consisted of a \$3.3 million increase in prepaid expenses due to fees paid for the KPI-121 0.25% NDA, a \$0.3 million decrease in lease liability, a \$1.0 million increase in inventory related to INVELTYS, partially offset by a \$1.0 million increase in accounts payable and accrued expenses primarily due to the decrease in external costs associated with our two Phase 3 clinical trials of KPI-121 0.25% for the treatment of dry eye disease.

### *Net Cash Used in Investing Activities*

Net cash used in investing activities was \$0.2 million for the nine months ended September 30, 2017, consisting primarily of purchases of laboratory equipment.

Net cash used in investing activities was \$0.7 million for the nine months ended September 30, 2018 consisting primarily of purchases of equipment and software.

### *Net Cash Provided by Financing Activities*

Net cash provided by financing activities was \$104.3 million for the nine months ended September 30, 2017, consisting of payments of \$96.3 million of IPO proceeds, net of underwriter discounts and commissions, \$2.2 million in offering costs related to our IPO, \$10.0 million in funding from the September 2017 draw down of the under our 2014 Debt Facility and \$0.2 million in proceeds from exercise of stock options.

Net cash provided by financing activities was \$1.2 million for the nine months ended September 30, 2018, consisting of \$2.7 million of proceeds from our 2014 Debt Facility, net of debt issuance costs, and \$0.3 million in proceeds from the exercise of stock options, offset by principal payments on our 2014 Debt Facility of \$1.7 million and payment of deferred offering costs of \$0.1 million.

### ***Funding Requirements***

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we commercialize INVELTYS in the United States and advance our preclinical activities and clinical trials for our product candidates. In addition, we expect to incur additional costs associated with operating as a public company and our transition into a fully integrated commercial organization.

Our expenses will also increase if and as we:

- commercially launch INVELTYS in the United States and seek regulatory approval for INVELTYS in the European Union;
- continue to grow our sales, marketing and distribution capabilities to commercialize INVELTYS and any products candidates for which we may submit for and obtain marketing approval.

- continue development of KPI-121 0.25%, including conducting our ongoing Phase 3 clinical trial, and continue to pursue marketing approval for KPI-121 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, seek to broaden the label of INVELTYS or, if approved, KPI-121 0.25%;
- pursue the preclinical and clinical development of product candidates, including our rTKI program for use in the treatment of retinal diseases;
- expand our sales, marketing and distribution capabilities for our other product candidates, prior to or upon receiving marketing approval;
- continue to scale up our manufacturing processes and capabilities to support commercialization of INVELTYS, and any of our other product candidates, including KPI-121 0.25%, for which we seek and/or obtain marketing approval;
- leverage our proprietary AMPPLIFY 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 initiate and expand our commercialization efforts.

On July 25, 2017, we completed an IPO of our common stock pursuant to which we issued and sold 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 \$94.0 million after deducting underwriting discounts and commission of \$7.3 million and offering costs incurred in 2017 of \$2.2 million.

On October 1, 2018, we entered into a credit agreement, or the Athyrium Credit Facility, with Athyrium Opportunities III Acquisition LP, or Athyrium. The Athyrium Credit Facility provides for a term A loan, or the Term A Loan, in the aggregate principal amount of \$75.0 million, and a term B loan, or the Term B Loan, in the aggregate principal amount of \$35.0 million. On October 1, 2018, we borrowed the entire principal amount of the Term A Loan. We may draw down the Term B Loan upon either (i) FDA approval of KPI-121 0.25% for a dry eye disease indication or (ii) reaching certain net product revenues for INVELTYS, in each case on or prior to June 30, 2020. The Athyrium Credit Facility has a six-year term and bears interest at a rate of 9.875% per annum. We used the a portion of the proceeds from the Athyrium Credit Facility to repay our 2014 Debt Facility.

In connection with the Athyrium Credit Facility, we issued to Athyrium a warrant to purchase up to 270,835 shares of the our common stock, at an exercise price per share of \$12.18456 . The warrant is immediately exercisable as to 184,660 shares and will become exercisable as to the remaining 86,175 shares only upon the draw of the Term B Loan. The warrant expires and is no longer exercisable on October 1, 2025, the seven-year anniversary of the closing of the Athyrium Credit Facility.

On August 9, 2018, we filed a shelf registration statement, or the Shelf, on Form S-3 with the SEC, which was declared effective on August 27, 2018. Under the Shelf, we may offer and sell up to \$250 million of a variety of securities including common stock, preferred stock, warrants, depositary shares, debt securities, purchase contracts, purchase units or any combination of such securities during the three-year period that commenced upon the Shelf becoming effective. Under the Shelf, we may periodically offer one or more types of securities in amounts, at prices and on terms announced, if and when the securities are ever offered. In connection with the filing of the Shelf, we entered into a sales agreement with Jefferies, LLC, or Sales Agreement, pursuant to which we may issue and sell, from time to time, up to an aggregate of \$50 million of its common stock in an at-the-market equity offering, or ATM Offering, through Jefferies, LLC., as sales agent.

On October 5, 2018, we sold 7,500,000 shares of our common stock in an underwritten offering at a price of \$8.25 per share, before underwriting discounts and commissions in a registered offering pursuant to our shelf registration statement on Form S-3. In addition, the underwriters were granted an overallotment option to purchase an additional 1,125,000 shares of the common stock at the same public offering price, less underwriting discounts and commissions. On October 11, 2018, the underwriters exercised in full their option to purchase the overallotment shares. We sold a total of 8,625,000 shares in the offering, or the Offering Shares, resulting in net proceeds to use, after underwriting discounts and offering expenses, of approximately \$66.4 million.

Between September 30, 2018 and November 8, 2018, we issued 518,135 shares of its common stock under the ATM Offering, resulting in net proceeds to us of approximately \$4.7 million.

We believe that our existing cash on hand as of September 30, 2018, together with the proceeds from our October 2018 Financings, will enable us to fund our planned operating expenses, debt service obligations and capital expenditure requirements through at least early 2020. 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:

- our ability to successfully commercialize and sell INVELTY in the United States;
- the cost and our ability to establish and maintain the commercial infrastructure and manufacturing capabilities required to support the commercialization of INVELTYS and any other products for which we receive marketing approval, including product sales, medical affairs, marketing, manufacturing and distribution;
- the progress, costs and results of our additional Phase 3 clinical trial for KPI-121 0.25%, STRIDE 3, and whether we determine, or are required to, conduct any additional clinical trials or other activities for KPI-121 0.25% ;
- the costs, timing and outcome of regulatory review of KPI-121 0.25%, including whether any additional trials or other activities are required for approval or label expansion;
- the progress, costs and results of any clinical activities for regulatory review of INVELTYS and KPI-121 0.25% outside of the United States;
- the costs and timing of process development and manufacturing scale-up activities associated with INVELTYS and KPI-121 0.25%;
- the costs of commercialization activities KPI-121 0.25% if we receive marketing approval and pre-commercialization costs KPI-121 0.25% incurred prior to receiving any such marketing approval, including

the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities;

- the amount of revenue received from commercial sales of INVELTYS and, assuming receipt of marketing approval, KPI-121 0.25% or any other product candidates;
- 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 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

The following is a summary of our significant contractual obligations as of September 30, 2018:

Contractual Obligations	Payments Due by Period For Years Ending September 30,				
	Total	Less Than 1 Year	More Than 1 Year and Less Than 3 Years	More Than 3 Years and Less Than 5 Years	More than 5 Years
	(in thousands)				
Short and long-term debt obligations(1)	\$ 20,000	\$ 3,333	\$ 13,333	\$ 3,334	\$ —
Interest on short and long-term debt obligations(2)	3,310	1,565	1,666	79	—
Operating lease obligation(3)	103	103	—	—	—
Other lease obligations(4)	30,982	3,058	7,302	7,748	12,874
Minimum license payments(5)	81	43	38	—	—
Total	<u>\$ 54,476</u>	<u>\$ 8,102</u>	<u>\$ 22,339</u>	<u>\$ 11,161</u>	<u>\$ 12,874</u>

(1) Short and long-term debt obligations relate to principal payments due on our 2014 Debt Facility as of September 30, 2018.



- (2) Interest payments due on our 2014 Debt Facility as of September 30, 2018.
- (3) Future minimum lease payments under our operating lease for our current corporate headquarters and lab space in Waltham, Massachusetts that expires on January 31, 2019 with an average rent of approximately \$34,000 per month.
- (4) Future minimum lease payments under our operating lease for our new corporate headquarters and lab space in Watertown, Massachusetts with an initial term of eight years and an average rent of approximately \$322,000 per month beginning November 1, 2018. Future minimum lease payments under our Waverley Oaks Lease Agreement that expires on March 14, 2019 with an average rent of approximately \$17,000 per month.
- (5) Consists of annual license payments associated with the JHU license agreement of \$38,000 per year prior to achievement of the first commercial sale in the United States, European Union or Japan and annual license payments associated with Massachusetts Eye and Ear Infirmary of \$5,000. As it relates to JHU, upon achievement of the first commercial sale in the United States, European Union or Japan, the minimum annual license payment will increase to approximately \$113,000 per year. This table does not include any other milestone or royalty payments which may become payable to third parties, as the amounts, timing and likelihood of such payments are not known with certainty.

#### **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 September 30, 2018. As of September 30, 2018, our exposure to the risk of changes in market interest rates related primarily to our borrowings under our 2014 Debt Facility, which were 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 \$100,000 related to our borrowings under our 2014 Debt Facility. The 2014 Debt Facility was repaid with proceeds of the Athyrium Credit Facility, which has a fixed interest of 9.875% per annum.

**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 September 30, 2018. 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 September 30, 2018, 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 that occurred during the period covered by this Quarterly Report on Form 10-Q 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.

## RISK FACTORS

### Risk Factors

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in our Annual Report on Form 10-K and this Quarterly Report on Form 10-Q, including our financial statements and the related notes appearing at the end of our Annual Report on Form 10-K and this Quarterly Report on Form 10-Q, before deciding to invest in our common stock. 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 \$41.5 million for the nine months ended September 30, 2018, \$42.2 million for the year ended December 31, 2017, \$33.2 million for the year ended December 31, 2016 and \$16.7 million for the year ended December 31, 2015. As of September 30, 2018, we had an accumulated deficit of \$175.9 million. We have not generated any revenues to date from product sales and have financed our operations primarily through our initial public offering, or IPO, private placements of preferred stock, convertible debt financings, borrowings under credit facilities, warrants and public common stock offerings and to a lesser extent, payments received in connection with various feasibility studies. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials and engaging in activities to prepare to commercially launch our first FDA approved product, INVELTYS™ (loteprednol etabonate ophthalmic suspension) 1% for the treatment of post-operative inflammation and pain following ocular surgery. Although we expect to generate revenue from sales of INVELTYS, there can be no assurance that we will generate any such revenue or as to the timing of any such revenue, and 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 commercially launch INVELTYS in the United States and engage in activities to prepare for commercialization of our product, 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 INVELTYS 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:

- commercially launch INVELTYS in the United States and seek regulatory approval for INVELTYS in the European Union;
- continue to grow our sales, marketing and distribution capabilities to commercialize INVELTYS and any product candidates for which we may submit for and obtain marketing approval;
- continue development of KPI-121 0.25%, including conducting our ongoing Phase 3 clinical trial, and/or seek marketing approvals for KPI-121 0.25% and any other product candidates;

- pursue the clinical development of KPI-121 for the treatment of other additional indications or for use in other patient populations or seek to broaden the label of INVELTYS or, if approved, KPI-121 0.25%;
- pursue the preclinical and clinical development of product candidates, including our topically applied MPP receptor Tyrosine Kinase Inhibitor program, or rTKI program, for use in the treatment of retinal diseases;
- expand our sales, marketing and distribution capabilities for our other product candidates, prior to or upon receiving marketing approval;
- continue to scale up our manufacturing processes and capabilities to support commercialization of INVELTYS, and any of our product candidates, including KPI-121 0.25%, for which we seek and/or obtain marketing approval;
- leverage our proprietary AMPPLIFY technology to advance additional potential 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 initiate and 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 from what we anticipate if:

- we elect to or are required by the FDA or non-U.S. regulatory agencies to perform clinical trials or studies in addition to those 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 or enforce our intellectual property rights.

Our ability to become and remain profitable depends on our ability to generate revenue. While we expect to begin to generate revenue from the sales of INVELTYS in 2019, there can be no assurance that we will generate any such revenue or as to the timing of any such revenue, and we may not achieve profitability for several years, if at all. Achieving and maintaining profitability will require us to be successful in a range of challenging activities, including:

- successfully completing the commercial launch of INVELTYS, including by further developing our sales force, marketing and distribution capabilities;
- obtaining marketing approval for KPI-121 0.25% or any other product candidates;
- manufacturing at commercial scale, marketing, selling and distributing INVELTYS or any product candidates for which we obtain marketing approval, including KPI-121 0.25%;

- maintaining regulatory and marketing approvals for INVELTYS and for any other product candidates for which we obtain approval;
- hiring and building a full commercial organization required for the marketing, selling and distributing for those products 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 INVELTYS and any other products we commercialize; and
- obtaining, maintaining and protecting our intellectual property rights.

INVELTYS is our only product that has been approved for sale and it has only been approved in the United States for the treatment of inflammation and pain following ocular surgery. Our ability to generate revenue from operations will depend, in part, on the timing and success of commercial sales of INVELTYS, which we plan to commercially launch in the United States in early 2019. However, the successful commercialization of INVELTYS in the United States is subject to many risks. We are currently undertaking our first commercial launch with INVELTYS, and we may not be able to do so successfully or on the currently expected timeline or at all. There are numerous examples of unsuccessful product launches and failures to meet expectations of market potential, including by pharmaceutical companies with more experience and resources than us. We do not anticipate our revenue from sales of INVELTYS alone will be sufficient for us to become profitable for several years, if at all.

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 INVELTYS and our product candidates, including KPI-121 0.25%, and engaging in activities to prepare for the commercial launch of INVELTYS. Although we are preparing for the launch and commercialization of INVELTYS, we have no history of commercializing products, are still in the process of preparing for the commercial launch of INVELTYS and, to date, have not generated revenue from the sale of INVELTYS. 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 are in the early stages of the process of transitioning 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 may 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 commercialize INVELTYS, 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 commercialize INVELTYS and advance our preclinical activities and clinical trials for our product candidates. In addition, our expenses will further increase as we conduct our third Phase 3 trial for KPI-121 0.25% and if we elect to or are required to conduct any further trials. 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.

We have begun to incur commercialization expenses related to INVELTYS, including beginning to build a commercial infrastructure, and increasing marketing, distribution and manufacturing capabilities. If we obtain marketing approval for KPI-121 0.25% or any other product candidate that we develop, we expect to incur significant additional commercialization expenses for such product candidate. 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:

- our ability to successfully commercialize and sell INVELTYS in the United States;
- the cost and our ability to establish and maintain the commercial infrastructure and manufacturing capabilities required to support the commercialization of INVELTYS, and any other products for which we receive marketing approval including product sales, medical affairs, marketing, manufacturing and distribution;
- the progress, costs and results of our additional Phase 3 trials for KPI-121 0.25%, STRIDE 3 (STRIDE—Short Term Relief In Dry Eye), and whether we determine, or are required, to conduct any additional clinical trials or other activities for KPI-121 0.25%;
- the costs, timing and outcome of regulatory review of KPI-121 0.25%, including whether any additional clinical trials or other activities are required for approval or label expansion;
- the progress, costs and results of any clinical activities for regulatory review of INVELTYS and KPI-121 0.25% outside of the United States;
- the costs and timing of process development and manufacturing scale-up activities associated with INVELTYS and KPI-121 0.25%;
- the costs of commercialization activities for KPI-121 0.25% if we receive marketing approval and pre-commercialization costs for KPI-121 0.25% incurred prior to receiving any such marketing approval, including the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities;
- the amount of revenue received from commercial sales of INVELTYS and, assuming receipt of marketing approval, KPI-121 0.25% or any other product candidates;
- 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 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.

We believe that our existing cash on hand as of September 30, 2018, together with the proceeds from our October 2018 Financings, will enable us to fund our planned operating expenses, debt service obligations and capital expenditure requirements through at least early 2020. 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, seeking market approvals and commercializing products are time-consuming, expensive and uncertain processes that take years to complete. Although we expect to commercially launch INVELTYS in early 2019, we do not anticipate that our revenue from product sales of INVELTYS will be sufficient for us to become profitable for several years, if at all. Additionally, in October 2018 we submitted a new drug application, or an NDA, to the FDA for KPI-121 0.25%, and the FDA may decide not to accept the NDA for filing, or, if accepted, we may not receive approval to commercialize KPI-121 0.25%. Based upon the recommendation of the FDA, we also initiated an additional Phase 3 clinical trial, STRIDE 3, in the third quarter of 2018 evaluating KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. We may determine to conduct additional Phase 3 trials for KPI-121 0.25% or to potentially expand the label of KPI-121 0.25% if we receive marketing approval for a narrower indication than we are targeting. In addition, we may never generate the necessary data or results required to obtain regulatory approval of KPI-121 0.25% or of any other product candidates. 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 INVELTYS or any other product candidates for which we obtain approval.

***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, royalty agreements, 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. The lenders under our Athyrium Credit Facility are currently entitled to exercise warrants for up to 184,660 shares of common stock. If we draw down on the remaining \$35.0 million of potentially available borrowings under our Athyrium Credit Facility, the lenders thereunder will be entitled to exercise warrants for up to an additional 86,175 shares of our common stock. Your ownership interest will be diluted to the extent any such warrants are exercised. Debt financing and preferred equity financing, if available, may involve agreements that include pledging of assets as collateral, 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 Athyrium Credit Facility may limit our ability to obtain additional debt financing. Under our Athyrium Credit Facility, we are also restricted from paying dividends on our common stock without the lenders' consent.

If we raise additional funds through collaborations, strategic alliances, licensing arrangements, royalty agreements, 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 current 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 substantial indebtedness may limit cash flow available to invest in the ongoing needs of our business.***

We have a significant amount of indebtedness. As of September 30, 2018, we had \$20.0 million of outstanding borrowings under our venture debt facility, or the 2014 Debt Facility. In October 2018 we entered into the Athyrium Credit Facility and repaid the 2014 Debt Facility in full. We currently have \$75.0 million of outstanding borrowings under the Athyrium Credit Facility and have the ability to draw an additional \$35.0 million prior to June 30, 2020 upon either FDA approval of KPI-121 0.25% for a dry eye indication or reaching net product revenues of INVELTYS of at least \$25.0 million for the two fiscal quarter period then most recently ended. Amounts outstanding under the Athyrium Credit Facility bear interest at a rate of 9.875% per annum. The Athyrium Credit Facility provides for quarterly interest-only payments for 48 months. Beginning on September 30, 2022, we will be required to make principal and interest payments through October 1, 2024. Our obligations under the Athyrium Credit Facility are secured by substantially all of our assets. We could in the future incur additional indebtedness beyond our borrowings under our Athyrium Credit 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 anticipated product revenue from INVELTYS. 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 and funds from external sources may not be available on acceptable terms, if at all. In addition, a failure to comply with the covenants under our Athyrium 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 our Athyrium Credit 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 INVELTYS and our lead product candidate, KPI-121 0.25%. If we are unable to successfully commercialize INVELTYS or obtain marketing approval for KPI-121 0.25%, or experience significant delays in doing so, or if, after obtaining marketing approval for KPI-121 0.25%, we fail to successfully commercialize KPI-121 0.25%, our business will be materially harmed.***

We have devoted a significant portion of our financial resources and business efforts to the development of INVELTYS 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 commercialize INVELTYS and to successfully obtain marketing approval for and commercialize KPI-121 0.25%. In January 2018, we announced that we had completed two Phase 3 clinical trials evaluating KPI-121 0.25%, STRIDE 1 and STRIDE 2, evaluating the safety and efficacy of KPI-121 0.25% versus placebo in patients with dry eye disease. In STRIDE 1, statistical significance was achieved for both primary endpoints. However, in STRIDE 2 we did not achieve statistical significance for the primary symptom endpoint of ocular discomfort severity. In October 2018, we



submitted an NDA to the FDA for KPI-121 0.25%. The FDA may decide not to accept the NDA for filing, or, if accepted, we may not receive approval to commercialize KPI-121 0.25%. Based upon the recommendation of the FDA, we initiated an additional Phase 3 clinical trial, STRIDE 3, in the third quarter of 2018 evaluating KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. We may also determine to conduct additional Phase 3 trials for KPI-121 0.25% or to potentially expand the label of KPI-121 0.25% if we receive marketing approval for a narrower indication than we are targeting. We cannot accurately predict when or if KPI-121 0.25% will receive marketing approval. Our ability to generate product revenues will depend on our successful commercialization of INVELTYS and our obtaining marketing approval for, and successfully commercializing, KPI-121 0.25%.

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

- successful commercialization of INVELTYS in the United States, including establishing sales, marketing and distribution capabilities for INVELTYS;
- successfully developing and applying for and receiving marketing approvals from applicable regulatory authorities for KPI-121 0.25% and other 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 AMPPLIFY technology to continue to develop our product candidates;
- establishing sales, marketing and distribution capabilities for 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 INVELTYS and, if and when approved, KPI-121 0.25% and our other product candidates 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 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 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 INVELTYS or our product candidates, including KPI-121 0.25%, which would materially harm our business.

***If clinical trials of 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, 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 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 INVELTYS.

In January 2018, we announced that we had completed two Phase 3 clinical trials evaluating KPI-121 0.25%, STRIDE 1 and STRIDE 2, evaluating the safety and efficacy of KPI-121 0.25% versus placebo in patients with dry eye disease. In STRIDE 1, statistical significance was achieved for both primary endpoints. However, in STRIDE 2 we did not achieve statistical significance for the primary symptom endpoint of ocular discomfort severity. In October 2018, we submitted an NDA to the FDA for KPI-121 0.25%. The FDA may decide not to accept the NDA for filing, or, if accepted, we may not receive approval to commercialize KPI-121 0.25%. Based upon the recommendation of the FDA, we initiated an additional Phase 3 clinical trial, STRIDE 3, in the third quarter of 2018 evaluating KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. We may also determine to conduct additional Phase 3 trials for KPI-121 0.25% or to potentially expand the label of KPI-121 0.25% if we receive marketing approval for a narrower indication than we are targeting. If the FDA determines that we have not sufficiently demonstrated efficacy for both signs and symptoms of dry eye, we may need to conduct additional clinical trials to support approval of KPI-121 0.25% for temporary relief of signs and symptoms of dry eye disease. If we conduct additional clinical trials of KPI-121 0.25%, our expenses will significantly increase and could delay or halt our ability to obtain marketing approval. 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 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 additional analyses on a post-hoc basis on the results of our completed Phase 2 clinical trial for KPI-121 0.25% for the purpose of designing our STRIDE 1 and STRIDE 2 clinical trials for KPI-121 0.25%. Following completion of these Phase 3 trials we conducted additional analyses on a post-hoc basis of the data from both these Phase 3 trials and the Phase 2 clinical trial to support our NDA submission and to inform the design of our STRIDE 3 clinical trial and our development plan. We may also conduct additional 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, may not be predictive of success in any future clinical trials and are given less weight by regulatory authorities than pre-specified analyses. If we are required to conduct additional clinical trials or other testing of KPI-121 0.25% 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 0.25% or any other product candidates that we may develop, including:

- clinical trials of our product candidates, including STRIDE 3, may produce negative or inconclusive results, and we may decide, or regulators may recommend or 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 may recommend or 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.

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 product candidates 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 serious adverse or unacceptable side effects are identified during the development or commercialization of our product or product candidates, we may need to abandon or limit our development of such product or product candidates.***

If INVELTYS or any of our product candidates, including KPI-121 0.25%, are associated with serious adverse events or undesirable side effects in clinical trials or following approval and/or commercialization, or if our product or product candidates have characteristics that are unexpected, we may need to abandon their development or limit development or marketing to narrower 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 INVELTYS and KPI-121 0.25% have been eye pain, instillation site pain, blurred vision 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. 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. Compounds that initially show promise in clinical or earlier stage testing for treating ophthalmic disease or other diseases may later be found to cause side effects that prevent further development and commercialization of the compound. In addition, adverse events which had initially been considered unrelated to the study treatment may later, even following approval and/or commercialization, be found to be caused by the study treatment. Moreover, incorrect or improper use of our product or 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 or our product candidates will be used correctly, and if used incorrectly, such misuse could hamper commercial adoption or market acceptance of our product or product candidates, if approved, at the rate we currently expect.

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

We are currently directing all of our development efforts towards applying our AMPPLIFY 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 AMPPLIFY 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 AMPPLIFY technology, 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 INVELTYS and our Product Candidates**

***INVELTYS or any of our product candidates that receives marketing approval, including KPI-121 0.25%, 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.***

INVELTYS or any other product candidate that we develop that receives marketing approval, including KPI-121 0.25%, may 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. Our current estimates of potential future revenue from sales of INVELTYS are based, in part, on market research data we have commissioned. For example, based on a market survey we commissioned of 100 ophthalmologists, we believe INVELTYS will offer advantages over existing post-surgical treatment options due to its twice-daily dosing, two-week course of treatment and safety data, including low incidence of reported IOP spikes, and efficacy data from our clinical trials. In this market survey, a majority of surveyed ophthalmologists indicated they were likely to prescribe INVELTYS. However, doctors may continue to rely on ocular steroids other than INVELTYS and other treatments rather than INVELTYS. 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<sup>®</sup>, Xiidra<sup>®</sup>, Cequa<sup>™</sup> and off-label use of corticosteroids. Our current expectations regarding market potential for KPI-121 0.25% are based, in part, on market research data we have commissioned. For example, based on a market survey we commissioned of 503 dry eye disease patients, which we refer to as our patient survey, 90% of surveyed patients reported experiencing short-term flares, with the majority experiencing multi-day episodes, and the most common reason given by patients for discontinuing the two leading branded dry eye treatments were insufficient efficacy and side effects. However, it is possible that doctors may continue to rely on other existing 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.

Our assessment of the potential market opportunity for INVELTYS and our product candidates, including KPI-121 0.25%, 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. The

results from our patient 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 INVELTYS or any of our product candidates, including KPI-121 0.25%, 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 INVELTYS or any of our product candidates for which we obtain marketing approval, including KPI-121 0.25%, do not achieve adequate levels 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 INVELTYS or any product candidates for which we obtain marketing approval, will depend on a number of factors, including:

- the efficacy and potential advantages of our product or 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.

***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 INVELTYS or any of our product candidates that we may develop if and when they are approved.***

We have only recently begun to establish a sales or marketing infrastructure for our commercial launch of INVELTYS, our first product, and have no prior 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.

We are building a specialty sales marketing and distribution infrastructure to market INVELTYS and plan to expand that infrastructure to market any of our product candidates that we develop in the United States, if and when such product candidates are approved. We have begun to build our commercial infrastructure for INVELTYS in the United States, including the hiring of a sales force. 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 INVELTYS or any of our product candidates for which we establish a commercial infrastructure is delayed or does not occur for any reason, including if we do not receive marketing approval for KPI-121 0.25% or our other product candidates on the timeframe we expect, 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 INVELTYS or any product candidates for which we receive marketing approval, including KPI-121 0.25%, 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, we plan to seek marketing approval and explore commercialization of KPI-121 0.25% in certain markets outside the United States, including the European Union, 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 the 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 INVELTYS or any of our product candidates, including KPI-121 0.25%, or we 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 INVELTYS or any of our product candidates for which we obtain marketing approval, including KPI-121 0.25%, 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 INVELTYS, or any of our product candidates for which we obtain marketing approval, including KPI-121 0.25%.

***We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. Our competitors include major pharmaceutical companies with significantly greater financial resources. INVELTYS, and our product candidates, including KPI-121 0.25%, if approved, will 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 INVELTYS and our product candidates, including KPI-121 0.25%, 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 and 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 or 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.

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<sup>®</sup> products and Durezol<sup>®</sup>. In addition, EyePoint Pharmaceuticals, Inc. received FDA approval in February 2018 for DEXYCU<sup>™</sup>, which is formulated as a drug delivery system, to be injected into the eye following cataract surgery for the treatment of inflammation. 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: Bausch Health Companies Inc. (formerly Valeant Pharmaceuticals International, Inc.) is developing a loteprednol etabonate gel, formulated for topical delivery and has filed an NDA with the FDA; and Ocular Therapeutix, Inc. is developing Dextenza<sup>™</sup>, a punctal plug and has filed an NDA for the treatment of ocular pain following ophthalmic surgery.

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; devices such as the TrueTear Intranasal Tear Neurostimulator, which received marketing authorization from the FDA in April 2017; 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, Xiidra and Cequa, which are the only prescription pharmaceutical products that are approved in the United States for use in patients with dry eye disease. Restasis, and the recently FDA approved Cequa, are 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 or 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 Oyster Point's OC-01 and OC-02, ReGenTree's RGN-259, Aldeyra Therapeutics' reproxalap ophthalmic solution, Aurinia Pharmaceuticals' voclosporin ophthalmic solution and Surface Pharmaceutical's SURF-100 and SURF-200.

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 which we may compete against 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. Given that we are developing products that utilize a known FDA-approved corticosteroid, our product and our product candidates, if approved, may face competition from generic and branded versions of existing drugs based on corticosteroids that are administered in a different manner.

***If our contracted manufacturing facilities experience production issues for any reason, we may be unable to manufacture commercial quantities of our product or 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 INVELTYS and KPI-121 0.25%. Specifically, we will rely on the following: Catalent Pharma Solutions, LLC, or Catalent, to manufacture and supply to us a minimum amount of INVELTYS 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 any other product candidates and commercial supplies of any other 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 or 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 our product or 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 or 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 products or 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, our product or our product candidates if 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 INVELTYS or any product candidate that we may develop, including KPI-121 0.25%, 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 INVELTYS or any of our product candidates, including KPI-121 0.25%, 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 INVELTYS or any product candidate 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, INVELTYS or 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 INVELTYS or any 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 INVELTYS or our product candidates, including KPI-121 0.25%, even if such product candidates 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 INVELTYS or 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 INVELTYS and any other products that we may 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 as we commercialize INVELTYS or any other products that we may 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 INVELTYS and any other products that we may 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 successfully commercialize INVELTYS and any other products that we may 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 commence or expand our clinical trials. We will need to further increase our insurance coverage as we commercialize INVELTYS and if we commence commercialization of KPI-121 0.25% or any other 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 rely on third parties, such as clinical research organizations, or CROs, clinical data management organizations, medical institutions and clinical investigators, in conducting our clinical trials, including STRIDE 3, and expect to continue to rely on such parties 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 could 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 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 INVELTYS 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 commercial quantities of INVELTYS and clinical or commercial quantities of KPI-121 0.25% or any other product candidates. We will rely on Catalent to manufacture and supply to us a minimum amount of INVELTYS 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 INVELTYS or any other product and KPI-121 0.25% and any other product candidate 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 active pharmaceutical ingredient, or 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 rounds of guidance on this point. In connection with any application for approval to market 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:

- INVELTYS, 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 INVELTYS or 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 INVELTYS or any of our product candidates, including KPI-121 0.25%, 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 or 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 United States. 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 of our product candidates and the commercialization of our products or the potential commercialization of our 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 or 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 the commercialization of a product or a product candidate 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, products 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, products and product candidates similar or identical to ours, and our ability to successfully commercialize our technology, products 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, products 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, products 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, products 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, products or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies, products and product candidates. 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, products 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, products or product candidates 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 AMPPLIFY 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, products or product candidates, or limit the duration of the patent protection of our technology, products 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 products or 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. We do not expect the U.S. patents covering INVELTYS to be eligible for patent term extension due to this limitation. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates. Nevertheless, we may not be able to seek or 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 products or 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 may 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 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 INVELTYS and our product candidates, including KPI-121 0.25%, 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, product candidates 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 products or product candidates and their uses. Thus, we do not know with certainty that INVELTYS or any of our product candidates, including KPI-121 0.25%, 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, product candidates 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, products or product candidates. 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 products or 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.

***INVELTYS, KPI-121 0.25% and certain aspects of our AMPPLIFY 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 INVELTYS and our product candidates, including KPI-121 0.25%, and some aspects of our AMPPLIFY technology. While we control patent prosecution of the licensed patent families relating to INVELTYS and KPI-121 0.25%, for the remainder of the patent families subject to our exclusive license agreement with JHU that relate to our AMPPLIFY 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 products or 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 financial condition, results of operations 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 AMPPLIFY 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 AMPPLIFY 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 INVELTYS and our product candidates, including KPI-121 0.25%, 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 or product candidate that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could diminish the value of our products or product candidates. 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, our financial condition, our results of operations 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 products or 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, our products 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 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.

On August 22, 2018, we received approval from the FDA to market INVELTYS in the United States, which is our first and only product candidate to receive marketing approval. We have not received approval to market KPI-121 0.25% or any other product candidate from regulatory authorities in any jurisdiction. In October 2018, we submitted an NDA to the FDA for KPI-121 0.25%. There can be no assurance as to whether the NDA will be accepted for filing by the FDA. Based upon the recommendation of the FDA, we also initiated an additional Phase 3 clinical trial, STRIDE 3 (STRIDE—Short Term Relief In Dry Eye), in the third quarter of 2018 evaluating KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. We may determine to conduct additional Phase 3 trials for KPI-121 0.25% or to potentially expand the label of KPI-121 0.25% if we receive marketing approval for a narrower indication than we are targeting. In addition, we may never generate the necessary data or results required to obtain regulatory approval of KPI-121 0.25% or any other products with the market potential sufficient to enable us to achieve profitability. We have only limited experience in submitting and supporting the applications necessary to gain marketing approvals and have relied on, and expect to continue 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 any 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 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.

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

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, or FDCA. 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 0.25% by potentially decreasing the amount of preclinical and clinical data that we would need to generate in order to obtain FDA approval.

We are seeking FDA approval of KPI-121 0.25% through the Section 505(b)(2) regulatory pathway. The FDA previously approved INVELTYS through the Section 505(b)(2) regulatory pathway. The FDA may refuse to accept for filing an application if it does not, on its face, contain information required under section 505(b)(2) of the act and the relevant implementing regulations. The FDA has also indicated that it will not file a 505(b)(2) application for a product that is a duplicate of a drug that is eligible for approval as a generic drug under section 505(j) of the FDCA. We do not believe that KPI-121 0.25% is a duplicate of a drug product that is eligible for approval as a generic drug.

If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional non-clinical and 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 0.25%, and complications and risks associated with approval of 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 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 0.25%.

Even if KPI-121 0.25% is approved under Section 505(b)(2), its 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.

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

In order to market and sell INVELTYS or our product candidates, including KPI-121 0.25%, 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 prescription medication. Our

Phase 3 clinical trials of KPI-121 0.25% or any other product candidate 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, which could significantly and materially harm our business.

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 INVELTYS or 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 INVELTYS or 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, we are limited to promoting INVELTYS in accordance with its approved label and the accompanying label may limit the approved use of any other product for which we obtain marketing approval, which could limit sales of such 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 FDCA relating to the promotion of prescription drugs or 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 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.

***Under the CURES Act and the Trump Administration's regulatory reform initiatives, the FDA's policies, regulations and guidance may be revised or revoked and that could prevent, limit or delay regulatory approval of our product candidates, which would impact our ability to generate revenue.***

In December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. An under-staffed FDA could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within the Office of Management and Budget on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. In addition, on February 24, 2017, President Trump issued an executive order directing each affected agency to designate an agency official as a "Regulatory Reform Officer" and establish a "Regulatory Reform Task Force" to implement the two-for-one provisions and other previously issued executive orders relating to the review of federal regulations, however it is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

***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 INVELTYYS and 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 INVELTYYS and 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 do or 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 INVELTYS or any product candidate, including KPI-121 0.25%, 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. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025 unless additional congressional action is taken, and the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of 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 INVELTYS and for any of our product candidates for which we may obtain regulatory approval or the frequency with which INVELTYS or any product candidate is prescribed or used. Further, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

We expect that these healthcare reforms, 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 INVELTYS or any other 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 our products 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.

Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. In May 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act of 2017. Thereafter, the Senate Republicans introduced and then updated a bill to replace the ACA known as the Better Care Reconciliation Act of 2017. The Senate Republicans also introduced legislation to repeal the ACA without companion legislation to replace it, and a "skinny" version of the Better Care Reconciliation Act of 2017. In addition, the Senate considered proposed healthcare reform legislation known as the Graham-Cassidy bill. None of these measures was passed by the U.S. Senate.



The Trump Administration has also taken executive actions to undermine or delay implementation of the ACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In October 2017, the President signed a second Executive Order allowing for the use of association health plans and short-term health insurance, which may provide fewer health benefits than the plans sold through the ACA exchanges. At the same time, the Trump Administration announced that it will discontinue the payment of cost-sharing reduction, or CSR, payments to insurance companies until Congress approves the appropriation of funds for such CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. A bipartisan bill to appropriate funds for CSR payments was introduced in the Senate, but the future of that bill is uncertain.

More recently, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the “individual mandate.” The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, will become effective in 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Further, each chamber of the Congress has put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures has been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA. The Congress will likely consider other legislation to replace elements of the ACA, during the next Congressional session.

We will continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business. It is possible that 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. While the timing and scope of any potential future legislation to repeal and replace ACA provisions is highly uncertain in many respects, it is also possible that some of the ACA provisions that generally are not favorable for the research-based pharmaceutical industry could also be repealed along with ACA coverage expansion provisions. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from INVELTYS or 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.

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 Trump 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. Finally, legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approval of INVELTYS or the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us and any future collaborators to more stringent product labeling and post-marketing testing and other requirements with respect to INVELTYS or any other product candidate for which we obtain approval.

***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.

***The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.***

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely), one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions) received as dividends by certain U.S. corporations, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

***We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.***

As of December 31, 2017, we had federal net operating loss carryforwards of \$120.9 million, which expire at various dates beginning in 2030 through 2037 and state net operating loss carryforwards of \$104.0 million, which expire at various dates beginning in 2030 through 2037. These net operating loss carryforwards could expire unused and be unavailable to offset our future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain how various states will respond to the newly enacted federal tax law. In addition, under Section 382 of the U.S. Internal Revenue Code of 1986, as amended, the amount of benefits from our NOL carryforwards may be impaired or limited if we incur a cumulative ownership change of more than 50%, as interpreted by the U.S. Internal Revenue Service, over a three-year period. We may have experienced ownership changes in the past and may experience changes in the future as a result of this offering and subsequent shifts in our stock ownership, some of which are outside our control. As a result, our use of federal NOL carryforward could be limited. State NOL carryforwards may be similarly limited. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and increased liabilities could adversely affect our business, results of operations, financial position and cash flows. If our ability to use our historical net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

## **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 President and Chief Executive Officer, Todd Bazemore, our Chief Operating Officer, Mary Reumuth, our Chief Financial 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 have expanded and expect to continue to expand our development, regulatory, commercial and manufacturing capabilities and are continuing to implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

We have experienced and expect to continue experiencing 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 current and 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 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.

### ***Our internal computer systems, or those of our contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.***

Our internal computer systems and those of our current and any future contractors or consultants, including any collaborator, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur

liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

### **Risks Related to Our Common Stock**

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

As of September 30, 2018, our executive officers and directors and principal stockholders in the aggregate, own shares representing approximately 61.3% 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 are 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 are 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 your ability to sell your 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. As a result of this volatility, you may not be able to sell your common stock at or above the public offering price. The market price for our common stock may be influenced by many factors, including:

- our success in launching and commercializing INVELTYS;
- results of clinical trials of any of our product candidates, including KPI-121 0.25%;
- results of clinical trials of product candidates of our competitors;
- our success in commercializing KPI-121 0.25% and other product candidates, if and when approved;
- 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 the commercial launch of INVELTYS and clinical development programs for any of our product candidates, including KPI-121 0.25%;
- the results of our efforts to discover, develop, acquire or in-license additional products, product candidates or technologies for the treatment of 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 fail to successfully launch and commercialize INVELTYS, or if we cannot obtain regulatory approvals for or otherwise fail to commercialize KPI-121 0.25% or our 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.

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

Sales of a substantial number of shares of our common stock in the public market, 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 November 6, 2018, we had outstanding 33,795,656 shares of common stock. Of these shares, 7,941,975 shares are subject to lock-up agreements entered into in connection with our recent common offering but may be sold beginning on December 2, 2018. J.P. Morgan Securities LLC, Merrill Lynch, Pierce, Fenner & Smith Incorporated and Jefferies LLC, in their sole discretion, may release the common stock and other securities subject to these lock-up agreements in whole or in part at any time with or without notice. Any of our remaining shares of common stock may be freely sold in the public market at any time to the extent permitted by Rules 144 and 701 under the Securities Act of 1933, as amended, or the Securities Act, or to the extent such shares have already been registered under the Securities Act and are held by non-affiliates of ours. Persons who were our stockholders prior to our initial public offering continue to hold a substantial number of shares of our common stock. If such persons sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. Moreover, holders of a substantial number of shares of our common stock, including shares of our common stock issuable upon exercise of outstanding warrants and options, have rights, 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. We have filed or intend to file registration statements registering all shares of common stock that we may issue under our equity compensation plans or pursuant to equity awards made to newly hired employees outside of equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

***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 until December 31, 2022, although if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th 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. 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;
- 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.

We cannot predict whether investors will 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 is now 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 devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and will make some activities more time-consuming and costly.

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.

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 your 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 Athyrium Credit 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 your 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**

On September 17, 2018, we granted stock options to seven new employees to purchase an aggregate of 69,500 shares of our common stock at an exercise price of \$10.68 per share, the closing price common stock on September 17, 2018. These options were inducement grants made outside of our 2017 Equity Incentive Plan in accordance with NASDAQ Listing Rules 5635(c)(4) and Section 4(a)(2) of the Securities Act of 1933, as amended. The options have a ten-year term and vest over four years, with 25% of the shares underlying each option award vesting on the one-year anniversary of the applicable employee's new hire date and the remaining 75% of the shares underlying each award vesting monthly thereafter for three-years. Vesting of each option is such to such employee's continued service with the our company through the applicable vesting dates. We intend to file a registration statement on a Form S-8 to register the shares of common stock underlying this option prior to the time at which this option becomes exercisable.

Other than as stated above, we did not sell any shares of our common stock, shares of our preferred stock or warrants to purchase shares of our stock, or restricted stock awards, during the period covered by this Quarterly Report on Form 10-Q that were not registered under the Securities Act of 1933, as amended, or the Securities Act, and that have not otherwise been described in a Current Report on Form 8-K.

### **Use of Proceeds from our Public Offering of Common Stock**

On July 25, 2017, we completed our IPO on Form S-1, as amended (File No. 333-218936), which was declared effective by the SEC on July 19, 2017.

In our IPO, we issued and sold 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 \$94.0 million after deducting underwriting discounts and commission and offering costs.

As of September 30, 2018, we had used approximately \$55.8 million of the net offering proceeds, primarily to fund KPI-121 development costs, general corporate purposes and to build a commercial organization. There has been no material change in the planned use of proceeds from our IPO from that described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on July 20, 2017.

### **Repurchase of Shares or of Company Equity Securities**

None.



**Item 6. Exhibits**

**Exhibit Index**

- EXHIBIT 10.1 - [Form of Inducement Grant Stock Option Agreement.](#)
  - EXHIBIT 10.2 - [Sales Agreement, dated August 9, 2018, by and between the Registrant and Jefferies LLC \(incorporated herein by reference to Exhibit 1.2 to the Registrant's Registration Statement on Form S-3 \(File No. 333-226748\) filed with the SEC on August 9, 2018\).](#)
  
  - 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.
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**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: November 8, 2018

By: /s/ Mark Iwicki  
Mark Iwicki  
Chairman of the Board, Chief Executive Officer and  
President (Principal Executive Officer)

Dated: November 8, 2018

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

**KALA PHARMACEUTICALS, INC.**  
**Non-qualified Stock Option Agreement**

1. Grant of Option.

This agreement evidences the grant by Kala Pharmaceuticals, Inc., a Delaware corporation (the “Company”), on [\_\_\_\_\_] (the “Grant Date”) to [\_\_\_\_\_] (the “Participant”), an employee of the Company, of an option to purchase, in whole or in part, on the terms provided herein, a total of [\_\_\_\_\_] shares (the “Shares”) of common stock, \$0.001 par value per share, of the Company (“Common Stock”) at \$[\_\_\_\_\_] per Share. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on [\_\_\_\_\_]’<sup>1</sup> (the “Final Exercise Date”).

The option evidenced by this agreement was granted to the Participant pursuant to the inducement grant exception under Nasdaq Listing Rule 5635(c)(4), and not pursuant to the Company’s 2017 Equity Incentive Plan (the “Plan”) or any equity incentive plan of the Company, as an inducement that is material to the Participant’s employment with the Company.

It is intended that the option evidenced by this agreement shall not be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the “Code”). Except as otherwise indicated by the context, the term “Participant”, as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

2. Vesting Schedule.

Except as otherwise provided herein, this option will become exercisable (“vest”) as to 25% of the original number of Shares on one-year anniversary of the Vesting Start Date and as to an additional 2.0833% of the original number of Shares at the end of each successive month following the one-year anniversary of the Vesting Start Date until the fourth anniversary of the Vesting Start Date. For purposes of this Agreement, the Vesting Start Date is [\_\_\_\_\_].

The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Final Exercise Date or the termination of this option under Section 3 hereof.

3. Exercise of Option.

(a) Form of Exercise. Each election to exercise this option shall be in writing, in the form of the Stock Option Exercise Notice attached as Annex A, signed by the Participant, and received by the Company at its principal office, accompanied by this agreement or in such

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<sup>1</sup> Termination date to be 10 years minus 1 day from Grant Date

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other form (which may be electronic) as is approved by the Company, and payment in full as follows:

- (1) in cash or by check, payable to the order of the Company;
- (2) by (i) delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding or (ii) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;
- (3) to the extent approved by the Board of Directors of the Company (the "Board"), by delivery (either by actual delivery or attestation) of shares of Common Stock owned by the Participant valued at their fair market value (valued in the manner determined by (or in a manner approved by) the Board) (the "Fair Market Value"), provided (i) such method of payment is then permitted under applicable law, (ii) such Common Stock, if acquired directly from the Company, was owned by the Participant for such minimum period of time, if any, as may be established by the Board and (iii) such Common Stock is not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;
- (4) to the extent approved by the Board in its sole discretion, by delivery of a notice of "net exercise" to the Company, as a result of which the Participant would receive (i) the number of shares underlying the portion of this option being exercised, less (ii) such number of shares as is equal to (A) the aggregate exercise price for the portion of this option being exercised divided by (B) the Fair Market Value on the date of exercise;
- (5) to the extent permitted by applicable law and approved by the Board, by payment of such other lawful consideration as the Board may determine; or
- (6) by any combination of the above permitted forms of payment.

The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share. Share of Common Stock subject to this option will be delivered by the Company as soon as practicable following exercise, subject to the terms and conditions of this Agreement.

(b) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he exercises this option, is, and has been at all times since the Grant Date, an employee, director or officer of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive option grants under the Plan (an "Eligible Participant").

(c) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (d) and (e) below, the right to exercise this option shall terminate three months after such cessation (but in no event after the Final Exercise Date), provided that this option shall be exercisable only to the extent

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that the Participant was entitled to exercise this option on the date of such cessation. Notwithstanding the foregoing, if the Participant, prior to the Final Exercise Date, violates the non-competition, non-solicitation or confidentiality provisions of any employment contract, restrictive covenant agreement (including, without limitation, any confidentiality or non-competition agreement) or other agreement between the Participant and the Company, the right to exercise this option, if and to the extent permitted by applicable law, shall terminate immediately upon such violation.

(d) Exercise Period Upon Death or Disability. If the Participant dies or becomes disabled (within the meaning of Section 22(e)(3) of the Code) prior to the Final Exercise Date while he is an Eligible Participant and the Company has not terminated such relationship for “cause” as specified in paragraph (e) below, this option shall be exercisable, within the period of one year following the date of death or disability of the Participant, by the Participant (or in the case of death by an authorized transferee), provided that this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his death or disability, and further provided that this option shall not be exercisable after the Final Exercise Date.

(e) Termination for Cause. If prior to the Final Exercise Date, the Participant’s employment or other relationship with the Company is terminated by the Company for Cause (as defined below), the right to exercise this option shall terminate immediately upon the effective date of such termination of employment or other relationship. If, prior to the Final Exercise Date, the Participant is given notice by the Company of the termination of his employment by the Company for Cause, and the effective date of such employment termination is subsequent to the date of delivery of such notice, the right to exercise this option shall be suspended from the time of the delivery of such notice until the earlier of (i) such time as it is determined or otherwise agreed that the Participant’s employment shall not be terminated for Cause as provided in such notice or (ii) the effective date of such termination of employment (in which case the right to exercise this option shall, pursuant to the preceding sentence, terminate upon the effective date of such termination of employment). If the Participant is subject to an individual employment agreement with the Company (other than any restrictive covenant or confidentiality agreement) or eligible to participate in a Company severance plan or arrangement, in any case which agreement, plan or arrangement contains a definition of “cause” for termination of employment or other relationship with us, “Cause” shall have the meaning ascribed to such term in such agreement, plan or arrangement. Otherwise, “Cause” shall mean willful misconduct by the Participant or willful failure by the Participant to perform his or her responsibilities to the Company (including, without limitation, breach by the Participant of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant’s employment shall be considered to have been terminated for Cause if the Company determines, within 30 days after the Participant’s resignation, that termination for Cause was warranted.

4. Withholding. No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld in respect of this option. The Participant must satisfy all applicable federal, state, and local or other income and employment tax withholding obligations before the Company will deliver stock certificates or otherwise recognize ownership of Common Stock under this option. The

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Company may elect to satisfy the withholding obligations through additional withholding on salary or wages. If the Company elects not to or cannot withhold from other compensation, the Participant must pay the Company the full amount, if any, required for withholding or have a broker tender to the Company cash equal to the withholding obligations. Payment of withholding obligations is due before the Company will issue any shares on exercise of this option or at the same time as payment of the exercise price, unless the Company determines otherwise. If approved by the Board, a Participant may satisfy the tax obligations in whole or in part by delivery (either by actual delivery or attestation) of shares of Common Stock, including shares retained from this option, valued at their Fair Market Value; provided, however, except as otherwise provided by the Board, that the total tax withholding where stock is being used to satisfy such tax obligations cannot exceed the Company's minimum statutory withholding obligations (based on minimum statutory withholding rates for federal and state tax purposes, including payroll taxes, that are applicable to such supplemental taxable income), except that, to the extent that the Company is able to retain shares of Common Stock having a Fair Market Value that exceeds the statutory minimum applicable withholding tax without financial accounting implications or the Company is withholding in a jurisdiction that does not have a statutory minimum withholding tax, the Company may retain such number of shares of Common Stock (up to the number of shares having a Fair Market Value equal to the maximum individual statutory rate of tax) as the Company shall determine in its sole discretion to satisfy the tax liability associated with this option. Shares used to satisfy tax withholding requirements cannot be subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements.

5. Transfer Restrictions. This option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution or pursuant to a qualified domestic relations order, and, during the lifetime of the Participant, this option shall be exercisable only by the Participant; provided, however, that, the Board may permit the gratuitous transfer of this option by the Participant to or for the benefit of any immediate family member, family trust or other entity established for the benefit of the Participant and/or an immediate family member thereof if the Company would be eligible to use a Form S-8 under the Securities Act of 1933, as amended, for the registration of the sale of the Common Stock subject to this option to such proposed transferee; provided further, that the Company shall not be required to recognize any such permitted transfer until such time as such permitted transferee shall, as a condition to such transfer, deliver to the Company a written instrument in form and substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms and conditions of this option. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees. For the avoidance of doubt, nothing contained in this Section 5 shall be deemed to restrict a transfer to the Company.

6. Adjustments for Changes in Common Stock and Certain Other Events.

(a) Changes in Capitalization. In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of Common Stock other than an ordinary cash dividend, the number and class of securities and exercise price per share of this option shall be equitably adjusted by the Company in the manner determined by the Board. Without limiting the generality of the foregoing, in the event the

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Company effects a split of the Common Stock by means of a stock dividend and the exercise price of and the number of shares subject to this option are adjusted as of the date of the distribution of the dividend (rather than as of the record date for such dividend), then the Participant, if he exercises this option between the record date and the distribution date for such stock dividend shall be entitled to receive, on the distribution date, the stock dividend with respect to the shares of Common Stock acquired upon exercise of this option, notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such stock dividend.

(b) Reorganization Events. A “Reorganization Event” shall mean: (a) any merger or consolidation of the Company with or into another entity as a result of which all of the Common Stock of the Company is converted into or exchanged for the right to receive cash, securities or other property or is cancelled, (b) any transfer or disposition of all of the Common Stock of the Company for cash, securities or other property pursuant to a share exchange or other transaction or (c) any liquidation or dissolution of the Company. In connection with a Reorganization Event, the Board may take any one or more of the following actions with respect to this option (or any portion thereof) on such terms as the Board determines: (i) provide that this option shall be assumed, or a substantially equivalent option shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (ii) upon written notice to the Participant, provide that the unvested portion of this option will be forfeited immediately prior to the consummation of the Reorganization Event and/or the unexercised portion of this option will terminate immediately prior to the consummation of such Reorganization Event unless exercised by the Participant (to the extent then exercisable) within a specified period following the date of such notice, (iii) provide that this option shall become exercisable, realizable, or deliverable, or restrictions applicable to this option shall lapse, in whole or in part prior to or upon such Reorganization Event, (iv) in the event of a Reorganization Event under the terms of which holders of Common Stock will receive upon consummation thereof a cash payment for each share surrendered in the Reorganization Event (the “Acquisition Price”), make or provide for a cash payment to the Participant with respect to this option equal to (A) the number of shares of Common Stock subject to the vested portion of this option (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such Reorganization Event) multiplied by (B) the excess, if any, of (I) the Acquisition Price over (II) the exercise price of this option and any applicable tax withholdings, in exchange for the termination of this option, (v) provide that, in connection with a liquidation or dissolution of the Company, this option shall convert into the right to receive liquidation proceeds (net of the exercise price thereof and any applicable tax withholdings) and (vi) any combination of the foregoing.

For purposes of clause (i) above, this option shall be considered assumed if, following consummation of the Reorganization Event, this option confers the right to purchase, for each share of Common Stock subject to this option immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, securities or other property) received as a result of the Reorganization Event by holders of Common Stock for each share of Common Stock held immediately prior to the consummation of the Reorganization Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of Common Stock); provided, however, that if the consideration received as a result of the Reorganization Event is not solely common stock of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent

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of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise of this option to consist solely of such number of shares of common stock of the acquiring or succeeding corporation (or an affiliate thereof) that the Board determines to be equivalent in value (as of the date of such determination or another date specified by the Board) to the per share consideration received by holders of outstanding shares of Common Stock as a result of the Reorganization Event.

7. Miscellaneous.

(a) No Right To Employment or Other Status. The grant of this option shall not be construed as giving the Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with the Participant free from any liability or claim hereunder, except as otherwise expressly provided herein.

(b) No Rights As Stockholder; Clawback. Subject to the provisions of this option, the Participant shall not have any rights as a stockholder with respect to any shares of Common Stock to be issued with respect to this option until becoming the record holder of such shares. In accepting this option, the Participant agrees to be bound by any clawback policy the Company has in effect or may adopt in the future.

(c) Entire Agreement. This Agreement constitutes the entire agreement between the parties, and supersedes all prior agreements and understandings, relating to the subject matter hereof.

(d) Amendment. The Board may amend, modify or terminate this Agreement, including but not limited to, substituting another option of the same or a different type and changing the date of exercise or realization. Notwithstanding the foregoing, the Participant's consent to such action shall be required unless (i) the Board determines that the action, taking into account any related action, would not materially and adversely affect the Participant's rights under this Agreement, or (ii) the change is permitted under Section 6.

(e) Acceleration. The Board may at any time provide that this option shall become immediately exercisable in whole or in part, free from some or all restrictions or conditions, or otherwise realizable in whole or in part, as the case may be.

(f) Conditions on Delivery of Stock. The Company will not be obligated to deliver any shares of Common Stock pursuant to this Agreement until (i) all conditions of this Agreement have been met to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and regulations and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations.

(g) Administration by Board. The Board will administer this Agreement and may construe and interpret the terms hereof. The Board may correct any defect, supply any omission or reconcile any inconsistency in this Agreement in the manner and to the extent it shall deem

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expedient to carry the Agreement into effect and it shall be the sole and final judge of such expediency. No director or person acting pursuant to the authority delegated by the Board shall be liable for any action or determination relating to or under this Agreement made in good faith.

(h) Appointment of Committees. To the extent permitted by applicable law, the Board may delegate any or all of its powers hereunder to one or more committees or subcommittees of the Board (a "Committee"). All references herein to the "Board" shall mean the Board or a Committee to the extent that the Board's powers or authority hereunder have been delegated to such Committee.

(i) Severability. The invalidity or unenforceability of any provision hereof shall not affect the validity or enforceability of any other provision hereof, and each such other provision shall be severable and enforceable to the extent permitted by law.

(j) Governing Law. This Agreement shall be governed by and interpreted in accordance with the laws of the State of Delaware, excluding choice-of-law principles of the law of such state that would require the application of the laws of a jurisdiction other than the State of Delaware.

(k) Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together will constitute one in the same instrument.

This option satisfies in full all commitments that the Company has to the Participant with respect to the issuance of stock, stock options or other equity securities.

KALA PHARMACEUTICALS, INC.

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Street Address

\_\_\_\_\_  
City/State/Zip Code

By: \_\_\_\_\_

Name of Officer

Title:

\_\_\_\_\_

KALA PHARMACEUTICALS, INC.  
Stock Option Exercise Notice

Kala Pharmaceuticals, Inc.  
100 Beaver Street, Suite 201  
Waltham, MA 02453

Dear Sir or Madam:

I, \_\_\_\_\_ (the "Participant"), hereby irrevocably exercise the right to purchase \_\_\_\_\_ shares of the Common Stock, \$0.001 par value per share (the "Shares"), of Kala Pharmaceuticals, Inc. (the "Company") at \$ \_\_\_\_\_ per share pursuant to that certain stock option agreement with the Company dated \_\_\_\_\_. Enclosed herewith is a payment of \$ \_\_\_\_\_, the aggregate purchase price for the Shares. The certificate for the Shares should be registered in my name as it appears below or, if so indicated below, jointly in my name and the name of the person designated below, with right of survivorship.

Dated: \_\_\_\_\_

\_\_\_\_\_  
Signature

Print Name:

Address:

Name and address of persons in whose name the Shares are to be jointly registered (if applicable):

\_\_\_\_\_

\_\_\_\_\_

## 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: November 8, 2018

By: /s/ Mark Iwicki

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

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## 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: November 8, 2018

By: /s/ Mary Reumuth

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

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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 September 30, 2018 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: November 8, 2018

/s/ Mark Iwicki

Mark Iwicki

President and Chief Executive Officer

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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 September 30, 2018 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: November 8, 2018

/s/ Mary Reumuth

\_\_\_\_\_  
Mary Reumuth  
Chief Financial Officer

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