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Filed Pursuant to Rule 424(b)(4)
Registration No. 333-218936

PROSPECTUS

6,000,000 Shares

Common Stock

This is an initial public offering of common stock by Kala Pharmaceuticals, Inc. We are selling 6,000,000 shares of common stock. The initial public offering price is $15.00 per share.

Prior to this offering, there has been no public market for our common stock. Our common stock has been approved for listing on the NASDAQ Global Select Market under the symbol "KALA."

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

	Per share	Total
Initial public offering price	$15.00	$90,000,000
Underwriting discounts and commissions(1)	$1.05	$6,300,000
Proceeds to Kala, before expenses	$13.95	$83,700,000

(1) We have agreed to reimburse the underwriters for certain FINRA-related expenses. See "Underwriting" on page 183.

We have granted the underwriters the right to purchase up to an additional 900,000 shares of common stock. The underwriters may exercise this right at any time within 30 days after the date of this prospectus.

Certain of our existing stockholders and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately $40.0 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, any of these entities may determine to purchase fewer shares than they indicate an interest in purchasing or not to purchase any shares in this offering. In addition, the underwriters could determine to sell fewer shares to any of these entities than these entities indicate an interest in purchasing or not to sell any shares to these entities. It is also possible that the underwriters could determine to sell more shares to any of these entities.

Investing in our common stock involves risks. See "Risk Factors" beginning on page 11 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to purchasers on or about July 25, 2017.

J.P. Morgan **BofA Merrill Lynch**

Wells Fargo Securities

Wedbush PacGrow

July 19, 2017

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Neither we nor the underwriters have authorized anyone to provide you with any information other than that contained in this prospectus, any amendment or supplement to this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

We own or have rights to trademarks, service marks and trade names that we use in connection with the operation of our business, including our corporate name, logos and website names. Other trademarks, service marks and trade names appearing in this prospectus are the property of their respective owners. The service marks and trademarks that we own include Kala® and Kala™. Solely for convenience, some of the trademarks, service marks and trade names referred to in this prospectus are listed without the ® and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights to our trademarks, service marks and trade names.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes appearing at the end of this prospectus, before making an investment decision. Unless the context otherwise requires, references in this prospectus to "Kala," "the Company," "we," "us" and "our" refer to Kala Pharmaceuticals, Inc.

Overview

We are a biopharmaceutical company focused on the development and commercialization of therapeutics using our proprietary nanoparticle-based Mucus Penetrating Particles, or MPP, technology, with an initial focus on the treatment of eye diseases. Our MPPs are selectively-sized nanoparticles and have proprietary coatings. We believe that these two key attributes enable even distribution of drug particles on mucosal surfaces and significantly increase drug delivery to target tissues by enhancing mobility of drug particles through mucus and preventing drug particles from becoming trapped and eliminated by mucus. We have applied the MPP technology to create nanosuspensions of loteprednol etabonate, or LE, a corticosteroid designed for ocular applications, resulting in two product candidates in Phase 3 clinical development, KPI-121 1.0% for the treatment of inflammation and pain following ocular surgery and KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. We anticipate submitting new drug applications, or NDAs, for these product candidates by the end of 2017 and the first half of 2018, respectively.

We have completed two Phase 3 clinical trials of KPI-121 1.0%, our topical twice-a-day product candidate for patients with inflammation and pain following cataract surgery, which is the most common type of ocular surgery in the United States. Commonly used topical ocular corticosteroid products for the treatment of post-operative inflammation and pain are approved for dosing four times a day. In 2014, we conducted our first Phase 3 clinical trial, which was designed to evaluate KPI-121 1.0% administered twice a day and KPI-121 0.25% administered four times a day. Statistical significance was achieved in the primary efficacy endpoints of complete resolution of inflammation at day eight maintained through day 15 with no need for rescue medication compared to placebo and complete resolution of pain at day eight maintained through day 15 with no need for rescue medications compared to placebo with both KPI-121 1.0% and KPI-121 0.25%. Both KPI-121 1.0% and KPI-121 0.25% were well-tolerated, with no treatment-related serious adverse events observed during the course of the trial. In May 2017, we announced topline results from the second, confirmatory Phase 3 clinical trial. In this second Phase 3 clinical trial, administration of KPI-121 1.0% two times a day achieved statistical significance for both primary efficacy endpoints of complete resolution of inflammation at day eight maintained through day 15 with no need for rescue medication compared to placebo and complete resolution of pain at day eight maintained through day 15 with no need for rescue medications compared to placebo and all secondary endpoints. In this trial, KPI-121 1.0% was well tolerated with no treatment-related significant adverse events observed during the course of the trial. Based on the results of our two completed Phase 3 trials of KPI-121 1.0%, we anticipate submitting an NDA for the approval of KPI-121 1.0% for the treatment of post-operative inflammation and pain following ocular surgery by the end of 2017. If approved, KPI-121 1.0% could be the first FDA-approved ocular corticosteroid product for the treatment of post-operative inflammation and pain with twice daily dosing.

KPI-121 0.25% is our product candidate for patients with dry eye disease utilizing a two-week course of therapy. After achieving positive results in a Phase 2 clinical trial, we initiated two parallel Phase 3 clinical trials of KPI-121 0.25% in June 2016. Each of these Phase 3 clinical trials has a target enrollment of at least 900 dry eye patients and we had enrolled over 1,550 dry eye patients across the

two trials as of June 30, 2017. We expect to receive topline results from these clinical trials by the end of 2017. Assuming positive results from these Phase 3 clinical trials, we anticipate submitting an NDA for KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease in the first half of 2018. If approved, KPI-121 0.25% could be the first FDA-approved product for the short-term treatment of dry eye disease.

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.

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

We have retained worldwide commercial rights for our current product candidates. If our current product candidates receive marketing approval, we expect to commercialize them in the United States with our own focused, specialty sales force of approximately 150 sales and marketing personnel that will call on ophthalmologists and optometrists. We are evaluating a variety of collaboration, distribution and other marketing arrangements with one or more third parties for the EU market.

We own and/or exclusively license patents relating to our product candidates and MPP technology. The earliest expiration date of an issued U.S. patent covering our current product candidates is in 2033. The earliest expiration date of an issued U.S. patent relating to our MPP technology is in 2027.

Our Product Candidates

The following table describes the development stage of each of our current development programs:

Indication	Preclinical	Phase 1	Phase 2	Phase 3	Expected Milestones and Planned Next Steps
Treatment of post-operative inflammation and pain following ocular surgery	KPI-121 1.0%				▪ Submit NDA by end of 2017
	Two Phase 3 trials complete				
Temporary relief of the signs and symptoms of dry eye disease	KPI-121 0.25%				▪ Complete parallel Phase 3 trials in 2H of 2017 ▪ Submit NDA in 1H of 2018
	Two parallel Phase 3 trials ongoing				
Retinal diseases	MPP rTKI Program				▪ Complete evaluation of our lead compound, KPI-285, for Wet AMD
	Lead compound selected				

KPI-121 1.0% for Post-Operative Inflammation and Pain. Ocular inflammation and pain are common complications following ocular surgery. According to Marketscope, a third-party provider of market data, in 2016 there were 7.7 million ocular surgeries in the United States. Tissue damage caused by ocular surgery leads to the production of prostaglandins, lipids that aid in recovery at the site of an injury, and an increase in blood flow to the affected area, which contribute to inflammation. The standard of care for post-operative inflammation and pain includes anti-inflammatory drugs such as corticosteroids, which improve patient comfort and accelerate recovery through disruption of the inflammatory cascade. The current four times a day dosing regimen for corticosteroid treatment can be burdensome for patients as they are taking multiple eye drop products following surgery, and is believed to reduce patient compliance. There are no ocular corticosteroid products currently approved in the United States for dosing two times a day for the treatment of post-operative inflammation and pain.

KPI-121 1.0%, our twice-a-day product candidate for the treatment of inflammation and pain following ocular surgery, has completed Phase 3 clinical trials and we anticipate submitting an NDA by the end of 2017. We believe that KPI-121 1.0% has a favorable profile for the treatment of inflammation and pain following ocular surgery, due to its twice-a-day dosing regimen, rapid onset of relief and tolerability profile. We believe these features of KPI-121 1.0% may be attractive to patients and prescribing clinicians.

In each of our successfully completed Phase 3 clinical trials of KPI-121 1.0% in patients who had undergone cataract surgery, administration of KPI-121 1.0% two times a day for 14 days achieved statistical significance for both primary efficacy endpoints of complete resolution of inflammation at day eight maintained through day 15 with no need for rescue medication and complete resolution of pain at day eight maintained through day 15 with no need for rescue medication. In each of these trials, KPI-121 1.0% was well tolerated with no increases in intraocular pressure, or IOP, a common side effect of steroids, compared to placebo with no treatment-related significant adverse events observed during the course of either trial.

KPI-121 0.25% for Dry Eye Disease. Dry eye disease is a chronic, episodic, multifactorial disease affecting the tears and ocular surface that can result in tear film instability, inflammation, discomfort, visual disturbance and ocular surface damage. Dry eye disease can have a significant impact on quality of life and can potentially cause long-term damage to the ocular surface. In addition, the vast majority of dry eye patients experience acute exacerbations of their symptoms, which are commonly referred to as flares, at various times throughout the year. These flares can be triggered by numerous factors, including exposure to allergens, pollution, wind and low humidity, intense visual concentration such as watching television and working at a computer, contact lens wear, smoking and sleep deprivation, which cause ocular surface inflammation and impact tear production and/or tear film stability.

We estimate dry eye disease affects approximately 33 million people in the United States based on an estimated dry eye disease prevalence of 14.5% described below and applied to the population of the United States over 20 years old. Based on third-party academic research, we believe dry eye disease results in approximately $55 billion in direct and indirect costs in the United States each year, of which approximately $3.8 billion are direct medical costs. The exact prevalence of dry eye disease is unknown due to the difficulty in defining the disease and the lack of a single diagnostic test to confirm its presence. The Beaver Dam Offspring Study, a major epidemiological study published in 2014 in the *American Journal of Ophthalmology*, reported that in a cohort of over 3,000 patients, dry eye disease was self-reported by 14.5% of the patients. The prevalence of dry eye disease increases with age, and we expect that the number of dry eye disease cases will increase as the U.S. population continues to age. Epidemiology and market research commissioned by us indicates that there are an estimated 16 million patients with a diagnosis of dry eye disease in the United States. The most commonly used treatments for dry eye disease in the United States are over-the-counter eye drops, often referred to as "artificial tears," and two prescription pharmaceutical products, Restasis® and Xiidra®. Artificial tears

are intended to supplement insufficient tear production or improve tear film instability, but do not treat the underlying inflammation in dry eye disease. Restasis increases tear production and Xiidra treats the signs and symptoms of dry eye disease, however, both Restasis and Xiidra are typically used chronically for dry eye patients who have continuous symptoms. As each of Restasis and Xiidra have a relatively long onset of action, they are not generally used for the short-term treatment of episodic dry eye flares. We believe there is a larger proportion of dry eye patients whose symptoms are primarily episodic as opposed to chronic, and for whom a chronic therapy is not necessary and an FDA-approved, acute, short-term therapy can address a significant unmet need.

We are developing KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease, utilizing a two-week course of therapy administered four times a day. We believe that KPI-121 0.25%'s broad mechanism of action, rapid onset of relief of both signs and symptoms, favorable tolerability profile and potential to be complementary to existing therapies, will result in a favorable profile for the management of dry eye flares and other dry eye associated conditions that would benefit from temporary relief of dry eye signs and symptoms. We believe these features of KPI-121 0.25% may be attractive to prescribing clinicians and could be a first line prescription medication choice for a substantial number of their dry eye patients.

In June 2016, we initiated two parallel Phase 3 clinical trials, each with a target enrollment of at least 900 dry eye patients, comparing KPI-121 0.25% to placebo, both administered four times a day for 14 days. As of June 30, 2017, we had enrolled over 1,550 dry eye patients across the two trials. We expect to receive topline results from both trials by the end of 2017. The primary endpoints in these trials are conjunctival hyperemia, or redness, at day 15 and ocular discomfort severity at day 15.

rTKI Program for Retinal Diseases. Commonly used therapies for retinal diseases must be injected directly into the patient's eye, often at monthly intervals. We believe that our MPP technology has the potential to facilitate the delivery of therapeutics into tissues in the back of the eye via topical dosing, which has the potential to provide a less invasive method of administration and a competitive advantage over therapies administered by intravitreal injection. In our rTKI program, we are initially targeting wet age-related macular degeneration, or Wet AMD, with our lead rTKI compound, KPI-285. KPI-285 inhibits the VEGF pathway. In preclinical rabbit studies, topical administration of KPI-285 achieved concentrations in tissues in the back of the eye well above the concentrations required for *in vitro* inhibition of 50% of the VEGF receptor kinase activity. Prior to initiating IND-enabling studies, we may consider potential collaborative partnership opportunities to advance product candidates we develop through our rTKI program, including KPI-285.

Other Potential Applications of our MPP Technology. While our current focus is on the application of our MPP technology in ophthalmology, we have conducted preclinical studies demonstrating the potential of our MPP technology in other therapeutic areas. Mucus limits delivery of conventionally formulated drugs to the lung, cervical/vaginal tract, gastrointestinal tract and other mucus-protected tissues. In preclinical studies, we have demonstrated that our MPP technology can be used to increase the mucus penetration of over fifteen classes of drugs, including anti-infective and anti-inflammatory drugs.

Our Strategy

Our goal is to become a leading biopharmaceutical company focused on the development and commercialization of therapeutics using our proprietary MPP technology. Key elements of our strategy include:

- successfully complete clinical development of, and seek regulatory approval for, our KPI-121 1.0% and KPI-121 0.25% product candidates;
- maximize the commercial potential of KPI-121 1.0% for post-operative inflammation and pain;

- maximize the commercial potential of KPI-121 0.25% for dry eye disease; and
- advance other early stage pipeline development programs, and further leverage our proprietary MPP technology.

Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus. These risks include the following:

- 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. As of March 31, 2017, we had an accumulated deficit of $101.9 million.
- We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- We are dependent on the success of our lead product candidates, KPI-121 1.0% and KPI-121 0.25%. If we are unable to successfully complete our Phase 3 clinical programs and obtain marketing approvals for either KPI-121 1.0% or KPI-121 0.25%, or experience significant delays in doing so, or if, after obtaining marketing approvals, we fail to commercialize these product candidates, our business will be materially harmed.
- If clinical trials of KPI-121 1.0% and KPI-121 0.25% or any other product candidate that we develop fail to demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidate.
- If the FDA does not conclude that KPI-121 1.0% and KPI-121 0.25% satisfy the requirements under Section 505(b)(2) of the Federal Food Drug and Cosmetics Act, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates may take longer, cost more and entail greater complications and risks than anticipated, and may not be successful.
- We may not be successful in our efforts to develop product candidates based on our MPP technology or expand the use of our MPP technology for treating additional diseases and conditions.
- Even if KPI-121 1.0%, KPI-121 0.25% or any other product candidates receives marketing approval, they may fail to achieve the degree of 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.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. Our product candidates will, if approved, also compete with existing branded, generic and off-label products.
- If our contracted manufacturing facilities experience production issues for any reason, we may be unable to manufacture commercial quantities of our product candidates for a substantial amount of time, which could have a material adverse effect on our business.
- Even if we are able to commercialize KPI-121 1.0%, KPI-121 0.25% or any other product candidate that we may develop, the products may become subject to unfavorable pricing

regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.

- We may be unable to obtain and maintain patent protection for our technology and product candidates, or the scope of the patent protection obtained may not be sufficiently broad or enforceable, such that our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired. 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 that may limit 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.

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

We were incorporated under the laws of the state of Delaware on July 7, 2009 under the name Hanes Newco, Inc. We subsequently changed our name to Kala Pharmaceuticals, Inc. on December 11, 2009. Our principal executive offices are located at 100 Beaver Street, Suite 201, Waltham, Massachusetts 02453, and our telephone number is (781) 996-5252. Our website address is www.kalarx.com. The information contained on, or that can be accessed through, our website is not a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Implications of Being an Emerging Growth Company

As a company with less than $1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure and other requirements that are applicable to public companies that are not emerging growth companies. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

THE OFFERING

Common stock offered	6,000,000 shares
Common stock to be outstanding immediately following this offering	23,283,399 shares
Option to purchase additional shares	We have granted the underwriters an option for a period of 30 days to purchase up to 900,000 additional shares of our common stock.
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $80.7 million, or $93.3 million if the underwriters exercise their option to purchase additional shares in full, based on the initial public offering price of $15.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to fund clinical development of our KPI-121 product candidates, including preparation of NDA submissions for KPI-121 1.0% and KPI-121 0.25%, to prepare for commercialization of KPI-121 1.0% and KPI-121 0.25%, to support the manufacture of a commercial supply of KPI-121 product candidates and to fund early stage pipeline development programs and for working capital and other general corporate purposes. See "Use of Proceeds."
Risk Factors	You should read the "Risk Factors" section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Proposed NASDAQ Global Select Market symbol	"KALA"

The number of shares of our common stock to be outstanding after this offering is based on 1,181,429 shares of our common stock outstanding as of June 30, 2017 and 16,101,970 shares of our common stock issuable upon the automatic conversion of all outstanding shares of our preferred stock upon the closing of this offering.

The number of shares of our common stock to be outstanding after this offering excludes:

- 3,292,177 shares of common stock issuable upon exercise of stock options outstanding as of June 30, 2017 at a weighted average exercise price of $3.27 per share;
- 241,548 shares of common stock reserved for future issuance under our 2009 Employee, Director and Consultant Equity Incentive Plan, as amended, or the 2009 Plan, as of June 30, 2017 which shares, upon the effectiveness of the registration statement of which this prospectus forms a part, will be available for future issuance under our 2017 Equity Incentive Plan, or the 2017 Plan;
- 1,786,883 additional shares of our common stock that will be available for future issuance, as of the closing of this offering, under our 2017 Plan;
- 223,341 additional shares of common stock that will be available for future issuance as of the closing of this offering under our 2017 Employee Stock Purchase Plan, or the 2017 ESPP;

- 202,020 shares of common stock issuable following the closing of this offering upon the exercise of outstanding warrants as of June 30, 2017, at a weighted average exercise price of $7.33 per share; and

- 48,374 shares of common stock issuable following the closing of this offering upon the exercise of outstanding warrants as of June 30, 2017 that become exercisable only upon our draw down of the remaining $10.0 million of available borrowings under our 2014 Debt Facility, at a weighted average exercise price of $8.27 per share.

Unless otherwise indicated, all information in this prospectus assumes:

- no exercise of the outstanding options described above;

- no exercise of the outstanding warrants described above or below;

- no exercise by the underwriters of their option to purchase additional shares of our common stock;

- the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 16,101,970 shares of our common stock upon the closing of this offering;

- the automatic conversion of outstanding warrants to purchase preferred stock into warrants to purchase 202,020 shares of common stock upon the closing of this offering;

- the automatic conversion upon the closing of this offering of outstanding warrants to purchase preferred stock into warrants to purchase 48,374 shares of common stock that become exercisable only upon our draw down of the remaining $10.0 million of available borrowings under our 2014 Debt Facility; and

- the filing and effectiveness of our restated certificate of incorporation and the adoption of our amended and restated bylaws upon the closing of this offering.

In addition, unless otherwise indicated, all information in this prospectus gives effect to a one-for-5.2083 reverse stock split of our common stock that became effective on July 7, 2017.

Certain of our existing stockholders and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately $40.0 million in shares of our common stock in this offering at the initial public offering price. At an initial public offering price of $15.00 per share, these potential purchasers would purchase an aggregate of up to approximately 2,666,666 of the 6,000,000 shares in this offering based on these indications of interest. However, because indications of interest are not binding agreements or commitments to purchase, any of these entities may determine to purchase fewer shares than they indicate an interest in purchasing or not to purchase any shares in this offering. In addition, the underwriters could determine to sell fewer shares to any of these entities than these entities indicate an interest in purchasing or not to sell any shares to these entities. It is also possible the underwriters could determine to sell more shares to any of these entities.

SUMMARY FINANCIAL DATA

The summary financial data for the years ended December 31, 2015 and 2016 have been derived from our audited financial statements appearing at the end of this prospectus. The summary financial data for the three months ended March 31, 2016 and 2017, and the balance sheet data as of March 31, 2017, have been derived from our unaudited financial statements appearing at the end of this prospectus and have been prepared on the same basis as the audited financial statements. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial information in those statements. You should read this data together with our historical financial statements and the related notes included elsewhere in this prospectus and the "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus. Our historical results are not necessarily indicative of our future results, and our interim results are not necessarily indicative of our future results to be expected for a full fiscal year or any other interim period. The summary financial data in this section are not intended to replace our financial statements and related notes appearing at the end of this prospectus.

	Year Ended December 31,		Three Months Ended March 31,	
	2015	2016	2016	2017
	(in thousands, except share and per share amounts)			
Revenue	$ 45	$ —	$ —	$ —
Operating expenses				
Research and development	11,382	25,029	3,911	8,039
General and administrative	4,609	7,640	1,165	1,532
Total operating expenses	15,991	32,669	5,076	9,571
Loss from operations	(15,946)	(32,669)	(5,076)	(9,571)
Other income (expense)				
Interest income	—	147	—	46
Interest expense	(604)	(767)	(194)	(198)
Change in fair value of warrant liability	(132)	122	18	(36)
Net loss attributable to common stockholders—basic and diluted	$ (16,682)	$ (33,167)	$ (5,252)	$ (9,759)
Net loss per share attributable to common stockholders—basic and diluted	$ (14.89)	$ (28.07)	$ (4.45)	$ (8.26)
Weighted average shares outstanding—basic and diluted	1,120,268	1,181,429	1,181,429	1,181,429
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited)(2)		$ (2.20)		$ (0.56)
Pro forma weighted average shares outstanding—basic and diluted (unaudited)(2)		15,106,343		17,283,399

	As of March 31, 2017		
	Actual	Pro Forma(2)	Pro Forma As Adjusted(3)
		(in thousands)	
Balance Sheet Data:			
Cash	$ 36,024	$ 36,024	$ 118,135
Total assets	37,608	37,608	119,088
Working capital(1)	30,089	30,089	112,182
Long-term debt—less current portion	8,293	8,293	8,293
Warrant liability	1,075	—	—
Other long-term liabilities	35	35	35
Convertible preferred stock	118,391	—	—
Total stockholders' (deficit) equity	(96,999)	22,467	104,560

(1) We define working capital as current assets less current liabilities.

(2) The pro forma information gives effect to:

- the automatic conversion of all outstanding shares of our preferred stock into 16,101,970 shares of common stock upon the closing of this offering;
- the automatic conversion of outstanding warrants to purchase preferred stock into warrants to purchase 202,020 shares of common stock upon the closing of this offering;
- the automatic conversion upon the closing of this offering of outstanding warrants to purchase preferred stock into warrants to purchase 48,374 shares of common stock that become exercisable only upon our draw down of the remaining $10.0 million of available borrowings under our 2014 Debt Facility; and
- the filing and effectiveness of our amended and restated certificate of incorporation upon the closing of this offering.

(3) The pro forma as adjusted balance sheet gives further effect to our issuance and sale of 6,000,000 shares of our common stock in this offering at the initial public offering price of $15.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

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 this prospectus, including our financial statements and the related notes appearing at the end of this prospectus, 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 $16.7 million for the year ended December 31, 2015, $33.2 million for the year ended December 31, 2016 and $9.8 million for the three months ended March 31, 2017. As of March 31, 2017, we had an accumulated deficit of $101.9 million. We have not generated any revenues to date from product sales and have financed our operations primarily through private placements of our preferred stock, convertible debt financings and borrowings under credit facilities. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year.

We anticipate that our expenses will increase substantially as compared to prior periods as we complete our Phase 3 trials of KPI-121 0.25% in patients with dry eye disease and prepare for commercialization of our product candidates, as a result of increased headcount, including management personnel to support our clinical, manufacturing and commercialization activities, expanded infrastructure, increased legal, compliance, accounting and investor and public relations expenses associated with being a public company and increased insurance premiums, among other factors. Our license agreement with The Johns Hopkins University, or JHU, under which we license certain of our patent rights and a significant portion of the technology for KPI-121 1.0% and KPI-121 0.25%, imposes royalty and other financial obligations on us, and we may enter into additional licensing and funding arrangements with third parties that may impose milestone payment, royalty, insurance and other obligations on us.

Our expenses will also increase if and as we:

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

- leverage our proprietary MPP technology to advance 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 and management personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company; and
- increase our product liability insurance coverage as we expand our commercialization efforts.

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

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

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

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

We may never succeed in these activities and may never generate revenue that is sufficient to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

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

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

developing KPI-121 and other product candidates. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

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

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

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

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

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

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

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

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

As of March 31, 2017, we had cash of approximately $36.0 million. We believe that the net proceeds from this offering, together with our existing cash as of March 31, 2017 and available borrowings under our 2014 Debt Facility, will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements through the second quarter of 2019. However, we have based this estimate 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 capital resources sooner than we currently expect.

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

Raising additional capital may cause dilution to our stockholders, including purchasers of our common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.

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

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

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

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

As of March 31, 2017, we had $10.0 million of outstanding borrowings under our 2014 Debt Facility, which we are required to begin repaying following the end of an interest-only period, in October 2017, in equal monthly installments until October 2020. We also are eligible to borrow an additional $10.0 million under the 2014 Debt Facility before October 13, 2017. Our obligations under this agreement are secured by substantially all of our assets other than our intellectual property. We could in the future incur additional indebtedness beyond our borrowings under the 2014 Debt Facility.

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

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

We intend to satisfy our current and future debt service obligations with our existing cash and funds from external sources. Nonetheless, we may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt. Funds from external sources may not be available on acceptable terms, if at all. In addition, a failure to comply with the covenants under our credit facility could result in an event of default and acceleration of amounts due. If an event of default occurs and Square 1 Bank accelerates the amounts due under the 2014 Debt Facility, we may not be able to make accelerated payments, and Square 1 Bank could seek to enforce security interests in the collateral securing such indebtedness.

Risks Related to Product Development

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

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

results from these parallel Phase 3 clinical trials by the end of 2017. The timing of the availability of such topline data and the completion of our Phase 3 clinical trials for KPI-121 0.25% is dependent, in part, on our ability to locate and enroll a sufficient number of eligible patients in our Phase 3 clinical trials on a timely basis. We cannot accurately predict when or if either of these product candidates will be proven to be effective or safe in humans or whether either will receive marketing approval. Our ability to generate product revenues will depend on our obtaining marketing approval for, and commercializing one or both of, KPI-121 1.0% and KPI-121 0.25%.

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

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

Successful development of KPI-121 1.0% or KPI-121 0.25% for additional indications, if any, or for use in broader patient populations and our ability, if it is approved, to broaden the label for KPI-121 1.0% or KPI-121 0.25% will depend on similar factors. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

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

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, including KPI-121 1.0% and KPI-121 0.25%, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to

complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. Furthermore, the failure of any other product candidates to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of our other product candidates and/or cause the FDA or other regulatory authorities to require additional testing before approving any of our product candidates. For example, we previously conducted a Phase 2 clinical trial of KPI-121 0.25% for the treatment of meibomian gland dysfunction which did not achieve its primary endpoint. The failure of this trial may have an adverse impact on the perceived safety or efficacy of KPI-121 0.25% in treating dry eye disease or other indications or of KPI-121 1.0%. In addition, we have not conducted any Phase 2 clinical trial of KPI-121 1.0%. The lack of Phase 2 trial data may have an adverse impact on the perceived safety or efficacy of KPI-121 1.0% for the treatment of post-operative inflammation and pain following ocular surgery or other indications, and may adversely affect our ability to obtain marketing approval for KPI-121 1.0% from the FDA or outside the United States.

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

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

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

If we are required to conduct additional clinical trials or other testing of KPI-121 0.25% or KPI-121 1.0% or any other product candidate that we develop beyond those that we currently expect, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the

results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

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

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize KPI-121 1.0%, KPI-121 0.25% or any other product candidates that we may develop, including:

- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their obligations to us in a timely manner, or at all;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- we may decide, or regulators or institutional review boards may require us, to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post-marketing testing requirements to maintain regulatory approval;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or may be delayed;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate trials; and

- regulatory authorities may withdraw their approval of a product or impose restrictions on its distribution, such as in the form of a modified Risk Evaluation and Mitigation Strategy, or REMS.

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

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

We may not be able to initiate or continue clinical trials for KPI-121 0.25% or any other product candidate we develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States.

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

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

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

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

We intend to seek FDA approval of KPI-121 1.0% and KPI-121 0.25% through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant, and for which the applicant has not received a right of reference, which could expedite the development

program for KPI-121 1.0% and KPI-121 0.25% by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for KPI-121 1.0% and KPI-121 0.25%, and complications and risks associated with approval of KPI-121 1.0% and KPI-121 0.25%, would likely substantially increase. Even if we are allowed to pursue the Section 505(b)(2) pathway to FDA approval, we cannot assure you that KPI-121 1.0% and KPI-121 0.25% will receive the requisite approvals for commercialization.

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

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

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

If KPI-121 1.0%, KPI-121 0.25% or any other product candidates are associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The most common adverse effects to date in trials evaluating the safety and efficacy of KPI-121 1.0% and KPI-121 0.25% have been eye pain, instillation site pain and photophobia, which is discomfort or pain due to exposure to light. There have been no serious adverse events related to the administration of KPI-121 reported in any of our clinical trials to date. Increases in IOP and cataract formation are additional adverse effects associated with the use of corticosteroids and in our Phase 2 trial of KPI-121 0.25%, one patient out of the 72 patients in the KPI-121 0.25% treatment arm had elevated IOP classified as an adverse event as of day 29. We have no clinical safety data on or patient exposure to either KPI-121 concentration for longer than 28 days. Our understanding of the relationship between our products and these adverse effects may change as we gather more information, and additional unexpected adverse effects may occur. Many compounds that initially showed promise in clinical or earlier stage testing for treating ophthalmic disease have later been found to cause side effects that prevented further development of the compound. In addition, adverse events which had initially been considered

unrelated to the study treatment may later be found to be caused by the study treatment. Moreover, incorrect or improper use of our product candidates (including use of KPI-121 0.25% more frequently than is prescribed) by patients could cause increases in IOP, and may result in additional unexpected side effects or adverse events. There can be no assurance that our product candidates will be used correctly, and if used incorrectly, such misuse could hamper commercial adoption of our product candidate, if approved, at the rate we currently expect.

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

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

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

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

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

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

Risks Related to the Commercialization of Our Product Candidates

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

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

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

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

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

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

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

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

Subject to successful results of our ongoing Phase 3 clinical trials and FDA approval of any of our product candidates, we plan to build a focused specialty sales and marketing infrastructure to market or co-promote KPI-121 1.0%, KPI-121 0.25% and possibly other product candidates that we develop in the United States, if and when they are approved, as well as distribution capabilities. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. Further, we may underestimate the size of the sales force required for a successful product launch and may need to expand our sales force earlier and at a higher cost than we anticipated. If the commercial launch of KPI-121 1.0%, KPI-121 0.25% or any other product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize KPI-121 1.0%, KPI-121 0.25% or any other product candidates on our own include:

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

- unforeseen costs and expenses associated with creating an independent sales, marketing and distribution organization.

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

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

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

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

Following ocular surgery, topical steroids are commonly used to manage and prevent complications from post-operative inflammation. The current market leaders for topical steroids in the United States, based on revenue, are Lotemax® products and Durezol®. There are also a number of companies in the United States developing products and therapies in preclinical research and clinical development for the treatment of inflammation and pain following ocular surgery, including the following: Valeant Pharmaceuticals International, Inc. is developing an LE gel, which is formulated for topical delivery and is currently in Phase 3 clinical development; Ocular Therapeutix, Inc. is developing Dextenza™, a

punctal plug that is currently in Phase 3 clinical development and has filed an NDA for the treatment of ocular pain following ophthalmic surgery; and Icon Bioscience, Inc. has filed an NDA for IBI-10090, which is formulated as a drug delivery system, or DDS, to be injected into the eye following cataract surgery for the treatment of inflammation.

Current disease management approaches for dry eye disease in the United States include the following: over-the-counter artificial tear eye drops, which are used on an intermittent or chronic basis to provide short term symptomatic relief of dryness and irritation; off-label prescription drugs, including topical steroid drops and/or other similar products, which are prescribed on occasion for treatment of dry eye disease; on-label prescription drugs, including Restasis and Xiidra, which are the only prescription pharmaceutical products that are approved in the United States for use in patients with dry eye disease. Restasis is approved for increasing tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation and Xiidra is approved for treatment of the signs and symptoms of dry eye disease. Both are typically used chronically as part of the dry eye management regimen, which also includes artificial tears and other palliative therapies, such as hot compresses for the eye and lid hygiene management; and devices, such as punctal plugs that are inserted into the tear ducts to inhibit tear drainage, resulting in more moisture on the surface of the eye.

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

See "Business—Competition" for additional information regarding competing products and product candidates.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than our products. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

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

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant

competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

We will rely on third-party contract manufacturers to manufacture commercial supplies of KPI-121 1.0% and KPI-121 0.25%. Specifically, we will rely on Catalent Pharma Solutions, LLC, or Catalent, to manufacture and supply to us a minimum amount of KPI-121 1.0% and KPI-121 0.25% for commercial use; Alliance Contract Pharma, LLC, or Alliance, for manufacturing bulk KPI-121 concentrates, and Chemo Iberica SA, or Chemo Iberica, to manufacture and supply to us a bulk supply of loteprednol, or LE. We expect to rely on third parties to manufacture clinical supplies of other product candidates and commercial supplies of all of our products, if and when approved for marketing by applicable regulatory authorities, as well as for packaging, serialization, storage, distribution and other production logistics. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or manufacture our product candidates in accordance with regulatory requirements, if there are disagreements between us and such parties, or if such parties are unable to expand capacities to support commercialization of any of our product candidates for which we obtain marketing approval, we may not be able to complete, or may be delayed in producing sufficient product candidates to meet our supply requirements. These facilities may also be affected by natural disasters, such as floods or fire, or such facilities could face manufacturing issues, such as contamination or regulatory concerns following a regulatory inspection of such facility. In such instances, we may need to locate an appropriate replacement third-party relationship, which may not be readily available or on acceptable terms, which would cause additional delay and increased expense, including as a result of additional required FDA approvals, and may have a material adverse effect on our business.

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

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

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

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

Inadequate reimbursement may adversely affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize KPI-121 1.0%, KPI-121 0.25% or any other product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop would compromise our ability to generate revenues and become profitable.

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

reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

There can be no assurance that our product candidates, even if they are approved for sale in the United States or in other countries, will be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, or that coverage and an adequate level of reimbursement will be available or that third-party payors' reimbursement policies will not adversely affect our ability to sell our product candidates profitably.

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

We face an inherent risk of product liability exposure related to the use of our product candidates that we develop in human clinical trials. We face an even greater risk if we commercially sell any products that we develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced time and attention of our management to pursue our business strategy; and
- the inability to commercialize any products that we develop.

We currently hold $10 million in product liability insurance coverage in the aggregate, with a per incident limit of $10 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials. We will need to further increase our insurance coverage if we commence commercialization of any of KPI-121 1.0%, KPI-121 0.25% or any product candidates for which we obtain marketing approval. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Dependence on Third Parties

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

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

by the third parties. If we need to enter into alternative arrangements, that would delay our product development activities.

Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

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

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of KPI-121 1.0% and KPI-121 0.25% or any other product candidates. We will rely on Catalent to manufacture and supply to us a minimum amount of KPI-121 1.0% and KPI-121 0.25% for commercial use; Alliance for manufacturing bulk KPI-121 concentrates, and Chemo Iberica to manufacture and supply to us a bulk supply of LE. We expect to rely on such third-party manufacturers to manufacture commercial supplies of all of our products and clinical supplies of any other product candidates if and when approved for marketing by applicable regulatory authorities. Our current and anticipated future dependence upon others for the manufacture of KPI-121 1.0% and KPI-121 0.25% and any other product candidate or product that we develop may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. In addition, any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval.

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

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

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

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

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and harm our business and results of operations.

Any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. We were previously required to change our third-party manufacturer when the manufacturer was purchased by a third party and exited the contract manufacturing business. The process of changing manufacturers can cause substantial time delays, and if we are required to change our manufacturer again in the future, it may delay our planned clinical trials or development timeline.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for bulk drug substances. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

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

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

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

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

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development of our product candidates or may elect not to continue or renew development programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may not pursue commercialization of our product candidates that receive marketing approval or may elect not to continue or renew commercialization programs based on changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;

- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would divert management attention and resources, be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and

- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this prospectus also apply to the activities of our collaborators.

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

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

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

for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

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

Risks Related to Our Intellectual Property

We may be unable to obtain and maintain patent protection for our technology and product candidates, or the scope of the patent protection obtained may not be sufficiently broad or enforceable, such that our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and product candidates. We have sought to protect our proprietary position by filing in the United States and in certain foreign jurisdictions patent applications related to our novel technologies and product candidates.

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

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

and methods for searching them, are inherently limited so we may not know the full scope of all issued and pending patent applications. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. In particular, during prosecution of any patent application, the issuance of any patents based on the application may depend upon our ability to generate additional preclinical or clinical data that support the patentability of our proposed claims. We may not be able to generate sufficient additional data on a timely basis, or at all. Moreover, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

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

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

On September 16, 2011, Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. The first to file provisions limit the rights of an inventor to patent an invention if not the first to file an application for patenting that invention, even if such invention was the first invention. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, which could have a material adverse effect on our business, financial condition, results of operations and prospects. For example, the Leahy-Smith Act provides a new administrative tribunal known as the Patent Trial and Appeals Board, or PTAB, that provides a venue for companies to challenge the validity of competitor patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long term impact the PTAB proceedings will have on the operation of our business, the initial results of patent

challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U.S. patent claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could therefore increase the likelihood that our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining, defending and enforcing them.

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

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

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

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

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

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

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

Competitors and other third parties may infringe, misappropriate or otherwise violate our owned and licensed patents, trade secrets, or other intellectual property. As a result, to counter infringement, misappropriation or unauthorized use, we may be required to file infringement or misappropriation claims or other intellectual property related proceedings, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our asserted patents are invalid. In addition, in a patent infringement or other intellectual property related proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly, and could put any of our patent applications at risk of not yielding an issued patent. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information or trade secrets could be compromised by disclosure during this type of litigation.

We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in other contested proceedings such as opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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

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

Our commercial success depends upon our ability to develop, manufacture, market and sell KPI-121 1.0%, KPI-121 0.25% and other product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. There is a considerable amount of intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, infringement litigation claims regarding our products and technology, including claims from competitors or from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. Moreover, we may become party to future adversarial proceedings or litigation regarding our patent portfolio or the patents of third parties. Such proceedings could also include contested post-grant proceedings such as oppositions, *inter partes* review, reexamination, interference or derivation proceedings before the U.S. Patent and Trademark Office or foreign patent offices. For example, we are aware of a third-party European patent that contains claims related to use of LE for the treatment of moderate to severe dry eye disease and the use of LE for

reducing conjunctival redness associated with dry eye disease. This European patent will expire in early 2025, and is in force in Germany, the United Kingdom, Spain, Italy, and France. There is no United States counterpart patent or pending U.S. patent application. While we have obtained an opinion of European counsel that this patent is invalid, until this patent expires or a court of competent jurisdiction finally determines the patent is invalid in each country, the patent holder may be able to block our ability to develop and commercialize KPI-121 0.25% for the treatment of dry eye disease in Europe unless we obtain a license under this patent in each country where it is in force. Such a license may not be available on commercially reasonable terms or at all. If we are unable to invalidate the patent in each country or obtain a license on commercially reasonable terms, our ability to commercialize KPI-121 0.25% for the treatment of dry eye disease in Europe may be impaired, delayed or halted altogether.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase as our product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. We may not be aware of all such intellectual property rights potentially relating to our product candidates and their uses. Thus, we do not know with certainty that KPI-121 1.0%, KPI-121 0.25% or any other product candidates, or our development and commercialization thereof, do not and will not infringe or otherwise violate any third party's intellectual property.

If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent and could be forced to indemnify our customers or collaborators. A finding of infringement could also result in an injunction that prevents us from commercializing our product candidates or forces us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign our product candidates, seek new regulatory approvals and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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

Periodic maintenance, renewal and annuity fees on any issued patent must be paid to the U.S. Patent and Trademark Office and foreign patent agencies in several stages or annually over the lifetime of our owned and licensed patents and patent applications. The U.S. Patent and Trademark Office and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. While an inadvertent lapse can in many cases be

cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, it would have a material adverse effect on our business.

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

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

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

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

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

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

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

Our license agreement with JHU, under which we license certain of our patent rights and a significant portion of the technology for KPI-121 1.0%, KPI-121 0.25% and other product candidates, imposes royalty and other financial obligations on us and other substantial performance obligations. We also may enter into additional licensing and funding arrangements with third parties that may impose diligence, development and commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under current or future license and collaboration agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could diminish the value of our product. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

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

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

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

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

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

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against

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

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

Many of our and our licensors' employees and contractors were previously employed at other biotechnology, medical device or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

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

If we or our licensors fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel which could have a material adverse effect on our competitive business position and prospects. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products, which may not be available on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

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

In addition to seeking patents for our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

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

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

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

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

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional

statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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

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

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

The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be sold in that country. We or our potential collaborators may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

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

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

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

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

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

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

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

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing

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

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

Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion or manufacturing of drug products or medical devices may lead to investigations by the FDA, Department of Justice and state Attorneys General alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

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

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

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

Healthcare providers, clinicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription and use of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain

the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which imposes obligations, including mandatory contractual terms, on covered healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and

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

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the clinicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government funded healthcare programs.

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

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

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for clinician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

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

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

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach

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

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

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

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

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

We and any third-party manufacturers we may engage in the future are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous materials, including chemicals and biological materials, and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our

resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

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

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

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

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

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

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

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of

information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

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

Risks Related to Employee Matters and Managing Growth

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

We are highly dependent on the research and development, clinical and business development expertise of Mark Iwicki, our Chief Executive Officer, Charlie McDermott, our President and Chief Business Officer, Kim Brazzell, Ph.D., our Chief Medical Officer, and Hongming Chen, Sc.D., our Chief Scientific Officer, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

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

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

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

Risks Related to Our Common Stock and This Offering

After this offering, 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.

Upon the closing of this offering, our executive officers and directors and our stockholders who owned more than 5% of our outstanding common stock before this offering will, in the aggregate, beneficially own shares representing approximately 63% of our capital stock (or 61% if the underwriters exercise their option to purchase additional shares in full). 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.

Certain of our existing stockholders, including stockholders who own more than 5% of our outstanding common stock before this offering, and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately $40.0 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, any of these entities may determine to purchase fewer shares than they indicate an interest in purchasing or not to purchase in this offering. In addition, the underwriters could determine to sell fewer shares to any of these entities than these entities indicate an interest in purchasing or not to sell any shares to these entities. It is also possible that the underwriters could determine to sell more shares to these entities. Accordingly, the foregoing discussion does not reflect any purchases by these potential purchasers.

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 that will become effective upon the closing of this offering may discourage, delay or prevent a merger, acquisition or other change in

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

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish 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 that will become effective upon the closing of this offering.

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.

If you purchase shares of common stock in this offering, you will suffer immediate dilution of your investment.

The initial public offering price of our common stock will be substantially higher than the pro forma net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our pro forma net tangible book value per share after this offering. To the extent outstanding options or warrants are exercised, you will incur further dilution. Based on the initial public offering price of $15.00 per share, you will experience immediate dilution of $10.51 per share, representing the difference between our pro forma net tangible book value per share, after giving effect to this offering, and the initial public offering price.

An active trading market for our common stock may not develop.

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock was determined through negotiations with the underwriters. Although our common stock has been approved for listing on The NASDAQ Global Select Market, an

active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop, it may be difficult for you to sell shares you purchase in this offering without depressing the market price for the shares or at all.

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

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 initial public offering price. The market price for our common stock may be influenced by many factors, including:

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

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

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds

effectively could result in financial losses that could cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have 23,283,399 shares of common stock outstanding based on the number of shares outstanding as of June 30, 2017. This includes the 6,000,000 shares that we are selling in this offering which may be resold in the public market immediately without restriction, unless purchased by our affiliates. The remaining 17,283,399 shares are currently restricted as a result of securities laws or lock-up agreements but will become eligible to be sold at various times after the offering. Moreover, beginning 180 days after the completion of this offering, holders of an aggregate of 16,086,480 shares of our common stock will have rights, along with holders of an additional 1,504,470 shares of our common stock issuable upon exercise of outstanding warrants and options, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus.

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

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

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

We have taken advantage of reduced reporting obligations in this prospectus. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging

growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

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

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

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

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

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be 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 2014 Debt Facility preclude us from paying dividends without the lenders' consent, and any future debt agreements that we may enter into may preclude us from paying dividends without the lenders' consent or at all. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Our certificate of incorporation that will become effective upon the closing of this offering 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 that will become effective upon the closing of this offering 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

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

The forward-looking statements in this prospectus include, among other things, statements about:

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

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking

statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

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

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties as well as our own estimates of potential market opportunities. 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. 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 may fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.

USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of 6,000,000 shares of our common stock in this offering will be approximately $80.7 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares of our common stock in full, we estimate that the net proceeds from this offering will be approximately $93.3 million.

As of March 31, 2017, we had cash on hand of $36.0 million and $10.0 million of available borrowings under our 2014 Debt Facility. We currently estimate that we will use the net proceeds from this offering as follows:

- approximately $25.0 million to fund clinical development of our KPI-121 product candidates, including preparation of NDA submissions for KPI-121 1.0% for the treatment of post-operative inflammation and pain following ocular surgery and for KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease;
- approximately $30.0 million to prepare for commercialization of KPI-121 1.0% and KPI-121 0.25%;
- approximately $20.0 million to support the manufacture of a commercial supply of KPI-121 product candidates;
- approximately $0.5 million to fund early stage pipeline development programs; and
- the remainder for working capital and other general corporate purposes, including scheduled payments on existing indebtedness and funding the costs of operating as a public company.

This expected use of net proceeds from this offering and our existing cash represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from clinical trials, the timing of regulatory submissions and the outcome of regulatory review, as well as any collaborations that we may enter into with third parties for our product candidates, and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Based on our planned use of the net proceeds from this offering and our existing cash and available borrowings described above, we estimate that such funds will be sufficient to enable us to complete our NDA submission and prepare for commercial launch of KPI-121 1.0% for the treatment of post-operative inflammation and pain following ocular surgery, complete our Phase 3 clinical trials and complete our NDA submission of KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease, fund early stage pipeline development programs and fund our operating expenses and capital expenditure requirements through the second quarter of 2019. We do not anticipate that the net proceeds from this offering together with our existing cash and available borrowings will be sufficient to allow us to complete preparation for commercial launch of KPI-121 0.25% or fund additional clinical trials for our pipeline development programs. We have based this estimate on assumptions that may prove to be wrong, including assumptions regarding the clinical trials necessary for FDA approval of our product candidates, and we could use our available capital resources sooner than we currently expect.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

DIVIDEND POLICY

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. In addition, our ability to pay cash dividends is currently restricted by the terms of our 2014 Debt Facility, and future debt financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any future determination to declare and pay dividends will be made at the discretion of our board of directors and will depend on then-existing conditions, including our results of operations, financial condition, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

CAPITALIZATION

The following table sets forth our cash and capitalization as of March 31, 2017:

- on an actual basis, except to the extent it has been adjusted to give effect to a one-for 5.2083 reverse split of our common stock that became effective on July 7, 2017;

- on a pro forma basis to give effect to: (i) the automatic conversion of all outstanding shares of our convertible preferred stock into 16,101,970 shares of common stock upon closing of this offering; (ii) the automatic conversion of outstanding warrants to purchase shares of our preferred stock into warrants to purchase 202,020 shares of our common stock upon closing of this offering; (iii) the automatic conversion upon closing of this offering of outstanding warrants to purchase shares of our preferred stock into warrants to purchase 48,374 shares of our common stock that become exercisable only upon our draw down of the remaining $10.0 million of available borrowings under our 2014 Debt Facility; and (iv) the filing and effectiveness of our amended and restated certificate of incorporation upon closing of this offering.

- on a pro forma as adjusted basis to give further effect to our issuance and sale of 6,000,000 shares of our common stock in this offering at the initial public offering price of $15.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information below is illustrative only. You should read this information together with our financial statements and related notes appearing at the end of this prospectus and the information set forth under the headings "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	As of March 31, 2017		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share amounts)		
Cash	$ 36,024	$ 36,024	$ 118,135
Long-term debt-less current portion	8,293	8,293	8,293
Warrant liability	1,075	—	—
Convertible preferred stock (Seed, Series A, B, B-1 and C), $0.001 par value, 170,336,260 shares authorized, 83,863,957 shares issued and outstanding, actual; no shares authorized, issued or outstanding pro forma and pro forma as adjusted	118,391	—	—
Stockholders' deficit:			
Preferred stock, $0.001 par value; no shares authorized, issued or outstanding, actual; 5,000,000 shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, $0.001 par value per share; 110,251,951 shares authorized, 1,181,429 shares issued and outstanding, actual; 120,000,000 shares authorized, 17,283,399 shares issued and outstanding, pro forma; 120,000,000 shares authorized, 23,283,399 shares issued and outstanding, pro forma as adjusted	1	17	23
Additional paid-in capital	4,919	124,369	206,456
Accumulated deficit	(101,919)	(101,919)	(101,919)
Total stockholders' (deficit) equity	(96,999)	22,467	104,560
Total capitalization	$ 30,760	$ 30,760	$ 112,853

The number of shares of common stock issued and outstanding, actual, pro forma and pro forma as adjusted in the table above excludes the following shares:

- 3,189,164 shares of common stock issuable upon exercise of stock options outstanding as of March 31, 2017 under the 2009 Plan at a weighted average exercise price of $3.26 per share;
- 344,562 shares of common stock reserved for future issuance under the 2009 Plan as of March 31, 2017;
- 1,786,883 additional shares of our common stock that will be available for future issuance, as of the closing of this offering, under our 2017 Plan;
- 223,341 additional shares of common stock that will be available for future issuance as of the closing of this offering under our 2017 ESPP;
- 202,020 shares of common stock issuable following the closing of this offering upon the exercise of outstanding warrants as of March 31, 2017, at a weighted average exercise price of $7.33 per share; and
- 48,374 shares of common stock issuable following the closing of this offering upon the exercise of outstanding warrants as of March 31, 2017, that become exercisable only upon our draw down of the remaining $10.0 million of available borrowings under our 2014 Debt Facility at a weighted average exercise price of $8.27 per share.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value as of March 31, 2017 was $20.8 million, or $17.57 per share of our common stock. Our historical net tangible book value is the amount of our total tangible assets less our total liabilities. Historical net tangible book value per share represents historical net tangible book value divided by the 1,181,429 shares of our common stock outstanding as of March 31, 2017.

Our pro forma net tangible book value as of March 31, 2017 was $21.8 million, or $1.26 per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into 16,101,970 shares of common stock upon the closing of this offering; (ii) the automatic conversion of outstanding warrants to purchase preferred stock into warrants to purchase 202,020 shares of our common stock upon the closing of this offering; and (iii) the automatic conversion upon the closing of this offering of outstanding warrants to purchase shares of our preferred stock into warrants to purchase 48,374 shares of our common stock that become exercisable only upon our draw down of the remaining $10.0 million of available borrowings under our 2014 Debt Facility. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of March 31, 2017, after giving effect to the pro forma adjustments described in (i), (ii) and (iii) above.

After giving effect to our issuance and sale of shares of our common stock in this offering at the initial public offering price of $15.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2017 would have been $104.6 million, or $4.49 per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of $3.23 to existing stockholders and immediate dilution of $10.51 per share in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Initial public offering price per share		$ 15.00
Historical net tangible book value per share as of March 31, 2017	$ 17.57	
Decrease in pro forma net tangible book value per share as of March 31, 2017 attributable to pro forma adjustments	(16.31)	
Pro forma net tangible book value per share as of March 31, 2017	$ 1.26	
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering	3.23	
Pro forma as adjusted net tangible book value per share after this offering		4.49
Dilution of pro forma net tangible book value per share to new investors		$ 10.51

If the underwriters exercise in full their option to purchase additional shares, our pro forma as adjusted net tangible book value per share after this offering would be $4.84 per share, representing an immediate increase in pro forma as adjusted net tangible book value per share of $0.35 to existing stockholders and immediate dilution of $0.35 in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering, at the initial public offering price of $15.00 per share.

The following table summarizes, as of March 31, 2017, on a pro forma as adjusted basis described above, the total number of shares purchased from us on an as converted to common stock basis, the total consideration paid, or to be paid, and the average price per share paid, or to be paid, by existing stockholders and by new investors in this offering at the initial public offering price of $15.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing shares in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	17,283,399	74%	$ 126,561,495	58%	$ 7.32
Investors purchasing common stock in this offering	6,000,000	26%	90,000,000	42%	15.00
Total	23,283,399	100%	$ 216,561,495	100%	9.30

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase additional shares is fully exercised, the number of shares of our common stock held by existing stockholders would be reduced to 71% of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors participating in the offering would be increased to 29% of the total number of shares of our common stock outstanding after this offering.

The foregoing discussion and tables are based on the number of shares of common stock outstanding as of March 31, 2017, and exclude:

- 3,189,164 shares of common stock issuable upon exercise of stock options outstanding as of March 31, 2017 under the 2009 Plan at a weighted average exercise price of $3.26 per share;
- 344,562 shares of common stock reserved for future issuance under the 2009 Plan as of March 31, 2017;
- 1,786,883 additional shares of our common stock that will be available for future issuance, as of the closing of this offering, under our 2017 Plan;
- 223,341 additional shares of common stock that will be available for future issuance as of the closing of this offering under our 2017 ESPP;
- 202,020 shares of common stock issuable following the closing of this offering upon the exercise of outstanding warrants as of March 31, 2017, at a weighted average exercise price of $7.33 per share; and
- 48,374 shares of common stock issuable following the closing of this offering upon the exercise of outstanding warrants as of March 31, 2017 that become exercisable only upon our draw down of the remaining $10.0 million of available borrowings under our 2014 Debt Facility at a weighted average exercise price of $8.27 per share.

Certain of our existing stockholders and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately $40.0 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, any of these entities may determine to purchase fewer shares than they indicate an interest in purchasing or not to purchase any shares in this offering. In addition, the underwriters could determine to sell fewer shares to any of these entities than these entities indicate an interest in purchasing or not to sell any shares to these entities. It is also possible that the underwriters could determine to sell more shares to any of these entities. Accordingly, the foregoing discussion and tables do not reflect any potential purchases by these potential purchasers.

SELECTED FINANCIAL DATA

The selected financial data as of and for the years ended December 31, 2015 and 2016 have been derived from our audited financial statements appearing at the end of this prospectus. The selected financial data for the three months ended March 31, 2016 and 2017, and the balance sheet data as of March 31, 2017, have been derived from our unaudited financial statements appearing at the end of this prospectus and have been prepared on the same basis as the audited financial statements. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial information in those statements. You should read this data together with our historical financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus. Our historical results are not necessarily indicative of our future results and our interim results are not necessarily indicative of results to be expected for a full fiscal year or any other interim period. The selected financial data in this section are not intended to replace our financial statements and related notes appearing at the end of this prospectus.

	Year Ended December 31,		Three Months Ended March 31,	
	2015	2016	2016	2017
	(in thousands, except share and per share amounts)			
Revenue	$ 45	$ —	$ —	$ —
Operating expenses				
Research and development	11,382	25,029	3,911	8,039
General and administrative	4,609	7,640	1,165	1,532
Total operating expenses	15,991	32,669	5,076	9,571
Loss from operations	(15,946)	(32,669)	(5,076)	(9,571)
Other income (expense)				
Interest income	—	147	—	46
Interest expense	(604)	(767)	(194)	(198)
Change in fair value of warrant liability	(132)	122	18	(36)
Net loss attributable to common stockholders—basic and diluted	$ (16,682)	$ (33,167)	$ (5,252)	$ (9,759)
Net loss per share attributable to common stockholders—basic and diluted	$ (14.89)	$ (28.07)	$ (4.45)	$ (8.26)
Weighted average shares outstanding—basic and diluted	1,120,268	1,181,429	1,181,429	1,181,429
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited)(2)		$ (2.20)		$ (0.56)
Pro forma weighted average shares outstanding—basic and diluted (unaudited)(2)		15,106,343		17,283,399

	As of December 31, 2015	As of December 31, 2016	As of March 31, 2017
		(in thousands)	
Balance Sheet Data:			
Cash	$ 5,759	$ 45,472	$ 36,024
Total assets	8,448	46,329	37,608
Working capital(1)	2,094	40,080	30,089
Long-term debt—less current portion	7,795	9,098	8,293
Warrant liability	936	1,039	1,075
Other long-term liabilities	3	17	35
Convertible preferred stock	50,871	118,391	118,391
Total stockholders' deficit	$ (56,664)	$ (87,762)	$ (96,999)

(1) We define working capital as current assets less current liabilities.

(2) The pro forma information gives effect to:

- the automatic conversion of all outstanding shares of our preferred stock into 16,101,970 shares of common stock upon the closing of this offering;
- the automatic conversion of outstanding warrants to purchase preferred stock into warrants to purchase 202,020 shares of common stock upon the closing of this offering;
- the automatic conversion upon the closing of this offering of outstanding warrants to purchase preferred stock into warrants to purchase 48,374 shares of common stock that become exercisable only upon our draw down of the remaining $10.0 million of available borrowings under our 2014 Debt Facility; and
- the filing and effectiveness of our amended and restated certificate of incorporation upon the closing of this offering.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes thereto appearing at the end of this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements and Industry Data." Because of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

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

We have completed two Phase 3 clinical trials of KPI-121 1.0%, our topical twice-a-day product candidate for patients with inflammation and pain following cataract surgery, which is the most common type of ocular surgery in the United States. Commonly used topical ocular corticosteroid products for the treatment of post-operative inflammation and pain are approved for dosing four times a day. In 2014, we conducted our first Phase 3 clinical trial, which was designed to evaluate KPI-121 1.0% administered twice a day and KPI-121 0.25% administered four times a day. Statistical significance was achieved in the primary efficacy endpoints of complete resolution of inflammation at day eight maintained through day 15 with no need for rescue medication compared to placebo and complete resolution of pain at day eight maintained through day 15 with no need for rescue medications compared to placebo with both KPI-121 1.0% and KPI-121 0.25%. Both KPI-121 1.0% and KPI-121 0.25% were well-tolerated, with no treatment-related serious adverse events observed during the course of the trial. In May 2017, we announced topline results from the second, confirmatory Phase 3 clinical trial. In this second Phase 3 clinical trial, administration of KPI-121 1.0% two times a day achieved statistical significance for both primary efficacy endpoints of complete resolution of inflammation at day eight maintained through day 15 with no need for rescue medication compared to placebo and complete resolution of pain at day eight maintained through day 15 with no need for rescue medications compared to placebo and all secondary endpoints. In this trial, KPI-121 1.0% was well tolerated with no treatment-related significant adverse events observed during the course of the trial. Based on the results of our two completed Phase 3 trials of KPI-121 1.0%, we anticipate submitting a new drug application, or NDA, for the approval of KPI-121 1.0% for the treatment of post-operative inflammation and pain following ocular surgery by the end of 2017. If approved, KPI-121 1.0% could be the first FDA-approved product for the treatment of post-operative inflammation and pain with twice daily dosing.

KPI-121 0.25% is our product candidate for patients with dry eye disease utilizing a two-week course of therapy. After achieving positive results in a Phase 2 clinical trial, we initiated two parallel

Phase 3 clinical trials of KPI-121 0.25% in June 2016. Each of these Phase 3 clinical trials has a target enrollment of at least 900 dry eye patients and we had enrolled over 1,550 dry eye patients across the two trials as of June 30, 2017. We expect to receive topline results from these clinical trials by the end of 2017. Assuming positive results from these Phase 3 clinical trials, we anticipate submitting an NDA for KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease in the first half of 2018. If approved, KPI-121 0.25% could be the first FDA-approved product for the short-term treatment of dry eye disease.

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.

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

After synthesizing and testing a number of new chemical entities, or NCEs, from our topically applied rTKI program, we are further evaluating compounds for the potential topical treatment of a number of retinal diseases, including wet age-related macular degeneration, or Wet AMD, Diabetic Retinopathy, or DR, Diabetic Macular Edema, or DME, and Retinal Vein Occlusion, or RVO, each of which involves either the leakage of existing blood vessels or the proliferation of poorly formed and leaky blood vessels at the back of the eye. These eye diseases can significantly reduce vision and eventually lead to blindness. VEGF is a protein that plays a critical role in the formation of new blood vessels and increased permeability, two pathological processes that contribute to the vision loss associated with certain retinal diseases. In our rTKI program, we are initially targeting Wet AMD with our lead rTKI compound, KPI-285. KPI-285 inhibits the VEGF pathway. In preclinical rabbit studies, topical administration of KPI-285 achieved concentrations in tissues in the back of the eye well above the concentrations required for *in vitro* inhibition of 50% of the VEGF receptor kinase activity. Prior to initiating IND-enabling studies, we may consider potential collaborative partnership opportunities to advance product candidates we develop through our rTKI program, including KPI-285.

Since our inception in July 2009, we have devoted substantial resources to the research and development of nanoparticle-based drug products and our proprietary MPP technology. We have no products approved for sale and all our revenue to date has been derived from feasibility agreements with our collaboration partners. To date, we have funded our operations primarily through private placements of preferred stock, convertible promissory notes and warrants. In addition, we have borrowed under venture debt facilities to fund our operations. Specifically, since our inception and through March 31, 2017, we have raised an aggregate of $131.4 million to fund our operations, of which $113.9 million was from the sale of preferred stock, $6.0 million was from convertible promissory notes and warrants and $11.5 million was from borrowings and warrants under venture debt facilities. As of March 31, 2017, we had cash on hand of $36.0 million.

Since inception, we have incurred significant operating losses. Our net loss was $16.7 million and $33.2 million for the years ended December 31, 2015 and 2016, respectively, and $5.3 million and $9.8 million for the three months ended March 31, 2016 and 2017, respectively. We recognized revenue

of $45,000 and $0 for the years ended December 31, 2015 and 2016, respectively, and $0 and $0 for the three months ended March 2016 and 2017, respectively. We have not generated any revenue from the sale of products. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our current product candidates and programs. Substantially all our operating losses resulted from expenses incurred in connection with our research programs and from general and administrative costs associated with our operations. As of March 31, 2017, we had an accumulated deficit of $101.9 million. We expect to continue to incur significant and increasing losses in the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if and as we:

- seek marketing approvals for KPI-121 1.0% and KPI-121 0.25% and any other product candidates that successfully complete clinical development;
- pursue the clinical development of KPI-121 product candidates for the treatment of other additional indications or for use in other patient populations or, if approved, seek to broaden the label of KPI-121 1.0% or KPI-121 0.25%;
- pursue the clinical development of product candidate derived from our rTKI program for use in the treatment of retinal diseases, such as AMD, DR, DME and RVO;
- establish sales, marketing and distribution capabilities for our product candidates for which we obtain marketing approval;
- scale up our manufacturing processes and capabilities to support our ongoing clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval;
- leverage our proprietary MPP technology to advance 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 and management personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company; and
- increase our product liability insurance coverage as we expand our commercialization efforts.

We do not expect to generate revenue from product sales until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which is subject to significant uncertainty. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Until such time, if ever, that we generate product revenue, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings and research collaboration and license agreements. We may be unable to raise capital or enter such other arrangements when needed or on favorable terms. Our failure to raise capital or enter such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our product candidates.

Financial Operations Overview

Revenue

Our revenue to date has been generated through payments received through feasibility agreements with collaboration partners. For each such agreement, we and our collaboration partners agreed to an investigational study with specified phases and endpoints. These studies were executed according to a predefined work plan. Under the terms of each agreement, we received an upfront payment upon consummation, additional upfront payments upon continuation to future phases after predefined objectives had been met and a final payment upon approval of a final report.

We do not currently anticipate generating any significant additional revenue through feasibility agreements or other collaboration arrangements in the future. If we fail to raise additional capital, obtain regulatory approval of our products or successfully commercialize our products, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

Research and Development Expenses

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

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

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

The following table summarizes our research and development expenses incurred during the years ended December 31, 2015 and 2016 and the three months ended March 31, 2016 and 2017:

	Year Ended December 31,		Three Months Ended	
	2015	2016	2016	2017
	(in thousands)			
KPI-121 external development costs	$ 4,683	$ 17,465	$ 2,410	$ 5,485
Employee-related costs	3,485	4,714	916	1,542
Other research and development costs	3,214	2,850	585	1,012
Total research and development	$ 11,382	$ 25,029	$ 3,911	$ 8,039

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

Our research and development programs are at various stages of development. Successful development and completion of clinical trials is uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each future product candidate and are difficult to predict. We will continue to make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to our ability to enter into collaborations with respect to each product candidate, the scientific and clinical success of each product candidate as well as ongoing assessments as to the commercial potential of product candidates. We will need to raise additional capital and may seek collaborations in the future to advance our various product candidates. Additional private or public financings may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a material adverse effect on our financial condition and our ability to pursue our business strategy.

General and Administrative Expenses

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

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

Interest Income

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

Interest Expense

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

Change in Fair Value of Warrant Liability

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

Critical Accounting Policies and Significant Judgments and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing at the end of this prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and adjust if necessary. Examples of estimated accrued expenses include fees payable to:

- vendors for clinical development activities;
- salary and employee benefits payable; and
- providers of consulting and related services.

We record accruals related to development activities based on our estimates of the services received and efforts expended pursuant to the terms of our contractual arrangements. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows and expense recognition. Payments under some of these contracts depend on clinical trial milestones. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Preferred Stock Warrant Liability

We classify warrants to purchase shares of our Series Seed, Series B and Series C preferred stock as a liability on our balance sheet as the warrants are free-standing financial instruments that are issuable for contingently redeemable securities. The warrants were initially recorded at fair value on the date of grant, and are subsequently remeasured to fair value at each balance sheet date. Changes in the fair value of the warrants are recognized separately in our statement of operations. We will continue to

adjust the liability for changes in fair value until the earlier of the exercise, conversion or expiration of the warrant.

We utilize the Black-Scholes option-pricing model, which incorporates assumptions and estimates, to value each preferred stock warrant. We assess these assumptions and estimates on a quarterly basis as additional information impacting the assumptions are obtained. Estimates and assumptions impacting the fair value measurement include the fair value per share of the underlying Series Seed, Series B, and Series C preferred stock, the remaining contractual term of the warrants, risk-free interest rate, expected dividend yield, expected volatility of the price of the underlying preferred stock, and to the extent the exercisable shares underlying the warrants are contingently adjustable, the probability that we will draw down on the remaining debt facility. We determine the fair value per share of the underlying preferred stock by taking into consideration our most recent sales of our preferred stock as well as additional factors that we deem relevant. We have historically been a private company and lack company-specific historical and implied volatility information of our stock. Therefore, we estimate expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrant. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrant. We have assumed a 0% dividend yield considering that our board of directors has no history of declaring dividends.

Upon the closing of this offering, the underlying preferred stock will be converted to common stock, the preferred stock warrants will become exercisable for common stock instead of preferred stock, and the fair value of the warrant liability at that time will be reclassified to additional paid-in capital. No further re-measurement of the warrants would occur if the warrants become exercisable for common stock.

Deferred Income Taxes

We file U.S. federal income tax returns and Massachusetts, California, Kentucky, New Hampshire, New York, North Carolina and Pennsylvania state tax returns. Our deferred tax assets were primarily comprised of federal and state tax net operating losses and research and development tax credit carryforwards and were recorded using enacted tax rates expected to be in effect in the years in which these temporary differences are expected to be utilized. As of December 31, 2016, the federal and state net operating loss carryforwards were approximately $85.3 million and $80.5 million, respectively, and the federal and state research and development tax credit carryforwards were $2.4 million and $0.5 million, respectively. These tax credits begin to expire in 2030 in the case of the federal tax credits and 2025 in the case of the state tax credits. At December 31, 2016, we had $0 of unrecognized tax benefits.

Utilization of the net operating loss and tax credit carryforwards may be subject to an annual limitation due to historical or future ownership percentage change rules provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of certain net operating loss and tax credit carryforwards before their utilization. However, due to uncertainties surrounding our ability to generate future taxable income to realize these tax assets, a full valuation allowance has been established to offset our deferred tax assets.

Stock-based Compensation and Common Stock Valuation

Stock-based Compensation

We measure stock options and other stock-based awards granted to employees and directors based on the fair value on the date of the grant and recognize the corresponding compensation expense of those awards, net of forfeitures, over the requisite service period, which is generally the vesting period of the respective award.

We generally issue stock option awards with service-based vesting conditions and record the expense for these awards using the straight-line method. We measure stock-based awards granted to consultants and non-employees based on the fair value of the award on the date at which the related service is complete. Compensation expense is recognized over the period during which services are rendered by such consultants and non-employees until completed. At the end of each financial reporting period prior to completion of the service, we remeasure the fair value of these awards using the then-current fair value of our common stock and updated assumption inputs in the Black-Scholes option pricing model.

Performance-based option awards vest subject to the achievement of performance criteria as determined by management. These criteria are milestone events that are specific to our corporate goals. The grant date and fair value for each award is determined on the date that the performance criteria are established. If, and when, we determine it is probable that the performance condition will be achieved, compensation expense will be recognized from the date of grant through the fiscal year under which the requisite service period has been rendered.

We recognize compensation expense for outstanding awards during the vesting period and account for the effect of forfeitures as they occur.

We estimate the fair value of each stock option grant using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield.

Common Stock Valuation

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuations of common stock and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Our common stock valuations were prepared using either a hybrid method, which used market approaches to estimate our enterprise value, or a probability-weighted expected return method, or PWERM, which used a combination of market approaches and a cost approach to estimate our enterprise value. The hybrid method is a PWERM where the equity value in one or more of the scenarios is calculated using an option-pricing method, or OPM. Under the PWERM methodology, the fair value of common stock is estimated based upon an analysis of future values for the Company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock.

In addition to considering the results of these third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, which may be as of a date later than the most recent third-party valuation date, including the prices at which we sold shares of preferred stock and the superior rights and preferences of securities senior to our common stock at the time of each grant, the progress of our research and development programs, external market conditions affecting and trends within the biotechnology industry and the likelihood of achieving a liquidity event.

The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

Following the closing of this offering, the fair value of our common stock will be determined based on the quoted market price of our common stock.

The following table summarizes our stock-based compensation for employees and non-employees' expenses incurred during the years ended December 31, 2015 and 2016 and the three months ended March 31, 2016 and 2017:

	Year Ended December 31,		Three Months Ended March 31,	
	2015	2016	2016	2017
	(in thousands)			
Research and development	$ 161	$ 461	$ 55	$ 187
General and administrative	477	1,608	270	335
Total	$ 638	$ 2,069	$ 325	$ 522

As of March 31, 2017, we had $5.0 million of total unrecognized compensation expense, which is expected to be recognized over a weighted average remaining vesting period of approximately 2.5 years. We expect the impact of our stock-based compensation expense for stock options and restricted stock granted to employees and non-employees to grow in future periods due to the potential increases in the value of our common stock and headcount.

Emerging Growth Company Status

In April 2012, the Jumpstart Our Business Startup Act, or JOBS Act, was enacted by the federal government. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Results of Operations

Comparison of the Years Ended December 31, 2015 and 2016

The following table summarizes the results of our operations for the years ended December 31, 2015 and 2016:

	Year Ended December 31,		Increase (Decrease)	
	2015	2016		
	(in thousands)			
Revenue	$ 45	$ —	$ (45)	(100)%
Operating expenses:				
Research and development	11,382	25,029	13,647	120%
General and administrative	4,609	7,640	3,031	66%
Total costs and expenses	15,991	32,669	16,678	104%
Loss from operations	(15,946)	(32,669)	(16,723)	105%
Other income (expense)				
Interest income	—	147	147	100%
Interest expense	(604)	(767)	(163)	27%
Change in fair value of warranty liability	(132)	122	254	(192)%
Net loss	$ (16,682)	$ (33,167)	$ (16,485)	99%

Revenue

Our revenue recognized during 2015 was derived from services performed under feasibility agreements with two collaboration partners that were completed by May 2015. We recognized revenue of $45,000 for the year ended December 31, 2015, compared to $0 for the year ended December 31, 2016. We were not party to any collaboration arrangements during the year ended December 31, 2016, and in the future, we do not anticipate generating any significant additional revenue from feasibility agreements or other collaboration arrangements.

Research and Development Expenses

	Year Ended December 31,		Increase (Decrease)	
	2015	2016		
	(in thousands)			
KPI-121 development costs	$ 4,683	$ 17,465	$ 12,782	273%
Employee-related costs	3,485	4,714	1,229	35%
Other research and development costs	3,214	2,850	(364)	11%
Total research and development	$ 11,382	$ 25,029	$ 13,647	120%

Research and development expenses were $11.4 million for the year ended December 31, 2015, compared to $25.0 million for the year ended December 31, 2016, an increase of $13.6 million, or 120%. This increase is primarily the result of a $12.8 million increase in KPI-121 development costs due to the increase in external costs associated with our second Phase 3 clinical trial of KPI-121 1.0% for the treatment of inflammation and pain following cataract surgery and our two parallel Phase 3 clinical trials of KPI-121 0.25% for the treatment of dry eye disease, all of which began in June 2016. Our KPI-121 external development costs for the year ended December 31, 2015 were comprised primarily of costs associated with our Phase 2 dry eye trial and our first Phase 3 post-operative trial, each of which had fewer patients than our ongoing Phase 3 trials. We incurred a $1.2 million increase

in employee-related costs during the year ended December 31, 2016 due to the additional hiring of clinical and regulatory personnel as a result of our progress on the Phase 3 trials, overall merit increases and an increase in stock compensation expense related to stock option grants. These increases were partially offset by a decrease of $0.4 million in other research and development costs. We expect our research and development expenses to continue to increase in the future as we continue spending on our development programs.

General and Administrative Expenses

General and administrative expenses were $4.6 million for the year ended December 31, 2015 compared to $7.6 million for the year ended December 31, 2016, an increase of $3.0 million, or 66%. The increase was primarily due to the write-off of $1.8 million in deferred offering costs resulting from our decision not to update our 2015 confidential S-1 filing during the second quarter of 2016 at which point in time our initial public offering was no longer considered to be probable of being consummated in 2016. We also incurred an increase in employee-related costs of $1.5 million. This was a result of an increase in stock compensation expense due to additional stock option grants, an increase in salaries due to hiring of additional finance and accounting personnel, and the impact of merit-based salary increases. These increases were partially offset by a $0.3 million decrease in our consulting costs as result of hiring permanent accounting and finance personnel. We expect general and administrative expenses to increase in the future as we expand our operating activities and incur additional costs associated with being a public company.

Interest Income

Interest income was $0 for the year ended December 31, 2015 compared to $0.1 million for the year ended December 31, 2016. The increase of $0.1 million was the result of interest income generated on our higher average cash balance for the year ended December 31, 2016 compared to the year ended December 31, 2015, due to the receipt of $67.5 million in net proceeds from our Series C financing in April 2016.

Interest Expense

Interest expense was $0.6 million for the year ended December 31, 2015 compared to $0.8 million for the year ended December 31, 2016, an increase of $0.2 million, or 27%. The higher interest expense during the year ended December 31, 2016 was primarily due to the additional $5.0 million draw of our venture debt facility in July 2015, resulting in a $10.0 million outstanding loan for the year ended December 31, 2016. Additionally, the variable portion of the interest rate applicable to our debt facility increased marginally during 2016, from 3.25% in January 2016 to 3.5% in December 2016.

Change in Fair Value of Warrant Liability

Changes in the fair value of our preferred stock warrants resulted in a $0.1 million loss for the year ended December 31, 2015, as compared to a $0.1 million gain for the year ended December 31, 2016. The gain recognized in the year ended December 31, 2016 was a result of a decrease in the fair value on the warrants, which was primarily due to the decrease in the fair value of the underlying preferred shares on a period-over-period basis. The loss recognized for the year ended December 31, 2015 was a result of an increase in the fair value of the warrants, which was due primarily to the increase in the fair value of the underlying preferred shares on a period-over-period basis.

Comparison of the Three Months ended March 31, 2016 and 2017

The following table summarizes the results of our operations for the three months ended March 31, 2016 and 2017:

	Three Months Ended March 31,		Increase (Decrease)	
	2016	2017		
	(in thousands)			
Operating expenses:				
Research and development	3,911	8,039	4,128	106%
General and administrative	1,165	1,532	367	32%
Total operating expenses	5,076	9,571	4,495	89%
Loss from operations	(5,076)	(9,571)	(4,495)	89%
Other income (expense)				
Interest income	—	46	46	100%
Interest expense	(194)	(198)	(4)	2%
Change in fair value of warranty liability	18	(36)	(54)	–300%
Net loss	$ (5,252)	$ (9,759)	$ (4,507)	86%

Research and Development Expenses

	Three Months Ended March 31,		Increase (Decrease)	
	2016	2017		
	(in thousands)			
KPI-121 external development costs	$ 2,410	$ 5,485	$ 3,075	128%
Employee-related costs	916	1,542	626	68%
Other research and development costs	585	1,012	427	73%
Total research and development	$ 3,911	$ 8,039	$ 4,128	106%

Research and development expenses were $3.9 million for the three months ended March 31, 2016, compared to $8.0 million for the three months ended March 31, 2017, an increase of $4.1 million, or 106%. This increase is primarily the result of a $3.1 million increase in KPI-121 development costs due to the increase in external costs associated with our second Phase 3 clinical trial of KPI-121 1.0% for the treatment of inflammation and pain following cataract surgery and our two parallel Phase 3 clinical trials of KPI-121 0.25% for the treatment of dry eye disease, all of which began enrolling patients in June 2016. We incurred a $0.6 million increase in employee-related costs during the three months ended March 31, 2017 due to the hiring of additional clinical and regulatory personnel throughout 2016 and an increase in stock compensation expense related to stock option granted in during 2016. We incurred a $0.5 million increase in other research and development costs due to the clinical consulting support for the three Phase 3 trials and the regulatory consulting support for our NDA preparation, and recruiting costs due to the additional hires. We expect our research and development expenses to continue to increase in the future as we continue spending on our development programs.

General and Administrative Expenses

General and administrative expenses were $1.1 million for the three months ended March 31, 2016 compared to $1.5 million for the three months ended March 31, 2017, an increase of $0.4 million, or 32%. We incurred an increase in employee-related costs of $0.2 million. This was a result of an

increase in salaries due to hiring of additional personnel and an increase in stock compensation expense due to additional stock option grants during 2016. We incurred an increase in external general and administrative costs of $0.1 million, which is primarily the result of the timing of the performance of the audit of our financial statements for the year ended December 31, 2016 during the three months ended March 31, 2017 compared to the audit of our financial statements for the year ended December 31, 2015 which took place during the three months ended June 30, 2016. We also incurred a $0.1 million increase in other general and administrative costs due to an increase in our corporate franchise taxes. We expect general and administrative expenses to increase in the future as we expand our operating activities and incur additional costs associated with being a public company.

Interest Income

Interest income was $0 for the three months ended March 31, 2016 compared to $46,000 for the three months ended March 31, 2017. The increase of $46,000 was the result of a higher cash balance from the receipt of $67.5 million in net proceeds from our Series C financing in April 2016. Our cash is held in an interest-bearing account.

Interest Expense

Interest expense was $0.2 million for the three months ended March 31, 2016 and 2017. The variable portion of the interest rate applicable to our debt facility increased marginally during the three months ended March 31, 2017, from 3.5% in January 2016 to 4.0% in March 31, 2017.

Change in Fair Value of Warrant Liability

Changes in the fair value of our preferred stock warrants resulted in income of less than $0.1 million for the three months ended March 31, 2016, as compared to a $0.1 million loss for the three months ended March 31, 2017. The change recognized in each respective period was a result of a change in the fair value of the warrants, which was primarily due to the decrease in the fair value of the underlying preferred shares on a period-over-period basis for the three months ended March 31, 2016 and the increase in the fair value of the underlying preferred shares on a period-over-period basis for the three months ended March 31, 2017.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have derived limited revenue to date from feasibility studies with collaboration partners. We have not yet commercialized any of our product candidates, which are in various phases of clinical development, and we do not expect to generate revenue from sales of any product before 2019, if ever. We have funded our operations to date with proceeds from the sale of preferred stock, borrowings under venture debt facilities, the issuance of convertible promissory notes and warrants and to a lesser extent, payments received in connection with various feasibility studies. Through March 31, 2017, we have received gross proceeds of $131.4 million, which consists of $113.9 million from the sale of preferred stock, $11.5 million from borrowings under venture debt facilities and $6.0 million from the issuance of convertible promissory notes.

On November 20, 2014, we entered into a venture debt facility, or the 2014 Debt Facility, for a total loan commitment of $10.0 million, of which we borrowed $5.0 million upon closing of the loan and another $5.0 million in July 2015. Under the terms of the agreement, the borrowings accrue interest at an annual rate equal to the greater of (i) 3.00% above the prime rate then in effect, or (ii) 6.25%. On October 13, 2016, we entered into a first amendment to the 2014 Debt Facility, or the Amendment. The Amendment reaffirmed the initial commitment of $10.0 million in funding. Additionally, the Amendment increased our borrowing capacity through the commitment of an

additional $10.0 million in funding, which we refer to as Term Loan B. The availability of Term Loan B will commence upon receipt of positive results sufficient to support an NDA submission, with no significant treatment-related safety findings, from our second Phase 3 clinical trial of KPI-121 1.0% for the treatment of inflammation and pain following cataract surgery and will continue until October 13, 2017. As of March 31, 2017, we had not completed the second Phase 3 trial and therefore Term Loan B was not available to be drawn. In May 2017, we announced positive topline results from our Phase 3 trial. KPI-121 1.0% dosed twice-a-day for two weeks achieved statistical significance versus placebo for both primary efficacy endpoints and all secondary endpoints. We believe, per the terms of the Amendment, that these results are sufficient to submit an NDA for KPI-121 1.0% and therefore Term Loan B will be available to be drawn through October 13, 2017. As of June 30, 2017, no amounts have been drawn against the incremental $10.0 million commitment. The 2014 Debt Facility, as amended on October 13, 2016, provides for interest only payments through October 13, 2017, and matures on October 13, 2020. Interest is payable monthly in arrears through to the maturity date.

Cash Flows

As of March 31, 2017, we had $36.0 million in cash on hand and $10.0 million in indebtedness. The indebtedness represents the aggregate outstanding principal amount under the 2014 Debt Facility.

The following table summarizes our sources and uses of cash for each of the periods presented:

	Year Ended December 31,		Three Months Ended March 31,	
	2015	2016	2016	2017
	(in thousands)			
Net cash used in operating activities	$ (15,089)	$ (27,348)	$ (4,540)	$ (9,357)
Net cash used in investing activities	(252)	(153)	—	(72)
Net cash provided by financing activities	10,480	67,214	276	(19)
(Decrease) increase in cash	$ (4,861)	$ 39,713	$ (4,264)	$ (9,448)

Operating Activities

We have incurred losses since inception. During the year ended December 31, 2015, our cash used in operating activities was primarily due to our net loss of $16.7 million as we incurred external research and development activities associated with our clinical trials and our general and administrative expenses. The loss was partially offset by non-cash charges of $1.3 million, including $0.6 million of stock-based compensation, and net cash provided by changes in our operating assets and liabilities of $0.3 million. Net cash provided by changes in our operating assets and liabilities was primarily due to an increase of $0.9 million in accounts payable related to the timing of vendor invoices and payments, partially offset by a decrease in accrued expenses of $0.6 million related to payments of development costs and development milestones in 2015.

During the year ended December 31, 2016, our cash used in operating activities was primarily due to our net loss of $33.2 million as we incurred increased external research and development costs associated with our clinical trials during 2016 and increased general and administrative costs, partially offset by non-cash charges of $2.3 million, consisting primarily of stock-based compensation, the write-off of deferred offering costs related to our confidential submission of a draft registration statement on Form S-1 in 2015 of $1.8 million and net cash provided by changes in our operating assets and liabilities of $1.7 million. Net cash provided by changes in our operating assets and liabilities was primarily due to an increase of $2.1 million in accrued expenses, partially offset by a $0.3 million decrease in accounts payable and a $0.1 million increase in prepaid expenses primarily as a result of prepayments made in connection with medical benefits and corporate insurance policies. The increase in accrued expense was primarily a result of an increase in amounts accrued for patients in the ongoing

clinical trials and the decrease in accounts payable was a result of the timing of vendor invoices and payments.

During the three months ended March 31, 2016, our cash used in operating activities was primarily due to our net loss of $5.3 million as we incurred increased external research and development costs associated with our clinical trials during the three months ended March 31, 2016 and increased general and administrative costs, partially offset by non-cash charges of $0.5 million, consisting primarily of stock-based compensation and net cash provided by changes in our operating assets and liabilities of $0.3 million. Net cash provided by changes in our operating assets and liabilities was primarily due to an increase of $0.3 million increase in accounts payable.

During the three months ended March 31, 2017, our cash used in operating activities was primarily due to our net loss of $9.8 million as we incurred increased external research and development costs associated with our clinical trials during the three months ended March 31, 2017 and increased general and administrative costs, and net cash used by changes in our operating assets and liabilities of $0.3 million partially offset by non-cash charges of $0.7 million, consisting primarily of stock-based compensation. Net cash used by changes in our operating assets and liabilities was primarily due to a decrease of $1.4 million in accrued expenses, and a $0.1 million increase in prepaid expenses primarily as a result of prepayments made in connection with our the manufacturing of our products offset by a $1.2 million increase in accounts payable. The decrease in accrued expense was primarily a result of our 2016 bonus payment during March 2017.

Investing Activities

Net cash used in investing activities for all periods presented consists of purchases of property and equipment, primarily laboratory equipment. Purchases of property and equipment were $0.3 million and $0.2 million for the years ended December 31, 2015 and 2016, respectively and $0 and $72,000 for the three months ended March 31, 2016 and 2017, respectively.

Financing Activities

Net cash provided by financing activities was $10.5 million for the year ended December 31, 2015, consisting of $6.9 million in net proceeds from the issuance of Series B-1 preferred stock, $5.0 million in net proceeds from the drawdown from the 2014 Debt Facility and proceeds of $0.1 million from the exercise of stock options, partially offset by the payment of deferred offering costs of $1.5 million.

Net cash provided by financing activities was $67.2 million for the year ended December 31, 2016, consisting of $67.5 million in net proceeds from the issuance of Series C preferred stock, partially offset by the payment of deferred offering costs of $0.3 million related to our confidential filing of a draft registration statement on form S-1 in 2015.

Net cash provided by financing activities was $0.3 million for the three months ended March 31, 2016, consisting of $0.5 million in proceeds received in advance for our Series C preferred stock financing, partially offset by payments for costs associated with the Series C preferred stock financing and payments of $0.2 million for deferred offering costs related to our confidential submission of a draft registration statement on Form S-1 in 2015.

Net cash used in financing activities was $19,000 for the three months ended March 31, 2017, consisting of payments of deferred offering costs related to our confidential submission of a draft registration statement on Form S-1 in 2017.

Funding Requirements

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

Our expenses will also increase if and as we:

- seek marketing approvals for KPI-121 1.0% and KPI-121 0.25% and any other product candidates that successfully complete clinical development;
- pursue the clinical development of KPI-121 for the treatment of other additional indications or for use in other patient populations or, if approved, seek to broaden the label of KPI-121 1.0% or KPI-121 0.25%;
- pursue the preclinical and clinical development of product candidates derived from our rTKI program for use in the treatment of retinal diseases, such as AMD, DR, DME and RVO;
- establish sales, marketing and distribution capabilities for our product candidates for which we obtain marketing approval;
- scale up our manufacturing processes and capabilities to support our clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval;
- leverage our proprietary MPP technology to advance 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 and management personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company; and
- increase our product liability insurance coverage as we expand our commercialization efforts.

As of March 31, 2017, we had cash on hand of $36.0 million. We believe that the anticipated net proceeds from this offering, together with our existing cash on hand as of March 31, 2017 and available borrowings under our 2014 Debt Facility, will enable us to fund our operating expenses and capital expenditure requirements through the second quarter of 2019. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

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

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

- the costs of commercialization activities for KPI-121 1.0% and KPI-121 0.25% if we receive, or expect to receive, marketing approval, including the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities;
- subject to receipt of marketing approval, revenue received from commercial sales of KPI-121 1.0% and KPI-121 0.25%;
- our ability to establish and maintain strategic collaborations, licensing or other agreements and the financial terms of such agreements;
- the scope, progress, results and costs of any product candidates that we may derive from our rTKI program or any other product candidates that we may develop;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property-related claims.

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

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

Contractual Obligations and Commitments

The following is a summary of our significant contractual obligations as of December 31, 2016:

Contractual Obligations	Payments Due by Period				
	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)	$ 10,000	$ 556	$ 6,666	$ 2,778	$ —
Interest on short- and long-term debt obligations(2)	1,568	680	816	72	—
Operating lease obligations(3)	840	396	444	—	—
Minimum license payments(4)	124	43	81	—	—
Total	$ 12,532	$ 1,675	$ 8,007	$ 2,850	$ —

(1) Short- and long-term debt obligations relate to principal payments due on our 2014 Debt Facility.

(2) Interest payments due on our 2014 Debt Facility.

(3) Future minimum lease payments under our operating lease for our 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) 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 MEEI 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.

We will rely on third-party contract manufacturers to manufacture commercial supplies of KPI-121 1.0% and KPI-121 0.25%. Under our Commercial Supply Agreement with Catalent Pharma Solutions, LLC, or the Catalent Agreement, we have annual minimum purchase requirements for each of KPI-121 1.0% and KPI-121 0.25%. Under the minimum unit purchase requirements, if both KPI-121 1.0% and KPI-121 0.25% are approved for commercial sale, our minimum payment obligation in the first 12-month period would be approximately $1.2 million, subject to specified annual increases. We will also pay certain fees in connection with validation and stability test services and commercialization ramp-up. Under our Amended and Restated Master Services Agreement with Alliance Contract Pharma, LLC, or the Alliance Agreement, we will provide a forecast of orders for the quantities of bulk KPI-121 concentrates we believe we will require, and forecasted quantities will become binding at a certain point before the firm delivery date set forth in the forecast. Because the amount, timing and likelihood of payments under the Catalent Agreement and the Alliance Agreement are not known with certainty, payments that we expect will become due under these agreements are not included in the table of contractual obligations above. See "Business—Manufacturing" for more information.

Under our Manufacturing and Supply Agreement with Chemo Iberica SA, or the Chemo Agreement, we will provide a forecast of orders for the quantities of lotepredno l we believe we will require, and we commit to purchasing 75% of the forecasted quantities. Payments that we expect will become due under the Chemo Agreement are not included in the table of contractual obligations above because we entered into the Chemo Agreement after December 31, 2016 and also because

amounts, timing and likelihood of potential payments under the agreement are not known with certainty. See "Business—Manufacturing" for more information.

In addition, we enter into contracts in the normal course of business with various third parties for preclinical research studies, clinical trials, manufacturing and other services. These contracts are cancellable by us typically upon prior notice of 60 days or less. Payments due upon cancellation generally consist only of payments for services provided and expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation. These payments are not included in the table of contractual obligations above.

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.

Recently Issued Accounting Pronouncements

From time to time the Financial Accounting Standards Board, or FASB, or other standard-setting bodies, issue new accounting pronouncements. Where applicable, we adopt these new standards according to the specified effective dates. Unless otherwise disclosed in the notes to the financial statements appearing at the end of this prospectus, we believe that the impact of any recently issued standard(s) that are not yet effective will not have a material impact on our financial position or results of operation upon adoption.

Quantitative and Qualitative Disclosure About Market Risk

We did not hold any cash equivalents or investments as of March 31, 2017. As of March 31, 2017, our exposure to the risk of changes in market interest rates related primarily to our borrowings under our 2014 Debt Facility, which are subject to a variable interest rate. See "Liquidity and Capital Resources" above for a discussion of the interest rates applicable to our 2014 Debt Facility. We do not expect any material impact on our operating results from a reasonably possible change in market interest rates. A 50-basis point increase or decrease in interest rates would increase or decrease annual interest expense by $50,000 related to our borrowings under our 2014 Debt Facility.

BUSINESS

Overview

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

We have completed two Phase 3 clinical trials of KPI-121 1.0%, our topical twice-a-day product candidate for patients with inflammation and pain following cataract surgery, which is the most common type of ocular surgery in the United States. Commonly used topical ocular corticosteroid products for the treatment of post-operative inflammation and pain are approved for dosing four times a day. In 2014, we conducted our first Phase 3 clinical trial, which was designed to evaluate KPI-121 1.0% administered twice a day and KPI-121 0.25% administered four times a day. Statistical significance was achieved in the primary efficacy endpoints of complete resolution of inflammation at day eight maintained through day 15 with no need for rescue medication compared to placebo and complete resolution of pain at day eight maintained through day 15 with no need for rescue medications compared to placebo with both KPI-121 1.0% and KPI-121 0.25%. Both KPI-121 1.0% and KPI-121 0.25% were well-tolerated, with no treatment-related serious adverse events observed during the course of the trial. In May 2017, we announced topline results from the second, confirmatory Phase 3 clinical trial. In this second Phase 3 clinical trial, administration of KPI-121 1.0% two times a day achieved statistical significance for both primary efficacy endpoints of complete resolution of inflammation at day eight maintained through day 15 with no need for rescue medication compared to placebo and complete resolution of pain at day eight maintained through day 15 with no need for rescue medications compared to placebo and all secondary endpoints. In this trial, KPI-121 1.0% was well tolerated with no treatment-related significant adverse events observed during the course of the trial. Based on the results of our two completed Phase 3 trials of KPI-121 1.0%, we anticipate submitting a new drug application, or NDA, for the approval of KPI-121 1.0% for the treatment of post-operative inflammation and pain following ocular surgery by the end of 2017. If approved, KPI-121 1.0% could be the first FDA-approved ocular corticosteroid product for the treatment of post-operative inflammation and pain with twice daily dosing.

KPI-121 0.25% is our product candidate for patients with dry eye disease utilizing a two-week course of therapy. After achieving positive results in a Phase 2 clinical trial, we initiated two parallel Phase 3 clinical trials of KPI-121 0.25% in June 2016. Each of these Phase 3 clinical trials has a target enrollment of at least 900 dry eye patients and we had enrolled over 1,550 dry eye patients across the two trials as of June 30, 2017. We expect to receive topline results from these clinical trials by the end of 2017. Assuming positive results from these Phase 3 clinical trials, we anticipate submitting an NDA for KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease in the first half of 2018. If approved, KPI-121 0.25% could be the first FDA-approved product for the short-term treatment of dry eye disease.

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.

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

We have retained worldwide commercial rights for our current product candidates. If our current product candidates receive marketing approval, we expect to seek approval and commercialize them in the United States with our own focused, specialty sales force. We believe that this commercial organization will consist of approximately 150 sales and marketing personnel that will call on ophthalmologists and optometrists. In anticipation of the potential to commercialize KPI-121 for dry eye disease in the EU we are evaluating a variety of collaboration, distribution and other marketing arrangements with one or more third parties.

We own and/or exclusively license patents relating to our product candidates and MPP technology, including U.S. and foreign issued patents and pending patent applications covering KPI-121, our rTKI program and our MPP technology, along with pending patent applications relating to ophthalmic applications of our MPP technology. The earliest expiration date of an issued U.S. patent covering our current product candidates is in 2033. The earliest expiration date of an issued U.S. patent relating to our MPP technology is in 2027.

Our Product Candidates

The following table describes the development stage of each of our current development programs:

Indication	Preclinical	Phase 1	Phase 2	Phase 3	Expected Milestones and Planned Next Steps
Treatment of post-operative inflammation and pain following ocular surgery	KPI-121 1.0% Two Phase 3 trials complete				▪ Submit NDA by end of 2017
Temporary relief of the signs and symptoms of dry eye disease	KPI-121 0.25% Two parallel Phase 3 trials ongoing				▪ Complete parallel Phase 3 trials in 2H of 2017 ▪ Submit NDA in 1H of 2018
Retinal diseases	MPP rTKI Program Lead compound selected				▪ Complete evaluation of our lead compound, KPI-285, for Wet AMD

KPI-121 1.0% for Post-Operative Inflammation and Pain

Ocular inflammation and pain are common complications following ocular surgery. According to Marketscope, a third-party provider of market data, in 2016 there were 7.7 million ocular surgeries in the United States. Tissue damage caused by ocular surgery leads to the production of prostaglandins, lipids that aid in recovery at the site of an injury, and an increase in blood flow to the affected area, which contribute to inflammation. The standard of care for post-operative inflammation and pain includes anti-inflammatory drugs such as corticosteroids, which improve patient comfort and accelerate recovery through disruption of the inflammatory cascade. The current four times a day dosing regimen for corticosteroid treatment can be burdensome for patients as they are taking multiple eye drop products following surgery, and is believed to reduce patient compliance. There are no ocular corticosteroid products currently approved in the United States for dosing two times a day for the treatment of post-operative inflammation and pain.

KPI-121 1.0%, our twice-a-day product candidate for the treatment of inflammation and pain following ocular surgery, has completed Phase 3 clinical trials and we anticipate submitting an NDA by the end of 2017. We believe that KPI-121 1.0% has a favorable profile for the treatment of inflammation and pain following ocular surgery, due to its twice-a-day dosing regimen, rapid onset of relief and tolerability profile. We believe these features of KPI-121 1.0% may be attractive to patients and prescribing clinicians.

In each of our successfully completed Phase 3 clinical trials of KPI-121 1.0% in patients who had undergone cataract surgery, administration of KPI-121 1.0% two times a day for 14 days achieved statistical significance for both primary efficacy endpoints of complete resolution of inflammation at day eight maintained through day 15 with no need for rescue medication and complete resolution of pain at day eight maintained through day 15 with no need for rescue medication. In each of these trials, KPI-121 1.0% was well tolerated with no increases in intraocular pressure, or IOP, a common side effect of steroids, compared to placebo and with no treatment-related significant adverse events observed during the course of either trial.

We anticipate submitting an NDA for KPI-121 1.0% by the end of 2017. Although our Phase 3 trials of KPI-121 1.0% are in patients who have undergone cataract surgery, we expect that these trials will support, and we intend to seek, an indication for post-operative inflammation and pain following ocular surgery. If approved, KPI-121 1.0% could be the first FDA-approved product for the treatment of post-operative inflammation and pain with twice daily dosing.

KPI-121 0.25% for Dry Eye Disease

Dry eye disease is a chronic, episodic, multifactorial disease affecting the tears and ocular surface that can result in tear film instability, inflammation, discomfort, visual disturbance and ocular surface damage. Dry eye disease can have a significant impact on quality of life and can potentially cause long-term damage to the ocular surface. Due to the impact of dry eye disease on tear film dynamics, the condition can affect performance of common vision-related activities such as reading, using a computer and driving, and can lead to complications associated with visual impairment. In addition, the vast majority of dry eye patients experience acute exacerbations of their symptoms, which are commonly referred to as flares, at various times throughout the year. These flares can be triggered by numerous factors, including exposure to allergens, pollution, wind and low humidity, intense visual concentration such as watching television and working at a computer, contact lens wear, smoking and sleep deprivation, which cause ocular surface inflammation and impact tear production and/or tear film stability.

We estimate dry eye disease affects approximately 33 million people in the United States based on an estimated dry eye disease prevalence of 14.5% described below and applied to the population of the United States over 20 years old. Based on third-party academic research, we believe dry eye disease

results in approximately $55 billion in direct and indirect costs in the United States each year, of which approximately $3.8 billion are direct medical costs. The exact prevalence of dry eye disease is unknown due to the difficulty in defining the disease and the lack of a single diagnostic test to confirm its presence. The Beaver Dam Offspring Study, a major epidemiological study published in 2014 in the *American Journal of Ophthalmology*, reported that in a cohort of over 3,000 patients, dry eye disease was self-reported by 14.5% of the patients. The prevalence of dry eye disease increases with age, and we expect that the number of dry eye disease cases will increase as the U.S. population continues to age. Epidemiology and market research commissioned by us indicate that there are an estimated 16 million patients with a diagnosis of dry eye disease in the United States. We commissioned ClearView Healthcare Partners, a life science strategy consulting firm, to conduct a survey of 30 dry eye disease patients, which we refer to as the patient survey. The patient survey included a representative set of dry eye patients based on demographics and disease characteristics, such as age, sex and therapeutic history. The patients represented a broad range of dry eye disease severity. In conducting the survey, Clearview asked patients about their existing dry eye symptoms, including the typical frequency and duration of their dry eye flares, as well as their current disease management approaches, if any. Clearview also described the KPI-121 0.25% expected product attributes and anticipated treatment regimen to gauge their level of interest in the product candidate. Although the patient survey involved a limited number of patients and thus may be less representative than a survey conducted with a larger sample size, we believe it provides useful insight into the prevalence and severity of dry eye disease. Based upon our review of the patient survey, we believe dry eye disease is a burdensome disease that has a significant impact on the quality of life of patients with dry eye disease.

The most commonly used treatments for dry eye disease in the United States are over-the-counter eye drops, often referred to as "artificial tears," and two prescription pharmaceutical products, Restasis® and Xiidra®. Artificial tears are intended to supplement insufficient tear production or improve tear film instability, but do not treat the underlying inflammation in dry eye disease. Restasis increases tear production and Xiidra treats the signs and symptoms of dry eye disease, however, both Restasis and Xiidra are typically used chronically for dry eye patients who have continuous symptoms. In 2016, Restasis had sales of approximately $1.42 billion in the United States, while Xiidra, which was FDA approved in July 2016 and commercially launched in the United States in August 2016, had sales of $54.0 million. As each of Restasis and Xiidra have a relatively long onset of action, they are not generally used for the short-term treatment of episodic dry eye flares. We believe there is a larger proportion of dry eye patients whose symptoms are primarily episodic as opposed to chronic, and for whom a chronic therapy is not necessary. For these patients, we believe an FDA-approved, acute, short-term therapy can address a significant unmet need. Our review of the patient survey indicates that approximately 90% of surveyed patients reported experiencing flares, with flares on average lasting approximately 11 days and occurring approximately 9 times per year.

We are developing KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease, utilizing a two-week course of therapy administered four times a day. We believe that KPI-121 0.25%'s broad mechanism of action, rapid onset of relief of both signs and symptoms, favorable tolerability profile and potential to be complementary to existing therapies, will result in a favorable profile for the management of dry eye flares and other dry eye associated conditions that would benefit from temporary relief of dry eye signs and symptoms. We believe these features of KPI-121 0.25% may be attractive to prescribing clinicians and could be a first line prescription medication choice for a substantial number of their dry eye patients. Based upon our review of the patient survey, we also believe patients with dry eye disease will be attracted to KPI-121 0.25%'s novelty, rapid efficacy and as-needed use.

In our Phase 2 clinical trial of 150 patients with dry eye disease, administration of KPI-121 0.25% four times a day for 4 weeks resulted in a statistically significant reduction in the primary sign endpoint of conjunctival hyperemia, or redness, at day 29 compared to placebo. Significant reduction in

conjunctival hyperemia was also observed at day 15, the first measurement point two weeks after initiation of dosing with KPI-121 0.25%. There was also a meaningful reduction in the primary symptom endpoint of patient-reported ocular discomfort severity at days 15 and 29, although the improvements did not achieve statistical significance. We did not expect to achieve statistical significance for ocular discomfort in light of the small number of patients in this Phase 2 trial. KPI-121 0.25% was generally well tolerated, with no clinically significant treatment-related adverse events observed during the course of the trial.

Following discussions with key advisors and a meeting with the FDA in June 2015, we initiated in June 2016 two parallel Phase 3 clinical trials, each with a target enrollment of at least 900 dry eye patients, comparing KPI-121 0.25% to placebo, both administered four times a day for 14 days. We expect to receive topline results from both trials by the end of 2017. As of June 30, 2017, we had enrolled over 1,550 dry eye patients across the two trials. The primary endpoints in these trials are conjunctival hyperemia, or redness, at day 15 and ocular discomfort severity at day 15. The trial design of the parallel Phase 3 trials is similar to our completed Phase 2 trial, other than the shortened length of dosing, the timing of the primary endpoint measurements and the increased number of patients. We believe that we will be able to demonstrate statistically significant reductions in our two primary endpoints in these Phase 3 trials. If these trials are successful, we anticipate submitting an NDA for KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease in the first half of 2018.

rTKI Program for Retinal Diseases

Commonly used therapies for retinal diseases must be injected directly into the patient's eye, often at monthly intervals. We believe that our MPP technology has the potential to facilitate the delivery of therapeutics into tissues in the back of the eye via topical dosing, which has the potential to provide a less invasive method of administration and a competitive advantage over therapies administered by intravitreal injection.

After synthesizing and testing a number of new chemical entities, or NCEs, from our topically applied rTKI program, we are further evaluating compounds in our rTKI program that inhibit the VEGF pathway for the potential topical treatment of a number of retinal diseases, including wet age-related macular degeneration, or Wet AMD, Diabetic Retinopathy, or DR, Diabetic Macular Edema, or DME, and Retinal Vein Occlusion, or RVO, each of which involves either the leakage of existing blood vessels or the proliferation of poorly formed and leaky blood vessels at the back of the eye. These eye diseases can significantly reduce vision and eventually lead to blindness. VEGF is a protein that plays a critical role in the formation of new blood vessels and increased permeability, two pathological processes that contribute to the vision loss associated with certain retinal diseases. In our rTKI program, we are initially targeting Wet AMD with our lead rTKI compound, KPI-285. KPI-285 inhibits the VEGF pathway. In preclinical rabbit studies, topical administration of KPI-285 achieved concentrations in tissues in the back of the eye well above the concentrations required for *in vitro* inhibition of 50% of the VEGF receptor kinase activity. Prior to initiating IND-enabling studies, we may consider potential collaborative partnership opportunities to advance product candidates we develop through our rTKI program, including KPI-285.

Other Potential Applications of our MPP Technology

While our current focus is on the application of our MPP technology in ophthalmology, we have conducted preclinical studies demonstrating the potential of our MPP technology in other therapeutic areas. Mucus limits delivery of conventionally formulated drugs to the lung, cervical/vaginal tract, gastrointestinal tract and other mucus-protected tissues. In preclinical studies, we have demonstrated that our MPP technology can be used to increase the mucus penetration of over fifteen classes of drugs, including anti-infective and anti-inflammatory drugs.

Strategy

Our goal is to become a leading biopharmaceutical company focused on the development and commercialization of therapeutics using our proprietary MPP technology. Key elements of our strategy include:

- ***Successfully complete the clinical development of, and seek regulatory approval for, our KPI-121 1.0% and KPI-121 0.25% product candidates.*** Having received positive topline data from our second Phase 3 clinical trial for KPI-121 1.0%, we plan to submit an NDA for the treatment of post-operative inflammation and pain following ocular surgery by the end of 2017. We are also focused on completing our two ongoing parallel Phase 3 clinical trials for KPI-121 0.25%, administered four times a day in patients with dry eye disease. We expect to receive topline data from our ongoing Phase 3 clinical trials by the end of 2017 and, if successful, plan to submit an NDA for the temporary relief of the signs and symptoms of dry eye disease in the first half of 2018.

- ***Maximize the commercial potential of KPI-121 1.0% for post-operative inflammation and pain.*** Assuming we submit an NDA by the end of 2017, we expect the FDA could approve the NDA for KPI-121 1.0% for the treatment of post-operative inflammation and pain following ocular surgery in the second half of 2018. Assuming we receive marketing approval for KPI-121 1.0% within this timeframe, we intend to commercialize KPI-121 1.0% in the United States by the end of 2019 with our own specialty sales force that will target ophthalmologists and optometrists.

- ***Maximize the commercial potential of KPI-121 0.25% for dry eye disease.*** If our ongoing parallel Phase 3 clinical trials for KPI-121 0.25% in patients with dry eye disease are successful and we submit an NDA in the first half of 2018, we expect the FDA could approve the NDA for KPI-121 0.25% for dry eye in late 2018 to early 2019. Assuming we receive marketing approval for KPI-121 0.25% within this timeframe, we intend to commercialize KPI-121 0.25% in the United States by the end of 2019 with our own specialty sales force that will target ophthalmologists and optometrists. If the results of our ongoing Phase 3 trials for patients with dry eye disease are positive, we also expect to submit an MAA for KPI-121 0.25% for the short-term treatment of dry eye disease. We also expect to explore commercialization of KPI-121 0.25% for the treatment of dry eye in certain markets outside the United States, including the EU, utilizing a variety of collaboration, distribution and other marketing arrangements with one or more third parties.

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

Our MPP Technology

Opportunities in Drug Delivery across Mucosal Barriers

The body is surrounded by boundary tissues that play the important physiological role of preventing foreign bodies from penetrating into the body. The mucus that coats these tissues, the eyes, lung, cervical/vaginal tract and gastrointestinal tract, for example, serves as a protective barrier to trap

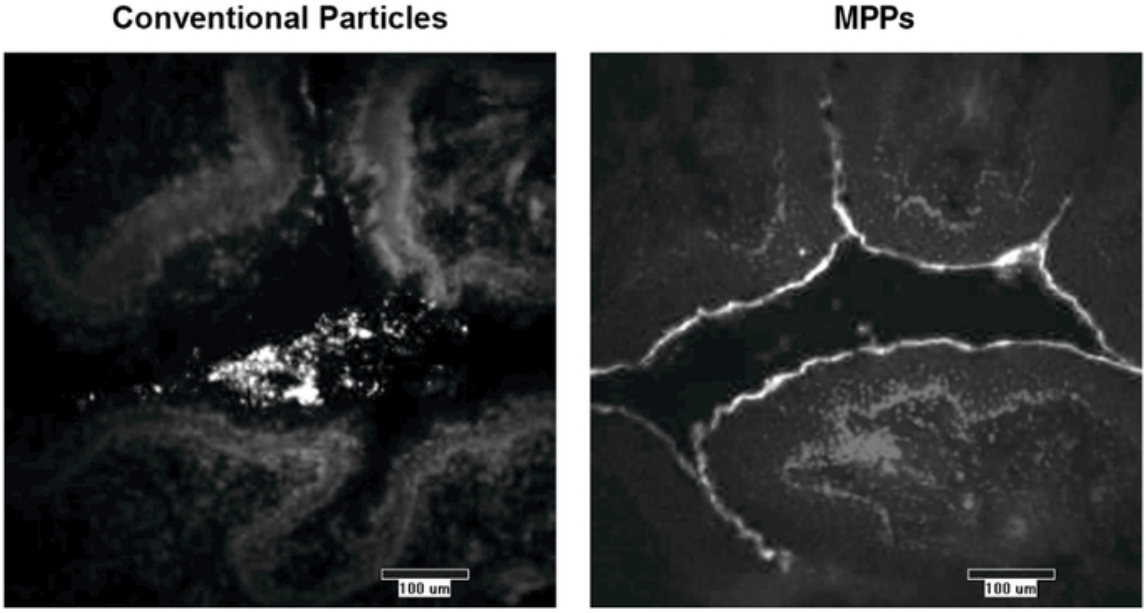
and eliminate particulate matter, such as viruses, bacteria and allergens, before these agents can enter the underlying tissues and cause infections or elicit reactions. However, in playing this pivotal role of protection, mucus can also hinder medical treatments by limiting the penetration of medications to mucus-protected tissues, thereby reducing their therapeutic effect.

Mucus also makes it difficult to treat many ophthalmic diseases. The body can rapidly eliminate drugs delivered to the eye via the tear film protecting the surface of the eye, which can significantly limit the effectiveness of these drugs. This is the case both for drugs designed to treat conditions in the front of the eye, such as dry eye disease and post-operative inflammation and pain, as well as for drugs designed to treat conditions in the back of the eye, such as retinal diseases. We believe that our proprietary MPP technology has the potential to address this clear unmet medical need for more efficient delivery of drugs administered via topical ocular dosing.

MPP Technology

Our MPPs are selectively-sized nanoparticles, with average diameters of approximately 330 nanometers, and have non-covalent 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 believe this enables enhanced efficacy at equal or lower doses as well as less frequent dosing for improved patient convenience and compliance.

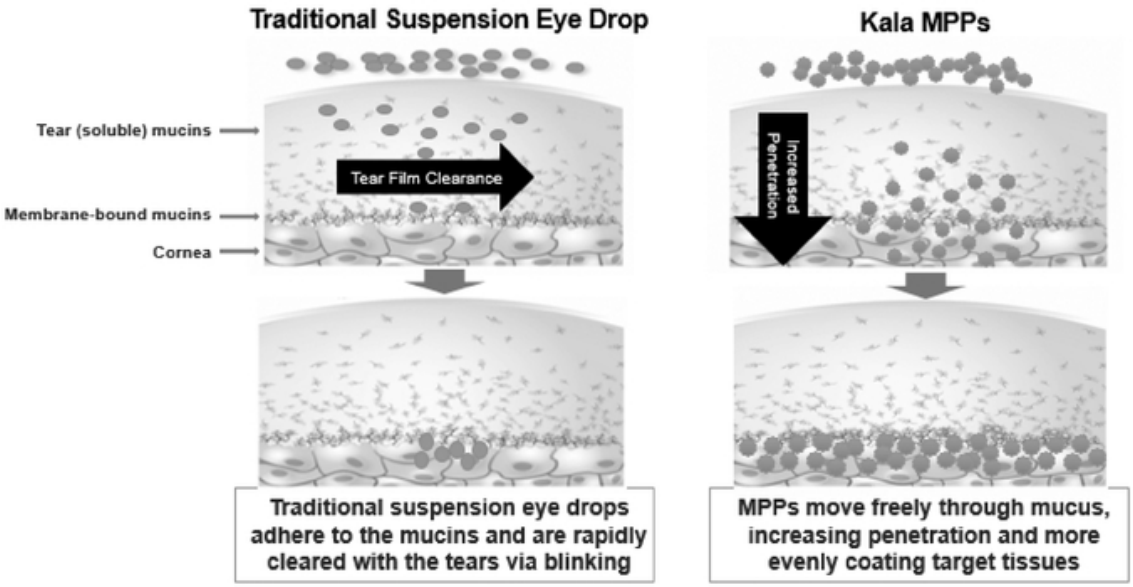
In a preclinical study, MPPs or conventional particles in a hypotonic solution were administered intravaginally to mice. Ten minutes after administration, the vaginal tissues were dissected and stained. The image on the left below shows the distribution of the conventional particles and the image on the right below shows the distribution of the MPPs. The conventional particles aggregated in the lumenal mucus and did not reach the target tissues. In contrast, the MPPs coated the entire vaginal epithelium, including all the target surfaces.



Source: Laura M. Ensign et al., Mucus-Penetrating Nanoparticles for Vaginal Drug Delivery Protect Against Herpes Simplex Virus, Science Translational Medicine, June 14, 2012.

While a significant portion of conventionally formulated ophthalmic drugs are rapidly eliminated via the tear film, we have shown that our MPPs are capable of achieving higher concentration on the surface of the eye, thereby enabling the active drug substance to reach cells in the underlying ocular tissue at higher levels.

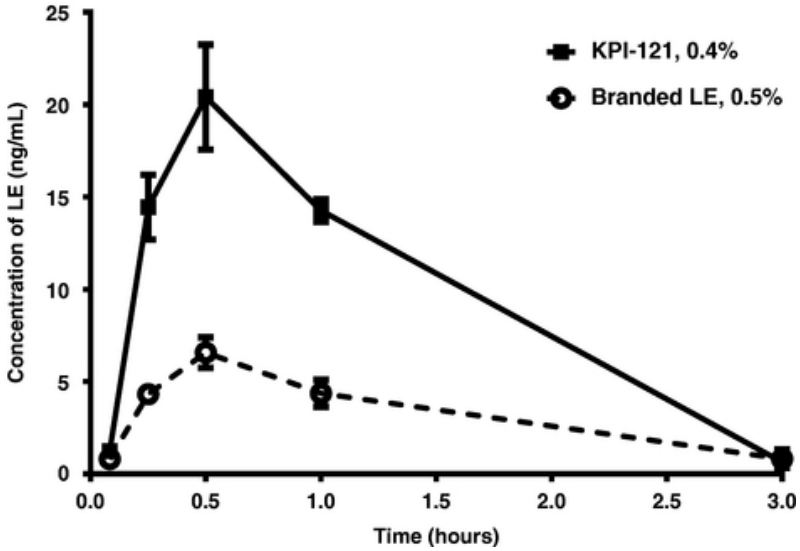
The graphic below illustrates the ability of our MPP drug nanoparticles to penetrate the tear and membrane-bound mucins to reach the ocular surface, as compared to conventional, non-coated particles, which adhere to the mucins in the tear film and are cleared with the tears through blinking.



This graphic is included for illustrative purposes only and is not intended to provide a complete representation of the way in which our MPP drug nanoparticles interact with the ocular surface.

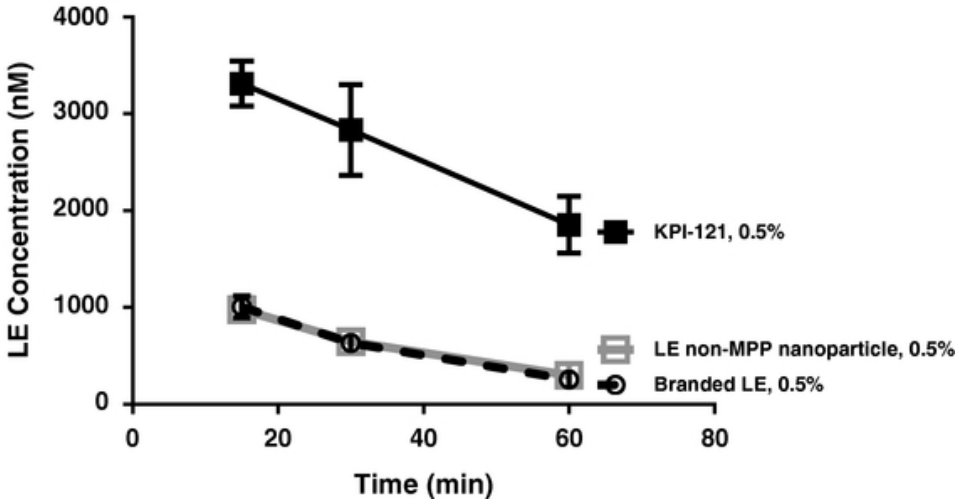
Our initial focus is to leverage our MPP technology to enhance delivery of drugs into the eye. In preclinical studies, KPI-121 demonstrated favorable pharmacokinetic characteristics and increased drug penetration into ocular tissues as compared to a branded form of LE. In a preclinical study of ocular inflammation in rabbits, KPI-121 0.5% administered four times a day, or QID, showed a larger reduction of inflammation as compared to a branded form of LE 0.5% given QID, as measured by the mean aqueous humor cell counts after intravitreal injection of lipopolysaccharide. We also administered either 0.4% KPI-121 or 0.5% branded LE to the eyes of two groups of rabbits. As illustrated in the line graph below, the concentrations of LE in aqueous humor, a transparent gelatinous fluid that fills the anterior and posterior chambers between the lens and the cornea, of the rabbit eyes treated with KPI-121 were more than three times higher than the rabbit eyes treated with branded LE 30 minutes after dosing, at a 20% lower concentration.

LE in Aqueous Humor



We administered KPI-121 0.5%, branded LE 0.5%, or 0.5% of an LE non-MPP nanoparticle, to the eyes of three groups of rabbits and measured the amount of LE that was delivered to the cornea. The non-MPP nanoparticle was similar in size to our MPP nanoparticles but lacked the proprietary surface coating used in our MPP nanoparticles. As illustrated in the line graph below, concentrations of LE in the cornea of the rabbit eyes treated with KPI-121 were more than three times higher than the concentrations in rabbits treated with branded LE between 20 and 40 minutes after dosing. In addition, the rabbit eyes treated with the non-MPP nanoparticles had concentrations of LE similar to that in the rabbit eyes treated with branded LE and did not display the improved drug bioavailability properties observed with KPI-121. We believe these results highlight the importance of our proprietary MPP technology and show that KPI-121's improved pharmacokinetic profile has the potential to reduce the dosing strength and/or frequency of administration of LE with KPI-121 as compared to branded LE.

LE in Cornea



We also have demonstrated the potential of our MPP nanoparticles to increase the mucus penetration of over fifteen classes of drugs. While our current focus is in ophthalmology, in preclinical studies, our MPP technology has been effective in delivering drugs to the lungs, cervical/vaginal tract, gastrointestinal tract and other mucus-protected tissues. We have the ability to vary the rate of drug release as appropriate for the targeted disease state and tissue. As a result, drugs can be delivered either in rapid release formulations or as sustained release formulations that slowly release drug over a time period that ranges from hours to days.

Eye Disease

The human eye is often segmented into two sections—the front and back of the eye. The front of the eye consists of tissues and structures responsible for the protection and maintenance of the eye (including the cornea, conjunctiva and tear film), for providing nutrition to the various tissues of the eye (aqueous humor) and for facilitating the optimal transfer and focusing of light to the retina (including the cornea, iris and lens). Front-of-the-eye diseases include ocular inflammation, dry eye disease, infection, allergy and refractive disorders. Clinicians typically treat diseases that affect the front of the eye with topically applied eye drops. A major limitation of these treatments is that the eye rapidly eliminates topically applied medications via the tear film, limiting the penetration of drugs into the ocular tissue.

The back of the eye contains the retina, which is the light sensing layer of tissue, the choroid, which is a key vascular layer of the eye, the vitreous humor, which is a transparent gel that fills the vitreous chamber between the lens and the retina, and the optic nerve, which transmits visual information from the retina to the brain. Common retinal diseases include AMD, DR, DME and RVO. These diseases frequently result in damage to the vasculature of the eye, leading to poor function and/or leaking of existing vessels and often leading to proliferation of new, abnormal and leaky blood vessels in the back of the eye. These conditions can lead to retinal damage, scarring and irreversible loss of vision. The most common treatments for these diseases involve administration of biologic agents that block the VEGF pathway and prevent or retard the blood vessel leakage and/or proliferation. Unfortunately, clinicians must inject these biologic agents directly into the vitreous of the eye via frequent intravitreal injections, or IVTs, to maintain vision. Topical administration of therapeutics to treat retinal diseases has not yet been demonstrated to be effective in the management of retinal disease, most likely due to insufficient delivery of drug to the back of the eye.

Our Product Candidates

KPI-121 Product Candidates

Both KPI-121 1.0% and KPI-121 0.25% consist of MPP nanosuspensions of LE designed to enhance penetration through the mucus layer of the tear film to enable LE to reach the underlying ocular tissue. We believe that both of our KPI-121 product candidates have a favorable profile for the treatment of front-of-the-eye inflammatory conditions due to their broad mechanism of action, rapid onset of relief and favorable tolerability profile. LE is a corticosteroid developed specifically for the treatment of ophthalmic conditions and is designed to limit side effects, such as increases in IOP and cataract formation, that are associated with other ocular steroids. The first LE containing product was approved by the FDA in 1998.

Both of our KPI-121 product candidates, KPI-121 1.0% and KPI-121 0.25%, are eye drops that are topically administered as an aqueous suspension of LE. In preclinical studies, MPP nanosuspensions of LE demonstrated superior pharmacokinetic characteristics and bioavailability as compared to branded LE, with increased penetration of LE into ocular tissues. These product candidates include:

- KPI-121 1.0%, administered two times a day, which we are developing for the treatment of post-operative inflammation and pain following ocular surgery; and

- KPI-121 0.25%, administered four times a day, which we are developing for the temporary relief of the signs and symptoms of dry eye disease.

We initially filed an IND for KPI-121 for the treatment of post-operative inflammation and pain following ocular surgery in December 2013, and subsequently amended the IND to also include the treatment of the signs and symptoms of dry eye disease in June 2014. We have completed two pivotal Phase 3 clinical trials of KPI-121 1.0% and a Phase 2 clinical trial of KPI-121 0.25%. We anticipate that we will submit an NDA for KPI-121 1.0% for the treatment of post-operative inflammation and pain following ocular surgery by the end of 2017. Assuming we achieve positive results from our ongoing Phase 3 clinical trials for KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease, we anticipate that we will submit an NDA for KPI-121 0.25% in the first half of 2018. We expect to file both of these NDA submissions under section 505(b)(2) of the FDCA. The section 505(b)(2) pathway provides an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations, or new uses of previously approved products, by enabling an applicant to rely, in part, on the FDA's findings of safety and efficacy for an existing product, or published literature, in support of the NDA. An NDA filed under section 505(b)(2) would allow us to reference the extensive data already collected by the FDA on LE to supplement the safety and efficacy data generated in our clinical trials of KPI-121 1.0% and KPI-121 0.25%.

KPI-121 1.0% for Post-Operative Inflammation and Pain

Post-Operative Inflammation and Pain Overview

Ocular inflammation and pain are common complications following cataract surgery. According to Marketscope, in 2016 there were 7.7 million ocular surgeries in the United States, including 3.9 million cataract surgeries. Marketscope also projected that there would be approximately 9.4 million ocular surgeries in the United States in 2021, including approximately 4.6 million cataract surgeries. Other commonly performed ocular surgeries include cornea and glaucoma procedures. Tissue damage caused by ocular surgery leads to the production of prostaglandins and increases in blood flow to the affected area, which contribute to inflammation. The standard of care for post-operative inflammation and pain includes anti-inflammatory drugs such as corticosteroids, which improve patient comfort and accelerate recovery through disruption of the inflammatory cascade. Commonly used topical ocular corticosteroid products for the treatment of post-operative inflammation and pain are approved for dosing four times a day. This dosing regimen can be burdensome for patients as they are taking multiple eye drops following surgery, and four-times-a-day dosing is believed to reduce patient compliance. There are no ocular corticosteroid products currently approved in the United States for dosing two times a day for the treatment of post-operative inflammation and pain.

Limitations of Existing Treatments for Post-Operative Inflammation and Pain

LE is a unique steroid that was designed to limit side effects, such as increases in IOP and cataract formation, that are associated with other ocular steroids. The first LE containing product, Lotemax®, was approved by the FDA in 1998. Subsequent gel and ointment formulations of Lotemax were approved by the FDA for the treatment of post-operative inflammation and pain following ocular surgery. Durezol® is a topical steroid approved by the FDA for the treatment of inflammation and pain associated with ocular surgery. Durezol eye drops are dosed four times a day for two weeks followed by dose tapering based on patient response.

The most commonly used ocular steroids, including Lotemax products and Durezol, are approved for the treatment of post-operative inflammation and pain with a four-times-a-day dosing regimen. This dosing regimen can be burdensome for patients as they are taking multiple eye drops following surgery, and four-times-a-day dosing may reduce patient compliance with the prescribed medication. There is currently no marketed ocular steroid product with an approved twice-a-day dosing regimen.

KPI-121 1.0% Opportunity in Post-Operative Inflammation and Pain

We believe that KPI-121 1.0% has a favorable profile for the treatment of inflammation and pain following ocular surgery, including the following attributes:

- *Twice daily dosing.* In our completed Phase 3 clinical trials, patients who had undergone cataract surgery and were treated with KPI-121 1.0% demonstrated a significant increase in the resolution of inflammation and pain after seven days of dosing using a twice daily dosing regimen as compared to patients treated with placebo. Given the generally accepted view that less frequent dosing leads to higher patient compliance, we believe the ability to achieve a significant reduction in inflammation and pain following surgery with a twice-a-day product will be a key differentiating attribute of KPI-121 1.0%.

- *Favorable tolerability profile.* LE is one of the safest topical ocular steroids available due to its unique pharmacokinetics. LE was designed to be metabolized after exerting its anti-inflammatory action in the eye. The metabolism of LE to inactive metabolites reduces exposure of the trabecular meshwork to the active steroid, thus reducing risk of IOP increase relative to other steroids. In our completed Phase 3 clinical trials, KPI-121 1.0% had a tolerability profile comparable to placebo, with no treatment-related serious adverse events observed during the course of either Phase 3 trial.

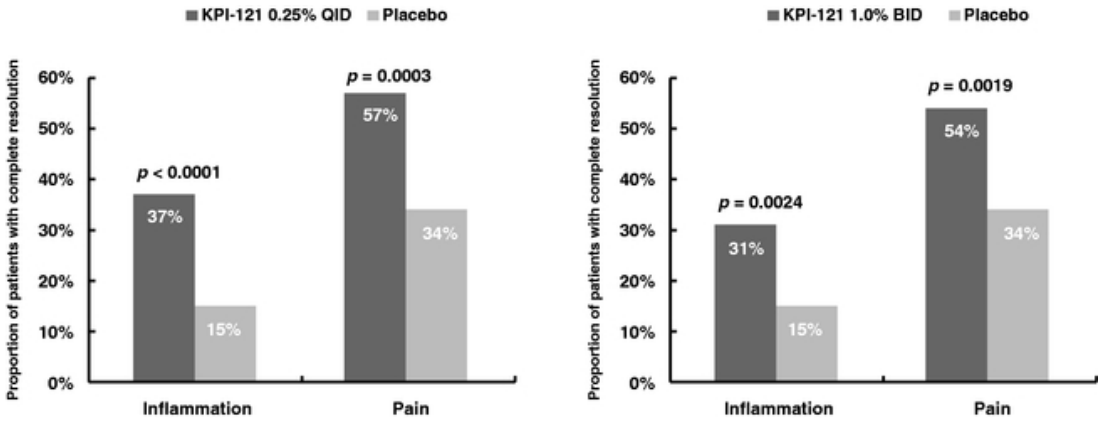
KPI-121 1.0% Phase 3 Clinical Development Program

In 2014, we conducted our first Phase 3 multi-center, randomized, double-masked, placebo-controlled, parallel-group trial designed to evaluate two dosing regimens of KPI-121 ophthalmic suspension versus placebo in 380 patients following cataract surgery. Patients who had a threshold degree of ocular inflammation on the day after surgery were randomized to receive either KPI-121 1.0% administered twice a day, or BID, KPI-121 0.25% administered QID or placebos administered with the same frequency, in each case for two weeks. The primary endpoints for each of the treatment arms were:

- the proportion of patients with complete resolution (grade=0) of anterior chamber cells, which is an objective measure of intraocular inflammation, at post-operative day eight and maintained through the end of the trial with no need for rescue medication; and

- the proportion of patients with complete resolution of pain (grade=0) at post-operative day eight and maintained through the end of the trial with no need for rescue medication.

At day eight, statistical significance in the primary endpoint of complete resolution of inflammation with no need for rescue medications was achieved with both KPI-121 1.0% ($p=0.0024$) and KPI-121 0.25% ($p<0.0001$). Statistical significance in the primary endpoint of complete resolution of ocular pain by day eight with no need for rescue medications was also achieved for KPI-121 1.0% ($p=0.0019$) and KPI-121 0.25% ($p=0.0003$). We determined statistical significance based on a widely used, conventional statistical method that establishes the p-value of clinical results. The p-value is a measure of compatibility between the observed outcomes and the hypothesis that there is no treatment effect attributable to the product candidate; the p-value represents the likelihood that the observed outcome occurred by chance alone. Typically, a p-value of 0.05 or less represents statistical significance. The bar graph on the left below shows the percentage of patients in the KPI-121 0.25% and placebo treatment arms who had complete resolution of inflammation and complete resolution of pain at day eight of treatment, and the bar graph on the right below shows the percentage of patients in the KPI-121 1.0% and placebo treatment arms who had complete resolution of inflammation and complete resolution of pain at day eight of treatment.



Both KPI-121 1.0% and KPI-121 0.25% were well-tolerated in this trial, with no treatment-related serious adverse events observed during the course of the trial. Six and four tenths percent (6.4%) of patients in the KPI-121 1.0% treatment arm and 10.1% of patients in the KPI-121 0.25% treatment arm reported ocular adverse events, compared to 15.9% of patients in the placebo arm. The most common ocular adverse events were reported by no more than 1.6% of patients in the KPI-121 1.0% treatment arm, 2.3% of patients in the KPI-121 0.25% treatment arm, and 4.0% of patients in the placebo arm. Patients in the KPI-121 1.0% and placebo treatment arms had a similar profile with respect to mean IOP on each of days four, eight, 15 and 18 of the trial. Furthermore, no more than 1.5% of patients at each testing point in each of the KPI-121 and placebo arms experienced increases in IOP of greater than 5 mm Hg resulting in total IOP greater than 20 mm Hg, each as compared to baseline (measured prior to onset of treatment) on days four, eight, 15 and 18 of the trial.

In June 2016, we initiated enrollment in a 520 patient confirmatory double-masked, randomized, controlled Phase 3 clinical trial of KPI-121 1.0% to evaluate the safety and efficacy of KPI-121 1.0% in subjects with inflammation and pain following cataract surgery. The Phase 3 clinical trial was designed to compare KPI-121 1.0% administered twice a day for 14 days to placebo.

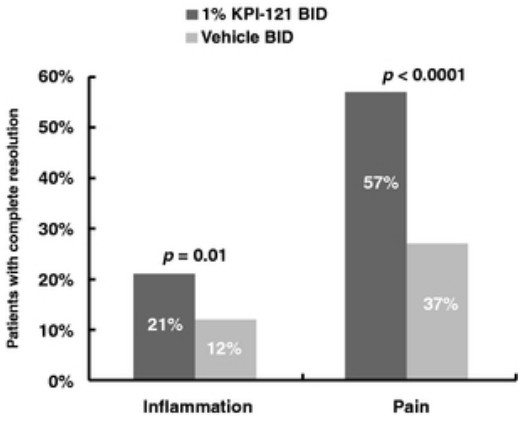
In this trial, patients who had a threshold degree of ocular inflammation on the day after surgery were randomized in an approximate 1:1 ratio to receive either KPI-121 1.0% ophthalmic suspension or placebo, in each case dosed twice a day for 14 days.

The primary endpoints in the trial are the same as those in the initial Phase 3 trial:

- the proportion of patients with complete resolution (grade=0) of inflammation as measured by anterior chamber cells at post-operative day eight and maintained through day 15 with no need for rescue medication; and

- the proportion of patients with complete resolution of pain (grade=0) at post-operative day eight and maintained through the day 15 with no need for rescue medication.

In May 2017 we announced topline results from this trial. In this second trial, statistical significance was achieved in the primary efficacy endpoint of complete resolution of inflammation at day eight maintained through day 15 with no need for rescue medications for KPI-121 1.0% (p=0.01) compared to placebo. Statistical significance was also achieved in the primary efficacy endpoint of complete resolution of pain at day eight maintained through day 15 with no need for rescue medications for KPI-121 1.0% (p<0.0001) compared to placebo. The bar graph below shows the percentage of patients in the KPI-121 1.0% and placebo treatment arms who had complete resolution of inflammation and complete resolution of pain at day eight of treatment.



KPI-121 1.0% also achieved statistical significance in each of the secondary endpoints of: complete resolution of pain at day four with no need for rescue medications (p<0.0001); complete resolution of anterior chamber flare at day four with no need for rescue medications (p<0.0001); and change from baseline in mean anterior cell count at day four (p=0.0078).

KPI-121 1.0% was well-tolerated in this trial, with no treatment-related serious adverse events observed during the course of the trial. Six and nine tenths percent (6.9%) of patients in the KPI-121 1.0% treatment arm reported ocular adverse events compared to 10.4% of patients in the placebo arm. The most common ocular adverse events were reported by no more than 1.1% of patients in the KPI-121 1.0% treatment arm and 2.3% of patients in the placebo arm. Patients in the KPI-121 1.0% and placebo treatment arms had a similar profile with respect to mean IOP on each of days four, eight, 15 and 18 of the trial. Furthermore, no more than 1% of patients at each testing point in each of the KPI-121 and placebo arms experienced increases in IOP of greater than 5 mm Hg resulting in total IOP greater than 20 mm Hg, each as compared to baseline (measured prior to onset of treatment) and on days four, eight, 15 and 18 of the trial.

Based on our discussions with the FDA, we believe that we have generated sufficient safety information to support an NDA submission and that the only additional clinical trial required is a pharmacokinetic trial in 20 healthy volunteers to evaluate plasma levels of LE and its key metabolites following topical dosing of KPI-121 1.0%. We recently completed this trial and found no detectable plasma concentrations of LE or its key metabolites during and following two weeks topical dosing of KPI-121 1.0% given BID. We expect to submit an NDA by the end of 2017. Although we have conducted our Phase 3 trials of KPI-121 1.0% in patients who have undergone cataract surgery, based upon our discussions with the FDA, we anticipate that these trials may support, and we intend to seek, an indication for the treatment of post-operative inflammation and pain following ocular surgery. In connection with our NDA submission, we intend to submit an application for pediatric exclusivity, which, if granted, could provide an additional six months of marketing exclusivity for KPI-121 1.0% once we complete a planned clinical trial in pediatric patients who have undergone cataract surgery. We also intend to seek "priority review" of our NDA submission.

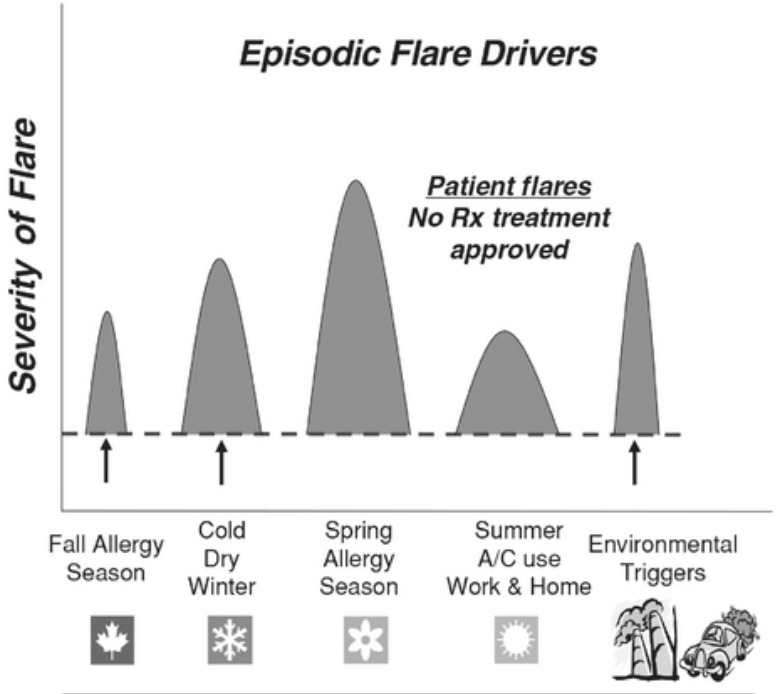
KPI-121 0.25% for Dry Eye Disease

Dry Eye Disease Overview

Dry eye disease is a chronic, episodic, multifactorial disease affecting the tears and ocular surface that can result in tear film instability, inflammation, discomfort, visual disturbance and ocular surface damage. While the precise cause of dry eye disease is not fully understood, it often involves impairment of the lacrimal unit, which consists of the lacrimal glands, ocular surface and the sensory and motor nerves that connect them, and has a significant inflammatory component. There is significant published

research that suggests that inflammation plays a major role in the development of dry eye disease. Dry eye disease can have a significant impact on quality of life and can potentially cause long-term damage to the ocular surface. Due to the impact of dry eye disease on tear film dynamics, the condition can affect performance of common vision-related activities such as reading, using a computer and driving, and can lead to complications associated with visual impairment. Dry eye disease is commonly treated by ophthalmologists and optometrists.

A significant number of dry eye disease patients experience acute, episodic exacerbations of their symptoms, which we refer to as flares, at various times throughout the year that can cause significant discomfort and disability. As illustrated in the graphic below, these flares can be triggered by numerous factors, such as environmental stimuli related to exposure to allergens, pollution, wind and low humidity. Intense visual concentration, such as watching television or working at a computer, can also trigger flares. Other potential triggers include contact lens wear, smoking and sleep deprivation, which cause ocular surface inflammation and impact tear production and/or tear film stability.



This graphic is included for illustrative purposes only and is not intended to provide an actual representation of the number or severity of flares, or the drivers thereof, either on an absolute basis or relative to one another.

We estimate dry eye disease affects approximately 33 million people in the United States. Based on third-party academic research, we believe dry eye disease results in approximately $55 billion in direct and indirect costs in the United States each year, of which approximately $3.8 billion are direct medical costs. The exact prevalence of dry eye disease is unknown due to the difficulty in defining the disease and the lack of a single diagnostic test to confirm its presence. The Beaver Dam Offspring Study, a major epidemiological study published in 2014 in the *American Journal of Ophthalmology*, reported that in a cohort of over 3,000 patients, dry eye disease was self-reported by 14.5% of the patients. The prevalence of dry eye disease increases with age, and we expect that the number of dry eye disease cases will increase as the U.S. population continues to age. Epidemiology and market research commissioned by us indicate that there are an estimated 16 million patients with a diagnosis of dry eye disease in the United States. The vast majority of dry eye patients experience acute exacerbations of their symptoms, which are commonly referred to as flares, at various times throughout the year.

The most commonly used treatments for dry eye disease in the United States are over-the-counter eye drops, often referred to as "artificial tears," and two prescription pharmaceutical products, Restasis and Xiidra. Artificial tears are intended to supplement insufficient tear production or improve tear film instability, but do not treat the underlying inflammation in dry eye disease. Restasis increases tear production and Xiidra treats the signs and symptoms of dry eye disease, however, both Restasis and Xiidra are typically used chronically for dry eye patients who have continuous symptoms. As each of Restasis and Xiidra have a relatively long onset of action, they are not generally used for the short-term treatment of episodic dry eye flares. We believe there is a larger proportion of dry eye patients whose symptoms are primarily episodic as opposed to chronic, and for whom a chronic therapy is not necessary and an FDA-approved, acute, short-term therapy can address a significant unmet need.

Limitations of Existing Treatments for Dry Eye Disease

Initial treatment for dry eye disease in the United States frequently consists of over-the-counter artificial tear/lubricating eye drops. Most over-the-counter artificial tears work by lubricating the eyes and helping to maintain moisture on the outer surface of the eye to provide temporary improvement in patient comfort. These products do not treat the underlying inflammatory components of dry eye disease.

In addition to over-the-counter artificial tears, Restasis and Xiidra are sometimes prescribed as a chronic therapy for the treatment of dry eye disease. Restasis is a topically applied, ophthalmic formulation of the immuno-suppressant cyclosporine. Restasis is not approved for the treatment of the signs and symptoms of dry eye disease, but rather for increasing tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with dry eye disease. We believe that less than 10% of patients diagnosed with dry eye disease in the United States use Restasis. In 2016, Restasis had sales of approximately $1.42 billion in the United States. Restasis, however, frequently causes burning upon instillation, and, according to the package insert, 17% of patients in clinical trials of Restasis reported ocular burning upon instillation. Xiidra is a topically applied ophthalmic formulation of lifitegrast, a small molecule LF1a antagonist, which was approved by the FDA in July 2016 for the treatment of the signs and symptoms of dry eye disease and was commercially launched in the United States in August 2016. Xiidra had sales of $54.0 million in the United States in partial launch year 2016. Xiidra, like Restasis, is typically used chronically. Due to each of Restasis and Xiidra having a relatively long onset of action, they are not generally used for the short-term treatment of episodic dry eye flares.

Topically applied steroids have been shown to provide some clinical benefit to patients with dry eye disease. However, no topical steroid products are approved in the United States for the treatment of dry eye disease, and there is no widely established treatment paradigm for the safe use of steroids in treating dry eye disease. As a result, treatment of dry eye disease represents a very small percentage of total ophthalmic steroid use in the United States.

KPI-121 0.25% Opportunity in Dry Eye Disease

Based on our completed Phase 2 trial, we believe that KPI-121 0.25% has a favorable profile for the management of dry eye disease flares, including the following attributes:

- *Broad mechanism of action.* LE is a corticosteroid. Corticosteroids are known for their broad anti-inflammatory properties.
- *Rapid onset of relief.* In our Phase 2 clinical trial, patients treated with KPI-121 0.25% reported reductions in ocular discomfort within one to two days of initiation of treatment.
- *Favorable tolerability profile.* LE is one of the safest topical ocular steroids available due to its unique pharmacokinetics. LE was designed to be metabolized after exerting its anti-inflammatory

action in the eye. The metabolism of LE to inactive metabolites reduces exposure of the trabecular meshwork, an area of tissue located in the anterior chamber that is responsible for draining the aqueous humor from the eye, to active steroid, thus reducing the risk of an increase in IOP relative to other steroids. To date, we have unmasked data from over 400 patients treated with KPI-121 and have seen similar profiles with respect to mean IOP and the frequency of increases in IOP levels in patients treated with KPI-121 compared to patients treated with placebo. In our Phase 2 clinical trial of KPI-121 0.25% in dry eye disease, only 6.9% of patients treated with KPI-121 0.25% reported instillation site pain as compared to 3.8% for placebo.

- *Specifically targeting relief of episodic dry eye flares.* The mechanism of action and rapid onset of relief of KPI-121 0.25% in dry eye disease is distinct from that of artificial tears and chronic therapies like Restasis and Xiidra. Therefore, we expect it to be used as a stand-alone short course therapy to provide rapid relief of dry eye flares by improving ocular discomfort (a dry eye symptom) and reducing ocular redness (a dry eye sign).

- *Potentially complementary to existing therapies.* We believe that patients on chronic therapies can also experience dry eye flares and could potentially benefit from using KPI-121 0.25% in addition to their maintenance therapy.

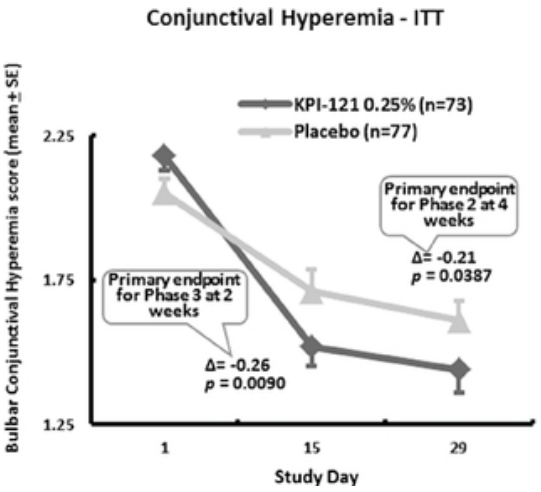
If we successfully complete our development program and receive FDA approval of our NDA for KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease, we believe that we will have the first FDA-approved product for this indication with demonstrated safety and efficacy and an easy-to-follow two-week course dosing regimen. We believe that these attributes will make KPI-121 0.25% attractive to prescribing clinicians for treating patients that suffer from dry eye flares.

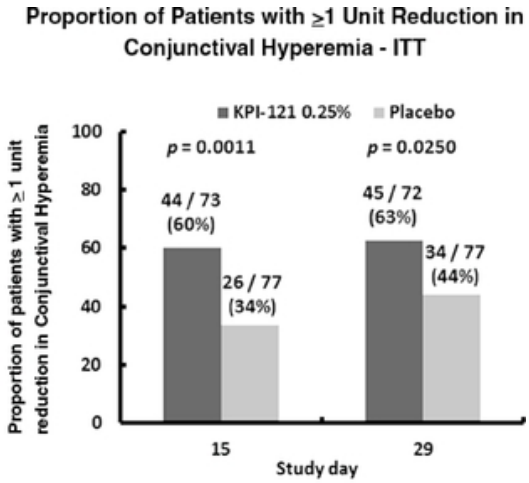
KPI-121 0.25% Phase 2 Clinical Trial Results

In 2014, we conducted a Phase 2 double-masked, randomized, controlled clinical trial of KPI-121 0.25% in 150 patients with dry eye disease at nine clinical sites. Patients were enrolled in the trial based on their magnitude of conjunctival hyperemia and ocular discomfort prior to treatment. Patients had a two week run-in with placebo administered four times a day and were required to maintain a similar magnitude of conjunctival hyperemia and ocular discomfort following this run-in period to be included in the randomization portion of the trial. Upon achieving the trial entry criteria after this run-in period, patients were randomized to receive either KPI-121 0.25% or a placebo four times a day for 28 days. Safety and efficacy assessments were made over the four week dosing period.

For our Phase 2 clinical trial, the primary sign endpoint was conjunctival hyperemia at day 29, as measured via a 0 to 4 scale ranging from no hyperemia (score=0) to severe hyperemia (score=4), and the primary symptom endpoint was ocular discomfort severity, as reported by the patient on a visual analog scale ranging from 0 to 100 mm (0 mm=very mild; 100 mm=very severe).

KPI-121 0.25% achieved statistical significance for the primary clinical sign endpoint of conjunctival hyperemia at day 29 with a treatment difference between KPI-121 0.25% and placebo of 0.21 units (p=0.0387). The line graph on the left below plots the mean conjunctival hyperemia score for patients in the KPI-121 0.25% treatment arm and the placebo treatment arm, in each case as measured on days one, 15 and 29 of the trial. As illustrated below, the treatment difference at day 15 between KPI-121 0.25% and placebo was 0.26 units (p=0.0090). In addition, a significantly higher proportion of patients treated with KPI-121 0.25% demonstrated a reduction of one unit or greater in conjunctival hyperemia as compared to patients treated with placebo. The bar graph on the right below shows the number and percentage of patients in each of the KPI-121 0.25% and placebo treatment arms who demonstrated a reduction of one unit or greater in conjunctival hyperemia scores at days 15 and 29 of the trial.

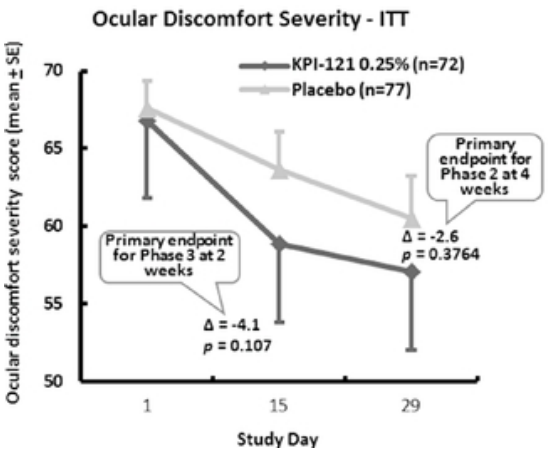


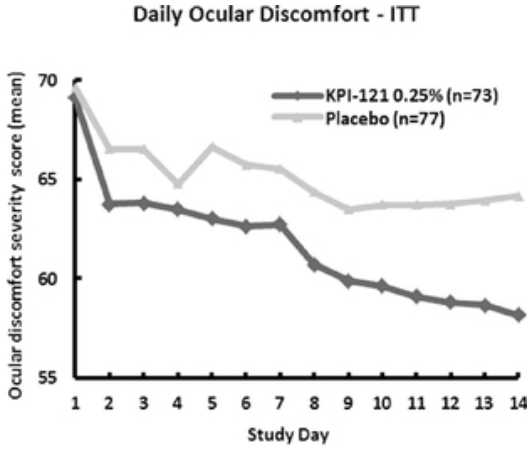


In the trial, patients treated with KPI-121 0.25% also showed reductions in the symptom endpoint of ocular discomfort severity. While KPI-121 0.25% did not achieve statistical significance for this endpoint, the treatment difference between KPI-121 0.25% and placebo for reduction of ocular discomfort was 4.1 mm at day 15 (p=0.1072) and 2.6 mm at day 29 (p=0.3674). We did not expect to achieve statistical significance for ocular discomfort in light of the small number of patients in the trial (73 patients were treated with KPI-121 0.25% and 77 patients were treated with placebo). We believe we will be able to demonstrate statistical significance for ocular discomfort severity in our upcoming Phase 3 trials, which will include much larger numbers of patients.

The line graph on the left below plots the mean ocular discomfort severity score for patients in the KPI-121 0.25% and placebo treatment arms, in each case measured as the mean of the seven days prior to days one, 15 and 29 of the trial. We conducted post-hoc analyses of the data using the three-and five-day ocular discomfort mean data for purposes of designing our Phase 3 clinical trials. Utilizing the three-day mean data for the statistical analysis yielded a treatment difference at day 15 of 5.01 mm (p=0.062). Although post-hoc analyses performed after unmasking trial results can result in the introduction of bias and may not be predictive of success in our Phase 3 clinical trials, we believe that these retrospective analyses provide additional information regarding our Phase 2 clinical trial. Based on our discussions with the FDA, we are using three-day ocular discomfort means for the statistical analysis of our primary efficacy endpoints in our ongoing Phase 3 clinical trials.

The line graph on the right below plots the mean daily ocular discomfort score for patients in the KPI-121 0.25% and placebo treatment arms for the first 14 days of the trial, showing rapid reduction in the severity of ocular discomfort for patients dosed with KPI-121.





KPI-121 0.25% was generally well tolerated, with no treatment-related significant adverse events observed during the course of the trial. The only treatment-emergent adverse event reported in greater than 3% of patients was instillation site pain, which was reported in 6.9% of patients treated with KPI-121 0.25% compared to 3.8% of patients treated with placebo. Patients in the KPI-121 0.25% and placebo treatment arms had a similar profile with respect to mean IOP, and the number of patients with an IOP increase of greater than 5 mm Hg was similar in the two treatment groups. The table below shows the mean IOP measurements for patients in the KPI-121 0.25% administered four times a day, or QID, and placebo treatment arms, in each case as measured on days one, 15 and 29 of the trial.

Mean IOP (mm Hg) in Study Eye

	KPI-121 0.25% QID Mean (SD)	Placebo Mean (SD)
Day 1	14.8 (2.33)	14.8 (2.61)
Day 15	15.3 (2.66)	15.3 (2.73)
Day 29	15.6 (3.12)	15.1 (2.80)

The table below shows the number of patients in the KPI-121 0.25% and placebo treatment arms who experienced an IOP increase of 5 mm Hg or greater from baseline (as measured at the onset of treatment) on days 15 and 29 of the trial. One patient in each of the KPI-121 0.25% and placebo treatment arms had elevated IOP classified as adverse events.

Number of Patients with IOP Increase of Greater than 5 mm Hg in Study Eye Leading to IOP Greater than 20 mm Hg

	KPI-121 0.25% QID	Placebo
Day 15	1 / 71 (1.4%)	1 / 78 (1.3%)
Day 29	1 / 72 (1.4%)	0 / 78 (0.0%)

KPI-121 0.25% Phase 3 Clinical Development Program

In June 2016, we initiated two parallel Phase 3 clinical trials, each with approximately 900 dry eye patients, comparing KPI-121 0.25% to placebo, both administered four times a day for 14 days. Both ongoing Phase 3 trials have the same patient inclusion/exclusion criteria as the Phase 2 trial and the same primary endpoints of conjunctival hyperemia and ocular discomfort severity, but in the Phase 3 trials these primary endpoints will be measured at day 15 compared to day 29 in the Phase 2 trial. We believe that measuring our primary endpoint at day 15 in the ongoing Phase 3 trials is advantageous because the statistical results of the Phase 2 trial were more robust at day 15 than at day 29. We believe ophthalmologists and optometrists are familiar with two-week dosing regimens from their use of other steroids for post-operative inflammation and pain, and we discussed with the FDA the use of a two-week dosing regimen for KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease in our June 2015 meeting. Except for the number of patients (approximately 900 in each of the Phase 3 trials versus 150 in the Phase 2 trial), the timing of the primary endpoint measurements (day 15 in the ongoing Phase 3 trials versus day 29 in the Phase 2 trial) and the duration of dosing (14 days in the Phase 3 trials versus 28 days in the completed Phase 2 trial), the key elements of the Phase 3 trial design are substantially similar to the Phase 2 trial design.

The two ongoing Phase 3, multi-center, double-masked, randomized, vehicle-controlled, parallel-group trials are designed to evaluate the safety and efficacy of KPI-121 0.25% ophthalmic suspension versus placebo in patients with dry eye disease. Patients are being enrolled in each trial based on their magnitude of conjunctival hyperemia and ocular discomfort prior to treatment. Patients have a two week run-in with placebo administered four times a day and are required to maintain a similar magnitude of conjunctival hyperemia and ocular discomfort following this run-in period to be included in the randomization portion of the trials. Upon achieving the trial entry criteria after this run-in period, patients are being randomized to either KPI-121 or placebo study arms in an approximate 1:1 ratio. Patients are receiving 1-2 drops in each eye four times a day for approximately 14 days. Key inclusion criteria include a diagnosis of dry eye in both eyes, a conjunctival hyperemia score of 2 or greater and a patient-reported ocular discomfort severity score of at least 50 mm at visit 1 (prior to the two week run-in period) and 40 mm at visit 2 (following the two week run-in period) using a visual analog scale. Patients are being evaluated at the beginning of the trial and evaluated at day eight and day 15.

The primary sign endpoint for each trial is mean change from baseline bulbar conjunctival hyperemia at day 15 as compared to day one in the region of highest severity of bulbar conjunctival hyperemia in the study eye as determined by photographic assessment using a masked photographic reading center. The primary symptom endpoint for each trial is mean change from baseline ocular discomfort severity as determined by the scores recorded in the patient's diary for the three days prior to day 15 compared to the three days prior to day one. In our Phase 2 trial, we achieved a treatment difference of 5.01 mm and the p-value of 0.062 using the mean for the three days prior to day 15 compared to three days prior to day one for the statistical analyses in post-hoc analyses.

We expect, based on our current development plan, that the FDA will require us to demonstrate effectiveness on both of our primary endpoints in our two Phase 3 clinical trials for market approval of an indication for the temporary relief of the signs and symptoms of dry eye disease. Based on our discussions with the FDA, we believe that following completion of the two Phase 3 trials, we will have generated sufficient safety information to support an NDA submission and that the only additional clinical trial required is a pharmacokinetic trial in 20 healthy volunteers to evaluate plasma levels of LE and its key metabolites following topical dosing of KPI-121 0.25%. We recently completed this trial and found no detectable plasma concentrations of LE or its key metabolites during and following two weeks topical dosing of KPI-121 0.25% given BID. We expect to submit an NDA by the end of 2017. We also intend to seek "priority review" of our NDA submission.

Based on our discussions with EU regulatory authorities, if the results of our ongoing Phase 3 trials are positive, we believe that we will be able to utilize the results from these U.S. dry eye disease trials to support a submission of an MAA for KPI-121 0.25% for the short-term treatment of dry eye disease in the EU through the Article 10(3) submission pathway. We also are currently evaluating the scope of additional manufacturing and stability data we may need to acquire to support our MAA submission. In anticipation of the potential to seek approval and commercialize KPI-121 for dry eye disease in the EU we are evaluating a variety of collaboration, distribution and other marketing arrangements with one or more third parties.

Other Preclinical Opportunities for Post-Operative Inflammation and Pain and Dry Eye Disease

Building on the results of our clinical trials for our KPI-121 1.0% and KPI-121 0.25% product candidates, 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.

rTKI Program

Retinal Disease

There are a range of retinal diseases and conditions that adversely affect vision.

Age-Related Macular Degeneration (AMD)

AMD is a degeneration of the macula of the retina that leads to impairment and loss of central vision. There are two categories of AMD: "Dry" AMD, which involves slow deterioration of the retina with submacular drusen, atrophy, loss of macular function and central vision impairment; and "Wet" AMD, which involves growth of abnormal blood vessels under the retina and macula, resulting in edema, tissue damage and rapid loss of central vision. If untreated, neovascularization in Wet AMD patients typically results in significant vision loss and the formation of a scar under the macular region of the retina. Most cases begin as Dry AMD, which can progress to Wet AMD. Wet AMD is a leading cause of blindness in people over the age of 55 in the United States and the European Union. The incidence of Wet AMD increases substantially with age, and we expect that the number of cases of Wet AMD will increase with growth of the elderly population in the United States.

The current standard of care for Wet AMD is intravitreal injection of drugs that target VEGF, one of the key proteins involved in neovascularization.

Diabetic Retinopathy (DR) and Diabetic Macular Edema (DME)

DR is an ocular complication of diabetes involving changes of retinal blood vessels that lead to significant visual impairment. These changes include dysfunction of retinal vasculature (nonproliferative retinopathy), with vascular occlusion and increased permeability, leading to retinal hypoxia and DME. The disease can further progress to proliferative retinopathy with retinal neovascularization, hemorrhage and retinal detachment.

Among an estimated 19.8 million adults in the United States aged forty years and older known to have diabetes, the prevalence rate for DME is 3.8%, or approximately 746,000 people. DME is the leading cause of visual impairment and blindness in Americans between 20 and 74 years old.

Retinal Vein Occlusion (RVO)

RVO is a blockage of the small veins that carry blood away from the retina. The disease can cause sudden blurring or vision loss in all or part of one eye. RVO has been estimated to affect 16 million people worldwide.

Limitations of Existing Treatments for Retinal Disease

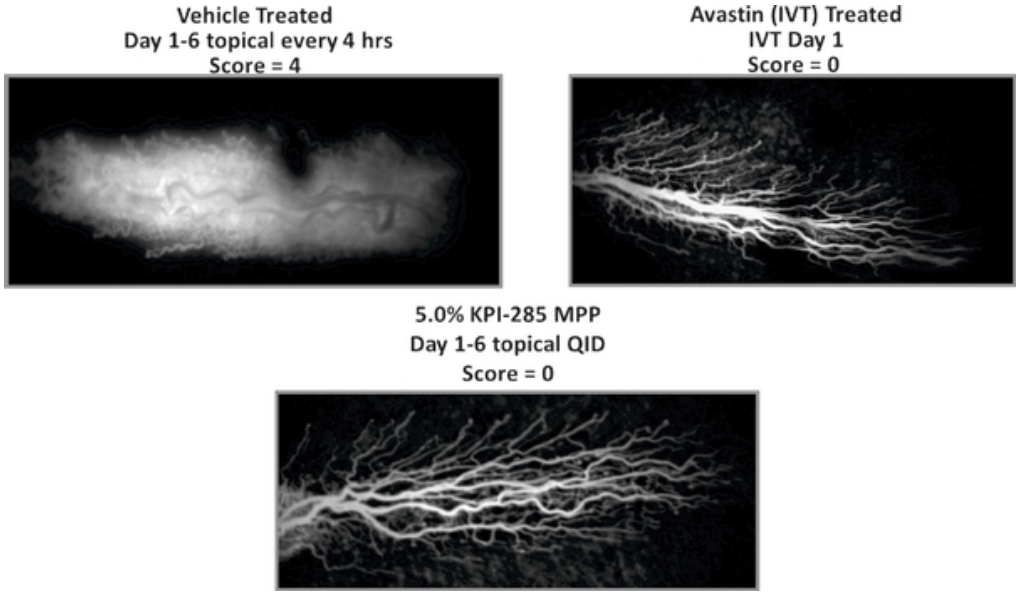
VEGF is a protein that plays a critical role in the formation of new blood vessels and increased permeability, two pathological processes that contribute to the vision loss associated with certain retinal diseases. Several VEGF tyrosine kinase inhibitors have been investigated in AMD patients in clinical trials. These inhibitors have been administered in a variety of ways, including intravitreal injection, oral administration and topical dosing. To date, no VEGF tyrosine kinase inhibitors have been approved in the United States for the treatment of ocular diseases. We believe that there is a substantial market opportunity for a safe and effective topically applied VEGF tyrosine kinase inhibitors to treat various retinal diseases, such as AMD, DR, DME, RVO and related neovascular diseases.

The most common treatments for retinal diseases involve administration of biologic agents that block the VEGF pathway and prevent or retard the blood vessel leakage and/or proliferation. Unfortunately, clinicians must inject these biologic agents directly into the eye via frequent IVTs to maintain vision. Sales of the two leading IVT biologic agents used to treat eye diseases associated with abnormal blood vessel proliferation, Genentech's Lucentis® and Regeneron's Eylea®, were $1.4 billion and $3.3 billion, respectively, in the in the United States in 2016. Topical administration of therapeutics to treat retinal diseases has not yet been demonstrated to be effective in the management of retinal disease, most likely due to insufficient delivery of drug to the back of the eye.

rTKI Program for the Potential Treatment of Wet AMD, DR, DME and RVO

Through our rTKI program we generate small molecule new chemical entities, or NCEs, that are designed to be potent VEGF receptor kinase inhibitors. KPI-285, our current rTKI lead compound, is engineered with our MPP technology to facilitate its penetration into tissues in the back of the eye following topical dosing. In preclinical rabbit studies, KPI-285 demonstrated a potency of less than one nanomolar against the VEGF receptor-2 kinase and good selectivity against particular growth factor receptor kinases, cell cycle kinases and other detrimental receptors. KPI-285 is designed to be administered topically as an eye drop.

In preclinical rabbit studies, topical administration of KPI-285 achieved concentrations in tissues in the back of the eye well above the concentrations required for *in vitro* inhibition of 50% of the VEGF receptor kinase activity. In addition, in a rabbit model of VEGF induced vascular leakage, topically applied KPI-285 MPP reduced leakage to an extent similar to that achieved with an IVT injection of Genentech's Avastin®, a recombinant human monoclonal antibody that binds to VEGF. In this model, vascular leakage of fluorescein was induced by IVT injections of VEGF. The extent of fluorescein leakage observed in various treatment groups was scored in a blinded fashion on a scale from 0 to 4, with 0 being no leakage and 4 being heavy leakage. As shown in the photographs below, the magnitude of the effect achieved with topical administration of KPI-285 5.0% was similar to that observed with IVT injection of Avastin.



We believe that an effective topical therapy for patients with retinal diseases such as AMD, DR, DME and RVO will be a significant advancement in the treatment of these diseases and could increase patient compliance and reduce treatment burden in patients suffering from these sight threatening diseases. Prior to initiating IND-enabling studies, we may consider potential collaborative partnership opportunities to advance our product candidates we develop through our rTKI program, including KPI-285.

Potential Applications in Other Diseases

Mucus limits delivery of conventionally formulated drugs to mucosal tissues such as the lung, cervical/vaginal and gastrointestinal tract. While our current focus is in ophthalmology, our MPP technology has been effective in preclinical studies in enhancing drug delivery to these other tissues. We also have demonstrated in preclinical studies that MPP technology can be used to increase mucus penetration of over fifteen classes of drugs.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technologies, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Our competitors include large pharmaceutical and biotechnology companies, and specialty pharmaceutical and generic drug companies. Many of our competitors 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. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in

acquiring technologies complementary to, or necessary for, our programs. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The key competitive factors affecting the success of KPI-121 0.25%, KPI-121 1.0% and other product candidates, if approved, are likely to be the product candidate's efficacy, safety, method of administration, convenience, price, the level of generic competition and the availability of insurance coverage and reimbursement from government and other third-party payors.

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 any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. In addition, our ability to compete may be affected because in many cases insurers or other third-party payors seek to encourage the use of generic products.

Competition in Inflammation and Pain Following Ocular Surgery

Following ocular surgery, topical steroids are commonly prescribed to manage and prevent complications from post-operative inflammation.

Currently marketed topical steroids are the main competition to KPI-121 for the treatment of inflammation and pain following ocular surgery. The current market leaders in the United States based on revenue are Lotemax products and Durezol. Generic topical steroid formulations consist mainly of products containing prednisolone, fluorometholone or dexamethasone. In addition, there are various formulations of steroids that are produced by compounding pharmacies and are injected into the eye following ocular surgery.

There are a number of product candidates in preclinical research and clinical development by third parties in the United States for the treatment of inflammation and pain following ocular surgery, including the following: Valeant Pharmaceuticals International, Inc. is developing an LE gel, which is formulated for topical delivery and is currently in Phase 3 clinical development; Ocular Therapeutix is developing Dextenza™, a punctal plug that is currently in Phase 3 clinical development and has filed an NDA for the treatment of ocular pain following ophthalmic surgery; and Icon Bioscience, Inc. has filed an NDA for IBI-10090, which is formulated as a drug delivery system, or DDS, to be injected into the eye following cataract surgery for the treatment of inflammation.

There also are other product candidates for treatment of pain and inflammation following ocular surgery in the United States that are in earlier stage development.

Competition in Dry Eye Disease

The current disease management approaches for dry eye disease in the United States include the following: over-the-counter artificial tear eye drops, which are used on an intermittent or chronic basis to provide short-term symptomatic relief of dryness and irritation; off-label prescription drugs, including topical steroid drops and/or other similar products, which are prescribed on occasion for treatment of dry eye disease; on-label prescription drugs, including Restasis and Xiidra, which are the only prescription pharmaceutical products that are approved in the United States for use in patients with dry eye disease. Restasis is approved for increasing tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation and Xiidra is approved for treatment of the signs and symptoms of dry eye disease. Both are typically used chronically as part of the dry eye management regimen, which also includes artificial tears and other palliative therapies, such as hot compresses for the eye and lid hygiene management, and devices, such as punctal plugs that are inserted into the tear ducts to inhibit tear drainage, resulting in more moisture on the surface of the eye.

We are developing KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease, which may include the management of dry eye disease flares. Any product that is developed for the temporary treatment of the signs and symptoms of dry eye disease could directly compete with KPI-121 0.25%.

There are several product candidates in preclinical research and clinical development by third parties in the United States for the treatment of dry eye disease. If any of these product candidates is approved and such product candidate either treats the signs and symptoms of dry eye disease or reduces the frequency of flares in dry eye patients, it could reduce the overall market opportunity for KPI-121 0.25%.

Based on publicly available information, we have identified, among others, various product candidates in clinical development for the chronic treatment of dry eye disease in the United States. Mimetogen has a small molecule topical TrkA agonist formulation, MIM-D3, which is currently in Phase 3 clinical development. Sun Pharmaceuticals has a topical cyclosporine formulation, Seciera™, that has completed a Phase 3 trial. ReGenTree has a topical thymosin Beta 4 formulation, TGN-259, that is currently in Phase 3 trials. Allergan has a topical dry eye program, AGN-195263, in Phase 3 trials for evaporative dry eye. There also are other product candidates for the treatment of dry eye disease in the United States in earlier stage development. Further, Oculeve, which was acquired by Allergan, is developing True Tear a nasal neurostimulation medical device that is intended to increase tear production. We are not aware of any product candidate in Phase 3 clinical development in the United States for the short-term treatment of dry eye disease.

Competition in Retinal Disease

Several therapies have been developed to block the effects of VEGF by binding to and sequestering the protein. These include Regeneron Pharmaceuticals, Inc.'s Eylea, and Genentech, Inc.'s Lucentis and Avastin. Avastin is approved as an anti-cancer agent, but is widely used off-label in ophthalmic diseases. All of these therapies are administered by intravitreal injections and must be regularly dosed for optimal efficacy.

In addition to IVTs, there also are two marketed DDS that are used to treat retinal diseases: Ozurdex®, which releases dexamethasone, a corticosteroid, and is marketed by Allergan, and Iluvien®, which releases fluocinolone acetonide and is marketed by Alimera Sciences.

There are a number of preclinical research and clinical development programs being conducted by third parties to develop treatments for retinal diseases, including programs utilizing topically applied small molecules. We expect that product candidates currently in clinical development, or that could enter clinical development in the near future, may represent significant competition if approved. These product candidates may provide efficacy, safety, convenience and other benefits that are not provided by currently marketed therapies.

Sales and Marketing

In light of our stage of development, we have not yet established a commercial organization or distribution capabilities. We have retained worldwide commercial rights for our product candidates. If our product candidates receive marketing approval, we plan to commercialize them in the United States with our own focused, specialty sales force. We believe that this commercial organization will consist of approximately 150 sales and marketing personnel that will call on ophthalmologists and optometrists. We would expect to conduct most of the buildout of this organization following NDA approval of any of our product candidates. We expect to explore commercialization of KPI-121 0.25% and potentially other product candidates in certain markets outside the United States, including the EU, utilizing a variety of collaboration, distribution and other marketing arrangements with one or more third parties.

Manufacturing

We utilize our substantial in-house expertise and know-how to develop and scale up our manufacturing processes before these processes are transferred to third-party contract manufacturers, and to understand and establish controls of critical process parameters. We also have personnel with deep product development experience who actively manage the third-party contract manufacturers producing KPI-121 and other products that we may develop in the future.

Our KPI-121 drug product is currently manufactured at qualified contract manufacturing facilities in compliance with current good manufacturing practice, or cGMP, regulations. We expect that the same facilities will be used to manufacture commercial lots of both dosage strengths of KPI-121. Preparation of the concentrated milled suspension is performed by a third party using a manufacturing process developed by us. The milled suspension is sterilized by gamma radiation at a separate third-party facility. The sterilized milled suspension is then diluted to the final drug product concentrations and filled into multi-dose ophthalmic dropper bottles at a third-party manufacturer. Our third-party manufacturers are subject to FDA inspections from time to time and 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. This third-party testing laboratory has determined that the observations are non-critical and do not pose any risk or have any impact on its analytical programs.

We have supply agreements in place with these contract manufacturers to support KPI-121 clinical and registration manufacturing, release testing, registration stability, and clinical labeling and packaging. We also have entered into long term commercial supply agreements with these contract manufacturers to supply KPI-121 in the event that we are granted marketing approval in the United States.

Catalent Commercial Supply Agreement. In June 2016, we entered into a Commercial Supply Agreement, or the Catalent Agreement, with Catalent Pharma Solutions, LLC, or Catalent, pursuant to which Catalent has agreed to manufacture and supply to us, and we have agreed to purchase from Catalent, a minimum amount of KPI-121 1.0% and KPI-121 0.25% for commercial use. The commercial supply agreement has an initial term of eight years from the date either of KPI-121 1.0% or KPI-121 0.25% has been approved for commercial sale in the United States or European Union and Catalent has been approved as a manufacturer of such approved product, and which is subject to three-year automatic renewal periods, absent termination by either party in accordance with the terms of the commercial supply agreement. The Catalent Agreement provides for pricing for KPI-121 1.0% and KPI-121 0.25% structured on a tiered basis, with the price reduced as the volume of each product ordered increases. We also have annual minimum purchase requirements for each of KPI-121 1.0% and KPI-121 0.25%. Under the minimum unit purchase requirements, if both KPI-121 1.0% and KPI-121 0.25% are approved for commercial sale, our minimum payment obligation in the first 12-month period would be approximately $1.2 million, subject to specified annual increases. We will also pay certain fees in connection with validation and stability test services and commercialization ramp-up following regulatory approval of the applicable NDA. We may cancel any purchase order under the Catalent Agreement at any time, subject to our minimum purchase obligation for each 12-month period. Each party has the right to terminate the commercial supply agreement for customary reasons such as material breach and bankruptcy. The Catalent Agreement contains provisions relating to compliance by Catalent with current Good Manufacturing Practices, indemnification, confidentiality, dispute resolution and other customary matters for an agreement of this kind.

Alliance Commercial Supply Agreement. In December 2016, we entered into an Amended and Restated Master Services Agreement, or the Alliance Agreement, with Alliance Contract Pharma, LLC, or Alliance, pursuant to which Alliance has agree to provide to us, and we have agreed to purchase from Alliance, bulk KPI-121 concentrates. The Alliance Agreement provides for pricing for KPI-121

concentrates structured on a tiered basis, with the price reduced as the volume of product ordered increases. Under the Alliance Agreement, we will provide a forecast of orders for the quantities of bulk KPI-121 concentrates we believe we will require, and forecasted quantities will become binding at a certain point before the firm delivery date set forth in the forecast. Unless earlier terminated pursuant to its terms, the Alliance Agreement has an initial term of ten years, after which it continues until terminated. Each party has the right to terminate the Alliance Agreement for customary reasons such as material breach and bankruptcy. In addition, we have the right to terminate the Alliance Agreement at any time for any or no reason upon sufficient advance notice, in which case we would owe payment to Alliance for any firm orders and certain raw materials. The Alliance Agreement contains provisions relating to compliance by Alliance with current Good Manufacturing Practices, indemnification, confidentiality, dispute resolution and other customary matters for an agreement of this kind.

Chemo Iberica Manufacturing and Supply Agreement. In January 2017, we entered into a Manufacturing and Supply Agreement, or the Chemo Agreement, with Chemo Iberica SA, or Chemo, pursuant to which Chemo has agreed to manufacture and supply to us, and we have agreed to purchase from Chemo, bulk supply of loteprednol, with pricing structured on a per-kilogram basis. Under the Chemo Agreement, we will provide a forecast of orders for the quantities of loteprednol we believe we will require, and we commit to purchasing 75% of the forecasted quantities. We can alter portions of a forecast at any time, except that, without Chemo's consent, we cannot alter a portion of the forecast less than ninety days before the period to which such portion pertains. Unless earlier terminated pursuant to its terms, the Chemo Agreement has an initial term of seven years, after which it renews in two year increments unless either party gives notice of non-renewal at least one year in advance. Each party has the right to terminate the Chemo Agreement for customary reasons such as material breach and bankruptcy. The Chemo Agreement contains provisions relating to compliance by Chemo with current Good Manufacturing Practices, indemnification, confidentiality, dispute resolution and other customary matters for an agreement of this kind.

Intellectual Property

Our success depends significantly on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. We seek to protect our proprietary position by, among other methods, filing U.S. and certain foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business, where patent protection is available. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

As of June 30, 2017, we owned eight U.S. issued patents and 17 U.S. patent applications, as well as two foreign issued patents and 87 foreign patent applications (including Patent Cooperation Treaty, or PCT, applications). We exclusively licensed a total of eleven U.S. issued patents and 16 U.S. patent applications, as well as twelve foreign issued patents and 47 foreign patent applications including original filings, continuations and divisional applications. Our patent portfolio includes the following patents and patent applications that we own or exclusively license:

- two U.S. issued composition-of-matter patents and one U.S. issued method patent covering KPI-121, and two U.S. patent applications, in-licensed from JHU, which are expected to expire in 2033, and six related patent applications jointly owned by us and JHU filed in Australia, Canada, the European Patent Office, Japan, Hong Kong and South Korea, which, if granted, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, are expected to expire in 2033;

- a U.S. composition-of-matter patent application in-licensed from JHU, covering KPI-121 1.0% and KPI-121 0.25%, and nine related patent applications owned by us filed in Australia, Canada, China, the European Patent Office, Hong Kong, India, Japan, Mexico, and New Zealand, which, if granted, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, are expected to expire in 2033;

- a U.S. patent application in-licensed from JHU, and fifteen related patent applications owned by us filed in the United States, Australia, Brazil, Canada, Chile, China, the European Patent Office, Hong Kong, Japan, South Korea, Mexico, New Zealand, and Thailand relating to ophthalmic applications of our MPP technology, which, if granted, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, are expected to expire in 2033;

- seven owned U.S. issued composition-of-matter patents covering rTKI compounds, including KPI-285, and 57 pending patent applications filed in the United States, Australia, Canada, China, the European Patent Office, Hong Kong, India, Japan, Korea, Mexico, and New Zealand, which, if granted, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, the earliest of which are expected to expire in 2034;

- two U.S. issued patents, exclusively sub-licensed from GrayBug Vision, Inc., covering methods for treating an eye disease or disorder by injecting or instilling a drug delivery system, which are expected to expire in 2031, a related granted Canadian patent, and related patent applications filed in the United States, and the European Patent Office, which, if granted, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, are expected to expire in 2031; and

- a composition-of-matter U.S. issued patent, exclusively in-licensed from JHU, related to our MPP technology, which is expected to expire in 2028, and two related patent applications filed in the United States and the European Patent Office, which, if granted, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, are expected to expire in 2025.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the length of time the drug is under regulatory review while the patent is in force. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. We cannot provide any assurance that any patent term extension with respect to any U.S. patent will be obtained and, if obtained, the duration of such extension.

Similar provisions are available in the European Union and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our product candidates receive approval by the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents covering those products, depending upon the length of the clinical trials for each drug and other factors. The expiration dates referred to above are without regard to potential patent term extension or other market exclusivity that may be available to us. However, we

cannot provide any assurances that any such patent term extension of a foreign patent will be obtained and, if obtained, the duration of such extension.

Trade Secrets

In addition to patents, we may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, and obtain and maintain ownership of certain technologies, in part, by confidentiality and invention assignment agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

License Agreements

The Johns Hopkins University

In November 2009, we entered into an exclusive license agreement with The Johns Hopkins University, or JHU, which was amended in November 2012, May 2014, and August 2014 and amended in part by the JHU settlement agreement described below. We refer to the amended license agreement with JHU as the JHU license agreement. Pursuant to the JHU license agreement, JHU granted us an exclusive, worldwide, sublicenseable license under specified patent rights covering various aspects of MPP technology, to research, develop, make, use and sell products and provide services in any field. JHU also granted us a non-exclusive license to use specified know-how with limits on JHU's right to license the know-how to other commercial entities.

Financial Terms

In connection with the JHU license agreement, we paid JHU an upfront license fee in the low tens of thousands of dollars and issued to JHU a low single digits percentage of our common stock. We also reimbursed JHU for the prosecution and maintenance costs incurred by JHU for the licensed patent rights prior to our entering into the JHU license agreement, and we are responsible for all or, in specified cases, a portion of the ongoing costs relating to the prosecution and maintenance of the JHU patent rights licensed to us. We paid JHU fees in the low tens of thousands of dollars upon entering into certain of the amendments to the JHU license agreement. We also have paid JHU an aggregate of approximately $261,000 in minimum annual royalty fees and development milestones and are obligated to pay fees upon achievement of additional specified development milestones and achievement of specified commercial milestones under the license agreement.

In connection with the JHU license agreement and the JHU settlement agreement described below, we are obligated to make certain future payments to JHU. Beginning in the fourth quarter of 2017, we are obligated to pay JHU future annual minimum royalties that will not exceed approximately $113,000 per year. In addition, we must pay JHU a tiered royalty rate in the low single-digits on annual sales by us or our affiliates of products or services covered by a valid issued claim, or certain pending claims, of a licensed JHU patent right in the country of sale, from which we may, under specified circumstances, offset portions of amounts we must pay as royalties on other patent rights in order to commercialize a licensed product or licensed service up to a maximum reduction of a mid-double digit percentage. We must also pay a percentage, in the high single digits, of certain consideration we or our affiliates receive from sublicensing rights under the licensed JHU intellectual property, subject to specified offsets and deductions. We may offset against each minimum annual payment the royalties and sublicense income that we pay to JHU in the preceding twelve-month period. We also are obligated to pay to JHU certain milestone payments, which will not exceed approximately $1.9 million in the aggregate, if certain development and commercial events are achieved. The JHU patent rights

sublicensed to us by GrayBug under the JHU settlement agreement described below are considered in the same way as the JHU patent rights directly licensed to us by JHU for purposes of determining these payments.

Diligence Obligations

We are required to use commercially reasonable efforts to develop and introduce the licensed products and licensed services to the market, including developing licensed products suitable for different indications, consistent with sound and reasonable business practice and judgment, and, after introducing a licensed product or licensed service into the market, we must endeavor to keep licensed products and licensed services reasonably available to the public consistent with sound and reasonable business practice and judgment.

Term and Termination

The JHU license agreement will expire on a country-by-country basis upon the expiration of the last to expire licensed patent in such country or, if no licensed patent issues in such country, then in November 2029. Either we or JHU may terminate the JHU license agreement for the other party's breach that is not cured within specified time periods or if the other party is subject to certain bankruptcy protections. In addition, we may terminate the JHU license agreement, for any reason, upon 90 days' prior written notice to JHU.

Assignment and Exclusive License

In April of 2017 we assigned to JHU certain Kala-owned patent applications and our interest in certain patents and patent applications formerly co-owned by JHU and Kala, unifying ownership of the assigned patent rights in JHU's name. As part of the assignment of these patent rights to JHU, Kala was granted an exclusive, non-royalty bearing, sub-licensable license from JHU under all of the patent rights Kala assigned in this transaction, which will expire upon the expiration of the last to expire licensed patent under the new license. No fees were paid fo JHU for this exclusive license.

GrayBug Vision, Inc. and The Johns Hopkins University

A dispute arose between us, JHU, and GrayBug Vision, Inc. (formerly known as GrayBug, LLC and Graybug, Inc.), or GrayBug, over rights licensed to us and GrayBug under certain patent rights owned by JHU. In October 2014, we, GrayBug, and JHU resolved this matter by entering into a Settlement and License Agreement, which was amended in January 2015, which we refer to as the JHU settlement agreement.

Under the JHU settlement agreement, GrayBug granted us, under specified patent rights that are exclusively licensed to GrayBug by JHU in all fields, an exclusive, worldwide royalty-free sublicense in the field of use of a particle with specified characteristics for delivery of a biologically active material through mucus, mucin, or a mucosal barrier where such delivery does not involve administration via injection to the eye, which we refer to as the Kala sublicense field. In turn, we granted GrayBug, under specified patent rights that are exclusively licensed to us by JHU in all fields an exclusive, worldwide royalty-free sublicense in the field of use of a particle with specified characteristics for delivery of a biologically active material to the eye via injection, excluding any particle comprising or consisting of loteprednol etabonate, which we refer to as the Graybug sublicense field. In addition, JHU granted us, under the terms of the JHU license agreement, an exclusive, sublicenseable, worldwide license under certain additional specified patent rights relating to further aspects of MPP technology in the Kala sublicense field. JHU also granted to GrayBug a similar license under these same patent rights in the GrayBug sublicense field. In January 2017, GrayBug terminated its license under all but one patent family in these patent rights, and in July 2017, Graybug terminated its license under the remaining patent family. As a result, for those patent rights terminated by Graybug, we are now licensed in both

the Kala sublicense field and the GrayBug sublicense field. JHU also granted us certain rights to obtain a non-exclusive license to certain additional patent rights and, if we obtain such a license, we would have the exclusive right to negotiate for a specified time period an exclusive license under such patent rights in the Kala sublicense field. Under the JHU settlement agreement, we agreed not to exercise our rights under the JHU patent rights licensed or sublicensed to us to use a particular active ingredient. Each party to the JHU settlement agreement may sublicense the rights granted to it pursuant to the JHU settlement agreement, subject to notice requirements and the requirement that any such sublicense must involve some aspect of collaboration, joint research, development, manufacture, partnership or the like. In any event, sublicenses beyond a specified number of tiers are not permitted without the original licensing party's written consent.

We, GrayBug and JHU each released the others, and certain persons affiliated with them, from any claims and losses known to the releasing party as of the effective date of the JHU settlement agreement in connection with the dispute that led to the JHU settlement agreement.

Financial Terms

The JHU settlement agreement also amended certain of our financial obligations under the JHU license agreement, which we have reflected in the description above. Neither we nor GrayBug owe the other any royalties, milestone payments or other payments with respect to the sublicenses and other rights granted to each other. In addition, JHU agreed that we are not responsible for paying to JHU any sublicense fees or other payments due under our JHU license agreement that may otherwise have arisen as a result of our granting GrayBug the sublicenses under the JHU settlement agreement.

For the specified patent rights directly licensed to us by JHU in the Kala sublicense field under the JHU settlement agreement, we reimbursed JHU for a portion of the patent prosecution and maintenance costs incurred prior to entering the JHU settlement agreement, and we are responsible for a portion of ongoing costs relating to the prosecution and maintenance of the JHU patent rights directly licensed to us by JHU under the JHU settlement agreement, except that we are responsible for all of the ongoing prosecution and maintenance costs of any of these JHU patent rights for which there is no other direct licensee of JHU, such as the JHU patent rights licensed to us in both the Kala sublicense field and the GrayBug sublicense field.

Term and Termination

The JHU settlement agreement will expire upon the expiration of all the patent rights that are the subject of the JHU settlement agreement. We may terminate one or more of the licenses or sublicenses granted to us in the JHU settlement agreement on a country-by-country basis for convenience upon 30 days' prior written notice to GrayBug. We or GrayBug may terminate one or more the sublicenses granted to the other party under the JHU patent rights if the other party, or its employees, officers, directors, agents or representatives, takes certain steps to oppose, attempt to invalidate or prevent the issuance of any of the patent rights directly licensed to the terminating party by JHU.

Government Regulation and Product Approvals

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Review and Approval of Drugs in the United States

In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources The failure to comply with applicable requirements under the FDCA and other applicable laws at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities.

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND, which must take effect before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of an NDA;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, and post-approval studies required by the FDA.

Preclinical Studies

Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, as well as *in vitro* and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. Some long-term

preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

Companies usually must complete some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and must also develop additional information about the chemistry and physical characteristics of the investigational product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the candidate product and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the candidate product does not undergo unacceptable deterioration over its shelf life.

The IND and IRB Processes

An IND is an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved NDA. In support of a request for an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects will be exposed to unreasonable health risks. At any time during this 30-day period, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin.

Following commencement of a clinical trial under an IND, the FDA may also place a clinical hold or partial clinical hold on that trial. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with FDA certain regulatory requirements in order to use the study as support for an IND or application for marketing approval. Specifically, on April 28, 2008, the FDA amended its regulations governing the acceptance of foreign clinical studies not conducted under an investigational new drug application as support for an IND or a new drug application. The final rule provides that such studies must be conducted in accordance with good clinical practice, or GCP, including review and approval by an independent ethics committee, or IEC, and informed consent from subjects. The GCP requirements in the final rule encompass both ethical and data integrity standards for clinical studies. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in

non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct a continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study. Suspension or termination of development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk. Other reasons for suspension or termination may be made by us based on evolving business objectives and/or competitive climate.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on its ClinicalTrials.gov website.

Human Clinical Trials in Support of an NDA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- *Phase 1.* The drug is initially introduced into healthy human subjects or, in certain indications such as cancer, patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.

- *Phase 2.* The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- *Phase 3.* The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans

exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality, purity, and potency of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Submission of an NDA to the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is subject to an application user fee, which for federal fiscal year 2017 is $2,038,100 for an application requiring clinical data. The sponsor of an approved NDA is also subject to annual product and establishment user fees, which for fiscal year 2017 are $97,750 per product and $512,200 per establishment. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for drugs with orphan designation and a waiver for certain small businesses, an exception from the establishment fee when the establishment does not engage in manufacturing the drug during a particular fiscal year, and an exception from the product fee for a drug that is the same as another drug approved under an abbreviated pathway.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to certain performance goals in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the date of filing, and most applications for "priority review" products are meant to be reviewed within six months of filing. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with an NDA submission, including drug component manufacturing (such as active pharmaceutical ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required

specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

In addition, as a condition of approval, the FDA may require an applicant to develop a REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

The FDA may refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Fast Track, Breakthrough Therapy, Priority Review and Regenerative Advanced Therapy Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as fast track designation, breakthrough therapy designation, priority review designation and regenerative advanced therapy designation.

Specifically, the FDA may designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a Fast Track application does not begin until the last section of the application is submitted. In addition, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, a product may be designated as a Breakthrough Therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to Breakthrough Therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case- by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Finally, with passage of the 21st Century Cures Act, or Cures Act, in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative advanced therapies. A product is eligible for this designation if it is a regenerative medicine therapy (as defined in the Cures Act) that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition. The benefits of a regenerative advanced therapy designation include early interactions with FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Section 505(b)(2) NDAs

NDAs for most new drug products are based on two full clinical studies which must contain substantial evidence of the safety and efficacy of the proposed new product. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the applicant to rely, in part, on the FDA's previous findings of safety and efficacy for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the applicant for approval of the application "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

Thus, Section 505(b)(2) authorizes the FDA to approve an NDA based on safety and effectiveness data that were not developed by the applicant. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the Section 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications

for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference-listed drug, or RLD.

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug..."

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the Orange Book. Clinicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing clinicians or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. For the purposes of this provision, a new chemical entity, or NCE, is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product. The FDA typically makes decisions about awards of data exclusivity shortly before a product is approved.

Hatch-Waxman Patent Certification and the 30-Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA

concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired (other than method of use patents involving indications for which the ANDA applicant is not seeking approval).

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. As a result, approval of a Section 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the Food and Drug Administration Safety and Innovation Act or FDASIA, in 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each

other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. We intend to submit an application for pediatric exclusivity for KPI-121 1.0% for the treatment of post-operative inflammation and pain following ocular surgery, however, we cannot provide any assurance that pediatric exclusivity will be obtained for KPI-121 1.0% or any other product candidates.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will be receiving orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the ultimate approval date. Patent term restoration

cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The U.S. Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA. We cannot provide any assurance that any patent term extension with respect to any U.S. patent will be obtained and, if obtained, the duration of such extension, in connection with any of our product candidates.

The 21st Century Cures Act

On December 13, 2016, President Obama signed the Cures Act into law. The Cures Act is designed to modernize and personalize healthcare, spur innovation and research, and streamline the discovery and development of new therapies through increased federal funding of particular programs. It authorizes increased funding for the FDA to spend on innovation projects. The new law also amends the Public Health Service Act to reauthorize and expand funding for the NIH. The Act establishes the NIH Innovation Fund to pay for the cost of development and implementation of a strategic plan, early stage investigators and research. It also charges NIH with leading and coordinating expanded pediatric research. Further, the Cures Act directs the Centers for Disease Control and Prevention to expand surveillance of neurological diseases.

With amendments to the FDCA and the Public Health Service Act, or PHSA, Title III of the Cures Act seeks to accelerate the discovery, development, and delivery of new medicines and medical technologies. To that end, and among other provisions, the Cures Act reauthorizes the existing priority review voucher program for certain drugs intended to treat rare pediatric diseases until 2020; creates a new priority review voucher program for drug applications determined to be material national security threat medical countermeasure applications; revises the FDCA to streamline review of combination product applications; requires FDA to evaluate the potential use of "real world evidence" to help support approval of new indications for approved drugs; provides a new "limited population" approval pathway for antibiotic and antifungal drugs intended to treat serious or life-threatening infections; and authorizes FDA to designate a drug as a "regenerative advanced therapy," thereby making it eligible for certain expedited review and approval designations.

Review and Approval of Drug Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Procedures Governing Approval of Drug Products in the European Union

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of a European

Union member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a competent ethics committee has issued a favorable opinion. Clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents.

To obtain marketing approval of a product under European Union regulatory systems, an applicant must submit a marketing authorization application, or MAA, either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the European Medicines Agency, or EMA, is responsible for conducting the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure is available to applicants who wish to market a product in various European Union member states where such product has not received marketing approval in any European Union member states before. The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state designated by the applicant, known as the reference member state. Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the European Commission, whose decision is binding on all member states.

Within this framework, manufacturers may seek approval of hybrid medicinal products under Article 10(3) of Directive 2001/83/EC. Hybrid applications rely, in part, on information and data from a reference product and new data from appropriate pre-clinical tests and clinical trials. Such applications are necessary when the proposed product does not meet the strict definition of a generic medicinal product, or bioavailability studies cannot be used to demonstrate bioequivalence, or there are changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration of the generic product compared to the reference medicinal product. In such cases the

results of tests and trials must be consistent with the data content standards required in the Annex to the Directive 2001/83/EC, as amended by Directive 2003/63/EC.

Hybrid medicinal product applications have automatic access to the centralized procedure when the reference product was authorized for marketing via that procedure. Where the reference product was authorized via the decentralized procedure, a hybrid application may be accepted for consideration under the centralized procedure if the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation, or the granting of a community authorization for the medicinal product is in the interest of patients at the community level.

Clinical Trial Approval in the European Union

Requirements for the conduct of clinical trials in the European Union including Good Clinical Practice, or GCP, are set forth in the Clinical Trials Directive 2001/20/EC and the GCP Directive 2005/28/EC. Pursuant to Directive 2001/20/EC and Directive 2005/28/EC, as amended, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the E.U. member states. Under this system, approval must be obtained from the competent national authority of each E.U. member state in which a study is planned to be conducted. To this end, a CTA is submitted, which must be supported by an investigational medicinal product dossier, or IMPD, and further supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and other applicable guidance documents. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country.

In April 2014, the E.U. passed the new Clinical Trials Regulation, (EU) No 536/2014, which will replace the current Clinical Trials Directive 2001/20/EC. To ensure that the rules for clinical trials are identical throughout the European Union, the new E.U. clinical trials legislation was passed as a regulation that is directly applicable in all E.U. member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive 2001/20/EC until the new Clinical Trials Regulation (EU) No 536/2014 becomes applicable. According to the current plans of EMA, the new Clinical Trials Regulation will become applicable in October 2018. The Clinical Trials Directive 2001/20/EC will, however, still apply three years from the date of entry into application of the Clinical Trials Regulation to (i) clinical trials applications submitted before the entry into application and (ii) clinical trials applications submitted within one year after the entry into application if the sponsor opts for old system.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trial in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the E.U. portal; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures that will spare sponsors from submitting broadly identical information separately to various bodies and different member states; a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts (Part I is assessed jointly by all member states concerned, and Part II is assessed separately by each member state concerned); strictly defined deadlines for the assessment of clinical trial applications; and the involvement of the ethics committees in the assessment procedure in accordance with the national law of the member state concerned but within the overall timelines defined by the Clinical Trials Regulation.

Periods of Authorization and Renewals

Marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in

respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the European Union market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

Data and Market Exclusivity in the European Union

In the European Union, new chemical entities qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic (abbreviated) application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity and the sponsor is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company can complete a full MAA with a complete database of pharmaceutical test, preclinical tests and clinical trials and obtain marketing approval of its product.

Orphan Drug Designation and Exclusivity

Regulation 141/2000 provides that a drug shall be designated as an orphan drug if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Community when the application is made, or that the product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Community and that without incentives it is unlikely that the marketing of the drug in the European Community would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Community or, if such method exists, the drug will be of significant benefit to those affected by that condition.

Regulation 847/2000 sets out criteria and procedures governing designation of orphan drugs in the European Union. Specifically, an application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. This period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify market exclusivity. Market exclusivity can be revoked only in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities of the product, demonstration of "clinically relevant superiority" by a similar medicinal product, or, after a review by the Committee for Orphan Medicinal Products, requested by a member state in the fifth year of the marketing exclusivity period (if the designation criteria are believed to no longer apply). Medicinal products designated as orphan drugs pursuant to Regulation 141/2000 shall be eligible for incentives

made available by the European Community and by the member states to support research into, and the development and availability of, orphan drugs.

Regulatory Requirements after Marketing Authorization

As in the United States, both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual EU Member States both before and after grant of the manufacturing and marketing authorizations. The holder of an EU marketing authorization for a medicinal product must, for example, comply with EU pharmacovigilance legislation and its related regulations and guidelines which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products. The manufacturing process for medicinal products in the European Union is also highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, including compliance with EU cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients.

In the European Union, the advertising and promotion of approved products are subject to EU Member States' laws governing promotion of medicinal products, interactions with clinicians, misleading and comparative advertising and unfair commercial practices. In addition, other legislation adopted by individual EU Member States may apply to the advertising and promotion of medicinal products. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion, which is prohibited in the European Union.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such products. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. Additionally, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of drugs have been a focus in this effort. Governments have shown

significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Outside the United States, ensuring adequate coverage and payment for our product candidates will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted regulatory approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, 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 created additional federal criminal laws that prohibit, among other things, knowingly and willingly executing, or attempting to execute, 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 and its implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments and other transfers of value to clinicians and teaching hospitals and clinician ownership and investment interests; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to clinicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Healthcare Reform

A primary trend in the United States healthcare industry and elsewhere is cost containment. There have been several federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States.

In March 2010, the United States Congress enacted the Affordable Care Act, or ACA, which, among other things, includes changes to the coverage and payment for products under government healthcare programs. Among the provisions of the ACA of importance to our potential drug candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient

prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans;

- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- expanded the types of entities eligible for the 340B drug discount program;

- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

- the Independent Payment Advisory Board, or IPAB, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs. However, the IPAB implementation has been not been clearly defined. The ACA provided that under certain circumstances, IPAB recommendations will become law unless Congress enacts legislation that will achieve the same or greater Medicare cost savings; and

- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation from 2011 to 2019.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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

Employees

As of June 30, 2017, we had 25 full-time employees, including a total of eleven employees with M.D., Sc.D. or Ph.D. degrees. Of these full-time employees, 18 employees are engaged in research and development. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Facilities

Our principal facilities consist of office and laboratory space. We occupy approximately 11,747 square feet of office space in Waltham, Massachusetts under a lease that currently expires in January 2019.

Legal Proceedings

We are not currently subject to any material legal proceedings.

MANAGEMENT

The following table sets forth the name, age as of June 30, 2017 and position of each of our executive officers and directors.

Name	Age	Position
Mark Iwicki	50	Chief Executive Officer and Chairman of the Board
Charles McDermott	45	President and Chief Business Officer
Kim Brazzell, Ph.D.	64	Chief Medical Officer
Hongming Chen, Sc.D.	46	Chief Scientific Officer
Mary Reumuth, C.P.A.	42	Chief Financial Officer and Treasurer
Michele LaRussa	47	Senior Vice President, Regulatory Affairs and Quality Assurance
Vincent Kosewski	54	Senior Vice President of Manufacturing and Supply Chain Management
Gregory Grunberg, M.D.(2)	44	Director
Paulina Hill, Ph.D.(1)	35	Director
Robert Langer, Sc.D.(3)	68	Director
Robert Paull(1)(3)	41	Director
Howard Rosen(1)	59	Director
Rajeev Shah(2)(3)	40	Director
Robert Tepper, M.D.(2)	62	Director
Chen Yu, M.D.(4)	43	Director

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Member of the Nominating and Corporate Governance Committee.

(4) Dr. Yu has notified us that he intends to resign from our board of directors contingent upon and effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

Mark Iwicki has served as our Chief Executive Officer and Chairman of our board of directors since September 2015. Previously he served as Executive Chairman of our board of directors from April 2015 to September 2015. Prior to joining us, Mr. Iwicki served as President and Chief Executive Officer of Civitas Therapeutics, Inc., or Civitas, a biopharmaceutical company which was acquired by Acorda Therapeutics, from January 2014 to November 2014. Prior to Civitas, Mr. Iwicki served as President and Chief Executive Officer at Blend Therapeutics, Inc., or Blend, a biopharmaceutical company, from December 2012 to January 2014. Prior to Blend, Mr. Iwicki was President and Chief Executive Officer of Sunovion Pharmaceuticals Inc. (formerly Sepracor Inc.), or Sunovion, a pharmaceutical company. Mr. Iwicki was at Sepracor/Sunovion from October 2007 to June 2012. Prior to joining Sepracor Inc., Mr. Iwicki was Vice President and Business Unit Head at Novartis Pharmaceuticals Corporation. He was at Novartis from March 1998 to October 2007. Prior to that, Mr. Iwicki held management positions at Astra Merck Inc. and Merck & Co., Inc. In addition to serving on our board of directors, Mr. Iwicki also currently serves on the boards of AimmuneTherapeutics, Inc., Merus N.V. and Pulmatrix Inc., all public companies, and privately held companies Nimbus Therapeutics, Inc., Taris Biomedical LLC, and Oxeia Biopharmaceuticals, Inc. Mr. Iwicki holds a B.S. in Business Administration from Ball State University and an M.B.A. from Loyola University. We believe that Mr. Iwicki's extensive experience as a pharmaceutical industry leader managing all stages of drug development and commercialization in multiple therapeutic areas qualifies him to serve as a member of our board of directors.

Charles McDermott has served as our President and Chief Business Officer since June 2015. Previously he served as our Interim President and Chief Business Officer from October 2014 to June 2015 and our Executive Vice President of Business Development from June 2013 to October 2014. Prior to joining us, Mr. McDermott served first as Director and then Vice President of Business Development, Eye Care and Drug Delivery at Allergan plc, or Allergan, an ophthalmic industry leader, where he worked from April 2005 to May 2013. Prior to joining Allergan, Mr. McDermott held a variety of business development positions at deCODE Genetics, Inc. (now DGI resolutions, Inc.), or deCODE Genetics, a biopharmaceutical company, from January 2001 to March 2005. Prior to deCODE Genetics, Mr. McDermott was a research scientist in the angiogenesis pharmacology group at Agouron Pharmaceuticals, Inc. Mr. McDermott currently serves on the board of Impact Biomedicines, Inc., a private company. Mr. McDermott holds an M.B.A. from the University of San Diego, an M.A. in Molecular, Cellular and Developmental Biology from the University of California at Santa Barbara, a B.S. in Biochemistry and Molecular Biology from the University of California Santa Cruz and a Certificate in Clinical Trial Design and Management from the University of California San Diego Extension.

Kim Brazzell, Ph.D. has served as our Chief Medical Officer since February 2013. He has also served as a Principal of Acuity Advisors, LLC, an ophthalmic consulting company, since January 2014. Dr. Brazzell served as Chief Medical Officer of Mimetogen Pharmaceuticals, Inc., a clinical stage biotechnology company, from January 2012 until December 2015. Dr. Brazzell also held several executive positions at Inspire Pharmaceuticals, Inc., or Inspire, a specialty pharmaceutical company focusing on ophthalmic products, including Executive Vice President of Medical and Scientific Affairs from 2010 to 2011, Executive Vice President and Head of Ophthalmology Business from 2009 to 2010, and Senior Vice President of Ophthalmic Research and Development from 2004 to 2008. Prior to joining Inspire, Dr. Brazzell served as Global Head of Clinical R&D and Senior Vice President, U.S. R&D, of Novartis Ophthalmics AG from 2000 to 2004. Dr. Brazzell also served as Vice President, R&D at Ciba Vision Ophthalmics, Inc. and as Associate Director, R&D, at Alcon Laboratories, Inc. Dr. Brazzell received a B.S. in Pharmacy and a Ph.D. in Pharmaceutical Sciences from the University of Kentucky.

Hongming Chen, Sc.D. has served as our Chief Scientific Officer since October 2014. Prior to that, Dr. Chen served as our Executive Vice President of Research from October 2013 to October 2014 and our Vice President of Research from January 2010 to October 2013. Prior to joining us, Dr. Chen served as Director of Formulation Development at TransForm Pharmaceuticals Inc., or TransForm, from 2000 to January 2010. Before joining TransForm, Dr. Chen conducted vaccine delivery research and development at AstraZeneca plc from 1997 to 2000, and at Merck & Co., Inc. from 1996 to 1997. In 2015, Dr. Chen was elected to the College of Fellows at the American Institute for Medical and Biological Engineering. Dr. Chen received a B.S. in Chemical Engineering from The University of Texas at Austin in 1992 and both an M.S. and a Sc.D. in Chemical Engineering from the Massachusetts Institute of Technology.

Mary Reumuth, C.P.A. has served as our Chief Financial Officer since July 2017, Senior Vice President, Finance from February 2017 to July 2017, our Vice President, Finance from December 2014 to February 2017, our Senior Director, Finance from February 2014 to December 2014, as our Corporate Controller from February 2014 to July 2017 and Treasurer since February 2014. Prior to joining us, Ms. Reumuth acted as an independent financial consultant from November 2012 to January 2014 and, prior to that, served as Corporate Controller for Enobia Pharma Corp., or Enobia, a global biopharmaceutical company acquired by Alexion Pharmaceuticals, Inc., from May 2011 to June 2012. Prior to Enobia, Ms. Reumuth served as Director of Finance at Verenium Corporation, or Verenium, a biotechnology company, from December 2007 to March 2011. Ms. Reumuth held a variety of finance and accounting positions at Genzyme Corporation, or Genzyme, (now a Sanofi Company), and ILEX Oncology, Inc., or ILEX (acquired by Genzyme) from 2001 to 2007. Prior to ILEX, Ms. Reumuth was

an auditor at Ernst & Young LLP. Ms. Reumuth earned her Bachelor's degree in Business Administration from Texas A&M University—Corpus Christi, and is a Certified Public Accountant.

Michele LaRussa has served as our Senior Vice President, Regulatory Affairs and Quality Assurance since October 2016. Prior to joining us, Ms. LaRussa served as Global Head of Regulatory Affairs, Dermatology at GlaxoSmithKline plc from July 2012 to September 2016, where she led a cross-functional, multi-national team to develop new chemical entities and integrate groups and technologies from a recent acquisition into GlaxoSmithKline's existing structure, and at Allergan from September 2007 to June 2012, where she led the review and approval procedures for three new chemical entities. Ms. LaRussa spent much of her career with Novartis (including CIBA Vision Ophthalmics, Inc, Novartis Ophthalmics AG, and Novartis AG) with increasing levels of responsibility in regulatory affairs from October 1994 to July 2007, including leading the Regulatory Affairs Dermatology Department, holding lead responsibility for BOTOX, Latisse and Aczone and submitting and gaining approval for an additional indication for BOTOX. Ms. LaRussa received a B.S. in Chemistry from the University of South Florida.

Vincent Kosewski has served as our Senior Vice President of Manufacturing and Supply Chain Management since July 2017. Prior to joining us, Mr. Kosewski served as Vice President, Supply Chain Operations at Sunovion Pharmaceuticals Inc. from October 2010 to June 2017. He was also Vice President and General Manager at Sunovion's manufacturing subsidiary, Sepracor Canada Ltd., from 2010 to 2015. Prior to joining Sunovion, Mr. Kosewski held several positions at Sepracor, Inc., including Vice President, Supply Chain Operations from 2007 to 2010. Mr. Kosewski began his pharmaceutical career at Astra USA, Inc., holding positions in quality assurance, manufacturing, procurement and business development. Mr. Kosewski holds a B.S. in Chemistry from Fairfield University and an M.B.A. from Bryant University.

Gregory Grunberg, M.D. has served as a member of our board of directors since April 2016. Dr. Grunberg has been a Managing Director at Longitude Capital Management Co., LLC, or Longitude, since 2012 and has focused on medical technology and drug development. Prior to joining Longitude, Dr. Grunberg was a Principal at Rho Ventures and an Engagement Manager at McKinsey & Company. Dr. Grunberg serves as a director of BAROnova and California Cryobank, Inc., and has previously served as a director of AqueSys, Inc. and as a Board Observer at SARCode Bioscience Inc. and PHT Corporation. Dr. Grunberg is Board Certified in Internal Medicine and completed his residency at Cornell's New York Presbyterian Hospital. He has maintained a limited clinical practice in Internal Medicine and affiliations with University of California, San Francisco and Kaiser Permanente. Dr. Grunberg received an M.D. and an M.B.A. from Duke University, where he was a Fuqua Scholar, and an A.B. degree from Amherst College. We believe that Dr. Grunberg's extensive experience investing in and guiding start-up and early phase companies, as well as his experience in the medical field, qualify him to serve as a member of our board of directors.

Paulina Hill, Ph.D. has served as a member of our board of directors since June 2017. Dr. Hill is a principal at Polaris Partners, or Polaris, where she has been since 2012 and has focused on investments in healthcare. Prior to joining Polaris, Dr. Hill completed her postdoctoral fellowship in the Chemical Engineering department at the Massachusetts Institute of Technology. Dr. Hill served as the founding chief executive officer of Marauder Therapeutics, a biotechnology company based in Cambridge, Massachusetts. Paulina serves on the boards of the private companies Arsenal Medical, Faraday Pharmaceuticals, KinDex Pharmaceuticals, Marauder Therapeutics and Neuronetics. She is an observer on the boards of the private companies 480 Biomedical, Microchips Biotech and Sofregen. She also serves on the board of The Capital Network, a non-profit that provides fundraising education to entrepreneurs. Dr. Hill completed her Ph.D. in Molecular Medicine with a Tissue Engineering focus at Wake Forest University School of Medicine. Dr. Hill graduated magna cum laude from East Carolina University with a quadruple major in biochemistry, neuroscience, biology and chemistry. We believe that Dr. Hill's experience in the venture capital industry, experience in the biopharmaceutical industry

and her experience on the boards of life sciences companies qualify her to serve as a member of our board of directors.

Robert Langer, Sc.D. has served as a member of our board of directors since December 2009. Dr. Langer has been an Institute Professor at the Massachusetts Institute of Technology, or MIT, since 2005, and prior to that was a Professor at MIT since 1977. Dr. Langer received his B.S. from Cornell University and his Sc.D. from MIT both in Chemical Engineering. Dr. Langer currently serves on the board of directors of UK public company Puretech Health plc, and previously served on the board of directors of public companies Momenta Pharmaceuticals, Inc., from 2001 to 2009, Wyeth from 2004 to 2009, Fibrocell Science, Inc. from 2010 to 2012 and Millipore Corp. from 2009 to 2010. Dr. Langer also served as a director on the Food and Drug Administration Science Board from 1995 to 2002, including his service as chairman from 1999 to 2002. We believe that Dr. Langer's pioneering academic work, and his extensive medical and scientific knowledge and experience and his previous service on public company boards of directors qualify him to serve as a member of our board of directors.

Robert Paull has served as a member of our board of directors since July 2009. Mr. Paull is a Co-founder and Venture Partner at Lux Capital Management, or Lux Capital, where he has been since October 2004 and has focused on ventures in healthcare. In addition to joining Lux Capital, Mr. Paull served as our founding Chief Executive Officer, President and Treasurer from July 2009 to June 2012. Mr. Paull also served as founding Chief Executive Officer of Genocea Biosciences Inc., a vaccine discovery and development company, from August 2006 to February 2009, and is the co-founder of Lux Research, Inc., an emerging technology market research and consulting firm, which was founded in January 2004. Mr. Paull holds a B.S. in Architecture from the University of Virginia. We believe that Mr. Paull's extensive experience guiding and investing in healthcare ventures qualifies him to serve as a member of our board of directors.

Howard Rosen has served as a member of our board of directors since January 2014. Since 2008, Mr. Rosen has served as a consultant to several companies in the biotechnology industry. He has also served as a lecturer at Stanford University in Chemical Engineering since 2009 and in Management since 2011. Mr. Rosen served as Chief Executive Officer of AcelRx Pharmaceuticals, Inc., or AcelRx, a public company developing products for pain relief, from April 2016 to March 2017, and Interim Chief Executive Officer from April 2015 to March 2016. Mr. Rosen also served as Interim President and Chief Executive Officer of Pearl Therapeutics, Inc. from June 2010 to March 2011. From 2004 to 2008, Mr. Rosen was Vice President of Commercial Strategy at Gilead Sciences, Inc., a biopharmaceutical company. Mr. Rosen was President of ALZA Corporation, a pharmaceutical and medical systems company that merged with Johnson & Johnson, a global healthcare company, in 2001, from 2003 until 2004. Prior to that, from 1994 until 2003, Mr. Rosen held various positions at ALZA Corporation. Mr. Rosen is chairman of the board of directors of AcelRx, a public company, and also serves on the board of directors of Alcobra, Ltd., a public company. Mr. Rosen is also currently a member of the board of directors of private biotechnology company Entrega, Inc. Mr. Rosen holds a B.S. in Chemical Engineering from Stanford University, an M.S. in Chemical Engineering from the Massachusetts Institute of Technology and an M.B.A. from the Stanford Graduate School of Business. We believe that Mr. Rosen's experience in the biopharmaceutical industry, including his specific experience with the development and commercialization of pharmaceutical products, qualifies him to serve as a member of our board of directors.

Rajeev Shah has served as a member of our board of directors since July 2015. Mr. Shah is a Managing Director and Portfolio Manager at RA Capital Management, LLC, or RA Capital. Prior to joining RA Capital in 2004, Mr. Shah was a Senior Project Leader at Altus Pharmaceuticals Inc., a spin-off of Vertex Pharmaceuticals Inc., from 2001 to 2004. Mr. Shah is currently a member of the board of directors of the public companies Ra Pharmaceuticals, Inc. and Kalvista Pharmaceuticals, Inc. Mr. Shah holds a B.A. in Chemistry from Cornell University. We believe that Mr. Shah's experience with biotechnology companies qualifies him to serve as a member of our board of directors.

Robert Tepper, M.D. has served as a member of our board of directors since December 2009. Dr. Tepper is a General Partner of Third Rock Ventures, L.P., or Third Rock, which he co-founded in March 2007 and focuses on the formation, development and scientific strategy of Third Rock's portfolio companies, as well as actively identifying and evaluating new investments. Prior to joining Third Rock, Dr. Tepper served as President of Research and Development at Millennium Pharmaceuticals, Inc., or Millennium. Prior to joining Millennium in 1994, he served as principal investigator in the laboratory of tumor biology at the Massachusetts General Hospital Cancer Center. Dr. Tepper is also a founder and former member of the scientific advisory board of Cell Genesys/Abgenix Inc. Dr. Tepper serves as an adjunct faculty member at Harvard Medical School and Massachusetts General Hospital and is an advisory board member of several healthcare institutions, including the Partners HealthCare Center for Personalized Genetic Medicine, Harvard Medical School and Tufts Medical School. Dr. Tepper is a board member of the public company Jounce Therapeutics, Inc. and was previously a board member of the public company bluebird bio, Inc. from 2010 to 2015. Dr. Tepper is currently a board member of private life sciences companies Allena Pharmaceuticals, Inc., Constellation Pharmaceuticals Inc. and Neon Therapeutics, Inc. Dr. Tepper also serves on the board of overseers at Tufts University and on the Council of the National Center for Advancing Translational Sciences at the National Institutes of Health. Dr. Tepper holds an A.B. in biochemistry from Princeton University and an M.D. from Harvard Medical School. We believe that Dr. Tepper's experience in the venture capital industry, particularly with biotech and pharmaceutical companies, combined with his experience building and operating research and development operations, on the boards of public and private life sciences companies and as faculty and advisory board member of several healthcare institutions, qualify him to serve as a member of our board of directors.

Chen Yu, M.D. has served as a member of our board of directors since April 2016. Dr. Yu has been a Managing Partner at Vivo Capital LLC, or Vivo, since 2011. Prior to joining Vivo in 2004, Dr. Yu worked at aQuantive, a private technology company. Dr. Yu has served as Chief Business Officer at China KangHui, a leading China based orthopedic company, and as Chief Operating Officer at Sagent Pharmaceuticals. Dr. Yu currently serves or has served on the boards of several private life science companies in both the United States and China, including SentreHeart, Rempex Pharmaceuticals, Nora Therapeutics, Jian Rui Bao Beijing GMT Science & Technology Development Co., Ltd, Outpost Medicine, LLC, PrinJohnson BioPharma, Inc., Nabriva Therapeutics, and Synaptic Medical. Dr. Yu currently serves on the California Leadership Council for the Nature Conservancy, an environmental non-profit with global reach, and was previously a member of the Stanford Medical School Alumni Board of Governors. Dr. Yu received his M.D. and M.B.A. from Stanford University and graduated magna cum laude with a B.A. in Biology from Harvard University. We believe that Dr. Yu's experience in the venture capital industry, his extensive operational and business experience, and his experience on the boards of public and private life sciences companies qualify him to serve as a member of our board of directors.

Board Composition and Election of Directors

Board Composition

Our board of directors is currently authorized to have nine members and currently consists of nine members. Contingent upon and immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, Dr. Yu will resign from our board of directors and, upon the closing of this offering, we will reduce the authorized number of members of our board of directors to eight. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal.

Our certificate of incorporation and bylaws that will become effective upon the closing of this offering provide that the authorized number of directors may be changed only by resolution of our board of directors. Our certificate of incorporation and bylaws will also provide that our directors may

be removed only for cause by the affirmative vote of the holders of 75% of our shares of capital stock present in person or by proxy and entitled to vote, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

In accordance with the terms of our certificate of incorporation and bylaws that will become effective upon the closing of this offering, our board of directors will be divided into three classes, class I, class II and class III, with members of each class serving staggered three-year terms. Upon the closing of this offering, the members of the classes will be divided as follows:

- the class I directors will be Dr. Tepper and Mr. Iwicki and their term will expire at the annual meeting of stockholders to be held in 2018;
- the class II directors will be Dr. Grunberg, Dr. Langer and Dr. Hill, and their term will expire at the annual meeting of stockholders to be held in 2019; and
- the class III directors will be Mr. Rosen, Mr. Paull and Mr. Shah and their term will expire at the annual meeting of stockholders to be held in 2020.

Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires.

The classification of our board of directors may have the effect of delaying or preventing changes in our control or management. See "Description of Capital Stock—Delaware Anti-Takeover Law and Certain Charter and Bylaw Provisions."

Director Independence

Applicable NASDAQ rules require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the NASDAQ rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under applicable NASDAQ rules, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (1) the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director; and (2) whether the director is affiliated with the company or any of its subsidiaries or affiliates.

In June 2017, our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations,

including family relationships, our board of directors has determined that each of our directors, with the exception of Mark Iwicki, is an "independent director" as defined under applicable NASDAQ rules. In making such determination, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director. Mr. Iwicki is not an independent director under these rules because he is our Chief Executive Officer.

There are no family relationships among any of our directors or executive officers.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which operates under a charter that has been approved by our board. The composition of each committee will be effective as of the date of this prospectus.

Audit Committee

Effective upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our audit committee are Mr. Rosen, Dr. Hill and Mr. Paull. Mr. Rosen is the chair of the audit committee. Our audit committee's responsibilities will include:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from that firm;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- overseeing our internal audit function;
- overseeing our risk assessment and risk management policies;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our internal auditing staff, if any, our independent registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by Securities and Exchange Commission, or SEC, rules.

All audit and non-audit services, other than *de minimis* non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

Our board of directors has determined that Mr. Rosen is an "audit committee financial expert" as defined in applicable SEC rules. We believe that the composition of our audit committee will meet the requirements for independence under current NASDAQ and SEC rules and regulations.

Compensation Committee

Effective upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our compensation committee are Mr. Shah, Dr. Grunberg and Dr. Tepper. Mr. Shah is the chair of the compensation committee. Our compensation committee's responsibilities will include:

- reviewing and approving, or making recommendations to our board of directors with respect to, the compensation of our chief executive officer and our other executive officers;
- overseeing an evaluation of our senior executives;
- overseeing and administering our cash and equity incentive plans;
- reviewing and making recommendations to our board of directors with respect to director compensation;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis" disclosure if and to the extent then required by SEC rules; and
- preparing the compensation committee report if and to the extent then required by SEC rules.

We believe that the composition of our compensation committee will meet the requirements for independence under current NASDAQ and SEC rules and regulations.

Nominating and Corporate Governance Committee

Effective upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our nominating and corporate governance committee are Mr. Paull, Dr. Langer and Mr. Shah. Mr. Paull is the chair of the nominating and corporate governance committee. Our nominating and corporate governance committee's responsibilities will include:

- recommending to our board of directors the persons to be nominated for election as directors and to each of our board's committees;
- reviewing and making recommendations to our board with respect to our board leadership structure;
- reviewing and making recommendations to our board with respect to management succession planning;
- developing and recommending to our board of directors corporate governance principles; and
- overseeing a periodic evaluation of our board of directors.

We believe that the composition of our nominating and corporate governance committee will meet the requirements for independence under current NASDAQ and SEC rules and regulations.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee. None of the members of our compensation committee is, or has ever been, an officer or employee of our company.

Code of Ethics and Code of Conduct

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We intend to post a current copy of the code on our website, www.kalarx.com. In addition, we intend to post on our website all disclosures that are required by law or NASDAQ stock market listing standards concerning any amendments to, or waivers from, any provision of the code.

EXECUTIVE COMPENSATION

The following discussion relates to the compensation of our Chief Executive Officer, Mark Iwicki, our Chief Medical Officer, Kim Brazzell, and our Chief Scientific Officer, Hongming Chen, for fiscal years 2015 and 2016. These three individuals are collectively referred to in this prospectus as our named executive officers. Each year, our compensation committee and board of directors review and determine the compensation of our named executive officers.

In preparing to become a public company, we have begun a thorough review of all elements of our executive compensation program, including the function and design of our equity incentive programs. We have begun, and expect to continue in the coming months, to evaluate the need for revisions to our executive compensation program to ensure that our program is competitive with the companies with which we compete for executive talent and is appropriate for a public company.

Summary Compensation Table

The following table sets forth information regarding compensation awarded to, earned by or paid to each of our named executive officers for the years ended December 31, 2015 and 2016, respectively.

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Option awards ($)(2)	All other compensation ($)(3)	Total ($)
Mark Iwicki	2016	472,738	254,300	1,533,531	1,298	2,261,867
Chief Executive Officer	2015	251,440	220,200	2,042,369	946	2,514,955
Kim Brazzell, M.D.	2016	340,973	141,750	375,055	1,710	859,488
Chief Medical Officer						
Hongming Chen, Sc.D.	2016	322,086	129,944	356,370	1,710	810,110
Chief Scientific Officer	2015	310,000	104,160	77,710	1,657	493,527

(1) Except where noted, the amounts reported in the "Bonus" column reflect discretionary annual cash bonuses payable to our executive officers for their performance.

(2) The amounts reported in the "Option awards" column reflect the aggregate fair value of stock-based compensation awarded during the year computed in accordance with the provisions of FASB ASC Topic 718. See Note 10 to our financial statements appearing at the end of this prospectus regarding assumptions underlying the valuation of equity awards.

(3) The compensation included in the "All other compensation" column consists of premiums we paid to each of our named executive officers for life insurance.

Narrative to Summary Compensation Table

In 2015, we paid Mr. Iwicki an annualized base salary of $250,000 beginning in April 2015, which was increased to $455,000 in September 2015, upon his appointment as Chief Executive Officer. In 2016, we paid Mr. Iwicki an annualized base salary of $470,925. In February 2017, our board of directors set Mr. Iwicki's 2017 annual base salary at $487,408. In 2016, we paid Dr. Brazzell an annualized base salary of $350,000. In February 2017, our board of directors set Dr. Brazzell's 2017 annual base salary at $362,250. In 2015, we paid Dr. Chen an annualized base salary of $310,000, and in 2016 we paid Dr. Chen an annualized base salary of $320,850. In February 2017, our board of directors set Dr. Chen's 2017 annual base salary at $332,080. Further, in July 2017 our board of directors agreed to raise the base salary of each of Mr. Iwicki, Dr. Brazzell and Dr. Chen to $516,600, $411,000 and $375,000, respectively, effective upon the effectiveness of the registration statement of which this prospectus forms a part.

We use base salaries to recognize the experience, skills, knowledge and responsibilities required of all our employees, including our named executive officers. None of our named executive officers is currently party to an employment agreement or other agreement or arrangement that provides for automatic or scheduled increases in base salary.

Performance-based bonuses, which are calculated as a percentage of base salary, are designed to motivate our employees to achieve annual goals based on our strategic, financial and operating performance objectives. From time to time, our board of directors has approved discretionary annual cash bonuses to our named executive officers with respect to their prior year performance.

Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, or any formal equity ownership guidelines applicable to them, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incents our executive officers to remain in our employment during the vesting period. Accordingly, our board of directors periodically reviews the equity incentive compensation of our named executive officers and from time to time may grant equity incentive awards to them in the form of stock options. In 2015, based upon our overall performance, we granted to Mr. Iwicki options to purchase 651,340 shares of our common stock, to Dr. Brazzell options to purchase 15,430 shares of our common stock, and to Dr. Chen options to purchase 21,431 shares of our common stock. In 2016, based upon our overall performance, we granted to Mr. Iwicki options to purchase 609,811 shares of our common stock, to Dr. Brazzell options to purchase 162,135 shares of our common stock, and to Dr. Chen options to purchase 154,635 shares of our common stock. In 2017 and prior to the date of this prospectus, based on overall performance, we granted to Mr. Iwicki options to purchase 78,632 shares of our common stock, to Dr. Brazzell options to purchase 47,142 shares of our common stock, and to Dr. Chen options to purchase 28,800 shares of our common stock, each of these options is contingent upon and effective upon the effectiveness of the registration statement of which this prospectus forms a part.

Prior to this offering, our executives were eligible to participate in our 2009 Employee, Director and Consultant Equity Incentive Plan, as amended, or the 2009 Plan. During 2015 and 2016, all stock options were granted pursuant to the 2009 Plan. Following the closing of this offering, our employees and executives will be eligible to receive stock options and other stock-based awards pursuant to the 2017 Equity Incentive Plan.

We use stock options to compensate our executive officers in the form of initial grants in connection with the commencement of employment and also at various times, often but not necessarily annually, if we have performed as expected or better than expected. Prior to this offering, the award of stock options to our executive officers, other than our Chief Executive Officer, has been made by our board or compensation committee, and the award of stock options to our Chief Executive Officer has been made by our board. None of our executive officers is currently party to an employment agreement that provides for automatic award of stock options. We have granted stock options to our executive officers with both time-based and performance-based vesting. The options that we have granted to our executive officers with time-based vesting typically become exercisable as to 25% of the shares underlying the option on the first anniversary of the grant date, and as to an additional 1/48th of the shares underlying the option monthly thereafter. Going forward, we expect annual and other grants made to existing executive officers and employees will vest monthly as to 1/48th of the shares underlying the option. The options that we have granted to date to our executive officers with performance-based vesting become exercisable upon the occurrence of specified business transactions or other specified milestones. Vesting and exercise rights cease shortly after termination of employment except in the case of death or disability and, in certain circumstances upon a change in control. Prior to

the exercise of an option, the holder has no rights as a stockholder with respect to the shares subject to such option, including no voting rights and no right to receive dividends or dividend equivalents.

We have historically granted stock options with exercise prices that are equal to the fair market value of our common stock on the date of grant as determined by our board of directors, based on a number of objective and subjective factors. The exercise price of all stock options granted after the closing of this offering will be equal to the fair market value of shares of our common stock on the date of grant, which will be determined by reference to the closing market price of our common stock on the date of grant.

Outstanding Equity Awards at December 31, 2016

The following table sets forth information regarding all outstanding stock options and restricted stock held by each of our named executive officers as of December 31, 2016.

	Option Awards				
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards; Number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date
Mark Iwicki	113,540	158,956(1)	—	$ 3.34	6/3/2025
	157,851	220,993(2)	—	$ 5.21	9/11/2025
	251,049	358,762(3)	—	$ 3.34	6/17/2026
Kim Brazzell, Ph.D.	35,342	752(4)	—	$ 0.68	5/10/2023
	13,536	4,512(5)	—	$ 0.68	5/10/2023
	35,189	27,371(6)	—	$ 2.30	10/2/2024
	4,500	10,930(7)	—	$ 5.21	10/2/2025
		162,135(8)	—	$ 3.34	6/17/2026
Hongming Chen, Sc.D.	4,992	—	—	$ 0.47(9)	6/18/2020
	5,760	—	—	$ 0.47	6/16/2021
	5,760	—	—	$ 0.58	6/26/2022
	4,687	1,082(10)	—	$ 2.24	9/27/2023
	66,601	43,635(11)	—	$ 2.30	10/2/2024
	6,250	15,181(12)	—	$ 5.21	10/2/2025
		154,635(13)	—	$ 3.34	6/17/2026

(1) Mr. Iwicki's option to purchase 272,496 shares of common stock vests over four years in equal monthly installments beginning May 8, 2015.

(2) Mr. Iwicki's option to purchase 378,844 shares of common stock vests over four years, with 25% of the shares underlying the option vested on April 8, 2016 and 2.0833% of the shares vesting monthly thereafter.

(3) Mr. Iwicki's option to purchase 609,811 shares of common stock vests over four years, with 2.0833% of the shares underlying the option vested on April 8, 2015 and 2.0833% of the shares vesting monthly thereafter.

(4) Dr. Brazzell's option to purchase 36,094 shares of common stock vests over four years, with 25% of the shares underlying the option vested on January 1, 2014, and 2.0833% of the shares vesting monthly thereafter.

(5) Dr. Brazzell's option to purchase 18,048 shares of common stock vested with respect to 25% of shares underlying the option 12 months after the date we submitted an investigational new drug application for our loteprednol etabonate program and as to an additional 2.0833% of the shares vesting monthly thereafter.

(6) Dr. Brazzell's option to purchase 62,560 shares of common stock vests over four years, with 25% of the shares underlying the option vested on September 25, 2015 and 2.0833% of the shares vesting monthly thereafter.

(7) Dr. Brazzell's option to purchase 15,430 shares of common stock vests over four years, with 25% of the shares underlying the option vested on October 2, 2016 and 2.0833% of the shares vesting monthly thereafter.

(8) Dr. Brazzell's option to purchase 162,135 shares of common stock vests over four years, with 25% of the shares underlying the option vesting on June 17, 2017 and 2.0833% of the shares vesting monthly thereafter.

(9) The original exercise price of this option to purchase 4,992 shares of common stock was $0.89 and was later amended to $0.47.

(10) Dr. Chen's option to purchase 5,769 shares of common stock vests over four years, with 25% of the shares underlying the option vested on September 27, 2014 and 2.0833% of the shares vesting monthly thereafter.

(11) Dr. Chen's option to purchase 110,236 shares of common stock vests over four years, in equal monthly installments, beginning on August 21, 2014.

(12) Dr. Chen's option to purchase 21,431 shares of common stock vests over four years, with 25% of the shares underlying the option vested on October 2, 2016 and 2.0833% of the shares vesting monthly thereafter.

(13) Dr. Chen's option to purchase 154,635 shares of common stock vests over four years, with 25% of the shares underlying the option vesting on June 17, 2017 and 2.0833% of the shares vesting monthly thereafter.

Employment Agreements

Letter Agreement with Mr. Iwicki

Mr. Iwicki was appointed as our Chief Executive Officer and Chairman of our board of directors pursuant to a letter agreement with us dated September 10, 2015, which amended and restated a prior letter agreement. Mr. Iwicki is an at-will employee, and his employment with us can be terminated by him or us at any time and for any reason. In February 2017, Mr. Iwicki's base salary was increased from $470,925 per annum to $487,408 per annum, and effective upon the effectiveness of the registration statement of which this prospectus forms a part, will increase to $516,600. Mr. Iwicki's base salary is subject to annual review and adjustment by our compensation committee. In addition, Mr. Iwicki is eligible to receive a discretionary bonus in a target amount of 60% of his annual base salary, as determined by our board of directors in its sole discretion.

Subject to his execution and nonrevocation of a release of claims in our favor, in the event of the termination of Mr. Iwicki's employment by us without cause or by him for good reason, each as defined in his employment letter agreement, Mr. Iwicki will be entitled to a lump sum payment in an amount equal to (i) twelve-months of his then-current annual base salary, (ii) any bonus earned for the year prior to the year of termination that has not yet been paid, (iii) an amount equal to 100% of his target bonus attributable to the year of termination, (iv) a pro-rated portion of any bonus attributable to the year of termination based upon performance against company but not individual objectives and

(v) twelve months of COBRA premiums for continued health benefit coverage on the same terms as were applicable to him prior to his termination.

In addition, in the event we terminate his employment or other service relationship with us without cause, he terminates his employment or other service relationship with us for good reason, or his employment or other service relationship with us terminates by reason of his death or disability, Mr. Iwicki is entitled to the automatic vesting and exercisability of any unvested options that would have vested if Mr. Iwicki's employment or other service relationship with us had continued for twelve months following such termination. In addition, provided Mr. Iwicki is an employee, member of our board of directors or is otherwise providing services to us at the time of a change of control, as defined in the letter agreement, or in the event of the termination of Mr. Iwicki's employment by us without cause or by him for good reason in contemplation of a change of control, as defined in the letter agreement, options referenced in the letter agreement will vest in full upon consummation of such change in control. Such options are exercisable for up to 18 months following the termination of his employment or other relationship with us other than a termination for cause. Mr. Iwicki also is entitled to piggyback registration rights with respect to options granted pursuant to his employment letter agreement. See "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights.

Letter Agreement with Dr. Brazzell

Dr. Brazzell was appointed to serve on a full-time basis as our Chief Medical Officer pursuant to a letter agreement with us dated May 10, 2016, which amended and restated a prior letter agreement. Dr. Brazzell is an at-will employee, and his employment with us can be terminated by him or us at any time and for any reason. In February 2017, Dr. Brazzell's base salary was increased from the $350,000 per annum to $362,250 per annum, and effective upon the effectiveness of the registration statement of which this prospectus forms a part, will increase to $411,000. Dr. Brazzell's base salary is subject to annual review and adjustment by our compensation committee. In addition, Dr. Brazzell is eligible to receive a discretionary bonus in a target amount of 40% of his annual base salary, as determined by our board of directors in its sole discretion.

Subject to his execution and nonrevocation of a release of claims in our favor, in the event of the termination of Dr. Brazzell's employment by us without cause or by him for good reason, each as defined in his employment letter agreement, Dr. Brazzell will be entitled to a lump sum payment in an amount equal to twelve months of his then-current annual base salary plus a pro-rated portion of any bonus attributable to the year of termination, as well as up to twelve months of COBRA premiums for continued health benefit coverage.

In addition, in the event we terminate his employment without cause or he terminates his employment for good reason, Dr. Brazzell is entitled to the automatic vesting and exercisability of any options and shares granted to him that vest solely based on his continued employment that would have vested if his employment had continued for twelve months following such termination. In the event of a change of control, as defined in his employment letter agreement, during his employment, Dr. Brazzell is entitled to the automatic vesting and exercisability of 100% of any options and restricted shares granted to him that vest solely based on his continued employment. The option referenced in his employment agreement is exercisable for a period of up to six months following his termination date.

Letter Agreement with Dr. Chen

Dr. Chen was appointed as our Chief Scientific Officer pursuant to a letter agreement with us dated August 19, 2014, which amended and restated a prior letter agreement. Dr. Chen is an at-will employee, and her employment with us can be terminated by her or us at any time and for any reason. In February 2017, Dr. Chen's base salary was increased from $320,850 per annum to $332,080 per

annum, and effective upon the effectiveness of the registration statement of which this prospectus forms a part, will increase to $375,000. Dr. Chen's base salary is subject to annual review and adjustment by our compensation committee. In addition, Dr. Chen is eligible to receive a discretionary bonus in a target amount of 40% of her annual base salary, as determined by our board of directors in its sole discretion.

In the event of the termination of Dr. Chen's employment by us without cause or by her for good reason, each as defined in her employment letter agreement, Dr. Chen will be entitled to a lump sum payment in an amount equal to ten months of her then-current annual base salary plus a pro-rated portion of any bonus attributable to the year of termination, as well as up to ten months of COBRA premiums for continued health benefit coverage.

In addition, subject to her execution and nonrevocation of a release of claims in our favor, Dr. Chen is entitled to the automatic vesting and exercisability of 100% of any options and restricted shares granted to her that vest solely based on her continued employment if, during her employment, we terminate her employment without cause or Dr. Chen terminates her employment for good reason or a change of control, as defined in the agreement, occurs and within twelve months following such change of control we or our successor terminate Dr. Chen's employment without cause or she terminates for employment for good reason.

Employee Non-Competition, Non-Solicitation, Confidentiality, and Assignment of Inventions Agreements

Each of our named executive officers has entered into a standard form agreement with respect to non-competition, non-solicitation, confidential information and assignment of inventions. Under this agreement, each executive officer has agreed not to compete with us during his or her employment and for a period of one year after the termination of his or her employment, not to solicit our employees or consultants during his or her employment and for a period of two years after the termination of his or her employment, and to protect our confidential and proprietary information indefinitely. In addition, under this agreement, each executive officer has agreed that we own all inventions, as defined in the agreement, that are developed during such executive officer's employment and for a period of one year after the termination of his or her employment, to the extent such invention is our field of interest, as defined in the agreement. Each executive officer also agreed to assign to us any inventions which were not prepared or originated in the performance of employment but that were provided to us or incorporated into any of our products or systems.

Stock Option and Other Compensation Plans

In this section we describe our 2009 Employee, Director and Consultant Equity Incentive Plan, as amended to date, or the 2009 Plan, our 2017 Equity Incentive Plan, or the 2017 Plan, and our 2017 Employee Stock Purchase Plan, or 2017 ESPP. Prior to this offering, we granted awards to eligible participants under the 2009 Plan. Upon and following the effectiveness of the registration statement for this offering, we expect to only grant awards to eligible participants under the 2017 Plan.

2009 Plan

Our 2009 Plan was adopted by our board of directors and approved by our stockholders on December 11, 2009 and subsequently amended by our board in 2012, 2013, 2014 and 2015. The 2009 Plan provides for the grant of incentive stock options, non-qualified options, shares, restricted or otherwise, of our common stock, and other stock-based awards. We refer to awards granted under our 2009 Plan as stock rights. Our employees, directors and consultants are eligible to receive stock rights under our 2009 Plan; however incentive stock options may only be granted to our employees who are deemed to be residents of the United States. As of December 31, 2016, a maximum of 3,711,949 shares of our common stock, or the equivalent of such number after our board of directors makes any

adjustments upon any change in capitalization or corporate transaction, were authorized for issuance under the 2009 Plan.

The type of stock right granted under our 2009 Plan and the terms of such stock right are set forth in the applicable stock right award agreement.

Pursuant to the 2009 Plan, our board of directors (or a committee to which our board delegates its authority) administers the 2009 Plan. Subject to the provisions of the 2009 Plan, our board of directors is authorized to:

- interpret the provisions of the 2009 Plan and all stock rights and make all rules and determinations that it deems necessary or advisable for the administration of the 2009 Plan;
- determine which employees, directors and consultants will be granted stock rights;
- determine the number of shares of our common stock for which a stock right will be granted;
- specify the terms and conditions upon which a stock right may be granted;
- amend any term or condition of an outstanding stock right, including, without limitation, to reduce or increase the exercise price or purchase price, accelerate the vesting or extend the expiration date, provided that no such change will impair a participant's rights under any prior grant unless we obtain the participant's consent;
- purchase and/or cancel a stock right previously granted and grant other stock rights in substitution, which may cover the same or a different number of shares and which may have a lower or higher exercise or purchase price per share, based on such terms and conditions as the board of directors establishes and the participant accepts; and
- adopt any sub-plans applicable to residents of any specified jurisdiction as it deems necessary or appropriate to facilitate the 2009 Plan or to comply with or take advantage of any tax or other laws applicable to us, any of our affiliates, or to participants, which sub-plans may include additional restrictions or conditions applicable to stock rights or shares issuable pursuant to a stock right.

Effect of certain changes in capitalization

If our shares of common stock are subdivided or combined into a greater or smaller number of shares, if we issue shares of common stock as a stock dividend, or if we make any distribution of additional, new or different shares or securities of ours or any distribution of non-cash assets with respect to our shares of common stock, then, subject to the terms of the 2009 Plan, our board of directors shall proportionately and appropriately adjust:

- the number of shares of our common stock available for issuance under the 2009 Plan;
- the number of shares of our common stock deliverable upon the exercise of an option or acceptance of a stock grant;
- the exercise or purchase price per share; and
- any other term or condition of a stock right.

Effect of certain corporate transactions

In the event that we are consolidated with or acquired by another entity in a merger, consolidation, or sale of all or substantially all of our assets (other than a transaction to merely change the state of incorporation), which we refer to as corporate transactions, our board of directors, or the board of directors of any entity assuming our obligations under the 2009 Plan, must take one of the

following actions pursuant to the 2009 Plan as to outstanding options, subject to the terms of the 2009 Plan:

- provide for the continuation of the outstanding options by equitably substituting for the shares of our common stock then underlying such options either with securities of any successor or acquiring entity or the consideration payable with respect to the outstanding shares of our common stock in connection with the corporate transaction;

- provide by written notice to the participants that the outstanding options will terminate unless exercised (to the extent then exercisable or made partially or fully exercisable by our board of directors for purposes of the corporate transaction) within a specified period following the date of the notice; or

- terminate each outstanding option in exchange for a payment equal to the consideration payable upon consummation of the corporate transaction to a holder of the number of shares of our common stock into which such option would have been exercisable (to the extent then exercisable or made partially or fully exercisable by our board of directors for purposes of the corporate transaction), minus the aggregate exercise price of such option.

If there is a corporate transaction, our board of directors, or the board of directors of any entity assuming our obligations under the 2009 Plan, must take one of the following actions pursuant to the 2009 Plan as to outstanding stock grants, restricted or otherwise, subject to the terms of the 2009 plan:

- provide for the continuation of the outstanding stock grants on the same terms and conditions by equitably substituting for the shares of our common stock then subject to such stock grants either with securities of any successor or acquiring entity or the consideration payable with respect to the outstanding shares of our common stock in connection with the corporate transaction; or

- provide that each outstanding stock grant will terminate in exchange for a payment equal to the consideration payable upon consummation of the corporate transaction to a holder of the number of shares of our common stock comprising such stock grant (to the extent such stock grant is no longer subject to any forfeiture or repurchase rights or our board of directors waives all forfeiture and repurchase rights upon the corporate transaction).

In taking any of the above actions with respect to stock rights, our board of directors will not be obligated to treat all stock rights, all stock rights held by a participant, or all stock rights of the same type, identically.

As of December 31, 2016, options to purchase 3,195,469 shares of common stock were outstanding under the 2009 Plan, at a weighted average exercise price of $3.26 per share, and 178,224 options to purchase shares of our common stock had been exercised.

Our board of directors may amend or terminate the 2009 Plan, except that any amendment that our board of directors determines is of a scope that requires shareholder approval will be subject to obtaining shareholder approval and any modification or amendment of the 2009 Plan that adversely affects a participant's rights will require such participant's consent.

No further awards will be made under our 2009 Plan on or after the effectiveness of the registration statement for this offering; however, awards outstanding under our 2009 Plan will continue to be governed by their existing terms.

2017 Equity Incentive Plan

Our board of directors has adopted and our stockholders have approved the 2017 Plan, which will become effective immediately prior to the effectiveness of the registration statement of which this

prospectus forms a part. The 2017 Plan provides for the grant of incentive stock options, non-qualified options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. Upon effectiveness of the 2017 Plan, the number of shares of our common stock that will be reserved for issuance under the 2017 Plan will be the sum of: (1) 1,786,883; plus (2) the number of shares (up to 3,533,757 shares) equal to the sum of the number of shares of our common stock then available for issuance under the 2009 Plan and the number of shares of our common stock subject to outstanding awards under the 2009 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right; plus (3) an annual increase, to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2018 and continuing until, and including, the fiscal year ending December 31, 2027, equal to the lowest of 3,573,766 shares of our common stock, 4% of the number of shares of our common stock outstanding on the first day of such fiscal year and an amount determined by our board of directors.

Our employees, officers, directors, consultants and advisors will be eligible to receive awards under the 2017 Plan. Incentive stock options, however, may only be granted to our employees. Contingent upon and effective upon the effectiveness of the registration statement of which this prospectus forms a part, we granted options to purchase an aggregate of 313,590 shares of common stock under our 2017 Plan to certain of our employees, including our named executive officers.

Pursuant to the terms of the 2017 Plan, our board of directors (or a committee delegated by our board of directors) will administer the plan and, subject to any limitations in the plan, will select the recipients of awards and determine:

- the number of shares of our common stock covered by options and the dates upon which the options become exercisable;
- the type of options to be granted;
- the duration of options, which may not be in excess of ten years;
- the exercise price of options, which must be at least equal to the fair market value of our common stock on the date of grant; and
- the number of shares of our common stock subject to and the terms of any stock appreciation rights, restricted stock awards, restricted stock units or other stock-based awards and the terms and conditions of such awards, including conditions for repurchase, issue price and repurchase price (though the measurement price of stock appreciation rights must be at least equal to the fair market value of our common stock on the date of grant and the duration of such awards may not be in excess of ten years).

If our board of directors delegates authority to an executive officer to grant awards under the 2017 Plan, the executive officer will have the power to make awards to all of our employees, except executive officers. Our board of directors will fix the terms of the awards to be granted by such executive officer, including the exercise price of such awards (which may include a formula by which the exercise price will be determined), and the maximum number of shares subject to awards that such executive officer may make.

Effect of certain changes in capitalization

Upon the occurrence 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 our common stock other than an ordinary cash dividend, our board of directors shall equitably adjust:

- the number and class of securities available under the 2017 Plan;

- the share counting rules under the 2017 Plan;
- the number and class of securities and exercise price per share of each outstanding option;
- the share and per-share provisions and the measurement price of each outstanding stock appreciation right;
- the number of shares subject to, and the repurchase price per share subject to, each outstanding restricted stock award; and
- the share and per-share related provisions and the purchase price, if any, of each other stock-based award.

Effect of certain corporate transactions

Upon a merger or other reorganization event (as defined in our 2017 Plan), our board of directors may, on such terms as our board determines (except to the extent specifically provided otherwise in an applicable award agreement or other agreement between the participant and us), take any one or more of, or a combination of, the following actions pursuant to the 2017 Plan as to some or all outstanding awards, other than restricted stock awards:

- provide that all outstanding awards shall be assumed, or substantially equivalent awards shall be substituted, by the acquiring or successor corporation (or an affiliate thereof);
- upon written notice to a participant, provide that all of the participant's unvested awards will be forfeited, and/or vested but unexercised awards 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 the notice;
- provide that outstanding awards shall become exercisable, realizable or deliverable, or restrictions applicable to an award shall lapse, in whole or in part, prior to or upon such reorganization event;
- in the event of a reorganization event pursuant to which holders of shares of our common stock will receive a cash payment for each share surrendered in the reorganization event, make or provide for a cash payment to participants with respect to each award held by a participant equal to (1) the number of shares of our common stock subject to the vested portion of the award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such reorganization event) multiplied by (2) the excess, if any, of the cash payment for each share surrendered in the reorganization event over the exercise, measurement or purchase price of such award and any applicable tax withholdings, in exchange for the termination of such award; and/or
- provide that, in connection with a liquidation or dissolution, awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings).

Our board of directors does not need to take the same action with respect to all awards, all awards held by a participant or all awards of the same type.

In the case of certain restricted stock units, no assumption or substitution is permitted, and the restricted stock units will instead be settled in accordance with the terms of the applicable restricted stock unit agreement.

Upon the occurrence of a reorganization event other than a liquidation or dissolution, the repurchase and other rights with respect to outstanding restricted stock awards will continue for the benefit of the successor company and will, unless our board of directors may otherwise determine,

apply to the cash, securities or other property into which shares of our common stock are converted or exchanged pursuant to the reorganization event. Upon the occurrence of a reorganization event involving a liquidation or dissolution, all restrictions and conditions on each outstanding restricted stock award will automatically be deemed terminated or satisfied, unless otherwise provided in the agreement evidencing the restricted stock award or any other agreement between the participant and us.

At any time, our board of directors may, in its sole discretion, provide that any award under the 2017 Plan will become immediately exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in whole or in part as the case may be.

No award may be granted under the 2017 Plan on or after July 19, 2027. Our board of directors may amend, suspend or terminate the 2017 Plan at any time, except that stockholder approval may be required to comply with applicable law or stock market requirements.

2017 Employee Stock Purchase Plan

Our board of directors has adopted, and our stockholders have approved, our 2017 ESPP, which will become effective immediately prior to the registration statement of which this prospectus forms a part. The 2017 ESPP will be administered by our board of directors or by a committee appointed by our board of directors. The 2017 ESPP initially will provide participating employees with the opportunity to purchase an aggregate of 223,341 shares of our common stock. The number of shares of our common stock reserved for issuance under the 2017 ESPP will automatically increase on the first day of each fiscal year, beginning on January 1, 2019 and ending on December 31, 2029, in an amount equal to the lowest of: (1) 893,441 shares of our common stock; (2) 1% of the total number of shares of our common stock outstanding on the first day of the applicable fiscal year; and (3) an amount determined by our board of directors.

All of our employees and employees of any of our designated subsidiaries, as defined in the 2017 ESPP, are eligible to participate in the 2017 ESPP, provided that:

- such person is customarily employed by us or a designated subsidiary for more than 20 hours a week and for more than five months in a calendar year;
- such person has been employed by us or by a designated subsidiary for at least three months prior to enrolling in the 2017 ESPP; and
- such person was our employee or an employee of a designated subsidiary on the first day of the applicable offering period under the 2017 ESPP.

We retain the discretion to determine which eligible employees may participate in an offering under applicable Treasury regulations.

We expect to make one or more offerings to our eligible employees to purchase stock under the 2017 ESPP beginning at such time and on such dates as our board of directors may determine, or the first business day thereafter. Each offering will consist of a six-month offering period during which payroll deductions will be made and held for the purchase of our common stock at the end of the offering period. Our board of directors or a committee appointed by our board, may, at its discretion, choose a different period of not more than 12 months for offerings.

On each offering commencement date, each participant will be granted the right to purchase, on the last business day of the offering period, a number of shares of our common stock determined by multiplying $2,083 by the number of full months in the offering period and dividing that product by the closing price of our common stock on the first day of the offering period. No employee may be granted an option under the 2017 ESPP that permits the employee's rights to purchase shares under the 2017 ESPP and any other employee stock purchase plan of ours or of any of our subsidiaries to accrue at a rate that exceeds $25,000 of the fair market value of our common stock (determined as of the first day

of each offering period) for each calendar year in which the option is outstanding. In addition, no employee may purchase shares of our common stock under the 2017 ESPP that would result in the employee owning 5% or more of the total combined voting power or value of our stock or the stock of any of our subsidiaries.

On the commencement date of each offering period, each eligible employee may authorize up to a maximum of 15% of his or her compensation to be deducted by us during the offering period. Each employee who continues to be a participant in the 2017 ESPP on the last business day of the offering period will be deemed to have exercised an option to purchase from us the number of whole shares of our common stock that his or her accumulated payroll deductions on such date will buy, not in excess of the maximum numbers set forth above. Under the terms of the 2017 ESPP, the purchase price shall be determined by our board of directors for each offering period and will be at least 85% of the applicable closing price of our common stock. If our board of directors does not make a determination of the purchase price, the purchase price will be 85% of the lesser of the closing price of our common stock on the first business day of the offering period or on the last business day of the offering period.

An employee may at any time prior to the close of business on the fifteenth business day prior to the end of an offering period, and for any reason, permanently withdraw from participation in an offering prior to the end of an offering period and permanently withdraw the balance accumulated in the employee's account. If an employee elects to discontinue his or her payroll deductions during an offering period but does not elect to withdraw his or her funds, funds previously deducted will be applied to the purchase of common stock at the end of the offering period. If a participating employee's employment ends before the last business day of an offering period, no additional payroll deductions will be taken and the balance in the employee's account will be paid to the employee.

We will be required to make equitable adjustments to the extent determined by our board of directors or a committee of our board of directors to the number and class of securities available under the 2017 ESPP, the share limitations under the 2017 ESPP and the purchase price for an offering period under the 2017 ESPP to reflect stock splits, reverse stock splits, stock dividends, recapitalizations, combinations of shares, reclassifications of shares, spin-offs and other similar changes in capitalization or events or any dividends or distributions to holders of our common stock other than ordinary cash dividends.

In connection with a merger or other reorganization event (as defined in the 2017 ESPP), our board of directors or a committee of our board of directors may take any one or more of the following actions as to outstanding options to purchase shares of our common stock under the 2017 ESPP on such terms as our board of directors or committee determines:

- provide that options shall be assumed, or substantially equivalent options shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof);
- upon written notice to employees, provide that all outstanding options will be terminated immediately prior to the consummation of such reorganization event and that all such outstanding options will become exercisable to the extent of accumulated payroll deductions as of a date specified by our board of directors or committee in such notice, which date shall not be less than ten days preceding the effective date of the reorganization event;
- upon written notice to employees, provide that all outstanding options will be cancelled as of a date prior to the effective date of the reorganization event and that all accumulated payroll deductions will be returned to participating employees on such date;
- in the event of a reorganization event under the terms of which holders of our common stock will receive upon consummation thereof a cash payment for each share surrendered in the reorganization event, change the last day of the offering period to be the date of the consummation of the reorganization event and make or provide for a cash payment to each

employee equal to (1) the cash payment for each share surrendered in the reorganization event times the number of shares of our common stock that the employee's accumulated payroll deductions as of immediately prior to the reorganization event could purchase at the applicable purchase price, where the cash payment for each share surrendered in the reorganization event is treated as the fair market value of our common stock on the last day of the applicable offering period for purposes of determining the purchase price and where the number of shares that could be purchased is subject to the applicable limitations under the 2017 ESPP minus (2) the result of multiplying such number of shares by the purchase price; and/or

- provide that, in connection with our liquidation or dissolution, options shall convert into the right to receive liquidation proceeds (net of the purchase price thereof).

Our board of directors may at any time, and from time to time, amend or suspend the 2017 ESPP, or any portion of the 2017 ESPP. We will obtain stockholder approval for any amendment if such approval is required by Section 423 of the Code. Further, our board of directors may not make any amendment that would cause the 2017 ESPP to fail to comply with Section 423 of the Code. The 2017 ESPP may be terminated at any time by our board of directors. Upon termination, we will refund all amounts in the accounts of participating employees.

401(k) Plan

We maintain a defined contribution employee retirement plan for our employees. Our 401(k) plan is intended to qualify as a tax-qualified plan under Section 401 of the Internal Revenue Code of 1986, as amended, so that contributions to our 401(k) plan, and income earned on such contributions, are not taxable to participants until withdrawn or distributed from the 401(k) plan. Our 401(k) plan provides that each participant may contribute up to 90% of his or her pre-tax compensation, up to a statutory limit, which is $18,000 for 2017. Participants who are at least 50 years old can also make "catch-up" contributions, which in 2016 may be up to an additional $5,500 above the statutory limit. As of January 2017, we also make discretionary matching contributions to our 401(k) plan equal to 50% of the employee contributions up to 2% of the employee's salary, subject to the statutorily prescribed limit, equal to $18,000 in 2017. Under our 401(k) plan, each employee is fully vested in his or her deferred salary contributions and our discretionary match. Employee contributions are held and invested by the plan's trustee, subject to participants' ability to give investment directions by following certain procedures.

Limitation of Liability and Indemnification

Our certificate of incorporation that will become effective upon the closing of this offering limits the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the Delaware General Corporation Law, or the DGCL, and provides that no director will have personal liability to us or to our stockholders for monetary damages for breach of fiduciary duty as a director. However, these provisions do not eliminate or limit the liability of any of our directors:

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- for voting for or assenting to unlawful payments of dividends, stock repurchases or other distributions; or
- for any transaction from which the director derived an improper personal benefit.

Any amendment to or repeal of these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission or claim that occurred or arose prior to such amendment or

repeal. If the DGCL is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of our directors will be further limited to the greatest extent permitted by the DGCL.

In addition, our certificate of incorporation that will become effective upon the closing of this offering provides that we must indemnify our directors and officers and we must advance expenses, including attorneys' fees, to our directors and officers in connection with legal proceedings, subject to very limited exceptions.

We maintain a general liability insurance policy that covers specified liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers. In addition, we have entered into indemnification agreements with all of our directors and officers. These indemnification agreements may require us, among other things, to indemnify each such director or officer for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by him or her in any action or proceeding arising out of his or her service as one of our directors or officers.

Some of our non-employee directors may, through their relationships with their employers, be insured or indemnified against specified liabilities incurred in their capacities as members of our board of directors.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, or the Securities Act, may be permitted to directors, executive officers or persons controlling us, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from the director or officer. It also is possible that the director or officer could amend or terminate the plan when not in possession of material, nonpublic information. In addition, our directors and executive officers may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

Director Compensation

The table below shows all compensation to our non-employee directors during 2016.

Name	Fees earned or paid in cash ($)	All other compensation ($)	Total ($)
Kevin Bitterman(1)	—	—	—
Gregory Grunberg	—	—	—
Robert Langer(2)	—	60,000(2)	60,000
Robert Paull	—	—	—
Howard Rosen(3)	40,000(3)	—	40,000
Rajeev Shah	—	—	—
Robert Tepper	—	—	—
Karen Wagner(4)	—	—	—
Chen Yu	—	—	—

(1) Dr. Bitterman resigned from our board of directors in May 2017. Dr. Hill joined our board of directors in June 2017 to fill the vacancy resulting from Dr. Bitterman's resignation.

(2) Dr. Langer received $60,000 in consulting fees in 2016 pursuant to a consulting agreement with us, which will terminate effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

(3) Mr. Rosen received a $40,000 board retainer fee in 2016.

(4) Ms. Wagner served as a member of our board of directors from April 2014 to April 2016.

Prior to this offering, we did not have a formal non-employee director compensation policy. We have historically reimbursed our non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending board of director and committee meetings. Mr. Iwicki, one of our directors who also serves as our Chief Executive Officer, does not receive any additional compensation for his service as a director. The compensation that we pay to our Chief Executive Officer is discussed under "—Summary Compensation Table" and "—Narrative to Summary Compensation Table."

Following this offering, our non-employee directors will be compensated for their services on our board of directors as follows:

- each non-employee director will receive an option to purchase 25,920 shares of our common stock upon his or her initial election or appointment to our board of directors, which option will vest with respect to 1/3 of the shares on the first anniversary of the grant and with respect to an additional 1/36th of the shares on each monthly anniversary thereafter and will vest automatically as to 100% of the unvested portion of such option upon specified change in control events;

- each non-employee director who has then served on our board of directors for at least six months will receive, on the date of the first board meeting held after each annual meeting of stockholders, an option to purchase 12,960 shares of our common stock, which option will vest in equal monthly installments until the one-year anniversary of the date of grant and will vest automatically as to 100% of the unvested portion of such option upon specified change in control events;

- each non-employee director will receive an annual fee of $40,000;

- the lead independent director will receive an additional annual fee of $18,750;
- each non-employee director who serves as member of a committee of our board of directors will receive additional compensation as follows:
    - audit committee—an annual retainer of $10,000; chair an additional annual retainer of $10,000;
    - compensation committee—an annual retainer of $7,500; chair an additional annual retainer of $7,500; and
    - nominating and corporate governance committee—an annual retainer of $5,000; chair an additional annual retainer of $5,000.

Contingent upon and effective upon the effectiveness of the registration statement of which this prospectus forms a part, we granted options to purchase 12,960 shares of our common stock under the 2017 Plan to the non-employee directors who will remain on the board following this offering. Such stock options shall become exercisable and vest, subject to the non-employee director's continued service as a director, with respect to 1/12th of the shares at the end of each successive one-month period until the first anniversary of the grant date and will vest automatically as to 100% of the unvested portion of such option upon specified change in control events.

Each member of our board of directors also will continue to be entitled to be reimbursed for reasonable travel and other expenses incurred in connection with attending meetings of our board of directors and any committee of our board of directors on which he or she serves.

TRANSACTIONS WITH RELATED PERSONS

Since January 1, 2014, we have engaged in the following transactions with our directors, executive officers and holders of more than 5% of our voting securities, and affiliates of our directors, executive officers and holders of more than 5% of our voting securities. We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

Participation in this offering

Certain of our existing stockholders, including beneficial owners of more than 5% of our voting securities, and their affiliated entities have indicated an interest in purchasing an aggregate of up to $40 million in shares of our common stock in this offering at the initial public offering price. Based on the initial public offering price of $15.00 per share, these entities would purchase an aggregate of approximately 2,666,666 of the 6,000,000 shares in this offering based on these indications of interest. In addition, the underwriters may determine to sell fewer shares to any of these entities than these entities indicate an interest in purchasing or not to sell any shares to these entities. It is also possible that the underwriters could determine to sell more shares to any of these entities.

Series B Preferred Stock Financing

In April 2014, we issued and sold an aggregate of 15,624,999 shares of our Series B preferred stock at a price per share of $1.44 for an aggregate purchase price of $22.5 million, which included conversion the outstanding principal and interest on $5 million in convertible promissory notes issued to various 5% holders in December 2013, or the 2013 Notes. Additionally, upon closing of the Series B preferred stock financing, the warrants issued to holders of our 2013 Notes became exercisable into 694,444 shares of our Series B preferred stock. The following table sets forth the aggregate number of shares of our Series B preferred stock and warrants to purchase our Series B preferred stock that we issued and sold to our 5% stockholders and their affiliates in these transactions and the aggregate purchase price for such shares:

Purchaser(1)	Shares of Series B Preferred Stock	Series B Preferred Stock Warrants	Cash Purchase Price
Entities affiliated with Lux Capital(2)	2,300,703	173,611	$ 3,313,012
Entities affiliated with Polaris Ventures	2,265,764	173,611	$ 3,262,700
Third Rock Ventures	2,265,764	173,611	$ 3,262,700
CVF, LLC	916,961	173,611	$ 1,320,424
Ysios Capital	3,472,222	—	$ 5,000,000
AbbVie, Inc.(3)	3,819,444	—	$ 5,500,000

(1) See "Principal Stockholders" for additional information about shares held by these entities.

(2) In August 2015, Lux Capital distributed certain of its shares of Series B preferred stock and certain of its warrants to its limited partners.

(3) AbbVie, Inc. sold its shares of Series B preferred stock to funds affiliated with RA Capital in July 2015.

Series B-1 Preferred Stock Financing

In August 2015, we issued and sold 4,629,629 shares of our Series B-1 preferred stock to an entity affiliated with Wellington Management Company at a price per share of $1.512 for an aggregate cash

purchase price of $7 million. See "Principal Stockholders" for additional information about the shares held by such entity.

Series C Preferred Stock Financing

In April 2016, we issued and sold an aggregate of 42,782,688 shares of our Series C preferred stock at a price per share of $1.5876 for an aggregate purchase price of $67.9 million. The following table sets forth the aggregate number of shares of our Series C preferred stock that we issued and sold to our 5% stockholders and their affiliates in these transactions and the aggregate purchase price for such shares:

Purchaser(1)	Shares of Series C Preferred Stock	Cash Purchase Price
Longitude Venture Partners	10,707,985	$ 16,999,997
Orbimed Private Investments	10,707,985	$ 16,999,997
Entities affiliated with Vivo Capital	5,983,874	$ 9,499,998
Entities affiliated with Wellington Management Company	4,409,170	$ 6,999,998
Entities affiliated with RA Capital	4,409,170	$ 6,999,998
CVF, LLC	1,880,801	$ 2,985,960
Entities affiliated with Polaris Ventures	1,231,723	$ 1,955,483
Entities affiliated with Lux Capital	31,494	$ 50,000

(1) See "Principal Stockholders" for additional information about shares held by these entities.

Guillaume Pfefer Loan

We granted a loan of $150,000 to Guillaume Pfefer, a former executive in 2012, as part of his offer letter agreement. The term of the loan was five years, maturing on December 28, 2017, and the interest rate was equal to the minimum applicable federal rate in effect at the date of the loan. Under the terms of the agreement, and provided that Mr. Pfefer remained an employee, the initial aggregate principal amount of the loan plus any accrued but unpaid interest would be forgiven in varying amounts upon each annual anniversary such that the entire loan would be forgiven on the fourth year anniversary of the issuance of the loan. In addition, in the event that Mr. Pfefer's employment was terminated other than for cause or good reason as defined in the loan agreement, 100% of the unforgiven portion of the outstanding balance of the loan would be forgiven as of the date of such occurrence. In September 2014, Mr. Pfefer left us and the outstanding balance of the loan plus accrued interest was forgiven.

Registration Rights

We are a party to a registration rights agreement with the holders of our preferred stock, including our 5% stockholders and their affiliates and entities affiliated with some of our directors. This registration rights agreement provides these holders the right, subject to certain conditions, beginning 180 days following the completion of this offering, to demand that we file a registration statement or to request that their shares be covered by a registration statement that we are otherwise filing.

See "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights.

Indemnification Agreements

Our certificate of incorporation that will become effective upon the closing of this offering provides that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. In addition, we have entered into indemnification agreements with all of our directors and officers.

Policies and Procedures for Related Person Transactions

Our board of directors has adopted written policies and procedures for the review of any transaction, arrangement or relationship in which our company is a participant, the amount involved exceeds $120,000 and one of our executive officers, directors, director nominees or 5% stockholders, or their immediate family members, each of whom we refer to as a "related person," has a direct or indirect material interest.

If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a "related person transaction," the related person must report the proposed related person transaction to our chief legal officer or, if none, to our chief financial officer, or individual performing a similar function. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by our audit committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the committee will review, and, in its discretion, may ratify the related person transaction. The policy also permits the chairman of the audit committee to review and, if deemed appropriate, approve proposed related person transactions that arise between committee meetings, subject to ratification by the committee at its next meeting. Any related person transactions that are ongoing in nature will be reviewed annually.

A related person transaction reviewed under the policy will be considered approved or ratified if it is authorized by the audit committee after full disclosure of the related person's interest in the transaction. As appropriate for the circumstances, the audit committee will review and consider:

- the related person's interest in the related person transaction;
- the approximate dollar value of the amount involved in the related person transaction;
- the approximate dollar value of the amount of the related person's interest in the transaction without regard to the amount of any profit or loss;
- whether the transaction was undertaken in the ordinary course of our business;
- whether the terms of the transaction are no less favorable to us than terms that could have been reached with an unrelated third party;
- the purpose of, and the potential benefits to us of, the transaction; and
- any other information regarding the related person transaction or the related person in the context of the proposed transaction that would be material to investors in light of the circumstances of the particular transaction.

Our audit committee may approve or ratify the transaction only if it determines that, under all of the circumstances, the transaction is in our best interests. Our audit committee may impose any conditions on the related person transaction that it deems appropriate.

In addition to the transactions that are excluded by the instructions to the SEC's related person transaction disclosure rule, our board of directors has determined that the following transactions do not

create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

- interests arising solely from the related person's position as an executive officer of another entity, whether or not the person is also a director of the entity, that is a participant in the transaction where the related person and all other related persons own in the aggregate less than a 10% equity interest in such entity, the related person and his or her immediate family members are not involved in the negotiation of the terms of the transaction and do not receive any special benefits as a result of the transaction and the amount involved in the transaction is less than the greater of $200,000 or 5% of the annual gross revenues of the company receiving payment under the transaction; and

- a transaction that is specifically contemplated by provisions of our certificate of incorporation or by-laws.

The policy provides that transactions involving compensation of executive officers shall be reviewed and approved by our compensation committee in the manner specified in the compensation committee's charter.

We did not have a written policy regarding the review and approval of related person transactions prior to this offering. Nevertheless, with respect to such transactions, it has been the practice of our board of directors to consider the nature of and business reasons for such transactions, how the terms of such transactions compared to those which might be obtained from unaffiliated third parties and whether such transactions were otherwise fair to and in the best interests of, or not contrary to, our best interests. In addition, all related person transactions required prior approval, or later ratification, by our board of directors.

PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of June 30, 2017 by:

- each of our directors;
- each of our named executive officers;
- all of our directors and executive officers as a group; and
- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock.

The column entitled "Percentage of shares beneficially owned—Before Offering" is based on a total of 17,283,399 shares of our common stock outstanding as of June 30, 2017, assuming the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 16,101,970 shares of our common stock upon the closing of this offering. The column entitled "Percentage of Shares Beneficially Owned—After Offering" is based on 6,000,000 shares of our common stock to be outstanding after this offering, including the shares of our common stock that we are selling in this offering, but not including any additional shares issuable upon exercise of outstanding options or warrants. The table also assumes the automatic conversion of outstanding warrants to purchase shares of our preferred stock into warrants to purchase shares of our common stock.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock. Shares of our common stock subject to options and warrants that are currently exercisable or exercisable within 60 days after June 30, 2017 are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all of the shares of our common stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise set forth below, the address of each beneficial owner is c/o Kala Pharmaceuticals, Inc., 100 Beaver Street, Suite 201, Waltham, MA 02453.

Certain of our existing stockholders and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately $40 million of shares of common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, any of these entities may determine to purchase fewer shares than they indicate an interest in purchasing or not to purchase in this offering. In addition, the underwriters could determine to sell fewer shares to any of these entities than these entities indicate an interest in purchasing or not to sell any shares to these entities. It is also possible that the underwriters could determine to sell more shares to any of these entities. Accordingly, the following table does not reflect any potential purchases by these potential purchasers. If any shares are purchased by these entities, the

number and percentage of shares of our common stock beneficially owned by them after this offering will differ from those set forth in the following table.

The following table excludes shares that will be beneficially owned upon the grant of options to purchase common stock that are contingent upon the effectiveness of the registration statement of which this prospectus forms a part.

Name and Address of Beneficial Owner	Number of shares beneficially owned	Percentage of shares beneficially owned	
		Before Offering	After Offering
5% Stockholders:			
Longitude Venture Partners(1)	2,055,946	11.90%	8.83%
OrbiMed Private Investments(2)	2,055,946	11.90%	8.83%
Entities affiliated with Polaris Ventures(3)	1,890,913	10.92%	8.11%
Entities affiliated with Wellington Management Company(4)	1,735,460	10.04%	7.45%
Third Rock Ventures(5)	1,654,425	9.55%	7.10%
Entities affiliated with RA Capital(6)	1,579,903	9.14%	6.79%
Entities affiliated with Lux Capital(7)	1,221,089	7.06%	5.24%
Vivo Capital Fund(8)	1,148,911	6.65%	4.93%
CVF, LLC(9)	1,050,509	6.07%	4.51%
Directors and Named Executive Officers:			
Mark Iwicki(10)	727,779	4.04%	3.03%
Kim Brazzell(11)	148,861	*	*
Hongming Chen, Sc.D.(12)	188,405	1.08%	*
Gregory Grunberg, M.D.(13)	2,055,946	11.90%	8.83%
Paulina Hill, Ph.D.(14)	—	*	*
Robert Langer, Sc.D.(15)	356,726	2.06%	1.53%
Robert Paull(16)	1,221,089	7.06%	5.24%
Howard Rosen(17)	41,529	*	*
Rajeev Shah(18)	1,579,903	9.14%	6.79%
Robert Tepper, M.D.(19)	1,654,425	9.55%	7.10%
Chen Yu, M.D.(20)	1,148,911	6.65%	4.93%
All current executive officers and directors as a group (14 persons)(21)	9,300,725	49.97%	37.79%

* Less than one percent

(1) Consists of 2,055,946 shares of common stock issuable upon conversion of preferred stock held by Longitude Venture Partners II, L.P. ("LVP2"). Longitude Capital Partners II, LLC ("LCP2") is the general partner of LVP2 and may be deemed to share voting and investment power over the shares held by LVP2. Patrick G. Enright and Juliet Tammenoms Bakker are managing members of LCP2 and may be deemed to share voting and investment power over the shares held by LVP2. Gregory Grunberg, a member of our board of directors, is a member of LCP2 and may be deemed to share voting and investment power over the shares held by LVP2. Each of these individuals disclaims beneficial ownership of such shares except to the extent of his or her pecuniary interest therein. The address for LCP2 is 800 El Camino Real, Suite 220, Menlo Park, CA 94025.

(2) Consists of 2,055,946 shares of common stock issuable upon conversion of preferred stock held by OrbiMed Private Investments VI, LP ("OPI VI"). OrbiMed Advisors LLC ("OrbiMed Advisors") is the managing member of OrbiMed Capital GP VI LLC ("GP VI"), which is the general partner of OPI VI. Samuel D. Isaly is the managing member of and owner of a controlling interest in OrbiMed Advisors. By virtue of such relationships, GP VI, OrbiMed Advisors and Mr. Isaly may

be deemed to have voting and investment power with respect to the shares held by OPI VI. Each of GP VI, OrbiMed Advisors and Mr. Isaly disclaims beneficial ownership of the shares held by OPI VI, except to the extent of its or his pecuniary interest therein, if any. The address of OPI VI is 601 Lexington Avenue, 54th Floor, New York, New York 10022.

(3) Consists of (a) 1,792,448 shares of common stock issuable upon conversion of preferred stock and 32,164 shares of common stock issuable upon the exercise of warrants held by Polaris Venture Partners V, L.P., (b) 34,934 shares of common stock issuable upon conversion of preferred stock and 626 shares of common stock issuable upon the exercise of warrants held by Polaris Venture Partners Entrepreneurs' Fund V, L.P., (c) 12,277 shares of common stock issuable upon conversion of preferred stock and 220 shares of common stock issuable upon the exercise of warrants held by Polaris Venture Partners Founders' Fund V, L.P. and (d) 17,923 shares of common stock issuable upon conversion of preferred stock and 321 shares of common stock issuable upon the exercise of warrants held by Polaris Venture Partners Special Founders' Fund V, L.P. (together with Polaris Venture Partners V, L.P., Polaris Venture Partners Entrepreneurs' Fund V, L.P. and Polaris Venture Partners Founders' Fund V, L.P., the "Polaris Funds"). Polaris Venture Management Co. V, L.L.C. ("PVM V") is the general partner of each of the Polaris Funds and may be deemed to have sole power to vote and dispose of the shares owned by the Polaris Funds. Each of Jonathan Flint and Terrance McGuire (collectively, the "Managing Members") are the managing members of PVM V and may be each deemed to have shared power to vote and dispose of the shares held by the Polaris Funds. Each of PVM V and the Managing Members disclaim beneficial ownership of all of the shares owned by the Polaris Funds, except to the extent of their respective and proportionate pecuniary interests therein. The address of the Polaris Funds is One Marina Park Drive, 10th Floor, Boston, Massachusetts 02210.

(4) Consists of 1,735,460 shares of common stock issuable upon conversion of preferred stock held by Hadley Harbor Master Investors (Cayman) L.P. Wellington Management Company LLP is the investment adviser to this entity. Wellington Management Company LLP is an investment adviser registered under the Investment Advisers Act of 1940, as amended, and is an indirect subsidiary of Wellington Management Group LLP. Wellington Management Company LLP and Wellington Management Group LLP may each be deemed to share beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of the shares indicated in the table, all of which are held of record by Hadley Harbor Master Investors (Cayman) LLP or a nominee (Italianflare & Co.) on its behalf. The business address of the entity named in the table is c/o Wellington Management Company LLP, 280 Congress Street, Boston, Massachusetts, 02110. The business address of Wellington Management Company LLP and Wellington Management Group LLP is 280 Congress Street, Boston, MA 02110.

(5) Consists of 1,621,092 shares of common stock issuable upon conversion of preferred stock and 33,333 shares of common stock issuable upon the exercise of warrants held by Third Rock Ventures, L.P. ("TRV LP"). Each of Third Rock Ventures GP, L.P., ("TRV GP LP"), the general partner of TRV LP, and Third Rock Ventures GP, LLC ("TRV GP LLC"), the general partner of TRV GP LP, and Mark Levin, Kevin Starr and Robert Tepper, the managers of TRV GP LLC, may be deemed to share voting and investment power with respect to all shares held by TRV LP. Dr. Tepper, a member of our board of directors, disclaims beneficial ownership of all shares held by TRV LP, except to the extent of his pecuniary interest therein. The address for TRV LP is 29 Newbury Street, Boston, MA 02116.

(6) Consists of (a) 1,300,057 shares of common stock issuable upon conversion of preferred stock held by RA Capital Healthcare Fund, L.P. ("RA Capital") and (b) 279,846 shares of common stock issuable upon conversion of preferred stock held by Blackwell Partners LLC—Series A ("Blackwell"). RA Capital Management, LLC ("RA Capital Management") is the general partner of RA Capital and the investment advisor to Blackwell. Investment decisions with respect to the

shares held by RA Capital and Blackwell were made by a portfolio management team at RA Capital Management of which Rajeev Shah, a member of our board of directors, is a member. Mr. Shah disclaims beneficial ownership of all shares held by RA Capital and Blackwell, except to the extent of his pecuniary interest therein. The address for each of RA Capital, Blackwell and RA Capital Management is 20 Park Plaza, Suite 1200, Boston, MA 02116.

(7) Consists of (a) 1,156,441 shares of common stock issuable upon conversion of preferred stock and 15,502 shares of common stock issuable upon the exercise of warrants held by Lux Ventures II, LP ("Lux II") and (b) 48,496 shares of common stock issuable upon conversion of preferred stock and 650 shares of common stock issuable upon the exercise of warrants held by Lux Ventures II Sidecar, L.P. ("Lux II Sidecar"). Lux Venture Partners II, L.P. ("Lux Venture Partners") is the general partner of Lux II and Lux II Sidecar. Lux Venture Associates II, LLC ("Lux Associates") is the general partner of Lux Venture Partners and Lux Capital Management, LLC ("Lux Management") is the sole member of Lux Venture Partners. Lux Management, as sole member, may be deemed to share voting and investment powers for the shares held by Lux II and Lux II Sidecar. Joshua Wolfe and Peter Hebert are the individual managers of Lux Management (the "Individual Managers"). Robert Paull, a member of our board of directors, is a venture partner at Lux Capital Management. Lux Venture Partners, Lux Associates and Lux Management disclaim beneficial ownership of such shares, except to the extent of their pecuniary interest therein. Each of the Individual Managers and Mr. Paull disclaim beneficial ownership over the shares reported herein, and in all events disclaim beneficial ownership except to the extent of his pecuniary interest therein. The mailing address of the beneficial owner is 295 Madison Avenue, 24th Floor, New York, NY 10017.

(8) Consists of (a) 1,009,510 shares of common stock issuable upon conversion of preferred stock held by Vivo Capital Fund VIII, L.P. ("Vivo Capital Fund") and (b) 139,401 shares of common stock issuable upon conversion of preferred stock held by Vivo Capital Surplus Fund VIII, L.P. ("Vivo Capital Surplus"). Vivo Capital VIII, LLC, the sole general partner of both Vivo Capital Fund and Vivo Capital Surplus, has shared voting power and shared investment power over such securities, may be deemed to beneficially own such shares, and disclaims beneficial ownership of the shares except to the extent of its pecuniary interests therein. Chen Yu, M.D. a managing member of Vivo Capital VIII, LLC and a member of our board of directors, disclaims beneficial ownership of such shares, except to the extent of his pecuniary interest therein. The mailing address of Vivio Capital Fund is 505 Hamilton Avenue, Suite 207, Palo Alto, CA 94301. The mailing address of Vivio Capital Surplus is 505 Hamilton Avenue, Suite 207, Palo Alto, CA 94301.

(9) Consists of 1,017,176 shares of common stock issuable upon conversion of preferred stock and 33,333 shares of common stock issuable upon the exercise of warrants held by CVF, LLC. Richard H. Robb, manager of CVF, LLC, exercises voting and investment power with respect to shares held by CVF, LLC. Mr. Robb disclaims beneficial ownership of all shares held by CVF, LLC except to the extent of his pecuniary interest therein. The mailing address of the beneficial owner is 222 N. LaSalle Street, Suite 2000, Chicago, IL 60601.

(10) Consists of shares of common stock underlying options held by Mr. Iwicki that are exercisable as of June 30, 2017 or will become exercisable within 60 days after such date.

(11) Consists of shares of common stock underlying options held by Dr. Brazzell that are exercisable as of June 30, 2017 or will become exercisable within 60 days after such date.

(12) Consists of (a) 29,569 shares of common stock owned by Dr. Chen and (b) 158,836 shares of common stock underlying options held by Dr. Chen that are exercisable as of June 30, 2017 or will become exercisable within 60 days after such date.

(13) Consists of the shares described in note 1 above.

(14) Dr. Hill is affiliated with the Polaris Funds. Dr. Hill does not have voting or dispositive power with respect to the shares owned by the Polaris Funds and referenced in footnote (3) above.

(15) Consists of (a) 326,420 shares of common stock owned by Dr. Langer and (b) 30,306 shares of common stock underlying options held by Dr. Langer that are exercisable as of June 30, 2017 or will become exercisable within 60 days after such date.

(16) Consists of the shares described in note 7 above.

(17) Consists of (a) 3,240 shares of common stock owned by Mr. Rosen and (b) 38,289 shares of common stock underlying options held by Mr. Rosen that are exercisable as of June 30, 2017 or will become exercisable within 60 days after such date.

(18) Consists of the shares described in note 6 above.

(19) Consists of the shares described in note 5 above.

(20) Consists of the shares described in note 8 above.

(21) Includes (a) 1,281,222 shares of common stock underlying options that are exercisable as of June 30, 2017 or will become exercisable within 60 days after such date and (b) 49,483 shares of common stock issuable upon the exercise of warrants that are exercisable as of June 30, 2017 or will become exercisable within 60 days after such date.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and provisions of our certificate of incorporation and bylaws are summaries and are qualified by reference to the certificate of incorporation and the bylaws that will be in effect upon the closing of this offering. We will file copies of these documents with the SEC as exhibits to our registration statement of which this prospectus forms a part. The description of the capital stock reflects changes to our capital structure that will occur upon the closing of this offering.

Upon the closing of this offering, our authorized capital stock will consist of 120,000,000 shares of our common stock, par value $0.001 per share, and 5,000,000 shares of our preferred stock, par value $0.001 per share, all of which preferred stock will be undesignated.

As of June 30, 2017, we had issued and outstanding:

- 1,181,429 shares of our common stock held by 18 stockholders of record;
- 11,243,209 shares of our Series Seed preferred stock held by 11 stockholders of record that are convertible into 2,158,708 shares of our common stock;
- 9,583,432 shares of our Series A preferred stock held by 10 stockholders of record that are convertible into 1,840,029 shares of our common stock;
- 15,624,999 shares of our Series B preferred stock held by 21 stockholders of record that are convertible into 3,000,017 shares of our common stock; and
- 4,629,629 shares of our Series B-1 preferred stock held by 1 stockholder of record that are convertible into 888,894 shares of our common stock; and
- 42,782,688 shares of our Series C preferred stock held by 25 stockholders of record that are convertible into 8,214,322 shares of our common stock.

Upon the closing of this offering, all of the outstanding shares of our preferred stock will automatically convert into an aggregate of 16,101,970 shares of our common stock.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. Each election of directors by our stockholders will be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of our liquidation or dissolution, the holders of our common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any of our outstanding preferred stock. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Preferred Stock

Under the terms of our certificate of incorporation that will become effective upon the closing of this offering, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights,

preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

Warrants

As of June 30, 2017, we had outstanding:

- warrants to purchase up to an aggregate of 80,000 shares of our Series Seed preferred stock, at an exercise price of $1.00 per share, which we refer to as the Series Seed warrants;
- warrants to purchase up to an aggregate of 972,222 shares of our Series B preferred stock, at an exercise price of $1.44 per share, which we refer to as the Series B warrants; and
- warrants to purchase up to an aggregate of 251,951 shares of our Series C preferred stock, at an exercise price of $1.59 per share, which we refer to as the Series C warrants, which warrants were not exercisable into shares as of June 30, 2017, as we had not borrowed the remaining $10.0 million under our 2014 Debt Facility.

Upon the closing of this offering:

- the Series Seed warrants will become exercisable for an aggregate of 15,360 shares of our common stock, at an exercise price of $5.21 per share;
- the Series B warrants will become exercisable for an aggregate of 186,660 shares of our common stock, at an exercise price of $7.50 per share;
- the Series C warrants will become exercisable for an aggregate of 48,374 shares of our common stock, at an exercise price of $8.27 per share, upon our draw down of the remaining $10.0 million under 2014 Debt Facility.

These warrants provide for adjustments in the event of specified mergers, reorganizations, reclassifications, stock dividends, stock splits or other changes in our corporate structure.

Options

As of June 30, 2017, options to purchase an aggregate of 3,292,177 shares of our common stock, at a weighted average exercise price of $3.27 per share, were outstanding.

Delaware Anti-Takeover Law and Certain Charter and Bylaw Provisions

Delaware Law

We are subject to Section 203 of the Delaware General Corporation Law. Subject to certain exceptions, Section 203 prevents a publicly held Delaware corporation from engaging in a "business combination" with any "interested stockholder" for three years following the date that the person became an interested stockholder, unless either the interested stockholder attained such status with the approval of our board of directors, the business combination is approved by our board of directors and stockholders in a prescribed manner or the interested stockholder acquired at least 85% of our outstanding voting stock in the transaction in which it became an interested stockholder. A "business

combination" includes, among other things, a merger or consolidation involving us and the "interested stockholder" and the sale of more than 10% of our assets. In general, an "interested stockholder" is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person. The restrictions contained in Section 203 are not applicable to any of our existing stockholders that will own 15% or more of our outstanding voting stock upon the closing of this offering.

Staggered Board; Removal of Directors

Our certificate of incorporation and our bylaws divide our board of directors into three classes with staggered three-year terms. In addition, our certificate of incorporation and our bylaws provide that directors may be removed only for cause and only by the affirmative vote of the holders of 75% of our shares of capital stock present in person or by proxy and entitled to vote. Under our certificate of incorporation and bylaws, any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office. Furthermore, our certificate of incorporation provides that the authorized number of directors may be changed only by the resolution of our board of directors. The classification of our board of directors and the limitations on the ability of our stockholders to remove directors, change the authorized number of directors and fill vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company.

Stockholder Action; Special Meeting of Stockholders; Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our certificate of incorporation and our bylaws provide that any action required or permitted to be taken by our stockholders at an annual meeting or special meeting of stockholders may only be taken if it is properly brought before such meeting and may not be taken by written action in lieu of a meeting. Our certificate of incorporation and our bylaws also provide that, except as otherwise required by law, special meetings of the stockholders can only be called by the chairman of our board of directors, our chief executive officer or our board of directors. In addition, our bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to our board of directors. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors, or by a stockholder of record on the record date for the meeting who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities. These provisions also could discourage a third party from making a tender offer for our common stock because even if the third party acquired a majority of our outstanding voting stock, it would be able to take action as a stockholder, such as electing new directors or approving a merger, only at a duly called stockholders meeting and not by written consent.

Super-Majority Voting

The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws unless a corporation's certificate of incorporation or bylaws, as the case may be, requires a greater percentage. Our bylaws may be amended or repealed by a majority vote of our board of directors or the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in

any election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our certificate of incorporation described above.

Exclusive Forum Selection

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 shall be the sole and exclusive forum for (1) any derivative action or proceeding brought on behalf of our company, (2) 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, (3) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware 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 (4) any action asserting a claim arising pursuant to any provision of our certificate of incorporation or bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. Although our certificate of incorporation contains the choice of forum provision described above, it is possible that a court could rule that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

Registration Rights

We have entered into a third amended and restated registration rights agreement dated April 6, 2016, or the registration rights agreement, with holders of our preferred stock. Beginning 180 days following the closing of this offering, holders of a total of 16,086,480 shares of our common stock, holders of an additional 164,687 shares of our common stock issuable upon the exercise of warrants and Mr. Iwicki, who upon the closing of this offering will hold 1,339,783 shares of our common stock issuable upon the exercise of stock options, will have the right to require us to register these shares under the Securities Act under specified circumstances. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. If not otherwise exercised, the rights under the registration rights agreement described below will expire seven years after the closing of this offering.

Demand and Form S-3 Registration Rights

Beginning 180 days after this offering, subject to specified limitations set forth in the registration rights agreement, at any time, the holders of at least 50% of the then outstanding shares having rights under the registration rights agreement (excluding shares held by our chief executive officer), or the registrable securities, may demand that we register registrable securities then outstanding under the Securities Act for purposes of a public offering having an aggregate offering price to the public of not less than $10.0 million. We are not obligated to file a registration statement pursuant to this provision on more than two occasions.

In addition, subject to specified limitations set forth in the registration rights agreement, at any time after we become eligible to file a registration statement on Form S-3, holders of the registrable securities then outstanding may request that we register their registrable securities on Form S-3 for purposes of a public offering for which the reasonably anticipated aggregate offering price to the public would exceed $1.0 million. We are not obligated to file a registration statement pursuant to this provision on more than two occasions in any 12-month period.

Incidental Registration Rights

If, at any time after the closing of this offering, we propose to register for our own account any of our securities under the Securities Act, the holders of registrable securities will be entitled to notice of the registration and, subject to specified exceptions, have the right to require us to use our reasonable

best efforts to register all or a portion of the registrable securities then held by them in that registration.

In the event that any registration in which the holders of registrable securities participate pursuant to our registration rights agreement is an underwritten public offering, we have agreed to enter into an underwriting agreement in usual and customary form and use our reasonable best efforts to facilitate such offering.

Expenses

Pursuant to the registration rights agreement, we are required to pay all registration expenses, including all registration and filing fees, exchange listing fees, printing expenses, fees and expenses of one counsel selected by the selling stockholders to represent the selling stockholders, state Blue Sky fees and expenses, and the expense of any special audits incident to or required by any such registration, but excluding underwriting discounts, selling commissions and the fees and expenses of the selling stockholders' own counsel (other than the counsel selected to represent all selling stockholders). We are not required to pay registration expenses if the registration request under the registration rights agreement is withdrawn at the request of holders of at least 50% of the registrable securities, unless the withdrawal is related to information concerning the business or financial condition of us learned by the selling stockholders after the initiation of such registration request.

The registration rights agreement contains customary cross-indemnification provisions, pursuant to which we are obligated to indemnify the selling stockholders in the event of material misstatements or omissions in the registration statement attributable to us or any violation or alleged violation whether by action or inaction by us under the Securities Act, the Exchange Act, any state securities or Blue Sky law or any rule or regulation promulgated under the Securities Act, the Exchange Act or any state securities or Blue Sky law in connection with such registration statement or the qualification or compliance of the offering, and they are obligated to indemnify us for material misstatements or omissions in the registration statement attributable to them.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be American Stock Transfer & Trust Company, LLC.

NASDAQ Global Select Market

Our common stock has been approved for listing on The NASDAQ Global Select Market under the symbol "KALA."

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options, or the anticipation of these sales, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of equity securities.

Upon the closing of this offering, we will have outstanding 23,283,399 shares of our common stock, after giving effect to the issuance of 6,000,000 shares of our common stock in this offering, assuming no exercise by the underwriters of their option to purchase 900,000 additional shares of our common stock.

Of the shares to be outstanding immediately after the closing of this offering, we expect that the 6,000,000 shares to be sold in this offering will be freely tradable without restriction under the Securities Act unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining 17,283,399 shares of our common stock will be "restricted securities" under Rule 144, and we expect that substantially all of these restricted securities will be subject to the 180-day lock-up period under the lock-up agreements as described below. These restricted securities may be sold in the public market upon release or waiver of any applicable lock-up agreements and only if registered or pursuant to an exemption from registration, such as Rule 144 or 701 under the Securities Act.

Rule 144

In general, under Rule 144, beginning 90 days after the date of this prospectus, any person who is not our affiliate and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell those shares without restriction, subject to the availability of current public information about us. In addition, under Rule 144, any person who is not our affiliate and has not been our affiliate at any time during the preceding three months and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available.

Beginning 90 days after the date of this prospectus, a person who is our affiliate or who was our affiliate at any time during the preceding three months and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 23,283 shares immediately after this offering; and
- the average weekly trading volume in our common stock on The NASDAQ Global Select Market during the four calendar weeks preceding the date of filing of a Notice of Proposed Sale of Securities Pursuant to Rule 144 with respect to the sale.

Sales under Rule 144 by our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

Upon waiver or expiration of the 180-day lock-up period described below, approximately 17,283,399 shares of our common stock will be eligible for sale under Rule 144. We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144.

Rule 701

In general, under Rule 701 of the Securities Act, any of our employees, consultants or advisors, other than our affiliates, who purchased shares from us in connection with a qualified compensatory stock plan or other written agreement is eligible to resell these shares 90 days after the date of this prospectus in reliance on Rule 144, but without compliance with the various restrictions, including the availability of public information about us, holding period and volume limitations, contained in Rule 144. Subject to the 180-day lock-up period described below, approximately 178,224 shares of our common stock, based on shares outstanding as of June 30, 2017, will be eligible for sale in accordance with Rule 701.

Lock-up Agreements

We, our directors and executive officers and substantially all of our stockholders have agreed that, without the prior written consent of J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated on behalf of the underwriters, we and they will not, subject to limited exceptions, during the period ending 180 days after the date of this prospectus:

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock, whether any such transaction is to be settled by delivery of shares of our common stock or such other securities, in cash or otherwise;

- enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our common stock or any securities convertible into or exchangeable or exercisable for share of our common stock, whether any such transaction is to be settled by delivery of shares of our common stock or such other securities, in cash or otherwise; or

- in our case, file a registration statement relating to any shares of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock, or in the case of our directors, executive officers and stockholders, make any demand for, or exercise any right with respect to, the registration of any shares of our common stock or any securities convertible into or exchangeable or exercisable for shares of our common stock.

These agreements are subject to certain exceptions, as described in the section of this prospectus entitled "Underwriting."

Registration Rights

Beginning 180 days after the closing of this offering, the holders of an aggregate of 16,086,480 shares of our common stock, along with holders of an additional 1,504,470 shares of our common stock issuable upon the exercise of warrants and options, will have rights, subject to certain 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. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. See "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights.

Stock Options and Form S-8 Registration Statement

As of June 30, 2017, we had outstanding options to purchase an aggregate of 3,292,177 shares of our common stock, of which options to purchase 1,507,751 shares were vested. Following this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and reserved for future options and other awards under our 2009 Plan and our 2017 Plan. See "Executive Compensation—Stock Option and Other Compensation Plans" for additional information regarding these plans. Accordingly, shares of our common stock registered under the registration statements will be available for sale in the open market, subject to Rule 144 volume limitations applicable to affiliates, and subject to any vesting restrictions and lock-up agreements applicable to these shares.

MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK

The following is a discussion of material U.S. federal income and estate tax considerations relating to ownership and disposition of shares of our common stock acquired in this offering by a non-U.S. holder. For purposes of this discussion, the term "non-U.S. holder" means a beneficial owner (other than a partnership or other pass-through entity) of our common stock that is not, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity treated as a corporation, created or organized in or under the laws of the United States or of any political subdivision of the United States;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

This discussion does not address the tax treatment of partnerships or other entities that are pass-through entities for U.S. federal income tax purposes or persons who hold their common stock through partnerships or such other pass-through entities. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its own tax advisor regarding the tax consequences of the ownership and disposition of our common stock through a partnership or other pass-through entity, as applicable.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change could alter the tax consequences to non-U.S. holders described in this prospectus. There can be no assurance that the Internal Revenue Service, or the IRS, will not challenge one or more of the tax consequences described in this prospectus.

We assume in this discussion that each non-U.S. holder holds shares of our common stock as a capital asset (generally, property held for investment) for U.S. federal income tax purposes. This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address any aspects of U.S. state, local or non-U.S. taxes, the alternative minimum tax, or the Medicare tax on net investment income. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- financial institutions;
- brokers or dealers in securities;
- tax-exempt organizations;
- pension plans;
- owners that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment or who have elected to mark securities to market;

- insurance companies;
- controlled foreign corporations;
- passive foreign investment companies;
- non-U.S. governments; and
- certain U.S. expatriates.

THIS DISCUSSION IS FOR INFORMATION ONLY AND IS NOT, AND IS NOT INTENDED TO BE, LEGAL OR TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS REGARDING THE U.S. FEDERAL, STATE, LOCAL, ESTATE AND NON-U.S. INCOME AND OTHER TAX CONSIDERATIONS OF ACQUIRING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGES IN APPLICABLE LAWS.

Distributions

As discussed under the heading "Dividend Policy" above, we do not expect to make cash dividends to holders of our common stock in the foreseeable future. If we make distributions in respect of our common stock, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles, subject to the tax treatment described in this section. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to the non-U.S. holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading "Gain on Sale, Exchange or Other Taxable Disposition of Our Common Stock." Any such distributions will also be subject to the discussions below under the headings "Information Reporting and Backup Withholding" and "FATCA" below.

Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States, and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements (generally including provision of a properly executed IRS Form W-8ECI (or applicable successor form) certifying that the dividends are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States). However, such U.S. effectively connected income, net of specified deductions and credits, is taxed in the hands of the non-U.S. holder at the same graduated U.S. federal income tax rates as would apply if such holder were a U.S. person (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is classified as a corporation for U.S. federal income tax purposes may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their own tax advisors

regarding their entitlement to benefits under a relevant income tax treaty and the specific methods available to them to satisfy these requirements.

A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS.

Gain on Sale, Exchange or Other Taxable Disposition of Our Common Stock

Subject to the discussion below under the headings "Information Reporting and Backup Withholding" and "FATCA," a non-U.S. holder generally will not be subject to U.S. federal income tax or withholding tax on any gain realized upon such non-U.S. holder's sale, exchange or other disposition of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States, and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States; in these cases, the non-U.S. holder generally will be taxed on a net income basis at the graduated U.S. federal income tax rates applicable to U.S. persons, and, if the non-U.S. holder is a foreign corporation, an additional branch profits tax at a rate of 30% (or a lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) may also apply;

- the non-U.S. holder is a non-resident alien present in the United States for 183 days or more in the taxable year of the disposition and certain other requirements are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the disposition, which may be offset by certain U.S.-source capital losses of the non-U.S. holder recognized in the taxable year of the disposition, if any; or

- we are or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation" unless our common stock is regularly traded on an established securities market and the non-U.S. holder held no more than 5% of our outstanding common stock, directly or indirectly, during the shorter of the five-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. Generally, a corporation is a "U.S. real property holding corporation" if the fair market value of its "United States real property interests" (as defined in the Code and applicable regulations) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we believe that we are not currently, and we do not anticipate becoming, a "U.S. real property holding corporation" for U.S. federal income tax purposes. If we are determined to be a U.S. real property holding corporation and our common stock is not regularly traded on an established securities market, then (i) a purchaser of shares of our common stock from a non-U.S. holder generally will withhold 15% of the proceeds payable to such non-U.S. holder and (ii) the non-U.S. holder's net gain derived from the disposition of shares of our common stock generally will be taxed in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply. The tax treatment described in (ii) of the preceding sentence will also generally apply to the non-U.S. holder's net gain derived from the disposition of shares of our common stock even if our common stock is regularly traded on an established securities market if such holder beneficially owns more than 5% of our outstanding common stock, during the applicable testing period.

U.S. Federal Estate Tax

Shares of our common stock that are owned or treated as owned by an individual who is not a citizen or resident of the United States (as specially defined for U.S. federal estate tax purposes) at the time of death are considered U.S.-situs assets and will be included in the individual's gross estate for U.S. federal estate tax purposes. Such shares, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax or other treaty provides otherwise.

Information Reporting and Backup Withholding

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders generally will have to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Generally, a holder will comply with such procedures if it provides a properly executed IRS Form W-8BEN or W-8BEN-E (or other applicable IRS Form W-8), or otherwise meets documentary evidence requirements for establishing that it is a non-U.S. holder, or otherwise establishes an exemption. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above under the heading "Distributions," will generally be exempt from U.S. backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or non-U.S., unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

FATCA

Provisions of the Code commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, generally impose a 30% withholding tax on dividends on, and gross proceeds from the sale or disposition of, our common stock if paid to a foreign entity unless (i) if the foreign entity is a "foreign financial institution," the foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a "foreign financial institution," the foreign entity identifies certain of its U.S. investors, or (iii) the foreign entity is otherwise exempt under FATCA.

Withholding under FATCA generally (1) applies to payments of dividends on our common stock, and (2) will apply to payments of gross proceeds from a sale or other disposition of our common stock made after December 31, 2018. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this section. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of the tax. Non-U.S. holders

should consult their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

The preceding discussion of material U.S. federal tax considerations is for information only. It is not, and is not intended to be, legal or tax advice. Prospective investors should consult their own tax advisors regarding the particular U.S. federal, state, local, estate and non-U.S. income and other tax consequences of acquiring, holding and disposing of our common stock, including the consequences of any proposed changes in applicable laws.

UNDERWRITING

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated are acting as joint book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Name	Number of Shares
J.P. Morgan Securities LLC	2,400,000
Merrill Lynch, Pierce, Fenner & Smith Incorporated	2,400,000
Wells Fargo Securities, LLC.	840,000
Wedbush Securities Inc.	360,000
Total	6,000,000

The underwriters are committed to purchase all the common shares offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

Certain of our existing stockholders and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately $40.0 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, any of these entities may determine to purchase fewer shares than they indicate an interest in purchasing or not to purchase any shares in this offering. In addition, the underwriters could determine to sell fewer shares to any of these entities than these entities indicate an interest in purchasing or not to sell any shares to these entities. It is also possible that the underwriters could determine to sell more shares to any of these entities.

The underwriters propose to offer the common shares directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $0.63 per share. Any such dealers may resell shares to certain other brokers or dealers at a discount of up to $0.21 per share from the initial public offering price. After the initial public offering of the shares, the offering price and other selling terms may be changed by the underwriters. Sales of shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to 900,000 additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased pursuant to the underwriters' option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The following table shows the per

share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Without option exercise	With full option exercise
Per Share	$ 1.05	$ 1.05
Total	$ 6,300,000	$ 7,245,000

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately $3.0 million. We have agreed to reimburse the underwriters up to $55,000 for expenses related to any filing with, and any clearance of this offering by, the Financial Industry Regulatory Authority, Inc.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We and our directors, executive officers and substantially all of our stockholders have agreed not to (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (including, without limitation, common stock or such other securities which may be deemed to be beneficially owned by such directors, executive officers, managers and members in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant) or (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common stock or such other securities, whether any such transaction described in clause (1) or (2) is to be settled by delivery of common stock or such other securities, in cash or otherwise, or (3) in our case, file a registration statement relating to any shares of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock, or in the case of our directors, executive officers and stockholders, make any demand for or exercise any right with respect to, the registration of any shares of our common stock or any security convertible into or exercisable or exchangeable for our common stock, in each case without the prior written consent of J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated for a period of 180 days after the date of this prospectus.

The restrictions described in the immediately preceding paragraph do not apply to certain transactions, including:

- the sale of shares to the underwriters in this offering;
- subject to certain limitations, transfers of such securities by any person other than us (A) as a *bona fide* gift or gifts, (B) to any trust for the direct or indirect benefit of such person or one or more of their immediate family members not involving a disposition for value, (C) by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary or a member of the immediate family of such person, (D) that occur by operation of law, such as pursuant to a qualified domestic order or in connection with a divorce settlement, (E) to partners, members or stockholders of such person, (F) to any corporation, partnership, limited liability company, investment fund or other entity controlled or managed by, or under common control or management with, such person or their in a transaction not involving a disposition for

value, (G) prior to the first public filing of a prospectus for this offering, and (H) in connection with the conversion of our outstanding preferred stock into shares of our common stock in connection with the consummation of this offering (which shares shall be subject to these restrictions on transfer);

- subject to certain limitations, the exercise of, and the issuance of any shares of our common stock upon the exercise of, options granted under out stock-based compensation plans or warrants described herein, provided that each recipient of such security shall execute a lock-up agreement substantially on the terms described herein if such recipient has not already delivered one;
- the issuance by us of any options and other awards granted under our stock-based compensation plans described herein, provided that each recipient of such grant shall execute a lock-up agreement substantially on the terms described herein if such recipient has not already delivered one;
- the filing by us of any registration statement on Form S-8 relating to shares of our common stock granted, or reserved for issuance, under our stock-based compensation plans described herein;
- transfers by any person other than us pursuant to any pre-existing contractual arrangement that provides for the repurchase of such securities by us;
- transfers by any person other than us pursuant to the terms of any stock incentive plan or stock purchase plan of ours solely to satisfy tax withholding obligations;
- transfers by any person other than us in connection with the termination of employment with the company;
- subject to certain limitations, the establishment by any person other than us of a trading plan pursuant to Rule 10b5-1 under the Exchange Act;
- subject to certain limitations, transfers of securities acquired in this offering or acquired on the open market following this offering;
- transfer shares by any person other than us of such securities pursuant to a *bona fide* third-party tender offer, merger, consolidation or other similar transaction made to all holders of our common stock involving a change of control of ownership of the company; and
- the issuance by us of shares of our common stock or other securities issued in connection with a transaction with an unaffiliated third party that includes a *bona fide* commercial relationship (including joint ventures, marketing or distribution arrangements, collaboration agreements or intellectual property license agreements) or any acquisition of assets or acquisition of not less than a majority or controlling portion of the equity of another entity, provided that (x) the aggregate number of shares issued pursuant to this bullet point will not exceed 5% of the total number of outstanding shares of our common stock immediately following the issuance and sale of the shares in this offering and (y) the recipient of any such shares and securities issued pursuant to this bullet point during the 180-day restricted period described above shall enter into a lock-up agreement substantially on the terms described herein.

J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time with or without notice. In addition, in the event that J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated grant an early release to certain beneficial holders of any common stock or other securities subject to the lock up agreements with respect to shares of common stock that, in the aggregate, exceed a specified

percentage of our then outstanding common stock, then certain other lock up parties shall also be granted an early release, on the same terms, from their obligations on a pro rata basis, subject to certain exceptions.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

Our common stock has been approved for listing on The NASDAQ Global Select Market under the symbol "KALA."

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of the common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' option to purchase additional shares referred to above, or may be "naked" shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on The NASDAQ Global Select Market, in the over-the-counter market or otherwise.

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;

- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our common shares, or that the shares will trade in the public market at or above the initial public offering price.

Other Relationships

The underwriters and their respective affiliates are full-service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In particular, we have entered into an engagement letter with Wedbush Securities Inc. pursuant to which Wedbush has agreed to provide us with advisory services from time to time for customary fees of up to 0.28% of the gross proceeds from this offering. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in our debt or equity securities or loans.

Selling Restrictions

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, each, a Relevant Member State, with effect from and including the date on which the European Union Prospectus Directive, or the EU Prospectus Directive, was implemented in that Relevant Member State, or the Relevant Implementation Date, no offer of securities may be made to the public in that Relevant Member State other than:

1. to any legal entity which is a qualified investor as defined under the EU Prospectus Directive;
2. to fewer than 150 natural or legal persons (other than qualified investors as defined in the EU Prospectus Directive), subject to obtaining the prior consent of the representatives; or

3. in any other circumstances falling within Article 3(2) of the EU Prospectus Directive;

provided that no such offer of securities shall require the Company or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive and each person who initially acquires any securities or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and the Company that it is a "qualified investor" within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive.

In the case of any securities being offered to a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the securities acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any securities to the public other than their offer or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer of securities to the public" in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the same may be varied in that Member State by any measure implementing the EU Prospectus Directive in that Member State. The expression "EU Prospectus Directive" means Directive 2003/71/EC (and any amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State) and includes any relevant implementing measure in each Relevant Member State, and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

Notice to Prospective Investors in the United Kingdom

In the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons") or otherwise in circumstances which have not resulted and will not result in an offer to the public of the securities in the United Kingdom.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards for, issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

In relation to its use in the Dubai International Financial Centre, or DIFC, this prospectus is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the shares may not be offered or sold directly or indirectly to the public in the DIFC.

Notice to Prospective Investors in Australia

This prospectus:

- does not constitute a product disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth), or the Corporations Act;
- has not been, and will not be, lodged with the Australian Securities and Investments Commission, or ASIC, as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document under Chapter 6D.2 of the Corporations Act;
- does not constitute or involve a recommendation to acquire, an offer or invitation for issue or sale, an offer or invitation to arrange the issue or sale, or an issue or sale, of interests to a "retail client" (as defined in section 761G of the Corporations Act and applicable regulations) in Australia; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, or Exempt Investors, available under section 708 of the Corporations Act.

The shares may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the shares may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the shares, you represent and warrant to us that you are an Exempt Investor.

As any offer of shares under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the shares you undertake to us that you will not, for a period of 12 months from the date of issue of the shares, offer, transfer, assign or otherwise alienate those securities to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

Notice to Prospective Investors in Hong Kong

The securities have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the securities has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of Non-CIS Securities may not be circulated or distributed, nor may the Non-CIS Securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the Non-CIS Securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the Non-CIS Securities pursuant to an offer made under Section 275 of the SFA except:

(a) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(b) where no consideration is or will be given for the transfer;

(c) where the transfer is by operation of law;

(d) as specified in Section 276(7) of the SFA; or

(e) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Notice to Prospective Investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

LEGAL MATTERS

The validity of the shares of common stock offered hereby is being passed upon for us by Wilmer Cutler Pickering Hale and Dorr LLP, Boston, Massachusetts. Davis Polk & Wardwell LLP, New York, New York is acting as counsel for the underwriters in connection with this offering.

EXPERTS

The financial statements as of December 31, 2015 and 2016, and for the years then ended, included in this prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein. Such financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock we are offering to sell. This prospectus, which constitutes part of the registration statement, does not include all of the information contained in the registration statement and the exhibits, schedules and amendments to the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits and schedules to the registration statement. Statements contained in this prospectus about the contents of any contract, agreement or other document are not necessarily complete, and, in each instance, we refer you to the copy of the contract, agreement or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You may read and copy the registration statement of which this prospectus is a part at the SEC's public reference room, which is located at 100 F Street, N.E., Room 1580, Washington, DC 20549. You can request copies of the registration statement by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's public reference room. In addition, the SEC maintains an Internet website, which is located at *http://www.sec.gov*, that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. You may access the registration statement of which this prospectus is a part at the SEC's Internet website. Upon completion of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act of 1934, as amended and we will file reports, proxy statements and other information with the SEC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Kala Pharmaceuticals, Inc.
Waltham, Massachusetts

We have audited the accompanying balance sheets of Kala Pharmaceuticals, Inc. (the "Company") as of December 31, 2015 and 2016, and the related statements of operations, convertible preferred stock and stockholders' deficit, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such financial statements present fairly, in all material respects, the financial position of Kala Pharmaceuticals, Inc. as of December 31, 2015 and 2016, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

March 30, 2017 (July 10, 2017 as to the effects of the reverse stock split and other matters described in Note 17)

KALA PHARMACEUTICALS, INC.

BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31,		March 31,	Pro Forma March 31,
	2015	2016	2017	2017
			(unaudited)	(unaudited)
Assets				
Current assets:				
Cash	$ 5,759	$ 45,472	$ 36,024	$ 36,024
Prepaid expenses and other current assets	1,842	154	878	878
Total current assets	7,601	45,626	36,902	36,902
Property and equipment, net	738	594	597	597
Restricted cash	109	109	109	109
Total assets	$ 8,448	46,329	37,608	37,608
Liabilities, Convertible Preferred Stock and Stockholders' (Deficit) Equity				
Current liabilities:				
Current portion of long-term debt	$ 2,000	$ 556	$ 1,389	1,389
Accounts payable	1,404	997	2,317	2,317
Accrued expenses	2,103	3,993	3,107	3,107
Total current liabilities	5,507	5,546	6,813	6,813
Long-term liabilities:				
Long-term debt—less current portion	7,795	9,098	8,293	8,293
Warrant liability	936	1,039	1,075	—
Other long-term liabilities	3	17	35	35
Total long-term liabilities	8,734	10,154	9,403	8,328
Total liabilities	14,241	15,700	16,216	15,141
Commitments (Note 14)				
Convertible preferred stock, 84,266,982 shares authorized as of December 31, 2015 and 170,336,260 shares authorized as of December 31, 2016 and March 31, 2017 (unaudited)				
Series Seed convertible preferred stock, $0.001 par value—11,323,209 shares designated as of December 2015 and 2016 and March 31, 2017 (unaudited); 11,243,209 shares issued and outstanding as of December 31, 2015 and 2016 and March 31, 2017 (unaudited), liquidation value of $11,243 at December 31, 2015 and 2016 and March 31, 2017 (unaudited), no shares issued or outstanding, pro forma as of March 31, 2017 (unaudited))	11,065	11,065	11,065	—
Series A convertible preferred stock, $0.001 par value—9,583,432 shares designated as of December 31, 2015 and 2016 and March 31, 2017 (unaudited); 9,583,432 shares issued and outstanding as of December 31, 2015 and 2016 and March 31, 2017 (unaudited), liquidation value of $11,500 as of December 31, 2015 and 2016 and March 31, 2017 (unaudited), no shares issued or outstanding, pro forma as of March 31, 2017 (unaudited)	10,736	10,736	10,736	—
Series B convertible preferred stock, $0.001 par value—16,597,221 shares designated as of December 31, 2015 and 2016 and March 31, 2017 (unaudited); 15,624,999 shares issued and outstanding as of December 31, 2015 and 2016 and March 31, 2017 (unaudited); liquidation value of $22,500 as of December 31, 2015 and 2016 and March 31, 2017 (unaudited); no shares issued or outstanding, pro forma as of March 31, 2017 (unaudited)	22,185	22,185	22,185	—
Series B-1 convertible preferred stock, $0.001 par value—4,629,629 shares designated as of December 31, 2015 and 2016 and March 31, 2017 (unaudited); 4,629,629 shares issued and outstanding as of December 31, 2015 and 2016 and March 31, 2017 (unaudited), liquidation value of $7,000 as of December 31, 2015 and 2016 and March 31, 2017 (unaudited); no shares issued or outstanding, pro forma as of March 31, 2017 (unaudited)	6,885	6,885	6,885	—
Series C convertible preferred stock, $0.001 par value—0 shares designated as of December 31, 2015 and 43,034,639 shares designated as of December 31, 2016 and March 31, 2017 (unaudited) respectively; 0 shares issued and outstanding as of December 31, 2015 and 42,782,688 shares issued and outstanding as of December 31, 2016 and March 31, 2017 (unaudited), respectively, liquidation value of $0 as of December 31, 2015 and $67,922 as of December 31, 2016 and March 31, 2017 (unaudited), respectively, no shares issued or outstanding, pro forma as of March 31, 2017 (unaudited)	—	67,520	67,520	—
Stockholders' deficit:				
Common stock, $0.001 par value—57,000,000 shares authorized as of December 31, 2015 and 110,251,951 shares authorized as of December 31, 2016 and March 31, 2017 (unaudited); 1,181,429 shares issued and outstanding as of December 31, 2015, December 31, 2016 and March 31, 2017 (unaudited), 120,000,000 shares authorized, 17,283,399 shares issued and outstanding, pro forma as of March 31, 2017 (unaudited)	1	1	1	17
Additional paid-in capital	2,305	4,374	4,919	124,369
Accumulated deficit	(58,970)	(92,137)	(101,919)	(101,919)
Total stockholders' (deficit) equity	(56,664)	(87,762)	(96,999)	22,467
Total liabilities, convertible preferred stock and stockholders' (deficit) equity	$ 8,448	$ 46,329	$ 37,608	$ 37,608

The accompanying notes are an integral part of these financial statements.

KALA PHARMACEUTICALS, INC.

STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

	Year Ended December 31,		Three Months Ended March 31,	
	2015	2016	2016	2017
			(unaudited)	
Revenue	$ 45	$ —	$ —	$ —
Operating expenses:				
Research and development	11,382	25,029	3,911	8,039
General and administrative	4,609	7,640	1,165	1,532
Total operating expenses	15,991	32,669	5,076	9,571
Loss from operations	(15,946)	(32,669)	(5,076)	(9,571)
Other income (expense):				
Interest income	—	147	—	46
Interest expense	(604)	(767)	(194)	(198)
Change in fair value of warrant liability	(132)	122	18	(36)
Total other income (expense)	(736)	(498)	(176)	(188)
Net loss attributable to common stockholders—basic and diluted	$ (16,682)	$ (33,167)	$ (5,252)	$ (9,759)
Net loss per share attributable to common stockholders—basic and diluted	$ (14.89)	$ (28.07)	$ (4.45)	$ (8.26)
Weighted average shares outstanding—basic and diluted	1,120,268	1,181,429	1,181,429	1,181,429
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited)		$ (2.20)		$ (0.56)
Pro forma weighted average shares outstanding—basic and diluted (unaudited)		15,106,343		17,283,399

The accompanying notes are an integral part of these financial statements

KALA PHARMACEUTICALS, INC.

STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

(In thousands, except share amounts)

	Convertible Preferred Stock $0.001 Par Value Seed		Convertible Preferred Stock $0.001 Par Value Series A		Convertible Preferred Stock $0.001 Par Value Series B		Convertible Preferred Stock $0.001 Par Value Series B-1		Convertible Preferred Stock $0.001 Par Value Series C		Common Stock $0.001 Par Value		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balances at January 1, 2015	11,243,209	$ 11,065	9,583,432	$ 10,736	15,624,999	$ 22,185	—	$ —	—	$ —	1,011,629	$ 1	$ 1,563	$ (42,288)	$ (40,724)
Issuance of Series B-1 preferred stock-net of issuance costs of $115	—	—	—	—	—	—	4,629,629	6,885			—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	638	—	638
Exercise of stock options	—	—	—	—	—	—	—	—	—	—	169,800	—	104	—	104
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(16,682)	(16,682)
Balances at December 31, 2015	11,243,209	11,065	9,583,432	10,736	15,624,999	22,185	4,629,629	6,885	—	—	1,181,429	1	2,305	(58,970)	(56,664)
Issuance of Series C preferred stock-net of issuance costs of $402	—	—	—	—	—	—	—	—	42,782,688	67,520	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	2,069	—	2,069
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(33,167)	(33,167)
Balances at December 31, 2016	11,243,209	11,065	9,583,432	10,736	15,624,999	22,185	4,629,629	6,885	42,782,688	67,520	1,181,429	1	4,374	(92,137)	(87,762)
Cumulative effect of a change in accounting policy (unaudited)													23	(23)	—
Stock-based compensation (unaudited)	—	—	—	—	—	—	—	—	—	—	—	—	522	—	522
Net loss (unaudited)	—	—	—	—	—	—	—	—	—	—	—	—	—	(9,759)	(9,759)
Balances at March 31, 2017 (unaudited)	11,243,209	$ 11,065	9,583,432	$ 10,736	15,624,999	$ 22,185	4,629,629	$ 6,885	42,782,688	$ 67,520	1,181,429	$ 1	$ 4,919	$ (101,919)	$ (96,999)

The accompanying notes are an integral part of these financial statements.

KALA PHARMACEUTICALS, INC.

STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		Three Months Ended March 31,	
	2015	2016	2016	2017
			(unaudited)	
Cash flows from operating activities:				
Net loss	$ (16,682)	$ (33,167)	$ (5,252)	$ (9,759)
Adjustments to reconcile net loss to cash used in operating activities:				
Depreciation	330	297	77	69
Change in fair value of warrant liability	132	(122)	(18)	36
Amortization of debt discount and debt issuance costs	134	106	30	28
Write-off of deferred offering costs	—	1,789	—	—
Stock-based compensation	638	2,069	325	522
Loss on disposal of fixed asset	19	—	—	—
Increase (decrease) in cash from:				
Accounts receivable	36	—	—	—
Prepaid expenses and other current assets	34	(66)	7	(92)
Accounts payable	911	(343)	309	1,191
Accrued expenses	(605)	2,108	(9)	(1,370)
Other liabilities	(36)	(19)	(9)	18
Net cash used in operating activities	(15,089)	(27,348)	(4,540)	(9,357)
Cash flows from investing activities:				
Purchases of property and equipment	(252)	(153)	—	(72)
Net cash used in investing activities	(252)	(153)	—	(72)
Cash flows from financing activities:				
Proceeds from issuance of Series B-1 convertible preferred stock	7,000	—	—	—
Proceeds from issuance of Series C convertible preferred stock	—	67,922	—	—
Proceeds received in advance of issuance of Series C convertible preferred stock	—	—	519	—
Proceeds from venture debt refinancing	5,000	1,333	—	—
Payment of principal on venture debt facility	—	(1,333)	—	—
Payment of venture debt issuance costs	(3)	(23)	—	—
Payment of Series B-1 issuance costs	(115)	—	—	—
Payment of Series C issuance costs	—	(402)	(40)	—
Payment of deferred offering costs	(1,506)	(283)	(203)	(19)
Proceeds from exercise of stock options	104	—	—	—
Net cash provided by financing activities	10,480	67,214	276	(19)
Net (decrease) increase in cash	(4,861)	39,713	(4,264)	(9,448)
Cash at beginning of period	10,620	5,759	5,759	45,472
Cash at end of period	$ 5,759	$ 45,472	$ 1,495	$ 36,024
Supplemental disclosure of non-cash investing and financing activities:				
Deferred offering costs included in accounts payable and accruals	$ 226	$ —	$ 139	$ 613
Fair value of warrants issued in connection with venture debt	—	$ 225	—	$ —
Supplemental cash flow information—Cash paid for interest	$ 442	$ 681	$ 163	$ 170

The accompanying notes are an integral part of these financial statements.

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

1. NATURE OF BUSINESS AND BASIS OF PRESENTATION

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

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

Basis of Presentation—The accompanying financial statements have been prepared on a going concern basis which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Since inception, the Company has not generated revenue from the sale of products and has incurred recurring losses and negative cash flows from operations, including a net loss of $16,682 and $33,167 for the years ended December 31, 2015 and 2016, respectively and $9,759 for the three months ended March 31, 2017 (unaudited), and used cash in operations of $15,089 and $27,348 in the years ended December 31, 2015 and 2016, respectively and $9,357 in the three months ended March 31, 2017 (unaudited). The Company has financed its operations to date primarily through the issuance of convertible preferred stock, convertible promissory notes and debt. The Company expects to incur additional operating losses and negative operating cash flows for the foreseeable future. The Company also has debt repayments of $556 due in 2017. The Company expects that its cash of $29,766 as of May 31, 2017 together with the incremental $10.0 million, which it believes is available to be drawn through October 13, 2017, under its Term Loan B, will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months from the date these financial statements were issued. This evaluation is based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued.

The viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations. There can be no assurance that the Company will be able to generate revenue sufficient to cover its costs or obtain capital on acceptable terms, if at all.

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

Unaudited Pro Forma Information—The unaudited pro forma balance sheet as of March 31, 2017 assumes the automatic conversion of all outstanding preferred stock into shares of common stock and the reclassification of the Company's outstanding warrants to purchase shares of Series Seed Convertible Preferred Stock ("Series Seed Preferred Stock"), Series B Convertible Preferred Stock ("Series B Preferred Stock"), and Series C Convertible Preferred Stock ("Series C Preferred Stock") from liability classification to equity classification, in each case occurring upon the closing of the Company's proposed initial public offering ("IPO"), as if these transactions had occurred on March 31, 2017.

Cash and Concentration of Credit Risk—Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

During the year ended December 31, 2015, two counterparties accounted for 100% of the Company's revenue.

Restricted Cash—The Company had restricted cash of $109 as of December 31, 2015 and 2016 and March 31, 2017 (unaudited), which represents certificates of deposit serving as collateral for the Company's credit card and facility leases. This cash is classified as a non-current asset in the accompanying balance sheets.

Deferred Offering Costs—The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with the IPO as other non-current assets until the IPO is consummated. After consummation of the IPO, these costs will be recorded in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. If the Company terminates its plan for an IPO, any costs deferred will be expensed immediately . On September 11, 2015, the Board authorized the Company to confidentially submit a draft registration statement to the Securities and Exchange Commission to sell shares of its common stock to the public. The Company incurred costs of $1,789 directly related to the proposed offering. During the second quarter of 2016, the Company determined that it was likely its IPO would be postponed for a period in excess of 90 days. As a result, in accordance with the Securities and Exchange Commission guidance in Staff Accounting Bulletin Topic 5-A, *Expenses of Offering*, the Company expensed the previously

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

deferred IPO costs of $1,789 as general and administrative expenses in the year ended December 31, 2016. During the three months ended March 31, 2017 (unaudited), the Company decided to pursue an initial public offering, pursuant to which the Company recorded deferred offering costs of $632.

Property and Equipment, net—Property and equipment are recorded at cost. Depreciation is provided using the straight-line method over the estimated useful lives of the related assets. Depreciation expense is included in research and development and general and administrative expenses. Laboratory equipment is depreciated over five years and office and computer equipment is depreciated over three years. Leasehold improvements are depreciated over the shorter of their useful life or the life of the lease. Major additions and upgrades are capitalized; maintenance and repairs, which do not improve or extend the life of the respective assets, are expensed as incurred. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in loss from operations.

Patent Costs—Costs to secure and defend patents are expensed as incurred and are classified as general and administrative expenses in the Company's statements of operations.

Impairment of Long-Lived Assets—Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. When such events occur, the Company compares the carrying amounts of the assets to their undiscounted expected future cash flows. If the undiscounted cash flows are insufficient to recover the carrying value, the assets are recorded at the lesser of the carrying value or fair value. For the years ended December 31, 2015 and 2016 and three months ended March 31, 2017 (unaudited), no impairments were recorded.

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

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

The Company's preferred stock warrant liability is carried at fair value determined according to the fair value hierarchy described above (See Note 8) and classified as a Level 3 measurement. The

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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.

Segment Information—Operating segments are identified as components of an enterprise about which separate discrete financial information is made available for evaluation by the chief operating decision maker ("CODM") in making decisions regarding resource allocation and assessing performance. The CODM is the Company's Chief Executive Officer. The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is on the development and commercialization of therapeutics using its proprietary nanoparticle-based Mucus Penetrating Particles technology. All of the Company's tangible assets are held in the United States. To date, all of the Company's revenue has been generated in the United States.

Revenue Recognition—Revenue is recognized when the following criteria have been met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered and risk of loss has passed; (3) the seller's price to the buyer is fixed or determinable; and (4) collectability is reasonably assured. Deferred revenue is recorded for any amounts received prior to satisfying the revenue recognition criteria. The Company recognized an immaterial amount of revenue during the year ended December 31, 2015, related to the completion of services associated with two feasibility arrangements that were substantially complete as of December 31, 2014. There was no revenue recognized during the year ended December 31, 2016 and the three months ended March 31, 2017 (unaudited), as there were no new revenue arrangements since the completion of the aforementioned feasibility studies.

Research and Development Costs—Research and development expenses consist of expenses incurred in performing research and development activities, including compensation and benefits for full-time research and development employees, an allocation of facilities expenses, overhead expenses, payments to universities under the Company's license agreements and other outside expenses. Research and development costs are expensed as incurred. Research and development costs that are paid in advance of performance, including nonrefundable prepayments for goods or services, are deferred and capitalized as a prepaid expense. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Accrued Expenses—The Company accrues expenses related to development activities performed by third parties based on an evaluation of services received and efforts expended pursuant to the terms of the contractual arrangements. Payments under some of these contracts depend on clinical trial milestones. There may be instances in which payments made to the Company's vendors will exceed the level of services provided and result in a prepayment of expenses. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual or prepaid expense accordingly.

Stock-Based Compensation—The Company accounts for all stock-based payment awards granted to employees and non-employees as compensation expense at fair value. The Company's stock-based payments include stock options and grants of common stock, including common stock subject to vesting. The measurement date for employee awards is the date of grant, and stock-based compensation costs are recognized as expense over the employees' requisite service period, which is the vesting period, on a straight-line basis. The measurement date for nonemployee awards is generally the date the services are completed, resulting in periodic adjustments to stock-based compensation during the vesting terms for changes in the fair value of the awards. Stock-based compensation costs for nonemployees are recognized as expense over the vesting period on a straight-line basis. Stock-based compensation is classified in the accompanying statements of operations based on the function to which the related services are provided.

The Company recognizes compensation expense for the portion of awards that have vested. Forfeitures are recorded as they occur.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company has historically been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Common Stock Valuation—Due to the absence of an active market for the Company's common stock, the Company utilized methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation, to estimate the fair value of its common stock. In determining the exercise prices for options granted, the Company has considered the estimated fair value of the common stock as of the measurement date. The estimated fair value of the common stock has been determined at each grant date based upon a variety of factors, including the illiquid nature of the common stock, arm's-length sales of the Company's capital stock (including redeemable convertible preferred stock), the effect of the rights and preferences of the preferred shareholders, and the prospects of a liquidity event. Among other factors are the Company's financial position and historical financial performance, the status of technological developments within the Company's research, the composition and ability of the current research and management team, an evaluation or benchmark of the Company's competition, and the current business climate in the marketplace. Significant changes to

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

Preferred Stock Warrants—The Company classifies warrants to purchase shares of its Series Seed Preferred Stock, Series A Convertible Preferred Stock ("Series A Preferred Stock"), Series B Preferred Stock, and Series C Preferred Stock as a liability on its balance sheets as these warrants are free-standing financial instruments that are exercisable for contingently redeemable shares. The warrants are recorded in long-term liabilities at fair value, estimated using the Black-Scholes model, and marked to market at each balance sheet date. The change in carrying value is reported as the change in fair value of warrant liability in the accompanying statements of operations. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise of the warrant, the expiration of the warrant or the warrant converting to a warrant to purchase common stock, which will occur upon the closing of the IPO in accordance with the conversion rights described in Note 8.

Income Taxes—Deferred tax assets and liabilities are recognized for the expected future tax consequences of events that have been included in the Company's financial statements and tax returns. Deferred tax assets and liabilities are determined based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions and other issues. The Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position is measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. As a result, reserves are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized following resolution of any potential contingencies present.

Net Loss per Share and Unaudited Pro Forma 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 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. Net loss per share attributable to common stockholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of the Company's common shares and participating securities. The Company's convertible preferred stock contains participation rights in any dividend paid by the Company and is deemed to be a participating security. Net loss attributable to common stockholders and participating preferred shares are allocated to each share on an as-converted basis as if all of the earnings for the period had been distributed. The participating securities do not

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

include a contractual obligation to share in losses of the Company and are not included in the calculation of net loss per share in the periods in which a net loss is recorded.

Diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the if converted method. The Company allocates earnings first to preferred stockholders based on dividend rights and then to common and preferred stockholders based on ownership interests. The weighted average number of common shares included in the computation of diluted net loss gives effect to all potentially dilutive common equivalent shares, including outstanding stock options, warrants, preferred stock and the potential issuance of stock upon the conversion of the Company's convertible notes. Common stock equivalent shares are excluded from the computation of diluted net loss per share if their effect is antidilutive. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. When a gain is recorded pursuant to a change in fair value of the warrant liability during the period, the Company assesses whether the impact of reversing the gain and including the additional securities is dilutive, and if so, will adjust dilutive EPS. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2015 and 2016 and the three months ended March 31, 2016 and 2017 (unaudited).

Unaudited pro forma net loss per share applicable to common stockholders is computed using the weighted-average number of common shares outstanding after giving effect to the conversion of all outstanding convertible preferred stock into shares of common stock as if such conversion had occurred on January 1, 2016, or the date of original issuance, if later.

Comprehensive Loss—Comprehensive loss is equal to net loss for the periods presented.

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

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

In November 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2015-17, *Balance Sheet Classification of Deferred Taxes* ("ASU 2015-17"). ASU 2015-17 requires deferred tax liabilities and assets to be classified as non-current in the balance sheet. ASU 2015-17 is required to be adopted for annual periods beginning after December 15, 2016, including interim periods within those fiscal years. The amendment may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. The Company elected to early adopt this guidance retrospectively to all periods presented, and its adoption had no impact on the Company's financial position, results of operations or cash flows.

In April 2015, the FASB issued ASU No. 2015-03, *Simplifying the Presentation of Debt Issuance Costs* ("ASU 2015-03"), which requires that debt issuance costs related to a debt liability be presented in the balance sheet as a direct reduction in the carrying amount of that debt liability and the costs are amortized over the life of the debt facility to interest expense. The amendments in ASU 2015-03 were effective for the annual periods ending after December 15, 2015. Early adoption was permitted. Upon adoption, the amendments in ASU No. 2015-03 were required to be applied on a retrospective basis as a change in accounting principle for all prior periods presented. The Company elected to early adopt this guidance as of September 30, 2015 and recorded all previously recognized debt issuance costs as a direct reduction to the carrying amount of the related debt liability at each reporting date.

In November 2014, the FASB issued ASU No. 2014-16, *Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity* ("ASU 2014-16"). The guidance requires an entity to determine the nature of the host contract by considering all stated and implied substantive terms and features of the hybrid financial instrument, weighing each term and feature on the basis of the relevant facts and circumstances (commonly referred to as the whole-instrument approach). The Company adopted the standard on the required effective date of January 1, 2016, and its adoption had no material impact on the Company's financial position, results of operations or cash flows.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's ability to Continue as a Going Concern*, which provides guidance in Generally Accepted Accounting Principles (GAAP) about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. The amendments in ASU 2014-15 are effective for the annual period ending after December 15, 2016 and for annual and interim periods thereafter. The adoption of this standard had no material impact on the Company's financial position, results of operations or cash flows.

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

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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. The Company is currently evaluating the impact that the adoption of ASU 2016-15, but believes its adoption will have no material impact on its statement of cash flows.

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

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which supersedes existing revenue recognition guidance. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The standard defines a five-step process to achieve this principle and will require companies to use more judgment and make more estimates than under the current guidance. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. In April 2016, the FASB issued ASU 2016-10, *Revenue From Contracts With Customers: Identifying Performance Obligations and Licensing* ("ASU 2016-10"), which addresses certain implementation issues and clarifies certain core revenue recognition principles of ASU 2014-09. In July 2015, the FASB voted to delay the effective date of this standard such that ASU 2014-09, as amended by ASU 2016-10, will be effective for the Company for annual periods beginning after December 15, 2017 and for interim periods within those fiscal years. Early adoption of the standard is permitted for annual periods beginning after December 15, 2016. Until such time the Company enters into a material revenue arrangement, it is not possible to evaluate whether the new standard will have a material impact on the Company's financial statements.

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

3. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following:

	December 31, 2015	December 31, 2016	March 31, 2017 (unaudited)
Rent	$ 53	$ 58	$ 61
Development costs	—	—	97
Insurance	14	55	48
Deferred offering costs	1,732	—	632
Other	43	41	40
Prepaid expenses and other current assets	$ 1,842	$ 154	$ 878

4. PROPERTY AND EQUIPMENT, NET

Property and equipment, net, consists of the following:

	December 31, 2015	December 31, 2016	March 31, 2017 (unaudited)
Laboratory equipment	$ 1,576	$ 1,729	$ 1,747
Leasehold improvements	93	93	114
Computer hardware and software	54	54	87
Office equipment	23	23	23
Furniture and fixtures	11	11	11
Property and equipment—at cost	1,757	1,910	1,982
Less: Accumulated depreciation	(1,019)	(1,316)	(1,385)
Property and equipment—net	$ 738	$ 594	$ 597

Depreciation expense for the years ended December 31, 2015 and 2016 and three months ended March 31, 2016 and 2017 was $330, $297, $77 (unaudited) and $69 (unaudited), respectively.

5. ACCRUED EXPENSES

Accrued expenses consist of the following:

	December 31, 2015	December 31, 2016	March 31, 2017 (unaudited)
Development costs	$ 701	$ 2,280	$ 1,823
Compensation and benefits	968	1,480	443
Professional fees	157	171	314
Deferred offering costs	184	—	485
Other	93	62	42
Accrued expenses	$ 2,103	$ 3,993	$ 3,107

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

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 $10,000, of which $5,000 was borrowed upon entering into the agreement and the remaining $5,000 was borrowed in July 2015. Under the terms of the facility, the borrowings accrued interest at an annual rate equal to the greater of (i) 3.00% above the Prime Rate then in effect, or (ii) 6.25%. The interest rate was 6.25% as of December 31, 2015, 6.50% as of December 31, 2016 and 7.0% as of March 31, 2017 (unaudited). Interest is payable monthly in arrears, and, prior to entering into the First Amendment to the 2014 Debt Facility (the "First Amendment"), as described below, monthly principal payments were to commence in July 2016. The Company incurred debt issuance costs of $72 and paid $138 in fees on behalf of the lender in connection with entering into the 2014 Debt Facility, all of which were recorded a reduction in the carrying value of the long-term debt balance. The discount balance resulting from these costs, in addition to the fair value of the warrants issued, as discussed below, is being amortized to interest expense through the maturity date using the effective interest method.

On October 13, 2016, the Company entered into the First Amendment. The First Amendment reaffirmed the initial commitment to a total of $10,000 of funding ("Term Loan A") and increased the Company's total borrowing capacity by an additional $10,000 ("Term Loan B" and together with Term Loan A, "Term Loans") subject to the following conditions: (i) the minimum borrowing amount is $250 for each incremental borrowing under Term Loan B; (ii) The Term Loans, once repaid, may not be re-borrowed; (iii) the Company may prepay the Term Loans subject to the payment of a prepayment fee ranging from 0.3% to 0.9%; and (iv) the commitment to fund Term Loan B is contingent upon the Company providing evidence of positive results sufficient to support an NDA submission for the treatment of inflammation and pain following ocular surgery based on the Company's second Phase 3 trial of KPI-121 1.0%. Funding under the Term Loan B commitment is available through October 13, 2017. In addition, the interest-only end date was extended from June 2016 to October 13, 2017 and the term loan maturity date was extended from December 1, 2018 to October 13, 2020. The Company has not accrued for the prepayment fee as it does not intend to prepay the outstanding balance. The 2014 Debt Facility is not subject to financial covenants. As of December 31, 2016 and March 31, 2017 (unaudited), the Company had not completed the second Phase 3 trial and therefore Term Loan B was not available to be drawn.

In May 2017 the Company announced positive topline results from its Phase 3 trial of KPI-121 1.0% for the treatment of inflammation and pain in patients who have undergone cataract surgery. KPI-121 1.0% dosed twice-a-day for two weeks achieved statistical significance versus placebo for both primary efficacy endpoints and all secondary endpoints. KPI-121 1.0% was well tolerated with no significant treatment-related adverse events observed during the trial. The Company believes, per the terms of the First Amendment, that these results are sufficient to submit an NDA for KPI-121 1.0% for the treatment of inflammation and pain following ocular surgery and therefore Term Loan B will be available to be drawn through October 13, 2017. The Company accounted for the First Amendment to the 2014 Debt Facility as a debt modification of the prior agreement and paid $23 in fees on behalf of the lender in connection with the First Amendment, all of which were capitalized and recorded within debt discount (a reduction to the long-term debt balance) and are being amortized to interest expense

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

6. DEBT (Continued)

using the effective interest method through the maturity date. New fees of $29, paid to third parties that were associated with the First Amendment, were expensed as incurred.

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 the 2014 Debt Facility and the initial borrowing of $5,000 under Term Loan A, the Company issued warrants to the lender to purchase 138,889 shares of Series B Preferred Stock at an exercise price of $1.44 per share (the "2014 Warrants"). During 2015 the Company borrowed an additional $5,000 under Term Loan A and the number of exercisable shares underlying the 2014 Warrants increased to 277,778 shares. Upon executing the First Amendment, the Company issued warrants to purchase up to 251,951 shares of Series C Preferred Stock at an exercise price of $1.59 per share (the "2016 Warrants"). Consistent with the warrants issued under the original 2014 Debt Facility, the number of shares of Series C Preferred Stock that become exercisable increases in proportion to the amount of Term Loan B borrowings. The 2016 Warrants were not exercisable into shares as of the First Amendment date or March 31, 2017 (unaudited), as the Company had not borrowed under the Term B Loan during 2016 or the three months ended March 31, 2017.

Upon issuance of the 2014 Warrants and 2016 Warrants, the Company estimated the fair value of the warrants using the Black-Scholes option-pricing model (see Note 7), and recorded the estimated fair value of the warrants as a liability separate from the loan balance, resulting in additional debt discount included within long-term debt that is amortized to interest expense over the term of the loan using the effective interest method. The initial fair value of the 2014 Warrants and 2016 Warrants was $140 and $225, respectively. The warrants are subsequently re-measured to fair value at every reporting date with changes in fair value recorded in the statement of operations as a component of other income (expense), as the shares underlying the warrants are exercisable into contingently redeemable shares.

As of December 31, 2015 and 2016 and March 31, 2017 (unaudited), the estimated fair value of the warrant liability associated with the original 2014 Debt Facility was $282, $274 and $307, respectively, and the estimated fair value of the warrant liability associated with the First Amendment was $0, $263 and $227, respectively.

The unpaid principal balance under the 2014 Debt Facility was $10,000 as of December 31, 2015, and 2016 and March 31, 2017 (unaudited). The unamortized discount was $205, $346 and $318 as of December 31, 2015, and 2016 and March 31, 2017 (unaudited), respectively. The Company recognized interest expense of $604 and $767 related to the 2014 Debt Facility during the years ended December 31, 2015 and 2016, respectively, which consisted of the amortization of the debt discount of

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

6. DEBT (Continued)

$134 and $106, respectively, and contractual coupon interest of $470 and $661, respectively. During the three months ended March 31, 2016 and 2017 (unaudited), the Company recognized interest expense of $194 and $198, respectively, which consisted of amortization of the debt discount of $30 and $28 and the contractual coupon interest of $164 and $170, respectively.

The future annual principal payments due under the 2014 Debt Facility as of December 31, 2016 were as follows:

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

7. PREFERRED STOCK WARRANTS

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

Issued	Exercisable for	Exercise Price	Expiration Date	Shares Exercisable at December 31, 2015	Shares Exercisable at December 31, 2016
2011 and 2012	Series Seed Preferred Stock	$ 1.00	July 2019	80,000	80,000
2013	Series B Preferred Stock	$ 1.44	April 2021	694,444	694,444
2014	Series B Preferred Stock	$ 1.44	November 2024	138,889	277,778
2016	Series C Preferred Stock	$ 1.59	October 2026	—	—(1)

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

8. FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company's preferred stock warrants associated with the issuances of the 2014 Debt Facility and the First Amendment, as well as debt transactions entered into prior to 2014, are recorded at fair value. The assets and liabilities measured at fair value on a recurring basis as of December 31, 2015

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

8. FAIR VALUE OF FINANCIAL INSTRUMENTS (Continued)

and 2016, and March 31, 2017 (unaudited) and the input categories associated with those assets and liabilities are as follows:

	Carrying Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
December 31, 2015				
2011 and 2012 Series Seed Warrants	$ 53	$ —	$ —	$ 53
2013 Series B Warrants	601	—	—	601
2014 Series B Warrants	282	—	—	282
Total warranty liability	$ 936	$ —	$ —	$ 936
December 31, 2016				
2011 and 2012 Series Seed Warrants	$ 39	$ —	$ —	$ 39
2013 Series B Warrants	463	—	—	463
2014 Series B Warrants	274	—	—	274
2016 Series C Warrants	263	—	—	263
Total warranty liability	$ 1,039	$ —	$ —	$ 1,039
March 31, 2017 (unaudited)				
2011 and 2012 Series Seed Warrants	$ 53	$ —	$ —	$ 53
2013 Series B Warrants	488	—	—	488
2014 Series B Warrants	307	—	—	307
2016 Series C Warrants	227	—	—	227
Total warranty liability	$ 1,075	$ —	$ —	$ 1,075

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

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

8. FAIR VALUE OF FINANCIAL INSTRUMENTS (Continued)

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

	2011 and 2012 Series Seed Warrants	2013 Series B Warrants	2014 Series B Warrants	Series C Warrants
December 31, 2015				
Volatility	98.50%	102.30%	103.10%	—
Risk-free interest rate	1.40%	1.80%	2.20%	—
Estimated fair value of underlying shares	$ 1.01	$ 1.16	$ 1.16	—
Remaining contractual term	3.5	5.0	9.0	—
Expected dividend yield	0%	0%	0%	—
December 31, 2016				
Volatility	100.00%	87.00%	114.00%	58.30%
Risk-free interest rate	1.30%	1.80%	2.30%	2.40%
Estimated fair value of underlying shares	$ 0.89	$ 1.11	$ 1.11	$ 1.54
Remaining contractual term (years)	2.6	4.3	7.9	9.8
Expected dividend yield	0%	0%	0%	0%
March 31, 2017 (unaudited)				
Volatility	117.10%	71.00%	95.70%	46.90%
Risk-free interest rate	1.30%	1.70%	2.30%	2.40%
Estimated fair value of underlying shares	$ 0.66	$ 0.70	$ 1.10	$ 0.90
Remaining contractual term (years)	2.3	4.0	7.6	9.5
Expected dividend yield	0%	0%	0%	0%

For purposes of determining the fair value of the warrants to purchase Series C Preferred Stock, the Company estimated that there is a 100% probability that it will draw down on the remaining $10,000 available under the 2014 Debt Facility, and as such, assumed that the warrants will be exercisable into the maximum number of shares stipulated in the First Amendment. With respect to the aggregate warrant liabilities recorded as of December 31, 2015 and 2016, and March 31, 2017 (unaudited), a change in the assumptions regarding estimated volatility and/or the estimated fair value of the preferred stock could have a significant impact on the resulting fair values of the warrant liabilities.

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

8. FAIR VALUE OF FINANCIAL INSTRUMENTS (Continued)

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

	Warranty Liability
Fair value—January 1, 2015	$ 804
Change in fair value of warrant liability	132
Fair value—December 31, 2015	$ 936
Fair value of 2016 Warrants upon First Amendment	225
Change in fair value of warrant liability	(122)
Fair value—December 31, 2016	$ 1,039
Change in fair value of warrant liability (unaudited)	36
Fair value—March 31, 2017 (unaudited)	$ 1,075

9. CONVERTIBLE PREFERRED STOCK

Preferred stock consisted of the following as of December 31, 2015:

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

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

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

9. CONVERTIBLE PREFERRED STOCK (Continued)

Preferred stock consisted of the following as of December 31, 2016 and March 31, 2017 (unaudited):

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

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

Series Seed Convertible Preferred Stock

In December 2009, the Company issued an aggregate of 2,000,001 shares of Series Seed Preferred Stock for gross proceeds of $2,000 or $1.00 per share. In October 2010, the Company issued an aggregate of 2,000,003 shares of Series Seed Preferred Stock to existing investors for gross proceeds of $2,000 or $1.00 per share. In February 2012, the Company issued an aggregate of 7,243,205 shares of Series Seed Preferred Stock to existing and new investors, which included 6,150,000 shares for gross proceeds of $6,150 and 1,093,205 shares converted from convertible debt of $1,000 principal and $93 accrued interest. Costs incurred in connection with each of the individual issuances of Series Seed Preferred Stock were $124, $39 and $15 respectively, which have been recorded as a reduction to the carrying amount of the Series Seed Preferred Stock.

Series A Convertible Preferred Stock

In February 2013, the Company issued 4,791,716 shares of Series A Preferred Stock, at a purchase price of $1.20 per share for gross proceeds of $5,750.

Additionally, in accordance with the terms of the Series A Preferred Stock Purchase Agreement, investors were granted the right to purchase up to an additional 4,791,716 shares of Series A Preferred

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

9. CONVERTIBLE PREFERRED STOCK (Continued)

Stock, at a price of $1.20 per share, upon the Company meeting certain milestone criteria by December 31, 2013, approval of the Board and approval of the investors holding a majority of the outstanding shares of Series A Preferred Stock.

In June 2013, the Board approved waiving one of the milestone events provided for in the Series A Preferred Stock Purchase Agreement. Accordingly, the second tranche of Series A Preferred Stock closed on July 15, 2013 and the Company issued 4,791,716 shares of Series A Preferred Stock for gross proceeds of $5,750, or $1.20 per share. Costs incurred in connection with the issuance of the Series A Preferred Stock were $93, which have been recorded as a reduction in the carrying amount of the Series A Preferred Stock.

Series B Convertible Preferred Stock

In April 2014, the Company issued 15,624,999 shares of Series B Preferred Stock for gross proceeds of $22,500 or $1.44 per share which included conversion of the outstanding principal and interest on the 2013 Notes (See Note 7) of $5,130, which converted into 3,562,785 shares of Series B Preferred Stock pursuant to the terms of the Notes. Costs incurred in connection with the issuance of the Series B Preferred Stock were $315, which have been recorded as a reduction in the carrying amount of the Series B Preferred Stock.

Series B-1 Convertible Preferred Stock

On August 17, 2015, the Company issued 4,629,629 shares of Series B-1 Senior Convertible Preferred Stock ("Series B-1 Preferred Stock") for gross proceeds of $7,000 or $1.512 per share. Costs incurred in connection with the issuance of the Series B-1 Preferred Stock were $115, which have been recorded as a reduction in the carrying amount of the Series B-1 Preferred Stock.

Series C Convertible Preferred Stock

On April 5, 2016, the Company issued 42,782,688 shares of Series C Preferred Stock for gross proceeds of $67,922 or $1.5876 per share. Costs incurred in connection with the issuance of the Series C Preferred Stock were $402, which have been recorded as a reduction in the carrying amount of the Series C Preferred Stock.

Terms Applicable to Each Series of Preferred Stock

The Series Seed Preferred Stock, Series A Preferred Stock, Series B Preferred Stock, Series B-1 Preferred Stock and Series C Preferred Stock are classified outside of stockholders' (deficit) equity because the shares contain certain redemption features that are not solely within the control of the Company.

The rights, preferences, and privileges of the preferred stock are as follows:

Voting—Preferred stockholders are entitled to vote on all matters and are entitled to the number of votes equal to the number of shares of common stock into which each share of preferred stock is then convertible.

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

9. CONVERTIBLE PREFERRED STOCK (Continued)

Dividends—Preferred stockholders are entitled to receive, when and if declared by the Board out of any funds legally available, dividends at the rate of 8% of the original issue price per share. No such dividends have been declared or paid through December 31, 2016.

Liquidation Rights—Upon any liquidation, dissolution, or winding-up of the Company, whether voluntary or involuntary, each holder of the then outstanding Series C Preferred Stock and then Series B Preferred Stock and Series B-1 Preferred Stock shall be entitled to distribution, before any distribution of payments is made to holders of Series Seed Preferred Stock or Series A Preferred Stock or common stockholders, an amount equal to the greater of (i) (A) in the case of the Series C Preferred Stock, $1.5876 per share (B) in the case of the Series B Preferred Stock, $1.44 per share and (C) in the case of the Series B-1 Preferred Stock, $1.512 per share, plus, in each case, any declared but unpaid dividends and (ii) the amount such holder would have received if such holder had converted its shares into common stock immediately prior to such liquidation, dissolution, or winding-up of the Company. After the payment of the preferential amounts to the holders of the Series C Preferred Stock, then Series B Preferred Stock and the Series B-1 Preferred Stock, the holders of the Series Seed Preferred Stock and Series A Preferred Stock are entitled to a distribution of an amount equal to the greater of (i) (A) in the case of the Series Seed Preferred Stock $1.00 per share, (B) in the case of the Series A Preferred Stock $1.20 per share, plus, in each case, an amount equal to all declared but unpaid dividends; and (ii) the amount such holder would have received if such holder had converted its shares into common stock immediately prior to such liquidation, dissolution, or winding-up of the Company.

If there are insufficient assets legally available to make the distribution to the holders of the Series Seed Preferred Stock, Series A Preferred Stock, Series B Preferred Stock, Series B-1 Preferred Stock, and Series C Preferred Stock in full, then the available assets shall be distributed on a pro rata basis, first to the holders of the Series C Preferred Stock and then to Series B Preferred Stock and Series B-1 Preferred Stock, then any remaining assets available will be distributed on a pro rata basis to the holders of the Series Seed Preferred Stock and Series A Preferred Stock. Any remaining assets legally available for distribution after satisfaction of the liquidation preferences of the preferred stock shall be distributed to the holders of common stock on a pro-rata basis based upon the number of shares of common stock held by the common stockholders.

Conversion—Each share of preferred stock is convertible into common stock, at any time, at the option of the holder, at the then applicable conversion rate for each series of preferred stock and subject to adjustment in accordance with anti-dilution provisions. Each share of Series A, Series B, Series B-1 and Series C Preferred Stock is convertible on a 5.2083 for one basis into common stock. The conversion ratio is subject to adjustment for certain dilutive events, such as, but not limited to, stock splits and dividends. Each share of preferred stock will automatically convert into common stock upon the earlier of (i) the closing of the Company's first underwritten public offering of its common stock, in which the Company receives aggregate gross proceeds of at least $30,000 and that is listed on the New York Stock Exchange or NASDAQ Stock Market or (ii) a date specified by vote or written consent of the majority of the outstanding preferred stock. In addition, in the event that any holder of at least 500,000 shares of preferred stock does not participate in a Qualified Financing, as defined in the Company's Certificate of Incorporation, and/or restated from time to time (the "Charter"), effective upon the consummation of the Qualified Financing, a portion of the holder's preferred stock

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

9. CONVERTIBLE PREFERRED STOCK (Continued)

(as determined in accordance with the Charter) will automatically convert into a new series of preferred stock with the conversion price for such new series fixed at the applicable conversion price in effect immediately prior to the consummation of the Qualified Financing, and such conversion price will not be subject to any adjustment thereafter.

10. COMMON STOCK

Voting, dividend and liquidation rights of the holders of the common stock is subject to and qualified by the rights, powers and preferences of the holders of the preferred stock.

Voting—Each holder of outstanding shares of common stock shall be entitled to one vote in respect of each share. The holders of outstanding shares of common stock, voting together as a single class, shall be entitled to elect one director. The number of authorized shares of common stock may be increased or decreased by the affirmative vote of a majority of the outstanding shares of common stock and preferred stock voting together as a single class.

Dividends—Subject to the payment in full of all preferential dividends to which the holders of the preferred stock are entitled hereunder, the holders of common stock shall be entitled to receive dividends out of funds legally available therefor at such times and in such amounts as the Board may determine in its sole discretion, with holders of preferred stock and common stock sharing pari passu in such dividends.

Liquidation Rights—Upon any liquidation, after the payment or provision for payment of all debts and liabilities of the Company and all preferential amounts to which the holders of preferred stock are entitled with respect to the distribution of assets in liquidation, the holders of common stock shall be entitled to share ratably in the remaining assets of the Company available for distribution.

Reserved Shares—As of December 31, 2015 and 2016 and March 31, 2017 (unaudited), the Company has reserved the following shares of common stock for potential conversion of the outstanding convertible preferred stock, convertible preferred stock issuable upon exercise of rights under warrants and exercise of stock options:

	December 31,		March 31,
	2015	2016	2017 (unaudited)
Convertible preferred stock	7,887,642	16,101,970	16,101,970
2013 Warrant rights to acquire Series B Preferred Stock	133,327	133,327	133,327
2014 Warrant rights to acquire Series B Preferred Stock	53,333	53,333	53,333
2016 Warrant rights to acquire Series C Preferred Stock(1)	—	48,374	48,374
2011 Warrant rights to acquire Series Seed Preferred Stock	15,360	15,360	15,360
2009 stock option plan	1,584,537	3,533,726	3,533,726
Total	9,674,199	19,886,090	19,886,090

(1) As of December 31, 2016 and March 31, 2017 (unaudited), warrants outstanding to acquire Series C Preferred Stock were not exercisable into shares of Series C Preferred Stock; however,

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

10. COMMON STOCK (Continued)

upon draw down of Term Loan B, the warrants will become exercisable into a maximum of 251,951 shares of Series C Preferred Stock, which represents a maximum of 48,374 potential common shares upon conversion of the Series C Preferred Stock into shares of common stock.

11. STOCK-BASED COMPENSATION

Stock Incentive Plan—On December 11, 2009, the Board adopted the 2009 Employee , Director and Consultant Equity Incentive Plan (the "2009 Plan") for the issuance of common stock and stock options to employees, officers, directors, consultants, and advisors. As of December 31, 2015, 2016 and March 31, 2017 (unaudited), the Board had authorized 1,762,761 shares, 3,711,949 shares and 3,711,949 shares, respectively, of common stock to be issued under the 2009 Plan. Under the 2009 Plan, the Board determined the number of shares of common stock to be granted pursuant to the awards, as well as the exercise price and terms of such awards. The exercise price of incentive stock options cannot be less than the fair value of the common stock on the date of grant.

Stock options awarded under the 2009 Plan expire 10 years after the grant date, unless the Board sets a shorter term. Options granted under the plan generally vest over a four-year period. As of December 31, 2015 and 2016 and March 31, 2017 (unaudited), there were 38,382 shares, 338,256 shares and 344,562 shares, respectively, of common stock available for future grant under the 2009 Plan. Upon the exercise of stock options, the Company issues new shares of common stock. The Company does not hold any treasury shares.

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

The Company has granted 86,056 stock options which contain performance-based vesting criteria. These criteria are milestone events that are specific to the Company's corporate goals. Stock-based compensation expense associated with performance-based stock options are recognized if the achievement of the performance condition is considered probable using management's best estimates. These milestones have not been deemed probable as of December 31, 2016 and March 31, 2017 (unaudited). As of December 31, 2015 and 2016 and March 31, 2016 and 2017 (unaudited), unrecognized compensation expense related to the performance-based awards was $53, $42, $39 and $24, respectively.

The Company granted 4,224, 0, 0 and 0 stock options to non-employees for the years ended December 31, 2015 and 2016 and the three months ended March 31, 2016 and 2017 (unaudited), respectively. The Company recognized $54, $57, $13, and $15 in stock compensation expense related to non-employees for the years ended December 31, 2015 and 2016 and the three months ended March 31, 2016 and 2017 (unaudited), respectively.

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

11. STOCK-BASED COMPENSATION (Continued)

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.

A summary of option activity for employee and non-employee awards under the 2009 Plan for the year ended December 31, 2016 and the three months ended March 31, 2017 (unaudited) is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at January 1, 2016	1,546,155	$ 3.17	8.7	$ 1,691
Granted	1,649,314	3.33		
Outstanding at December 31, 2016	3,195,469	$ 3.26	8.6	$ 1,200
Forfeited	(6,305)	3.33		
Outstanding at March 31, 2017 (unaudited)	3,189,164	$ 3.26	8.4	$ 2,601
Vested and expected to vest at December 31, 2016	2,899,032	$ 3.23	8.6	$ 1,141
Options exercisable at December 31, 2016	1,035,928	$ 2.89	8.0	$ 823
Vested and expected to vest at March 31, 2017 (unaudited)	2,941,885	$ 3.23	8.3	$ 2,438
Options exercisable at March 31, 2017 (unaudited)	1,162,765	$ 2.94	7.9	$ 1,364

The Company records stock-based compensation related to stock options granted at fair value. The Company utilizes the Black-Scholes option-pricing model to estimate the fair value of stock option grants and to determine the related compensation expense. The assumptions used in calculating the fair value of stock-based payment awards represent management's best estimates. The assumptions used in determining fair value of the stock options granted in the years ended December 31, 2015 and 2016 are as follows:

	Year Ended December 31,	
	2015	2016
Expected volatility	106% - 115%	106% - 110%
Risk-free interest rate	1.49% - 2.24%	1.21% - 1.45%
Expected dividend yield	0%	0%
Expected term (in years)	5.87 - 9.46	5.62 - 6.18

There were no options granted during the three months ended March 31, 2016 and 2017 (unaudited).

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

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

11. STOCK-BASED COMPENSATION (Continued)

The weighted average grant-date fair value of options granted during the years ended December 31, 2015 and 2016 was $4.17 and $2.71, respectively. There were no options granted during the three months ended March 31, 2016 and 2017 (unaudited). The fair value is being expensed over the vesting period of the options on a straight-line basis as the services are being provided. The Company has recorded aggregate stock-based compensation expense related to the issuance of stock option awards of $638 and $2,069 during the years ended December 31, 2015 and 2016 and $325 and $522 during the three months ended March 31, 2016 and 2017 (unaudited), respectively. As of December 31, 2016, and March 31, 2017 (unaudited), there was $4,784 and $5,039 respectively, of unrecognized compensation cost related to the stock options granted under the 2009 Plan, which is expected to be expensed over a weighted-average period of 2.73 and 2.53 years, respectively. Stock-based compensation expense was classified in the statements of operations as follows:

	Year Ended December 31,		Three Months Ended March 31,	
	2015	2016	2016	2017
			(unaudited)	
Research and development	$ 161	$ 461	$ 55	$ 187
General and administrative	477	1,608	270	335
Total	$ 638	$ 2,069	$ 325	$ 522

The Company received cash proceeds from the exercise of stock options of $104, $0, $0 and $0 during the years ended December 31, 2015, and 2016 and the three months ended March 31, 2016 and 2017 (unaudited), respectively. The total intrinsic value of options exercised in 2015 was $552.

12. INCOME TAXES

The Company has had no income tax expense due to operating losses incurred for the years ended December 31, 2015 and 2016. The Company has also not recorded any income tax benefits for the net operating losses incurred in each period due to its uncertainty of realizing a benefit from those items. All of the Company's losses before income taxes were generated in the United States.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2015	2016
Federal statutory income tax rate	35.0%	35.0%
Effect of:		
Change in valuation allowance	(43.2)	(42.3)
State income taxes, net of federal benefit	6.3	4.7
Research and development tax credits	2.9	3.1
Other	(1.0)	(0.5)
Effective income tax rate	0.0%	0.0%

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

12. INCOME TAXES (Continued)

Net deferred tax assets as of December 31, 2015 and 2016 consisted of the following:

	December 31,	
	2015	2016
Net operating loss carryforwards	$ 23,301	$ 36,280
Research and development tax credit carryforwards	2,119	2,940
Start-up costs and other	1,048	1,807
Total deferred tax assets	26,468	41,027
Depreciation and amortization	(8)	8
Total deferred tax liabilities	(8)	8
Valuation allowance	(26,460)	(41,035)
Net deferred tax assets	$ —	$ —

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2015 and 2016. The valuation allowance increased by $7,807 in 2015 and $14,575 in 2016 due to the increase in the net operating loss carryforwards and research and development tax credits. Management reevaluates the positive and negative evidence at each reporting period.

At December 31, 2015 and 2016, the Company has federal net operating loss carryforwards of $54,518 and $85,325, respectively, which may be available to offset future federal tax liabilities and expire at various dates beginning in 2030 through 2036. At December 31, 2015 and 2016, the Company has state net operating loss carryforwards of $53,073 and $80,500, respectively, which may be available to offset future state income tax liabilities and expire at various dates beginning in 2030 through 2036. As of December 31, 2015 and 2016, the Company also had federal and state research and development credit carryforwards of approximately $2,119 and $2,940, respectively, which are available to reduce future income taxes, if any, from 2030 through 2036 (federal) and 2025 through 2031 (state). During the three months ended March 31, 2017 (unaudited), gross deferred tax assets increased by approximately $3,900 due to the operating loss incurred by the Company during the period.

Realization of the future tax benefits is dependent on many factors, including the Company's ability to generate taxable income within the net operating loss carryforward period. Under the provisions of Section 382 of the Internal Revenue Code of 1986, certain substantial changes in the Company's ownership, including a sale of the Company, or significant changes in ownership due to sales of equity, may have limited, or may limit in the future, the amount of net operating loss carryforwards, which could be used annually to offset future taxable income. The Company files its corporate income tax returns in the United States and Massachusetts, California, Kentucky, Pennsylvania, New York, Texas and New Hampshire. All tax years since the date of incorporation remain open to examination by the major taxing jurisdictions (state and federal) to which the Company

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

12. INCOME TAXES (Continued)

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 December 31, 2015 and 2016, the Company had no uncertain tax positions. The Company's policy is to recognize interest and penalties related to income tax matters as a component of income tax expense, of which no interest or penalties were recorded for the years ended December 31, 2015 and 2016.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2015 and 2016 related primarily to the increases in net operating loss carryforwards and research and development tax credit carryforwards.

13. NET LOSS PER SHARE AND UNAUDITED PRO FORMA NET LOSS PER SHARE

Net Loss per Share—Basic and diluted net loss per share attributable to common stockholders were calculated as follows:

	Year Ended December 31,		Three Months Ended March 31,	
	2015	2016	2016	2017
			(unaudited)	
Numerator:				
Net loss attributable to common stockholders	$ (16,682)	$ (33,167)	$ (5,252)	$ (9,759)
Denominator:				
Weighted average shares outstanding—basic and diluted	1,120,268	1,181,429	1,181,429	1,181,429
Net loss per share attributable to common stockholders—basic and diluted	$ (14.89)	$ (28.07)	$ (4.45)	$ (8.26)

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

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

13. NET LOSS PER SHARE AND UNAUDITED PRO FORMA NET LOSS PER SHARE (Continued)

computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	December 31,		March 31,	
	2015	2016	2016	2017
			(unaudited)	
Convertible preferred stock (as converted to common stock)	7,887,642	16,101,970	7,887,642	16,101,970
Options to purchase common stock	1,546,155	3,195,469	1,546,155	3,189,164
Preferred stock warrants(1)	202,020	250,394	202,020	250,394
	9,635,817	19,547,833	9,635,817	19,541,528

(1) Warrants outstanding as of December 31, 2016 and March 31, 2017 (unaudited) include warrants to purchase Series C Preferred Stock for which the underlying shares included above of 48,374 are only exercisable upon the Company's draw down of the full amount of Term Loan B of $10,000.

Unaudited Pro Forma Net Loss per Share—The unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2016 and the three months ended March 31, 2017 gives effect to adjustments arising upon the closing of a qualified initial public offering. The unaudited pro forma net loss attributable to common stockholders used in the calculation of unaudited basic and diluted pro forma net loss per share attributable to common stockholders does not include the effects of the gain or loss from revaluation of the preferred stock warrant liability because it assumes that the conversion of convertible preferred stock into common stock had occurred on the later of January 1, 2016 or the issuance date of the convertible preferred stock.

The unaudited pro forma basic and diluted weighted average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2016 and the three months ended March 31, 2017 give effect, upon a qualified initial public offering, to (i) the automatic conversion of all shares of convertible preferred stock outstanding as of December 31, 2016 and March 31, 2017 into 16,101,970 shares of common stock, and (ii) the outstanding warrants to purchase preferred stock becoming warrants to purchase shares of common stock, in each case as if the proposed initial public offering had occurred on the later of January 1, 2016 or the issuance date of the convertible preferred stock.

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

13. NET LOSS PER SHARE AND UNAUDITED PRO FORMA NET LOSS PER SHARE (Continued)

Unaudited pro forma basic and diluted net loss per share attributable to common stockholders were calculated as follows:

	Year Ended December 31, 2016	Three Months Ended March 31, 2017
		(unaudited)
Numerator:		
Net loss	$ (33,167)	$ (9,759)
Change in fair value of preferred stock warrant liability	(122)	36
Pro forma net loss attributable to common stockholders	$ (33,289)	$ (9,723)
Denominator:		
Weighted average common shares outstanding—basic and diluted	1,181,429	1,181,429
Pro forma adjustment to reflect assumed automatic conversion of convertible preferred stock upon the closing of the proposed initial public offering	13,924,914	16,101,970
Pro forma weighted average common shares outstanding—basic and diluted	15,106,343	17,283,399
Pro forma net loss per share attributable to common stockholders—basic and diluted	$ (2.20)	$ (0.56)

14. COMMITMENTS AND CONTINGENCIES

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

On June 30, 2016, the lease was amended to extend the term from January 31, 2017 to January 31, 2019. In connection with the lease agreement, the Company issued a letter of credit to the landlord for $84. The Company secured the letter of credit using restricted cash for the full amount of the letter. The restricted cash as of December 31, 2015 and 2016 and March 31, 2017 (unaudited) is included in other noncurrent assets in the accompanying balance sheets.

Total rent expense for the lease for the years ended December 31, 2015 and 2016 and three months ended March 31, 2016 and 2017 (unaudited), which is recorded on a straight-line basis, was $321, $338, $79 and $97, respectively.

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

14. COMMITMENTS AND CONTINGENCIES (Continued)

At December 31, 2016, future minimum commitments due under the lease are as follows:

Year Ending December 31,	
2017	$ 396
2018	410
2019	34
2020	—
Total minimum lease payments	$ 840

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

After 2016 and until the first commercial sale of product, the minimum annual payment will be $38. 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. 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 $152, $169, $9 and $18 for the years ended December 31, 2015 and 2016 and three months ended March 31, 2016 and 2017 (unaudited), respectively.

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

The Company's minimum obligations due under its license agreements as of December 31, 2016, are as follows:

Year Ending December 31,	
2017	$ 43
2018	43
2019	38
2020	—
Total minimum license payments	$ 124

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

14. COMMITMENTS AND CONTINGENCIES (Continued)

The Company entered into a commercial supply agreement with Catalent Pharma Solutions, LLC to manufacture commercial supplies of KPI-121 1.0% and KPI-121 0.25%, with annual minimum purchase requirements. Under the minimum unit purchase requirements, if both KPI-121 1.0% and KPI-121 0.25% are approved for commercial sale, the Company has a minimum payment obligation in the first 12-month period of approximately $1.2 million, along with certain fees in connection with validation and stability test services and commercialization ramp-up.

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

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

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

As of December 31, 2015 and 2016 and March 31, 2017 (unaudited), the Company had not experienced any losses related to these indemnification obligations, and no claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and has no amount accrued related to these contingencies. The Company does not expect these indemnifications to have a material adverse effect on these financial statements.

15. DEFINED CONTRIBUTION PLAN

The Company has a 401(k) defined contribution plan (the "401(k) Plan") for substantially all of its employees. Eligible employees may make pretax contributions to the 401(k) Plan up to statutory limits.

In January 2017, the Board approved a discretionary matching contribution to be made under the 401(k) Plan in an amount equal to 50% of the first 2% of compensation contributed to the 401(k) Plan by each participant. The Company made matching contributions of $20 to the 401(k) Plan during the three months ended March 31, 2017 (unaudited).

16. RELATED PARTIES

The Company has engaged in the following related-party transactions:

A founder, who is also a stockholder and director, serves as a consultant to the Company. The individual is employed by a university, which has no relationship to the Company. The Company paid the individual $60 in each of 2015 and 2016 and $15 in each of the three months ended March 31, 2016 and 2017 (unaudited) for the consulting services which are included in research and development expense in the accompanying statements of operations.

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

17. SUBSEQUENT EVENTS

The Company evaluated subsequent events through March 30, 2017, the date on which the December 31, 2016 financial statements were originally issued and June 2, 2017, the date on which the interim financial statements were issued. For each of these financial statement periods, the Company also evaluated subsequent events through July 10, 2017, the date on which the retroactively revised consolidated financial statements were reissued (as a result of the reverse stock split discussed below).

Automatic Conversion of Common Stock

On July 1, 2017 the Board approved a further amendment to the Company's Amended and Restated Certificated of the Incorporation, as amended to eliminate the minimum price per share of Common Stock for an underwritten public offering that would result in the automatic conversion of all outstanding shares of the Company's Series Seed, Series A, Series B, Series B-1 and Series C Preferred Stock. This amendment became effective on July 7, 2017.

Reverse Stock Split

On July 5, 2017, the Board approved a one-for-5.2083 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for the Company's Convertible Preferred Stock (see Note l0). Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios. The reverse stock split became effective on July 7, 2017.

2017 Equity Incentive Plan

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

KALA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

17. SUBSEQUENT EVENTS (Continued)

2017 Employee Stock Purchase Plan

On July 5, 2017, the Company's stockholders approved the 2017 Employee Stock Purchase Plan (the "2017 ESPP"), which will become effective upon the effectiveness of the registration statement for the Company's initial public offering. Under the 2017 ESPP the Company may issue up to an aggregate of (i) 223,341 shares of Common Stock, plus (ii) an annual increase to be added on the first day of each fiscal year, commencing on January 1, 20l9 and continuing for each fiscal year until, and including, the fiscal year ending December 31, 2029, equal to the least of (a) 893,441 shares of Common Stock, (b) 1% of the outstanding shares on such date and (c) an amount determined by the Board; provided that no offering under such plan shall commence prior to the closing of the Offering.

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6,000,000 Shares

Common Stock

Prospectus

J.P. Morgan **BofA Merrill Lynch**

Wells Fargo Securities

Wedbush PacGrow

July 19, 2017

Until August 13, 2017 (25 days after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.