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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2017
OR

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

For the transition period from to
Commission file number 001-38150

KALA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**Nasdaq Global Select Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). YES ☒ NO ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

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

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

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

As of June 30, 2017, the last day of the registrant's most recently completed second fiscal quarter, there was no public market for the registrant's Common Stock. The registrant's Common Stock began trading on the NASDAQ Global Select Market on July 20, 2017. As of March 26, 2018, the aggregate market value of the Common Stock held by non-affiliates of the registrant was approximately $220.4 million, based on the closing price of the registrant's common stock on March 26, 2018.

There were 24,556,094 shares of Common Stock ($0.001 par value) outstanding as of March 26, 2018.

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References to Kala

Throughout this Annual Report on Form 10-K, the "Company," "Kala", "Kala Pharmaceuticals," "we," "us," and "our," except where the context requires otherwise, refer to Kala Pharmaceuticals, Inc. and its consolidated subsidiary, and "our board of directors" refers to the board of directors of Kala Pharmaceuticals, Inc.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this Annual Report on Form 10-K, 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 Annual Report on Form 10-K include, among other things, statements about:

- our plans to develop and commercialize INVELTYS™ (KPI-121 1.0%), KPI-121 0.25% and any other product candidates, if they are approved;
- the timing of and our ability to obtain and maintain regulatory approvals for INVELTYS;
- the timing of and our ability to submit applications for, obtain and maintain regulatory approvals for KPI-121 0.25% and other product candidates;
- our expectations regarding our ability to fund our operating expenses and capital expenditure requirements with our cash on hand;
- the potential advantages of our product candidates;
- the rate and degree of market acceptance and clinical utility of our products;
- our estimates regarding the potential market opportunity for our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- our estimates regarding expenses, future revenue, timing of any future revenue, capital requirements and needs for additional financing;
- the impact of government laws and regulations;
- our competitive position;
- developments relating to our competitors and our industry;
- our ability to maintain and establish collaborations or obtain additional funding; and

- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart our Business Startups Act of 2012.

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 Annual Report on Form 10-K, 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 Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K and have filed as exhibits to this Annual Report on Form 10-K 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 Annual Report on Form 10-K are made as of the date of this Annual Report on Form 10-K, and we do not assume any obligation to update any forward-looking statements except as required by applicable law.

This Annual Report on Form 10-K 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.

Part I

Item 1. 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 loteprednol etabonate, or LE, a corticosteroid designed for ocular applications, resulting in two lead product candidates. These product candidates are INVELTYS™ (KPI-121 1.0%) for the treatment of inflammation and pain following ocular surgery, for which we have submitted a new drug application, or NDA, and KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. The brand name INVELTYS has been conditionally approved by the U.S. Food and Drug Administration, or the FDA.

KPI-121 0.25% is our product candidate for patients with dry eye disease utilizing a two-week course of therapy. In January 2018, we announced topline results from two completed Phase 3 clinical trials, which we refer to as STRIDE 1 and STRIDE 2 (STRIDE - **S**hort **T**erm **R**elief **I**n **D**ry **E**ye), evaluating the safety and efficacy of KPI-121 0.25% versus placebo in patients with dry eye disease. In STRIDE 1, statistical significance was achieved for the primary sign endpoint of conjunctival hyperemia and the primary symptom endpoint of ocular discomfort severity change from baseline to day 15 in the intent to treat, or ITT, population; in addition, statistical significance was also achieved in STRIDE 1 for a second pre-specified primary symptom endpoint of ocular discomfort severity change from baseline to day 15 in patients with more severe baseline ocular discomfort. In STRIDE 2, statistical significance was achieved for the primary sign endpoint of conjunctival hyperemia, but statistical significance was not achieved for the primary symptom endpoint of ocular discomfort severity. KPI-121 0.25% was generally well tolerated in both STRIDE 1 and STRIDE 2, with no clinically significant treatment-related adverse events observed during the course of either trial, and with elevations in interocular pressure, or IOP in both trials similar to placebo. We expect to meet with the FDA in the second quarter of 2018 to discuss the results of STRIDE 1 and STRIDE 2 and potential next steps for our dry eye disease program. If approved, KPI-121 0.25% could be the first FDA-approved product for the temporary relief of the signs and symptoms of dry eye disease.

In December 2017, the FDA accepted for filing our NDA for the approval of INVELTYS, our topical twice-a-day product candidate, for the treatment of inflammation and pain following ocular surgery. The FDA has set August 24, 2018 as the Prescription Drug User Fee Act, or PDUFA, action goal date for our NDA. If approved, INVELTYS could be the first FDA-approved ocular corticosteroid product with a twice-a-day dosing regimen for the treatment of post-operative inflammation and pain. Other approved topical ocular corticosteroid products for this indication are dosed four times a day. Supporting the NDA submission are data from two completed Phase 3 clinical trials of INVELTYS in patients with inflammation and pain following cataract surgery, which is the most common type of ocular surgery in the United States. The first Phase 3 clinical trial was conducted in 2014 and was designed to evaluate INVELTYS 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 for both INVELTYS and KPI-121 0.25% when compared to placebo. Both INVELTYS 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, the second, confirmatory Phase 3 clinical trial was completed, in which administration of INVELTYS two times a day achieved statistical significance compared to placebo 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 medications and all secondary endpoints. INVELTYS was well tolerated with no treatment-related significant adverse events observed during the course of the trial.

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 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 INVELTYS, we are seeking FDA approval under Section 505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act, or the FDCA, which we plan to rely on for the approval of KPI-121 0.25% as well. We have retained worldwide commercial rights for our current product candidates. If INVELTYS and KPI-121 0.25% receive marketing approval, we expect to commercialize both in the United States, and we have started to build a commercial infrastructure to do so, with our own focused, specialty sales force. If INVELTYS receives marketing approval, we expect our commercial organization will initially consist of approximately 75 sales and marketing personnel. If KPI-121 0.25% is approved for the short-term treatment of dry eye disease, we expect to further expand our sales force by up to an additional 100 personnel. We expect to commercialize in the United States any of our other product candidates that receive marketing approval as well. In anticipation of the potential to commercialize our product candidates in other global markets, 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:

Program	Pre-clinical	Phase 1	Phase 2	Phase 3	Registration	Expected Milestones and Planned Next Steps
KPI-121 0.25% for Temporary relief of the signs and symptoms of dry eye disease	Completed two Phase 3 trials					▪ Topline results announced in January 2018
INVELTYS™ (KPI-121 1%) for Treatment of inflammation and pain following ocular surgery	Completed two Phase 3 trials					▪ NDA filed in October 2017 ▪ PDUFA target date of August 24, 2018
MPP rTKI for Retinal Diseases	Lead compound selected					▪ Complete evaluation of our lead compound, KPI-285, for retinal disease

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. Restasis had sales in 2017 of approximately $1.41 billion in the United States. Xiidra, which was commercially launched in the United States in August 2016, had sales in 2017 of approximately $259 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 June 2016, we initiated two Phase 3 clinical trials, STRIDE 1 and STRIDE 2 each with enrollment of over 900 dry eye patients, comparing KPI-121 0.25% to placebo, both administered four times a day for 14 days. We announced topline results from both trials in January 2018. Statistical significance was achieved for the primary sign and both pre-specified primary symptom endpoints in STRIDE 1. Statistical significance was achieved for the primary sign endpoint in STRIDE 2 with a trend towards a treatment effect for the primary symptom endpoint. KPI-121 0.25% was generally well tolerated in both STRIDE 1 and STRIDE 2, with no clinically significant treatment-related adverse events observed during the course of either the trial. We expect to meet with the FDA in the second quarter of 2018 to discuss the results of STRIDE 1 and STRIDE 2 and potential next steps for our dry eye disease program.

INVELTYS 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.

INVELTYS, our twice-a-day product candidate for the treatment of inflammation and pain following ocular surgery, has completed Phase 3 clinical trials and the FDA accepted our NDA for filing in December 2017. We believe that INVELTYS 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 INVELTYS may be attractive to patients and prescribing clinicians.

In each of our two successfully completed Phase 3 clinical trials of INVELTYS in patients who had undergone cataract surgery, administration of INVELTYS 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, INVELTYS was well tolerated with no increases in 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.

The FDA has set August 24, 2018 as the PDUFA action goal date for our NDA. Although our Phase 3 trials of INVELTYS are in patients who have undergone cataract surgery, we believe these trials support, and we have submitted our NDA for, an indication of inflammation and pain following ocular surgery. If approved, INVELTYS could be the first FDA-approved product for the treatment of post-operative inflammation and pain with twice daily dosing.

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:

- ***Obtain regulatory approval for, and maximize the commercial potential of, INVELTYS for post-operative inflammation and pain.*** In December 2017, the FDA accepted for filing our NDA for INVELTYS and set a PDUFA date of August 24, 2018. Assuming we receive marketing approval for INVELTYS on or around August 24, 2018, we intend to commercialize INVELTYS in the United States in 2019 with our own specialty sales force that will target ophthalmologists.

- ***Seek and obtain regulatory approval for, and maximize the commercial potential of, KPI-121 0.25% for the treatment of dry eye disease.*** Having received topline data from STRIDE 1 and STRIDE 2 for KPI-121 0.25%, we expect to meet with the FDA in the second quarter of 2018 to discuss the results of these trials and potential next steps for our dry eye disease program. If approved, we intend to commercialize KPI-121 0.25% in the United States with our own specialty sales force that will target ophthalmologists and optometrists. 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 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. We also 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. 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

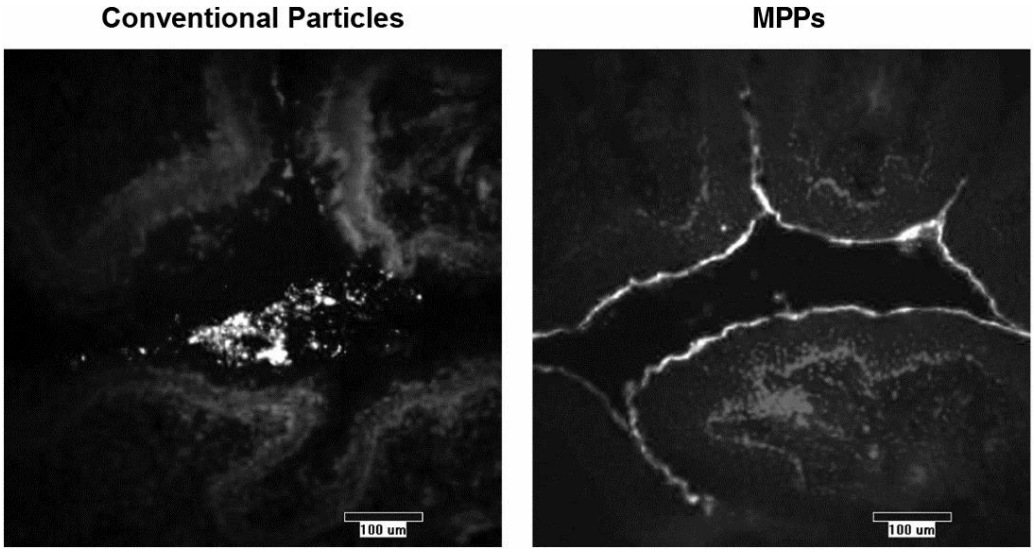
The body is surrounded by boundary tissues that play the important physiological role of preventing foreign bodies from penetrating into the body. The mucus that coats these tissues, the eyes, lung, cervical/vaginal tract and gastrointestinal tract, for example, serves as a protective barrier to trap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

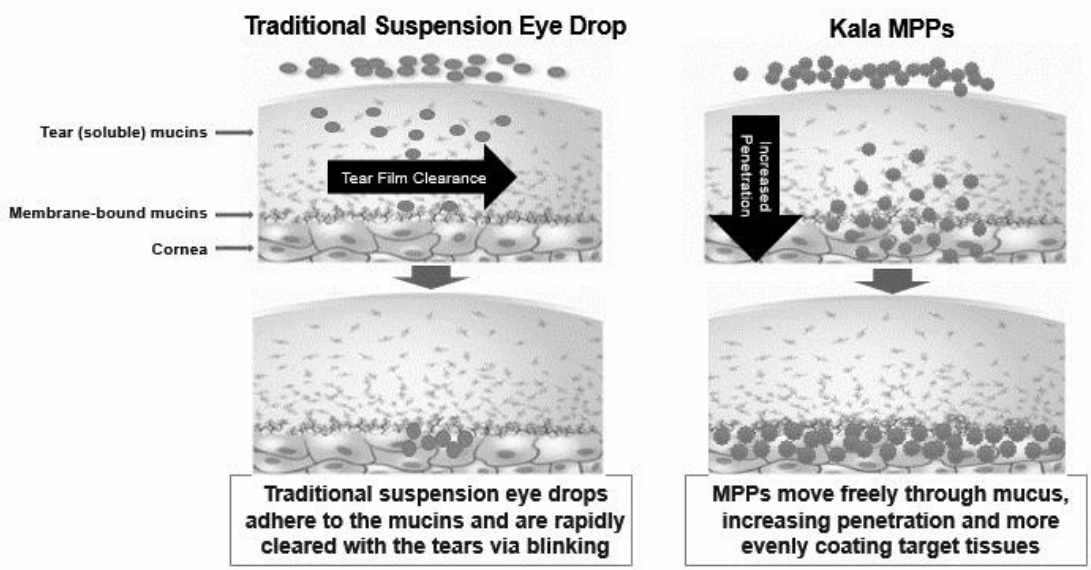
In a preclinical study, MPPs or conventional particles in a hypotonic solution were administered intravaginally to mice. Ten minutes after administration, the vaginal tissues were dissected and stained. The image on the left below shows the distribution of the conventional particles and the image on 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.

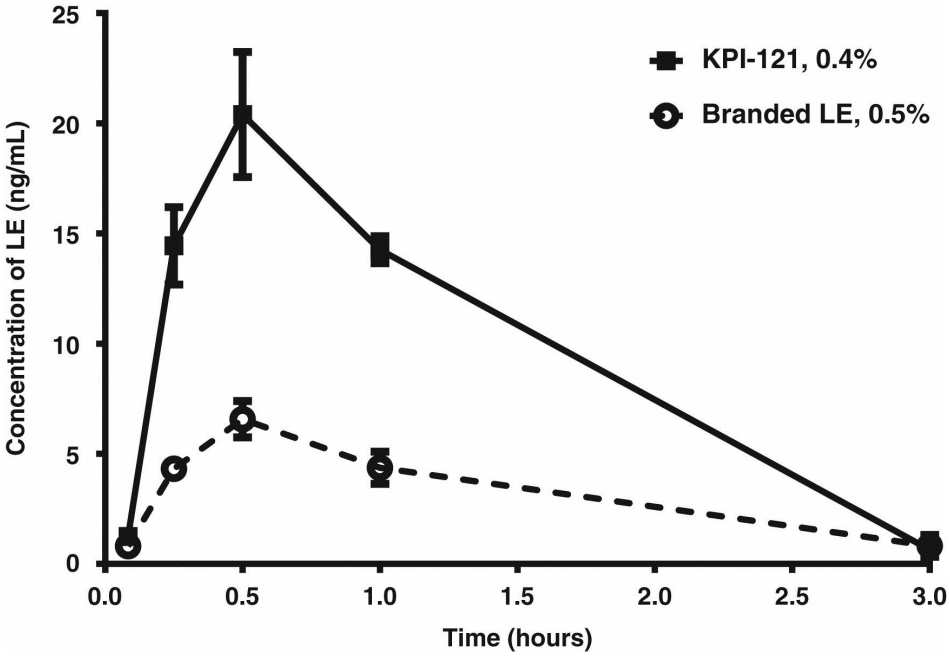
The graphic below illustrates the ability of our MPP drug nanoparticles to penetrate the tear and membrane-bound mucins to reach the ocular surface, as compared to conventional, non-coated particles, which adhere to the mucins in the tear film and are cleared with the tears through blinking.



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.

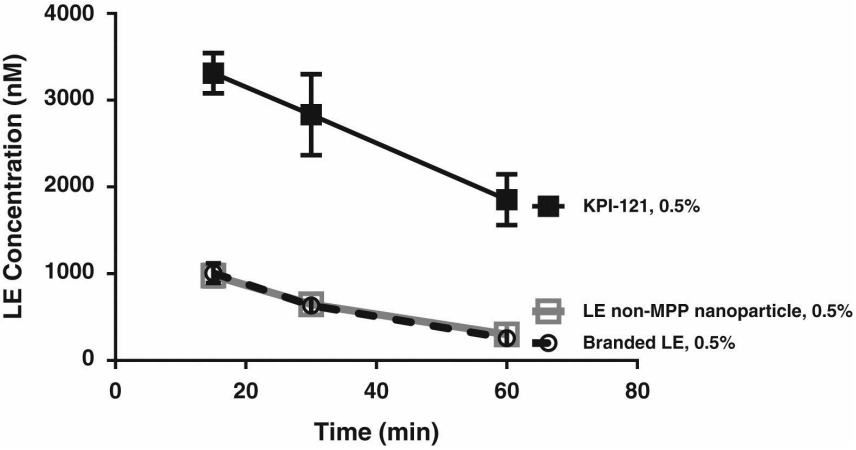
Our initial focus is to leverage our MPP technology to enhance delivery of drugs into the eye. In preclinical studies, KPI-121 demonstrated favorable pharmacokinetic characteristics and increased drug penetration into ocular tissues as compared to a branded form of LE. In a preclinical study of ocular 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 INVELTYS 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, INVELTYS 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:

- INVELTYS, 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.

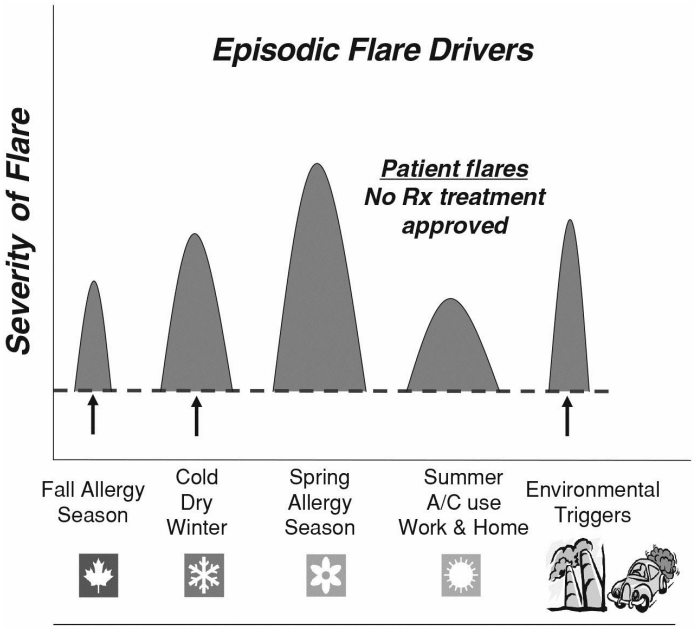
We initially filed an IND for KPI-121 for the treatment of post-operative inflammation and pain following ocular surgery in December 2013, and subsequently amended the IND to also include the treatment of the signs and symptoms of dry eye disease in June 2014. We submitted an NDA for INVELTYS for the treatment of inflammation and pain following ocular surgery in October 2017 under section 505(b)(2) of the FDCA. In December 2017, the FDA accepted the NDA for filing and set a PDUFA date of August 24, 2018. 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) allows us to reference the FDA's prior findings of safety and efficacy for LE to supplement the safety and efficacy data generated in our clinical trials.

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. We believe that less than 15% of patients diagnosed with dry eye disease in the United States use a chronic therapy to treat their 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. In 2017, Restasis had sales of approximately $1.41 billion in the United States. Restasis 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 approximately $259 million in 2017. 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 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

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 and Phase 3 clinical trials, patients treated with KPI-121 0.25% reported reductions in ocular discomfort within 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. In both STRIDE 1 and STRIDE 2, KPI-121 0.25% had comparable rates of IOP to placebo. No serious adverse events were associated with KPI-121 0.25% in either study.
- *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 receive FDA approval of an 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.

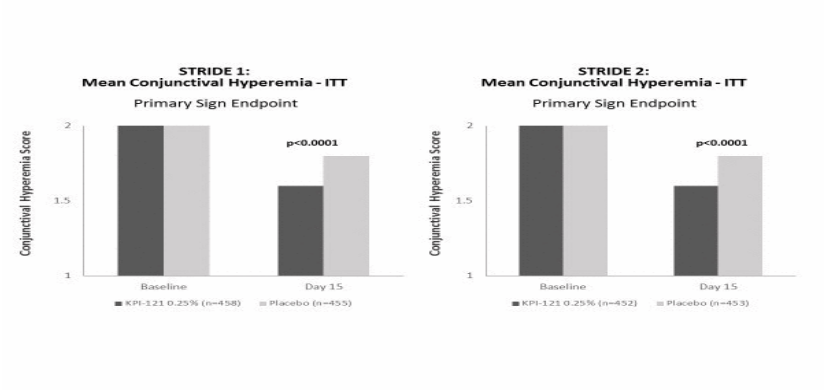
KPI-121 0.25% Phase 3 Clinical Development Program

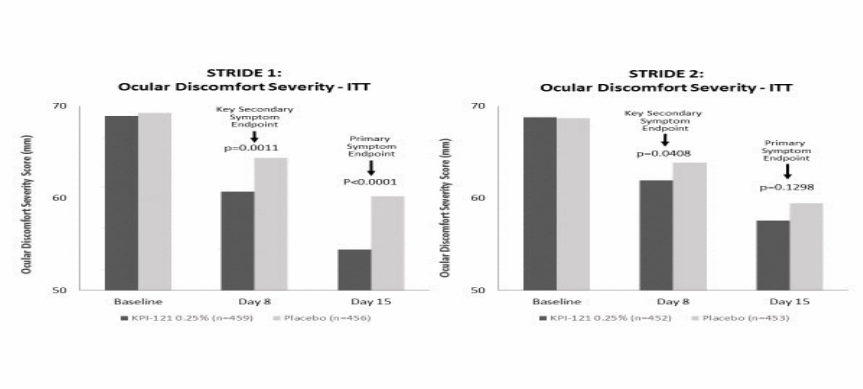
In June 2016, we initiated two Phase 3 clinical trials, STRIDE 1 and STRIDE 2, comparing KPI-121 0.25% to placebo, both administered four times a day for 14 days. These clinical trials were each multicenter, randomized, double-masked, placebo controlled, parallel-arm studies comparing KPI-121 0.25% to placebo each dosed QID for 14 days. Patients who met initial screening and inclusion/exclusion criteria underwent a two week run-in period with placebo dosed in each eye QID for 14 days. Patients who continued to meet inclusion and exclusion criteria after the run-in were randomized to either KPI-121 0.25% or placebo. A total of 918 patients were randomized in STRIDE 1 and 909 patients were randomized in STRIDE 2. Conjunctival hyperemia was measured using a 0 to 4 scale ranging from no hyperemia (score=0) to severe hyperemia (score=4). Ocular discomfort severity was graded daily by the patient over the entire course of the trial using a visual analog grading scale ranging from 0 to 100 mm (0 mm=very mild; 100 mm=very severe) recorded in a patient diary.

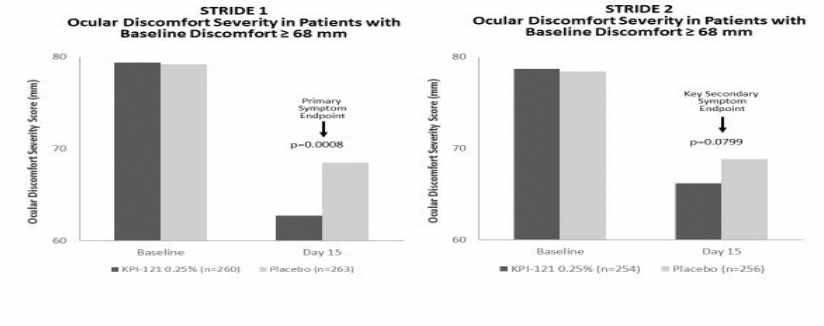
In STRIDE 1, statistical significance was achieved for the primary sign endpoint of conjunctival hyperemia change from baseline to day 15 in the ITT population ($p<0.0001$) and the primary symptom endpoint of ocular discomfort severity change from baseline to day 15 in the ITT population ($p<0.0001$). Statistical significance was also achieved for a second pre-specified primary symptom endpoint of ocular discomfort severity change from baseline to day 15 in patients with more severe baseline ocular discomfort ($p=0.0008$). Statistical significance was not achieved for a second pre-specified primary sign endpoint, inferior corneal staining change from baseline to day 15 ($p=0.1128$). A positive treatment effect for ocular discomfort was also observed in the ITT population at day eight ($p=0.0011$), a key secondary endpoint.

In STRIDE 2, statistical significance was achieved for the primary sign endpoint of conjunctival hyperemia change from baseline to day 15 in the ITT population ($p<0.0001$). Statistical significance was not achieved for the primary symptom endpoint of ocular discomfort severity change from baseline to day 15 in the ITT population ($p=0.1298$), although a positive treatment effect was observed at day eight ($p=0.0408$), a key secondary endpoint. A trend towards a positive treatment effect was observed for ocular discomfort severity change from baseline to day 15 in the patients with more severe baseline ocular discomfort ($p=0.0799$), which was a key secondary endpoint in this trial.

The results for ocular hyperemia, ocular discomfort in the ITT population and ocular discomfort in patients with more severe baseline discomfort are shown below.


STRIDE 1:
Mean Conjunctival Hyperemia - ITT
Primary Sign Endpoint
Conjunctival Hyperemia Score
2
1.5
1
p<0.0001
Baseline
Day 15
KPI-121 0.25% (n=458)
Placebo (n=455)
STRIDE 2:
Mean Conjunctival Hyperemia - ITT
Primary Sign Endpoint
Conjunctival Hyperemia Score
2
1.5
1
p<0.0001
Baseline
Day 15
KPI-121 0.25% (n=452)
Placebo (n=453)


STRIDE 1:
Ocular Discomfort Severity - ITT
Ocular Discomfort Severity Score (mm)
70
60
50
Key Secondary Symptom Endpoint
p=0.0011
Primary Symptom Endpoint
P<0.0001
Baseline
Day 8
Day 15
KPI-121 0.25% (n=459)
Placebo (n=456)
STRIDE 2:
Ocular Discomfort Severity - ITT
Ocular Discomfort Severity Score (mm)
70
60
50
Key Secondary Symptom Endpoint
p=0.0408
Primary Symptom Endpoint
p=0.1298
Baseline
Day 8
Day 15
KPI-121 0.25% (n=452)
Placebo (n=453)


STRIDE 1
Ocular Discomfort Severity in Patients with Baseline Discomfort ≥ 68 mm
Ocular Discomfort Severity Score (mm)
80
70
60
Primary Symptom Endpoint
p=0.0008
Baseline
Day 15
KPI-121 0.25% (n=260)
Placebo (n=263)
STRIDE 2
Ocular Discomfort Severity in Patients with Baseline Discomfort ≥ 68 mm
Ocular Discomfort Severity Score (mm)
80
70
60
Key Secondary Symptom Endpoint
p=0.0799
Baseline
Day 15
KPI-121 0.25% (n=254)
Placebo (n=256)

We have conducted additional analyses on a post-hoc basis of STRIDE 1, STRIDE 2 and our Phase 2 data to better understand our clinical results, inform our developmental plans and potentially support an NDA submission. One key analysis was evaluation of the Phase 2 ocular discomfort data using the same statistical analysis plan as used to test the primary symptom endpoints in the Phase 3 trials. Using this analysis we observe a treatment effect for ocular discomfort at day 15 of similar magnitude as was observed in STRIDE 1 (-5.27 mm difference in Phase 2 compared to -5.44 mm in STRIDE 1) and a p-value of 0.0489. In addition, we performed an analysis of the pooled data from the ITT populations from STRIDE 1 and STRIDE 2, which resulted in an observed positive treatment effect for ocular discomfort at day 15 ($p < 0.0001$). The pooled results in 2 exploratory analyses in subgroups defined by geographical regions of east and west achieved p-values of 0.0071 and 0.0021 respectively and north and south achieved p-values of 0.0002 and 0.0176, respectively. Further, when we analyzed the ocular discomfort data at days 9 through 14 in STRIDE 1 and STRIDE 2 using the same statistical method as day 8 and 15, we observed a positive treatment effect with p values less than 0.002 at all time points between days 8 and 15 in STRIDE 1 and p-values less than 0.05 at 6 of 8 time points in STRIDE 2. Although post-hoc analyses may be given less weight by regulatory authorities than pre-specified analyses, we believe these analyses may provide important information regarding KPI-121 0.25% and may be helpful in informing our potential NDA submission.

KPI-121 0.25% was well tolerated in both trials. The most common adverse event observed in STRIDE 1 was instillation site pain, which was observed in 6.1% of patients in both the KPI-121 0.25% treatment group and the placebo group. The only other adverse event reported by greater than 1% of patients in STRIDE 1 was eye irritation, which was reported in 1.1% of patients on KPI-121 0.25% vs. 1.5% of patients on placebo. Elevations in IOP, a known side effect with topical corticosteroid administration, were similar between the two groups in STRIDE 1 with 0.4% in the KPI-121 0.25% group experiencing an increase in IOP of 5 mm of mercury (mmHg) or greater resulting in an IOP of 21 mmHg or greater compared to 0.4% in the placebo group.

The most common adverse event observed in STRIDE 2 was instillation pain which was reported by 5.7% of patients in the KPI-121 0.25% treatment group vs. 4.4% in the placebo group. The only other adverse event reported by greater than 1% of patients was blurred vision, which was reported in 0.2% of patients on KPI-121 0.25% vs. 1.3% of patients on placebo. Elevations in IOP were similar between the two groups with 1.1% in the KPI-121 group experiencing an increase in IOP of 5 mmHg or greater resulting in an IOP of 21 mmHg or greater compared to none in the placebo group.

We expect to meet with the FDA in the second quarter of 2018 to discuss the results of STRIDE 1 and STRIDE 2 and potential next steps for our dry eye disease program, which may include conducting additional Phase 3 trials of KPI-121 0.25%.

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 at day 29, 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. A positive treatment effect for hyperemia was also achieved at day 15 ($p=0.0090$). In addition, a 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. Patients treated with KPI-121 0.25% also showed reductions in

the symptom endpoint of ocular discomfort severity at days 29 and 15 but did not reach statistical significance for this endpoint based on the analysis that was pre-defined in the statistical analysis plan.

Following completion of our Phase 3 trials, we conducted additional analysis on a post-hoc basis of our Phase 2 data using the same statistical analysis plan as used to test the primary symptom endpoints in the Phase 3 trials. Using this analysis we observe a treatment effect for ocular discomfort at day 15 of a similar magnitude as was observed in STRIDE 1 (-5.27 mm difference in Phase 2 compared to -5.44 mm in STRIDE 1) and a p value of 0.0489. Although post-hoc analyses may be given less weight by regulatory authorities than pre-specified analyses, we believe these analyses may provide important information regarding KPI-121 0.25% and may be helpful in informing our potential NDA submission.

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.

INVELTYS 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.

INVELTYS Opportunity in Post-Operative Inflammation and Pain

We believe that INVELTYS 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 INVELTYS 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 INVELTYS.

- *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, INVELTYS had a tolerability profile comparable to placebo, with no treatment-related serious adverse events observed during the course of either Phase 3 trial.

INVELTYS Phase 3 Clinical Development Program

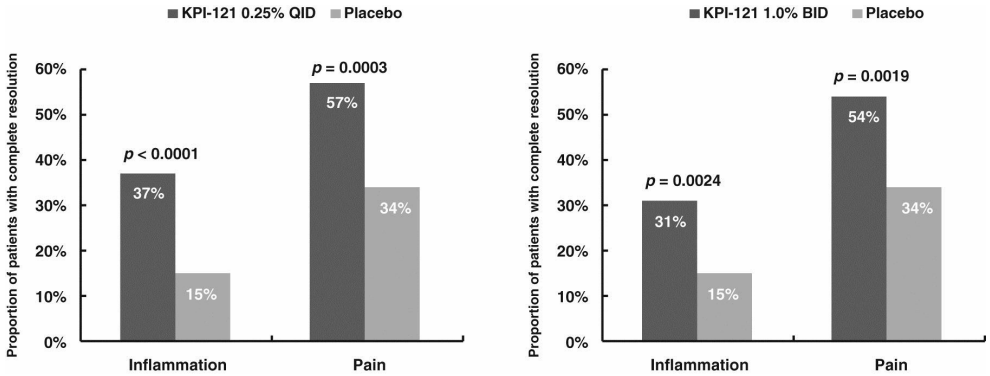
In 2014, we conducted our first Phase 3 multi-center, randomized, double-masked, placebo-controlled, parallel-group trial designed to evaluate two dosing regimens of KPI-121 ophthalmic suspension versus placebo in 380 patients following cataract surgery. Patients who had a threshold degree of ocular inflammation on the day after surgery were randomized to receive either INVELTYS 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 INVELTYS ($p=0.0024$) 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 INVELTYS ($p=0.0019$) 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 INVELTYS and placebo treatment arms who had complete resolution of inflammation and complete resolution of pain at day eight of treatment.



Both INVELTYS 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 INVELTYS 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 INVELTYS 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 INVELTYS 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.

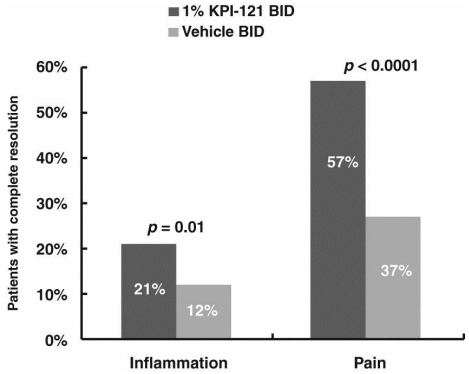
In June 2016, we initiated enrollment in a 520 patient confirmatory double-masked, randomized, controlled Phase 3 clinical trial of INVELTYS to evaluate the safety and efficacy of INVELTYS in subjects with inflammation and pain following cataract surgery. The Phase 3 clinical trial was designed to compare INVELTYS 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 INVELTYS 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 INVELTYS (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 INVELTYS (p<0.0001) compared to placebo. The bar graph below shows the percentage of patients in the INVELTYS and placebo treatment arms who had complete resolution of inflammation and complete resolution of pain at day eight of treatment.



INVELTYS 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).

INVELTYS 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 INVELTYS 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 INVELTYS treatment arm and 2.3% of patients in the placebo arm. Patients in the INVELTYS 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.

In December 2017, the FDA accepted for filing our NDA for the approval of INVELTYS for the treatment of post-operative inflammation and pain following ocular surgery. The FDA has set August 24, 2018 as the PDFUA action goal date for our NDA.

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

Building on the results of our clinical trials for our INVELTYS 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

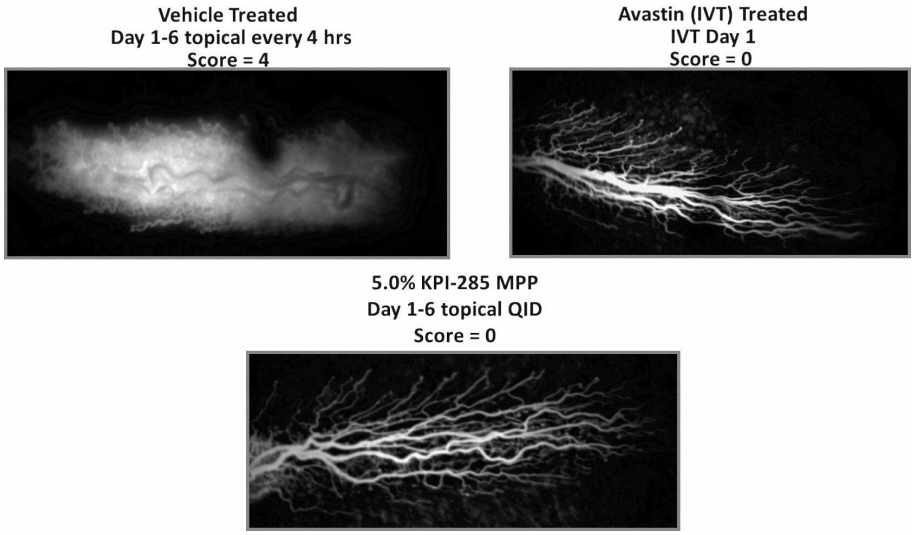
VEGF is a protein that plays a critical role in the formation of new blood vessels and increased permeability, two pathological processes that contribute to the vision loss associated with certain retinal diseases. Several VEGF tyrosine kinase inhibitors have been investigated in AMD patients in clinical 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%, INVELTYS 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 INVELTYS 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. Further, recent successful court challenges to certain patents covering Restasis could cause generic versions of Restasis to become earlier than was previously expected at lower costs.

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. In April 2017, Allergan received marketing authorization from the FDA for the TrueTear Intranasal Tear Neurostimulator. 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. Ocugen recently reported positive Phase 2 results for their combination of brimondine tartrate and loteprednol Etabonate. There also are other product candidates for the treatment of dry eye disease in the United States in earlier stage development. 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 have begun to establish our commercial infrastructure, but do not expect to establish a complete sales force until a product candidate receives marketing approval. If INVELTYS receives marketing approval, we believe our commercial organization will initially consist of approximately 75 sales and marketing personnel. If KPI-121 0.25% is approved for the short-term treatment of dry eye disease, we expect to further expand our sales force by up to an additional 100 personnel. We would expect to conduct most of the buildout of this organization following NDA approval of the applicable 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.

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, which we amended in February 2018, 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 INVELTYS and KPI-121 0.25% for commercial use. The commercial supply agreement has an initial term of eight years from the date either of INVELTYS 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 INVELTYS 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 INVELTYS and KPI-121 0.25%. Under the minimum unit purchase requirements, if both INVELTYS and KPI-121 0.25% are approved for commercial sale, our minimum payment obligation in the first 12-month period would be approximately $1.5 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 October 2017, 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 February 28, 2018, we owned 16 U.S. issued patents and 14 U.S. patent applications, as well as 13 foreign issued patents and 88 foreign patent applications (including Patent Cooperation Treaty, or PCT, applications). We exclusively licensed a total of 15 U.S. issued patents and 18 U.S. patent applications, as well as 20 foreign issued patents and 77 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 two U.S. issued method patents covering KPI-121, and one U.S. patent application, in-licensed from The Johns Hopkins University, or 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;

- one issued U.S. composition-of-matter patent and one patent application in-licensed from JHU, covering INVELTYS and KPI-121 0.25%, and one related issued foreign patent and eight related patent applications owned by us filed in Australia, Canada, China, the European Patent Office, Hong Kong, India, Japan and Mexico, 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 one issued foreign patent and 14 related patent applications owned by us filed in 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;

- 14 owned U.S. issued composition-of-matter patents covering rTKI compounds, including KPI-285, six issued foreign patents, and 55 pending patent applications filed in the United States, Australia, Brazil, Canada, China, the European Patent Office, Hong Kong, India, Japan, South Korea, Mexico, PCT, 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, if permitted under the applicable laws, regulations, and rules and 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 any 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, sublicensable 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 digit 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 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. As of December 31, 2017, we also have paid JHU an aggregate of approximately $299,000 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. In the fourth quarter of 2017, we paid JHU a minimum annual royalty fee of approximately $38,000, and we are obligated to pay JHU annual minimum royalties that will not exceed approximately $113,000 per year in the future. 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 to 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 December 2017, GrayBug terminated its exclusive license from JHU as to one patent family among these patent rights. Pursuant to the JHU settlement agreement, these patent rights are now automatically directly licensed to us under the terms of the JHU license agreement, and we are now responsible for all future patent prosecution costs for these patent rights. In turn, pursuant to the JHU settlement agreement 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, sublicensable, 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 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, or DSMB. 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 2018 is $2,421,495 for an application requiring clinical data. The sponsor of an approved NDA is also subject to a program fee for fiscal year 2018 of $304,162. 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.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt and strives to inform 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. The FDA must implement a protocol to expedite review of responses to inspection reports pertaining to certain drug applications, including applications for drugs in a shortage or drugs for which approval is dependent on remediation of conditions identified in the inspection report.

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 the marketing, labeling, advertising and promotion of prescription drug products placed on the market. This regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet and social media. Promotional claims about a drug's safety or effectiveness are prohibited before the drug is approved. After approval, a drug product generally may not be promoted for uses that are not approved by the FDA, as reflected in the product's prescribing information. In the United States, healthcare professionals are generally permitted to prescribe drugs for such uses not described in the drug's labeling, known as off-label uses, because the FDA does not regulate the practice of medicine. However, FDA regulations impose rigorous restrictions on manufacturers' communications, prohibiting the promotion of off-label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information. If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion, and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, and its implementation regulations, as well as the Drug Supply Chain Security Act, or DSCSA, which regulates the distribution of and tracing of prescription drugs and prescription drug samples at the federal level, and sets minimum standards for the regulation of drug distributors by the states. The PDMA, its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples, and the DSCSA imposes requirements to ensure accountability in distribution and to identify and remove counterfeit and other illegitimate products from the market.

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.

The FDA must establish a priority review track for certain generic drugs, requiring the FDA to review a drug application within eight months for a drug that has three or fewer approved drugs listed in the Orange Book and is no longer protected by any patent or regulatory exclusivities, or is on the FDA's drug shortage list. The new legislation also

authorizes FDA to expedite review of "competitor generic therapies" or drugs with inadequate generic competition, including holding meetings with or providing advice to the drug sponsor prior to submission of the application.

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. For drugs intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of an applicant, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments. In addition, FDA will meet early in the development process to discuss pediatric study plans with drug sponsors. The legislation requires FDA to meet with drug sponsors by no later than the end-of-phase 1 meeting for serious or life-threatening diseases and by no later than 90 days after FDA's receipt of the study plan.

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. With regard to patents, the six-month pediatric exclusivity period will not attach to any patents for which a generic (ANDA or 505(b)(2) NDA) applicant submitted a paragraph IV patent certification, unless the NDA sponsor or patent owner first obtains a court determination that the patent is valid and infringed by a proposed generic product.

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.

Orphan drug exclusivity will not bar approval of another orphan drug under certain circumstances, including if a subsequent product with the same drug for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. With the adoption of recent legislative amendments in

2017, the FDCA reverses prior precedent holding that the Orphan Drug Act unambiguously required the FDA to recognize orphan exclusivity regardless of a showing of clinical superiority.

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 EU clinical trials legislation was passed as a regulation that is directly applicable in all EU 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 2019. 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 trials 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.

Brexit and the Regulatory Framework in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom (U.K.) voted in favor of leaving the European Union (commonly referred to as "Brexit"). Thereafter, on March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The withdrawal of the U.K. from the European Union will take effect either on the effective date of the withdrawal agreement or, in the absence of agreement, two years after the U.K. provides a notice of withdrawal pursuant to the E.U. Treaty. Since the regulatory framework for pharmaceutical products in the U.K. covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the U.K. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the U.K.

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.

These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices that companies may obtain for any product candidates for which they may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Further, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

These healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the prices of approved products and/or the level of reimbursement physicians receive for administering any approved product. Reductions in reimbursement levels may negatively impact prices or the frequency with which products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by President Trump on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, will become effective in 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Congress will likely consider other legislation to replace elements of the ACA, during the next Congressional session.

The Trump Administration has also taken executive actions to undermine or delay implementation of the ACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In October 2017, the President signed a second Executive Order allowing for the use of association health plans and short-term health insurance, which may provide fewer health benefits than the plans sold through the ACA exchanges. At the same time, the Administration announced that it will discontinue the payment of cost-sharing reduction (CSR) payments to insurance companies until Congress approves the

appropriation of funds for such CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA.

A bipartisan bill to appropriate funds for CSR payments was introduced in the Senate, but the future of that bill is uncertain. Further, each chamber of the Congress has put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures has been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA. The Congress will likely consider other legislation to replace elements of the ACA during the next Congressional session. 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.

Employees

As of December 31, 2017, we had 37 full-time employees, including a total of eleven employees with M.D., Sc.D. or Ph.D. degrees. Of these full-time employees, 26 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.

Our Corporate Information

We were incorporated under the laws of the State of Delaware in July 2009. Our office is located at 100 Beaver Street, Suite 201, Waltham, MA 02453, and our telephone number is (781) 996-5252. Our website address is www.kalarx.com.

Available Information

Through our website, we make available free of charge our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act of 1934, or the Exchange Act. We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the Securities and Exchange Commission, or the SEC. You can find, copy and inspect information we file at the SEC's public reference room, which is located at 100 F Street, N.E., Room 1580, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's public reference room. You can review our electronically filed reports and other information that we file with the SEC on the SEC's web site at http://www.sec.gov. We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. In addition, we regularly use our website to post information regarding our business, product development programs and governance, and we encourage investors to use our website, particularly the information in the section entitled "Investors & Media," as a source of information about us.

The information on our website is not incorporated by reference into this Annual Report on Form 10-K and should not be considered to be a part of this Annual Report on Form 10-K. Our website address is included in this Annual Report on Form 10-K as an inactive technical reference only.

Item 1A 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 Annual Report on Form 10-K, including our financial statements and the related notes appearing at the end of this Annual Report on Form 10-K, 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 $42.2 million for the year ended December 31, 2017, $33.2 million for the year ended December 31, 2016 and $16.7 million for the year ended December 31, 2015. As of December 31, 2017, we had an accumulated deficit of $134.4 million. We have not generated any revenues to date from product sales and have financed our operations primarily through our initial public offering, or IPO, private placements of 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 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 INVELTYS™ (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 approval for INVELTYS and establish our sales, marketing and distribution capabilities for INVELTYS in advance of and upon any such approval;
- conduct any necessary clinical trials and other development activities and/or seek marketing approvals for KPI-121 0.25% and any other product candidates;
- pursue the clinical development of KPI-121 for the treatment of other additional indications or for use in other patient populations or, if approved, seek to broaden the label of INVELTYS or KPI-121 0.25%;
- pursue the preclinical and clinical development of product candidates derived from our topically applied MPP receptor Tyrosine Kinase Inhibitor program, or rTKI program, for use in the treatment of retinal diseases;
- expand our sales, marketing and distribution capabilities for our other product candidates, prior to or upon receiving marketing approval;

- scale up our manufacturing processes and capabilities to support commercialization of INVELTYS, for which the FDA has accepted our NDA for filing, KPI-121 0.25% and any of our other product candidates for which we seek and/or obtain marketing approval;
- leverage our proprietary MPP technology to advance additional potential high-value therapeutics into preclinical and clinical development;
- in-license or acquire the rights to other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control, scientific, manufacturing, commercial and management personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company; and
- increase our product liability insurance coverage as we initiate and expand our commercialization efforts.

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

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

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

- obtaining marketing approval for INVELTYS, for which the FDA has accepted our NDA for filing, 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;
- hiring and building a full commercial organization required for the marketing, selling and distributing for those products which we obtain marketing approval.
- achieving an adequate level of market acceptance of and obtaining and maintaining coverage and adequate reimbursement from third-party payors for any products we commercialize; and
- obtaining, maintaining and protecting our intellectual property rights.

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

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

We are an early-stage company. Our operations to date have been limited to organizing and staffing our company, acquiring rights to intellectual property, business planning, raising capital and developing KPI-121 and other product candidates. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

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

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

We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we seek marketing approval and prepare for commercialization of INVELTYS, seek marketing approval for KPI-121 0.25%, and continue the development of and potentially seek marketing approval for other product candidates. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we commercialize INVELTYS, if approved, and advance our preclinical activities and clinical trials. In addition, our expenses will further increase if we are required to conduct any additional trials for INVELTYS or KPI-121 0.25%. We also expect to devote additional financial resources to conducting research and development, initiating clinical trials of, and potentially seeking regulatory approval for, other potential product candidates, including product candidates that we may develop using our rTKI program.

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

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

- whether we determine to conduct any additional clinical trials or other activities for KPI-121 0.25% prior to submitting an NDA to the FDA;
- the costs, timing and outcome of regulatory review of INVELTYS and KPI-121 0.25%, including whether any additional clinical trials or other activities are required for approval or label expansion;

- the progress, costs and results of any clinical activities for regulatory review of INVELTYS and KPI-121 0.25% outside of the United States;
- the costs and timing of process development and manufacturing scale-up activities associated with INVELTYS and KPI-121 0.25%;
- the costs of commercialization activities for INVELTYS and/or KPI-121 0.25% if we receive marketing approval and pre-commercialization costs for INVELTYS and/or KPI-121 0.25% incurred prior to receiving, any such marketing approval, including the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities;
- assuming receipt of marketing approval, the amount of revenue received from commercial sales of INVELTYS and KPI-121 0.25% or any other product candidates;
- our ability to establish and maintain strategic collaborations, licensing or other agreements and the financial terms of such agreements;
- the scope, progress, results and costs of any product candidates that we may derive from any other product candidates that we may develop;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property-related claims.

We believe that our existing cash on hand as of December 31, 2017, will enable us to fund our planned operating expenses, debt service obligations and capital expenditure requirements for at least the next twelve months. We have based these estimates on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. As a result, we could deplete our available capital resources sooner than we currently expect.

Conducting preclinical testing and clinical trials and seeking market approvals are time-consuming, expensive and uncertain processes that take years to complete. Although the FDA has accepted for filing our NDA for INVELTYS, we may not receive approval to commercialize the product candidate, and even if we do, the resulting revenue may not enable us to achieve profitability. Additionally, we are currently considering our regulatory plans for KPI-121 0.25% and may determine to conduct an additional Phase 3 trial prior to submission or an NDA or to potentially expand the label of KPI-121 0.25% if we receive marketing approval for a more narrow indication than we are targeting. In addition, we may never generate the necessary data or results required to obtain regulatory approval of any other products with the market potential sufficient to enable us to achieve profitability. We do not expect to generate revenue from sales of INVELTYS or any other product candidates until at least 2019, if at all. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. Adequate additional financing may not be available to us on acceptable terms, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and marketing and distribution arrangements. 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. 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 December 31, 2017, we had $18.9 million of outstanding borrowings under our a venture debt facility, or the 2014 Debt Facility, which we began repaying following the end of an interest-only period, in October 2017, in equal monthly installments until October 2020. 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 our 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. Nonetheless, we may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt and funds from external sources may not be available on acceptable terms, if at all. In addition, a failure to comply with the covenants under our 2014 Debt Facility could result in an event of default and acceleration of amounts due. If an event of default occurs and the lender accelerates the amounts due under our 2014 Debt Facility, we may not be able to make accelerated payments, and the lender could seek to enforce security interests in the collateral securing such indebtedness.

Risks Related to Product Development

We are dependent on the success of our lead product candidates, INVELTYS and KPI-121 0.25%. If we are unable to successfully obtain marketing approvals for INVELTYS 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 INVELTYS for the post-operative treatment of inflammation and pain following ocular surgery and KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. There is a significant risk that we will fail to successfully obtain marketing approval and/or commercialize INVELTYS and/or KPI-121 0.25%. Following completion of two Phase 3 clinical trials, we submitted an NDA for INVELTYS for the treatment of inflammation and pain following ocular surgery in October 2017. In December 2017, the FDA accepted the INVELTYS NDA for filing and set a PDUFA date of August 24, 2018. However, the FDA's decision to accept the NDA for filing and set a PDUFA date does not indicate that it has made any decision regarding approval nor does it guarantee approval by August 24, 2018, if at all. In January 2018, we announced that we had completed two Phase 3 clinical trials evaluating KPI-121 0.25%, STRIDE 1 and STRIDE 2, evaluating the safety and efficacy of KPI-121 0.25% versus placebo in patients with dry eye disease. In STRIDE 1, statistical significance was achieved for both primary endpoints. However, in STRIDE 2 we did not achieve statistical significance for the primary symptom endpoint of ocular discomfort severity. We expect to meet with the FDA in the second quarter of 2018 to discuss the results of STRIDE 1 and STRIDE 2 and potential next steps for our dry eye disease program, including whether an additional Phase 3 clinical trial will be required or recommended prior to our submission for an NDA. Even if not required by the FDA, following this meeting, we may determine to conduct an additional Phase 3 clinical trial of KPI-121 0.25% prior to or following submission of an NDA. We cannot accurately predict when or if either of these product candidates will receive marketing approval. Our ability to generate product revenues will depend on our obtaining marketing approval for, and commercializing one or both of, INVELTYS and KPI-121 0.25%.

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

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

In December 2017, the FDA accepted for filing our NDA for INVELTYS, which included results from our Phase 3 clinical trials evaluating INVELTYS in patients with inflammation and pain following cataract surgery, in which INVELTYS achieved statistical significance for both of its primary efficacy endpoints and all secondary endpoints. 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 INVELTYS to the satisfaction of the FDA or other regulatory authorities. If the FDA's interpretation of our data differs from ours, the FDA could determine that we have not adequately demonstrated the safety and efficacy of INVELTYS and determine not to approve the NDA without further clinical trials or data, or at all.

In January 2018, we announced that we had completed two Phase 3 clinical trials evaluating KPI-121 0.25%, STRIDE 1 and STRIDE 2, evaluating the safety and efficacy of KPI-121 0.25% versus placebo in patients with dry eye disease. In STRIDE 1, statistical significance was achieved for both primary endpoints. However, in STRIDE 2 we did not achieve statistical significance for the primary symptom endpoint of ocular discomfort severity. We expect to meet with the FDA in the second quarter of 2018 to discuss the results of STRIDE 1 and STRIDE 2 and potential next steps for our dry eye disease program. If the FDA determines that we have not sufficiently demonstrated efficacy for both signs and symptoms of dry eye, they may require us to conduct additional clinical trials to support approval of KPI-121

0.25% for temporary relief of signs and symptoms of dry eye disease. If we conduct additional clinical trials of KPI-121 0.25%, our expenses will significantly increase and could delay or halt our ability to obtain marketing approval. Regulatory authorities outside the United States, in particular in the European Union, have not issued guidance on the requirements for approval of a dry eye drug. Our Phase 3 clinical trials of KPI-121 0.25% may not be sufficient to support an application for marketing approval outside the United States. Further, if regulatory authorities outside the United States do not accept the data from any trial we conduct in the United States, in particular if the European Union does not allow us to utilize the results from our Phase 3 clinical trials of KPI-121 0.25% pursuant to the Article 10(3) submission pathway or otherwise, we will likely need to conduct additional trials to obtain marketing approval in such jurisdiction, which would be costly and time-consuming and could delay or permanently halt our ability to commercialize the applicable product candidates in the applicable jurisdictions.

We performed additional analyses on a post-hoc basis on the results of our completed Phase 2 clinical trial for KPI-121 0.25% for the purpose of designing our Phase 3 clinical trials for KPI-121 0.25%. Following completion of our Phase 3 trials we conducted additional analyses on a post-hoc basis of the data from both our Phase 3 and Phase 2 clinical trials to support our planned NDA submission and inform our development plan. We may also conduct additional post-hoc analyses on the results of clinical trials in the future. Post-hoc analyses performed after unmasking trial results can result in the introduction of bias, may not be predictive of success in any future clinical trials and are given less weight by regulatory authorities than pre-specified analyses.

If we are required to conduct additional clinical trials or other testing of KPI-121 0.25% or INVELTYS 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 INVELTYS, 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 product candidates we develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States.

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

- the prevalence and severity of the ophthalmic disease or condition under investigation;
- the patient eligibility criteria for the trial in question;
- the perceived risks and benefits of the product candidate under study;
- the existence of existing treatments for the indications for which we are conducting clinical trials;

- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of clinicians;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients;
- the conducting of clinical trials by competitors for product candidates that treat the same indications as our product candidates; and
- the lack of adequate compensation for prospective patients.

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

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

If INVELTYS, KPI-121 0.25% or any other product candidates are associated with serious adverse events or undesirable side effects in clinical trials or following approval and/or commercialization, or if any of our product candidates have characteristics that are unexpected, we may need to abandon their development or limit development or marketing 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 INVELTYS and KPI-121 0.25% have been eye pain, instillation site pain, blurred vision and photophobia, which is discomfort or pain due to exposure to light. There have been no serious adverse events related to the administration of KPI-121 reported in any of our clinical trials to date. Increases in intraocular pressure, or IOP, and cataract formation are additional adverse effects associated with the use of corticosteroids. We have no clinical safety data on or patient exposure to either KPI-121 concentration for longer than 28 days. Our understanding of the relationship between our products and these adverse effects may change as we gather more information, and additional unexpected adverse effects may occur. Compounds that initially show promise in clinical or earlier stage testing for treating ophthalmic disease may later be found to cause side effects that prevent further development and commercialization of the compound. In addition, adverse events which had initially been considered unrelated to the study treatment may later, even following approval and/or commercialization, be found to be caused by the study treatment. Moreover, incorrect or improper use of our product 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 INVELTYS, 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 INVELTYS, 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 the FDA has accepted for filing our NDA seeking approval of INVELTYS with twice-a-day dosing, doctors may continue to rely on ocular steroids other than INVELTYS and other treatments rather than INVELTYS, if and when it is approved for marketing by the FDA. It is also possible that other therapeutics will be approved for treatment of inflammation and pain following ocular surgery with twice-a-day or less frequent dosing.

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

candidates, if approved. As a result, clinicians, patients and third-party payors may choose to rely on such products rather than our product candidates.

If INVELTYS 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 INVELTYS, 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 INVELTYS, 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 INVELTYS, 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 INVELTYS, KPI-121 0.25% or any other product candidates that we may develop if and when they are approved.

We have only recently begun to establish 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.

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

Factors that may inhibit our efforts to commercialize INVELTYS, 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, we plan to seek marketing approval and explore commercialization of KPI-121 0.25% in certain markets outside the United States, including the European Union, utilizing a variety of collaboration, distribution and other marketing arrangements with one or more third parties. Our product revenues and our profitability, if any, under any such third-party collaboration, distribution or other marketing arrangements are likely to be lower than if we were to market, sell and distribute KPI-121 0.25% ourselves. We may also consider seeking marketing approval outside the United States for other product candidates in the future. If we decide to seek regulatory approval for any of our product candidates outside the United States, we may need to seek additional patent approvals, seek licenses to patents held by third parties and/or face claims of infringing third-party patent rights.

In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute INVELTYS, 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 INVELTYS, 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 INVELTYS, 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 competitors include major pharmaceutical companies with significantly greater financial resources. 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 INVELTYS, 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.

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; devices such as the TrueTear Intranasal Tear Neurostimulator, which received marketing authorization from the FDA in April 2017; off-label prescription drugs, including topical steroid drops and/or other similar products, which are prescribed on occasion for treatment of dry eye disease; on-label prescription drugs, including Restasis 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.'s MIM-D3, Sun Pharmaceuticals' Seciera™ and ReGenTree's RGN-259. In addition, Ocugen recently reported positive Phase 2 results for their combination of brimondine tartrate and loteprednol Etabonate. There are also other product candidates for the treatment of dry eye disease in the United States in earlier stage development, such as Aldeyra Therapeutics' ADX-102

ophthalmic solution. Further, Allergan was granted marketing authorization by the FDA for TrueTear, a nasal neurostimulation medical device that is intended to temporarily increase tear production.

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

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

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Given that we are developing products that utilize a known FDA-approved corticosteroid, our product candidates, if approved, may face competition from generic and branded versions of existing drugs based on corticosteroids that are administered in a different manner.

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

We will rely on third-party contract manufacturers to manufacture commercial supplies of INVELTYS and KPI-121 0.25%. Specifically, we will rely on Catalent Pharma Solutions, LLC, or Catalent, to manufacture and supply to us a minimum amount of INVELTYS and KPI-121 0.25% for commercial use; Alliance Contract Pharma, LLC, or Alliance, for manufacturing bulk KPI-121 concentrates, and Chemo Iberica SA, or Chemo Iberica, to manufacture and supply to us a bulk supply of loteprednol, or LE. We expect to rely on third parties to manufacture clinical supplies of 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 INVELTYS, 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 INVELTYS, 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 INVELTYS, 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 INVELTYS, 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 INVELTYS, 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 INVELTYS for the treatment of inflammation and pain following cataract surgery and our completed Phase 2 clinical trial and Phase 3 clinical trials of KPI-121 0.25% in patients with dry eye disease. 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 could delay our product development activities.

Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, 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 INVELTYS and KPI-121 0.25% for commercialization and for clinical trials and commercialization of any of our other existing and any future product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of INVELTYS 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 INVELTYS and KPI-121 0.25% for commercial use; Alliance for manufacturing bulk KPI-121 concentrates, and Chemo Iberica to manufacture and supply to us a bulk supply of LE. We expect to rely on such third-party manufacturers to manufacture commercial supplies of all of our products and clinical supplies of any other product candidates if and when approved for marketing by applicable regulatory authorities. Our current and anticipated future dependence upon others for the manufacture of INVELTYS 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 INVELTYS, KPI-121 0.25% or other product candidates in the United States, we may be required to conduct a comparability study if the product we intend to market is supplied by a manufacturer different from the one who

supplied the product evaluated in our clinical studies. Delays in designing and completing this study to the satisfaction of the FDA could delay or preclude our development and commercialization plans and thereby limit our revenues and growth.

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

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

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

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

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

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

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

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

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

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development of our product candidates or may elect not to continue or renew development programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may not pursue commercialization of our product candidates that receive marketing approval or may elect not to continue or renew commercialization programs based on changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would divert management attention and resources, be time-consuming and expensive;

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

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

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

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

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

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

For some of our product candidates, we may decide to collaborate with pharmaceutical or biotechnology companies for the development 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 able to seek or be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

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

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering 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 may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

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

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

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

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

Our commercial success depends upon our ability to develop, manufacture, market, and sell INVELTYS, 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 INVELTYS, 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.

INVELTYS, 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 INVELTYS 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 INVELTYS and KPI-121 0.25%, for the remainder of the patent families subject to our exclusive license agreement with JHU that relate to our 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 INVELTYS, 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 INVELTYS 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 INVELTYS, KPI-121 0.25% or any other product candidate from regulatory authorities in any jurisdiction. In December 2017, the FDA accepted for filing our NDA for INVELTYS and set a PDUFA date of August 24, 2018. However, the FDA's decision to accept an NDA for filing and set a PDUFA date does not indicate that the FDA has made any decision regarding approval nor does it guarantee approval by the PDUFA date, if at all. We have only limited experience in submitting and supporting the applications necessary to gain marketing

approvals and have relied on, and expect to continue to rely on, third-party consultants and vendors to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA or other regulatory authorities may determine that INVELTYS, 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 INVELTYS, KPI-121 0.25% or any other product candidate that we develop, the commercial prospects for such product candidate may be harmed and our ability to generate revenues will be materially impaired.

If the FDA does not conclude that INVELTYS and KPI-121 0.25% satisfy the filing and approval 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.

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 INVELTYS and KPI-121 0.25% by potentially decreasing the amount of preclinical and clinical data that we would need to generate in order to obtain FDA approval.

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

If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional 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 INVELTYS and KPI-121 0.25%, and complications and risks associated with approval of INVELTYS 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 INVELTYS 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 INVELTYS or KPI-121 0.25%.

Even if INVELTYS 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.

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

In order to market and sell INVELTYS, 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.

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

In December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or

if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

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

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

Healthcare providers, clinicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription and use of 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 INVELTYS, 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. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025 unless additional congressional action is taken, and the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for 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. Further, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for 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 our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. In May 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act of 2017. Thereafter, the Senate Republicans introduced and then updated a bill to replace the

ACA known as the Better Care Reconciliation Act of 2017. The Senate Republicans also introduced legislation to repeal the ACA without companion legislation to replace it, and a "skinny" version of the Better Care Reconciliation Act of 2017. In addition, the Senate considered proposed healthcare reform legislation known as the Graham-Cassidy bill. None of these measures was passed by the U.S. Senate.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As of December 31, 2017, we had federal net operating loss carryforwards of $120.9 million, which expire at various dates beginning in 2030 through 2037 and state net operating loss carryforwards of $104.0 million, which expire at various dates beginning in 2030 through 2037. These net operating loss carryforwards could expire unused and be unavailable to offset our future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain how various states will respond to the newly enacted federal tax law. If our ability to use our historical net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Risks Related to Employee Matters and Managing Growth

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

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

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

We 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.

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

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

Risks Related to Our Common Stock

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

As of December 31, 2017, our executive officers and directors and principal stockholders in the aggregate, own shares representing approximately 58% of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

This concentration of voting power may:

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

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

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

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

- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws.

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

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

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

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

Our stock price is likely to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the public offering price. The market price for our common stock may be influenced by many factors, including:

- results of clinical trials of any of our product candidates;
- results of clinical trials of product candidates of our competitors;
- our success in commercializing INVELTYS 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 INVELTYS, 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.

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

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Persons who were our stockholders prior to our initial public offering continue to hold a substantial number of shares of our common stock. If such persons sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. Moreover, holders of a substantial number of shares of our common stock, including shares of our common stock issuable upon exercise of outstanding warrants and options, have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. In July 2017, we registered all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company until December 31, 2022, although if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th or if we have annual gross revenues of $1.07 billion or more in any fiscal year, we would cease to be an emerging growth company as of December 31 of the applicable year. We also would cease to be an emerging growth company if we issue more than $1 billion of non-convertible debt over a three-year period. As an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

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

We have taken advantage of reduced reporting obligations in this Annual Report on Form 10-K . In particular, in this Annual Report on Form 10-K , we 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 as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and will make some activities more time-consuming and costly.

For as long as we remain an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies as described in the preceding risk factor.

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

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of our 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 designates the state courts in the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against the company and our directors, officers and employees.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or employees to our company or our stockholders, any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws or as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of

Chancery of the State of Delaware, or any action asserting a claim against us governed by the internal affairs doctrine. This exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees.

Item 1B Unresolved Staff Comments

None.

Item 2. Properties

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.

On February 28, 2018 we entered into a lease for our new corporate headquarters located in Watertown, Massachusetts which consists of 66,052 rentable square feet with an initial term of 8 years.

On March 15, 2018, we enterd into a lease for the portion of an office building located in Waltham, Massachusetts which consists of 6,294 rentable square feet. The term of the lease is one year.

Item 3. Legal Proceedings

We are not currently subject to any material legal proceedings.

Item 4. Mine Safety Disclosures

None.

Part II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer's Purchases of Equity Securities

Our common stock has been publicly traded on the Nasdaq Global Select Market under the symbol "KALA" since July 20, 2017 in connection with our public initial public offering, or IPO. Prior to that time, there was no public market for our common stock. The following table sets forth, for the periods indicated, the high and low intraday sales prices of our common stock as reported by The Nasdaq Global Select Market:

	Market Price	
2017	**High**	**Low**
Third Quarter (beginning July 20, 2017)	$ 26.75	$ 16.38
Fourth Quarter	$ 23.32	$ 13.51

Holders

As of December 31, 2017, there were approximately 52 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividend policy

We have not declared or paid any cash dividends on our common stock since our inception. We intend to retain all available funds and any future earnings to finance the operation and expansion of our business and 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.

Information about our equity compensation plans

The information required by this item will be set forth in our Proxy Statement for the 2018 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

Recent Sales of Unregistered Securities.

Set forth below is information regarding shares of our common stock issued and stock options granted by us for the twelve months ended December 31, 2017 that were not registered under the Securities Act of 1933, as amended, or the Securities Act and that have not otherwise been described in a Quarterly Report on Form 10-Q. In October 2017, warrants to purchase an aggregate of 72,286 shares of our common stock were exercised, of which 21,775 were cashless exercises. The issuance of shares pursuant to the warrant exercises was made in reliance on the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. The investor represented that it was an accredited investor and was acquiring the warrants and shares issuable upon exercise of the warrants for its own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the warrants for an indefinite period of time and appropriate legends were affixed to the instruments representing such warrants

issued in such transactions. Such recipients either received adequate information about us or had, through their relationships with us, access to such information.

Purchase of equity securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

Use of proceeds from registered securities

On July 19, 2017, our registration statement on Form S-1 (File No. 333-218936) relating to the IPO of our common stock became effective. In the IPO, we issued 6,900,000 shares of our common stock at an initial offering price of $15.00 per share, including 900,000 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares of common stock. We received net proceeds of $94.0 million after deducting underwriting discounts and commissions of $7.3 million and offering costs incurred in 2017 of $2.2 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to our affiliates. J.P. Morgan and BofA Merrill Lynch acted as joint book-running managers and Wells Fargo Securities and Wedbush PacGrow acted as co-managers for the offering. The offering commenced on July 19, 2017 and did not terminate until the sale of all of the shares offered.

As of December 31, 2017, we had used approximately $17.0 million of the net offering proceeds, primarily to fund KPI-121 development costs association with our second Phase 3 clinical trial of INVELTYS for the treatment of inflammation and pain following cataract surgery and our two Phase 3 clinical trials of KPI-121 0.25% for the treatment of dry eye disease which began in June 2016, as well as for working capital and general corporate purposes. There has been no material change in the planned use of proceeds from the IPO of our common stock from that described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on July 20, 2017.

Item 6. Selected Financial Data

You should read the following selected consolidated financial data together with our consolidated financial statements and accompanying notes appearing elsewhere in this Annual Report on Form 10-K and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this Annual Report on Form 10-K. We have derived the consolidated statement of operations data for the years ended December 31, 2017, 2016 and 2015 and the consolidated balance sheet data as of December 31, 2017 and 2016 from our audited consolidated financial statements included in "Item 8 – Financial Statements and Supplementary Data". We have derived the balance sheet data as of December 31, 2015 from our audited financial statements not included in this Annual Report on Form 10-K. Our historical results for any prior period are not necessarily indicative of the results that may be expected in any future period.

	Year Ended December 31,		
	2017	2016	2015
	(in thousands, except share and per share amounts)		
Revenue	$ —	$ —	$ 45
Operating expenses			
Research and development	29,008	25,029	11,382
General and administrative	10,867	7,640	4,609
Total operating expenses	39,875	32,669	15,991
Loss from operations	(39,875)	(32,669)	(15,946)
Other income (expense)			
Interest income	527	147	—
Interest expense	(1,019)	(767)	(604)
Change in fair value of warrant liability	(1,844)	122	(132)
Net loss attributable to common stockholders	$ (42,211)	$ (33,167)	$ (16,682)
Net loss per share attributable to common stockholders—basic and diluted	$ (6.11)	$ (28.07)	$ (14.89)
Weighted average shares outstanding—basic and diluted	6,903,239	1,181,429	1,120,268

	As of December 31,		
	2017	2016	2015
Balance Sheet Data:			
Cash	$ 114,565	$ 45,472	$ 5,759
Total assets	116,133	46,329	8,448
Working capital(1)	100,755	40,080	2,094
Long-term debt—less current portion	11,987	9,098	7,795
Other long-term liabilities	9	17	3
Total stockholders' equity (deficit)	89,679	(87,762)	(56,664)

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

Item 7. 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 Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, 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 Annual Report on Form 10-K, 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 loteprednol etabonate, or LE, a corticosteroid designed for ocular applications, resulting in two lead product candidates. These product candidates are INVELTYS™ (KPI-121 1.0%) for the treatment of inflammation and pain following ocular surgery, for which we have submitted a new drug application, or NDA, and KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. The brand name INVELTYS has been conditionally approved by the U.S. Food and Drug Administration, or the FDA.

KPI-121 0.25% is our product candidate for patients with dry eye disease utilizing a two-week course of therapy. In January 2018, we announced topline results from two completed Phase 3 clinical trials of KPI-121 0.25%, which we refer to as STRIDE 1 and STRIDE 2 (STRIDE - **S**hort **T**erm **R**elief **I**n **D**ry **E**ye), evaluating the safety and efficacy of KPI-121 0.25% versus placebo in patients with dry eye disease In STRIDE 1, statistical significance was achieved for the primary sign endpoint of conjunctival hyperemia and the primary symptom endpoint of ocular discomfort severity change from baseline to day 15 in the intent to treat, or ITT, population; in addition, statistical significance was also achieved in STRIDE 1 for a second pre-specified primary symptom endpoint of ocular discomfort severity change from baseline to day 15 in patients with more severe baseline ocular discomfort. In STRIDE 2, statistical significance was achieved for the primary sign endpoint of conjunctival hyperemia, but statistical significance was not achieved for the primary symptom endpoint of ocular discomfort severity. KPI-121 0.25% was generally well tolerated in both STRIDE 1 and STRIDE 2, with no clinically significant treatment-related adverse events observed during the course of either trial, and with elevations in intraocular pressure, or IOP, in both trials similar to placebo. We expect to meet with the FDA in the second quarter of 2018 to discuss the results of STRIDE 1 and STRIDE 2 and potential next steps for our dry eye disease program, including whether an additional phase 3 clincial trial will be required prior to our submission of an NDA. If approved, KPI-121 0.25% could be the first FDA-approved product for the short-term treatment of dry eye disease.

In December 2017, the FDA accepted for filing our NDA for the approval of INVELTYS, our topical twice-a-day product candidate, for the treatment of post-operative inflammation and pain following ocular surgery. The FDA has set August 24, 2018 as the Prescription Drug User Fee Act action goal date for our NDA. If approved, INVELTYS could be the first FDA-approved ocular corticosteroid product with a twice-a-day dosing regimen for the treatment of post-operative inflammation and pain. Other approved topical ocular corticosteroid products for this indiciation are dosed four times a day. Supporting the NDA submission are data from two completed Phase 3 clinical trials of INVELTYS in patients with inflammation and pain following cataract surgery, which is the most common type of ocular surgery in the United States. The first Phase 3 clinical trial was conducted in 2014 and was designated to evaluate INVELTYS 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 INVELTYS

and KPI-121 0.25%. Both INVELTYS 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, the second, confirmatory Phase 3 clinical trial was completed, in which administration of INVELTYS 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, INVELTYS was well tolerated with no treatment-related significant adverse events observed during the course of the trial.

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 INVELTYS, we are seeking FDA approval under Section 505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act, or the FDCA, which we plan to rely on for the approval of KPI-121 0.25% as well. We have retained worldwide commercial rights for our current product candidates. If INVELTYS and KPI-121 0.25% receive marketing approval, we expect to commercialize both in the United States, and we have started to build a commercial infrastructure to do so, with our own focused, specialty sales force. If INVELTYS receives marketing approval, we expect our commercial organization will initially consist of approximately 75 sales and marketing personnel. If KPI-121 0.25% is approved for the short-term treatment of dry eye disease, we expect to further expand our sales force by up to approximately an additional 100 personnel. We expect to commercialize in the United States any of our other product candidates that receive marketing approval as well. In anticipation of the potential to commercialize our product candidates in other global markets, we are evaluating a variety of collaboration, distribution and other marketing arrangements with one or more third parties.

On July 25, 2017, we completed our initial public offering of our common stock, or IPO, pursuant to which we issued and sold 6,900,000 shares of our common stock at a price of $15.00 per share, which included 900,000 shares sold pursuant to the exercise of the underwriters' option to purchase additional shares. We received net proceeds of $94.0 million, after deducting underwriting discounts and commissions and offering expenses.

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 our IPO, 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 December 31, 2017, we have raised an aggregate of $234.9 million to fund our operations, of which $113.4 million was from the sale of preferred stock, $94.0 million was from our IPO, $6.0 million was from convertible promissory notes and warrants and $21.5 million was from borrowings and warrants under venture debt facilities. As of December 31, 2017, we had cash on hand of $114.6 million.

Since inception, we have incurred significant operating losses. Our net loss was $42.2 million, $33.2 million and $16.7 million for the years ended December 31, 2017, 2016 and 2015, respectively. We recognized revenue of $0, $0, and $45,000 for the years ended December 31, 2017, 2016 and 2015, 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 December 31, 2017, we had an accumulated deficit of $134.4 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 approval for INVELTYS and establish our sales, marketing and distribution capabilities for INVELTYS in advance of and upon any such approval;

- seek marketing approvals for 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 INVELTYS 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;
- expand our sales, marketing and distribution capabilities for our other product candidates, prior to or upon receiving marketing approval;
- scale up our manufacturing processes and capabilities to support commercialization of INVELTYS, for which the FDA has accepted our NDA for filing, and any of our other product candidates for which we seek and/or obtain marketing approval;
- leverage our proprietary MPP technology to advance additional high-value therapeutics into preclinical and clinical development;
- in-license or acquire the rights to other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control, scientific, manufacturing, commercial and management personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company; and
- increase our product liability insurance coverage as we initiate and 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.

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.

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

	Year Ended December 31,		
	2017	2016	2015
	(in thousands)		
KPI-121 development costs	$ 16,814	$ 17,465	$ 4,683
Employee-related costs	7,761	4,714	3,485
Other research and development costs	4,433	2,850	3,214
Total research and development	$ 29,008	$ 25,029	$ 11,382

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.

Change in Fair Value of Warrant Liability

Prior to our IPO, we issued warrants for the purchase of our Series Seed, Series B and Series C preferred stock. These warrants were financial instruments that were issuable for contingently redeemable securities. Therefore, these warrants were classified as liabilities as of December 31, 2016. The warrants were re-measured to fair value at each reporting period and prior to their conversion into common stock warrants immediately prior to our IPO. 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 and these gains and losses were recorded as a component of other income (expense). Upon the closing of our IPO, the underlying preferred stock was converted into common stock, the preferred stock warrants were converted into warrants for common stock, and the fair value of the warrant liability at that time was reclassified to additional paid-in capital.

Critical Accounting Policies and Significant Judgments and Estimates

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

While our significant accounting policies are described in more detail in the notes to our financial statements appearing at the end of this Annual Report on Form 10-K , 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 classified 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 were subsequently remeasured to fair value at each balance sheet date. Changes in the fair value of the warrants were recognized separately in our statement of operations. We continued to adjust the liability for changes in fair value until the earlier of the exercise, conversion or expiration of the warrant.

We utilized 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 determined 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 estimated 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.

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. At December 31, 2017 and 2016, we had federal net operating loss carryforwards of $120.9 million and $85.3 million, respectively, which may be available to offset future federal tax liabilities and expire at various dates beginning in 2030 through 2037. At December 31, 2017 and 2016, we had state net operating loss carryforwards of $104.0 million and $80.5 million, respectively, which may be available to offset future state income tax liabilities and expire at various dates beginning in 2030 through 2037. As of December 31, 2017 and 2016, we had federal and state research and development credit carryforwards of approximately $4.5 million and $2.9 million, respectively, which are available to reduce future income taxes, if any, from 2030 through 2037 (federal) and 2025 through 2032 (state). At December 31, 2017, 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 fair value for each award is determined on the grant date and the expense is only recognized once probable that the performance condition will be met. 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

Prior to our IPO, there was no public market for our common stock. The estimated fair value of our common stock was 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 was estimated based upon an analysis of future values for the Company, assuming various outcomes. The common stock value was 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 have been 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 represented management's best estimates, which involved inherent uncertainties and the application of management judgment.

Following the closing of our IPO, we have determined the fair value of our common stock based on the quoted market price of our common stock.

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

	Year Ended December 31,		
	2017	2016	2015
Research and development	$ 1,267	$ 461	$ 161
General and administrative	2,304	1,608	477
Total	$ 3,571	$ 2,069	$ 638

As of December 31, 2017, we had $15.4 million of total unrecognized compensation expense, which is expected to be recognized over a weighted average remaining vesting period of approximately 3.11 years. We expect the impact of our stock-based compensation expense for stock options and restricted stock granted to employees and non-employee consultants 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, 2017 and 2016

The following table summarizes the results of our operations for the years ended December 31, 2017 and 2016:

	Year Ended December 31,		
	2017	2016	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 29,008	$ 25,029	$ 3,979
General and administrative	10,867	7,640	3,227
Total costs and expenses	39,875	32,669	7,206
Loss from operations	(39,875)	(32,669)	(7,206)
Other income (expense)			
Interest income	527	147	380
Interest expense	(1,019)	(767)	(252)
Change in fair value of warranty liability	(1,844)	122	(1,966)
Net loss	$ (42,211)	$ (33,167)	$ (9,044)

Research and Development Expenses

	Year Ended December 31,		
	2017	2016	Change
	(in thousands)		
KPI-121 external development costs	$ 16,814	$ 17,465	$ (651)
Employee-related costs	7,761	4,714	3,047
Other research and development costs	4,433	2,850	1,583
Total research and development	$ 29,008	$ 25,029	$ 3,979

Research and development expenses were $29.0 million for the year ended December 31, 2017 compared to $25.0 million for the year ended December 31, 2016, an increase of $4.0 million. This increase is primarily attributed to a $3.0 million increase in employee-related costs comprised of a $2.1 million increase related to additional clinical and regulatory headcount and a $0.8 million increase in stock compensation expense from stock option grants, and a $1.6 million increase in other research and development costs primarily associated with clinical consulting services for our Phase 3 trials and regulatory consulting support for our NDA preparation. These increases were partially offset by a $0.7 million decrease in KPI-121 development costs due to the decrease in external costs associated with our second Phase 3 clinical trial of INVELTYS for the treatment of inflammation and pain following ocular surgery and our two Phase 3 clinical trials of KPI-121 0.25% for the treatment of dry eye disease which began in June 2016 and completed during the second half of 2017.

General and Administrative Expenses

General and administrative expenses were $10.9 million for the year ended December 31, 2017 compared to $7.6 million for the year ended December 31, 2016, an increase of $3.3 million. This increase was primarily due to a $2.0 million increase in employee-related costs comprised of a $1.2 million increase in general and administrative salaries and benefits expenses due to the hiring of additional employees and overall merit increases, and by a $0.7 million increase in stock compensation expense related to increased stock options being granted during the year. There was a $1.1 million increase in external consulting fees associated with accounting services and legal fees; and a $0.2 million increase in external general and administrative costs as a result of being a public company, comprised primarily of directors' and officers' liability insurance, board of directors' fees and investor relations costs.

Interest Income

Interest income was $527,000 for the year ended December 31, 2017 compared to $147,000 for the year ended December 31, 2016 an increase of $380,000. This increase was due to a higher average cash balance in our interest-bearing deposit account during the year ended December 31, 2017 compared to the same period in 2016 as a result of the proceeds from the IPO.

Interest Expense

Interest expense was $1.0 million for the year ended December 31, 2017 compared to $767,000 for the year ended December 31, 2016 an increase of $252,000. The interest expense was comprised of the contractual coupon interest and the amortization of the debt discount associated with our 2014 Debt Facility. In September 2017, the total debt balance increased to $20 million. The average interest rate in 2017 and 2016 was 7.10% and 6.51%, respectively.

Change in Fair Value of Warrant Liability

The change in the fair value of our preferred stock warrant liability consisted of a loss of $1.8 million for the year ended December 31, 2017 compared with a gain of $0.1 million for the year ended December 31, 2016. This change was the result of an increase in the fair value of the underlying preferred stock prior to our IPO. Upon closing of the IPO, the underlying preferred stock was converted into common stock, the preferred stock warrants were converted into warrants for common stock, and the fair value of the warrant liability at that time was reclassified to additional paid-in capital.

Comparison of the Years Ended December 31, 2016 and 2015

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

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

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 $0 for the year ended December 31, 2016 compared to $45,000 for the year ended December 31, 2015. 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,		Change
	2016	2015	
	(in thousands)		
KPI-121 development costs	$ 17,465	$ 4,683	$ 12,782
Employee-related costs	4,714	3,485	1,229
Other research and development costs	2,850	3,214	(364)
Total research and development	$ 25,029	$ 11,382	$ 13,647

Research and development expenses were $25.0 million for the year ended December 31, 2016 compared to $11.4 million for the year ended December 31, 2015, 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 INVELTYS for the treatment of inflammation and pain following ocular surgery and our two 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 completed Phase 3 trials of KPI-121 0.25%. 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 primarily related to a reduction in consulting costs due to the additional hiring of clinical and regulatory personnel. 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 $7.6 million for the year ended December 31, 2016 compared to $4.6 million for the year ended December 31, 2015; 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 IPO 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 $0.1 million for the year ended December 31, 2016 compared to $0 for the year ended December 31, 2015. 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 $0.8 million for the year ended December 31, 2016 compared to $0.6 million for the year ended December 31, 2015, 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 gain for the year ended December 31, 2016 compared to a $0.1 million loss for the year ended December 31, 2015. 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.

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 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 our IPO, 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.

On November 20, 2014, we entered into our 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 First Amendment. The First Amendment reaffirmed the initial commitment of $10.0 million in funding. Additionally, the First 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 the Term Loan B was contingent 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 INVELTYS for the treatment of inflammation and pain following ocular surgery through October 13, 2017. On May 1, 2017, we announced positive results from our Phase 3 trial. INVELTYS dosed twice a day for two weeks achieved statistical significance versus placebo for both primary efficacy endpoints and all secondary endpoints. On September 28, 2017, we drew down the incremental $10.0 million commitment. The 2014 Debt Facility, as amended, provides for interest-only payments through October 13, 2017, and matures on October 13, 2020. On November 22, 2017, the Company entered into a Second Amendment to the 2014 Debt Facility to account for the formation of the Company's wholly-owned subsidiary. We are required to repay the 2014 Debt Facility in equal monthly installments following the end of the interest-only period. Interest is payable monthly in arrears through to the maturity date.

In July 2017, we completed our IPO pursuant to which we issued and sold 6,900,000 shares of our common stock, which included 900,000 shares sold pursuant to the exercise of the underwriters' option to purchase additional shares, at a price of $15.00 per share. We received net proceeds of $94.0 million after deducting underwriting discounts and commission of $7.3 million and offering costs incurred in 2017 of $2.2 million

In November 2017, we formed a wholly owned subsidiary, Kala Pharmaceuticals Security Corporation, a Massachusetts corporation for the sole purpose of buying, selling and holding securities on our behalf.

Cash Flows

As of December 31, 2017, we had $114.6 million in cash on hand and $18.9 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,		
	2017	2016	2015
	(in thousands)		
Net cash used in operating activities	$ (34,098)	$ (27,348)	$ (15,089)
Net cash used in investing activities	(480)	(153)	(252)
Net cash provided by financing activities	103,696	67,214	10,480
Increase (decrease) in cash and restricted cash	$ 69,118	$ 39,713	$ (4,861)

Operating Activities

During the year ended December 31, 2017, our cash used in operating activities was primarily due to our net loss of $42.2 million as we incurred external research and development costs associated with our clinical trials and general and administrative costs partially offset by non-cash charges of $5.8 million, consisting primarily of a $1.8 million increase in fair value of warrant liability and $3.6 million in stock-based compensation and net cash provided by changes in our operating assets and liabilities of $2.3 million. Net cash provided by changes in our operating assets and liabilities was primarily due to an increase of $2.6 million in accrued expenses, partially offset by an increase of $0.5 million in prepaid expenses primarily as a result of prepayments made in connection with director and officer insurance. The increase in accrued expense was primarily a result of an increase in amounts accrued for clinical and regulatory consulting support for our clinical trials and support for our NDA submission and the increase in accounts payable was a result of the timing of vendor invoices and payments.

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 external research and development costs associated with our clinical trials and 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 statement on Form S-1 filing 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 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.

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 $0.5 million, $0.2 million and $0.3 million for the years ended December 31, 2017, 2016 and 2015, respectively.

Financing Activities

Net cash provided by financing activities was $103.7 million for the year ended December 31, 2017, consisting of $94.0 million of IPO proceeds, net of underwriter discounts and offering costs, $10.0 million in funding from the September 2017 draw down of the Term B Loan of our 2014 Debt Facility and $0.8 million in proceeds from the

exercise of stock options and warrants, partially offset by $1.1 million in principal payments toward the venture debt facility.

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 $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.

Funding Requirements

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

Our expenses will also increase if and as we:

- seek marketing approval for INVELTYS and establish our sales, marketing and distribution capabilities for INVELTYS in advance of and upon any such approval;
- conduct any necessary clinial trials and other development activities and/or seek marketing approvals for KPI-121 0.25%;
- 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 INVELTYS 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;
- expand our sales, marketing and distribution capabilities for our other product candidates, prior to or upon receiving marketing approval;
- scale up our manufacturing processes and capabilities to support commercialization of INVELTYS, for which the FDA has accepted our NDA for filing, KPI-121 0.25% and any of our other product candidates for which we seek and/or obtain marketing approval;
- leverage our proprietary MPP technology to advance additional high-value therapeutics into preclinical and clinical development;
- in-license or acquire the rights to other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control, scientific, manufacturing, commercial and management personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company; and
- increase our product liability insurance coverage as we initiate and expand our commercialization efforts.

We believe that with our existing cash on hand as of December 31, 2017, will enable us to fund our planned operating expenses, debt service obligations and capital expenditure requirements for at least the next 12 months. 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 capital requirements will depend on many factors, including:

- whether we need to conduct any additional clinical trials or other activities for KPI-121 0.25% prior to submitting an NDA to the FDA;
- the costs, timing and outcome of regulatory review of INVELTYS and KPI-121 0.25%, including whether any additional clinical trials or other activities are required for approval;
- the progress, costs and results of any clinical activities for regulatory review of INVELTYS and KPI-121 0.25% outside of the United States;
- the costs and timing of process development and manufacturing scale-up activities associated with INVELTYS and KPI-121 0.25%;
- the costs of commercialization activities for INVELTYS and/or KPI-121 0.25% if we receive marketing approval and pre-commercialization costs for INVELTYS and/or KPI-121 0.25% incurred prior to receiving any such marketing approval, including the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities;
- assuming receipt of marketing approval, revenue received from commercial sales of INVELTYS and KPI-121 0.25% or any other product candidates;
- our ability to establish and maintain strategic collaborations, licensing or other agreements and the financial terms of such agreements;
- the scope, progress, results and costs of any product candidates that we may derive from any other product candidates that we may develop;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property-related claims.

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

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

funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

The following is a summary of our significant contractual obligations as of December 31, 2017:

	Payments Due by Period				
Contractual Obligations	**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)	$ 18,889	$ 6,667	$ 12,222	$ —	$ —
Interest on short- and long-term debt obligations(2)	1,992	1,157	835	—	—
Operating lease obligations(3)	444	410	34	—	—
Minimum license payments(4)	81	43	38	—	—
Total	$ 21,406	$ 8,277	$ 13,129	$ —	$ —

(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. Excluded from the table above is the February 28, 2018 lease agreement we entered into for our new headquarters in Watertown, Massachusetts with an initial term of 8 years and an average rent of approximately $322,000 per month beginning November 1, 2018.

(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 INVELTYS 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 INVELTYS and KPI-121 0.25%. Under the minimum purchase requirements, if both INVELTYS and KPI-121 0.25% are approved for commercial sale, our minimum payment obligation in the first 12-month period would be approximately $1.5 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 loteprednol 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.

On February 28, 2018, we entered into a lease, the Watertown Lease, with 480 Arsenal Group LLC for the lease of a portion of the building located at 490 Arsenal Way Watertown, Massachusetts consisting of 66,052 rentable square feet at an initial rate of $53 per square foot and annual increases of 3% for the next 7 years. The initial term of the Watertown Lease is 8 years. We expect to occupy the premises by the end of 2018. We plan to use the premises as our corporate headquarters and for research and development.

On March 15, 2018, we entered into a lease, the Waverley Oaks Lease, with Duffy Associates, LLC for the lease of a portion of the building located at 465 Waverely Oaks Road Suite 301, Waltham, Massachusetts consisting of 6,294 rentable square feet at a rate of $32 per square foot. The term of the Waverley Oaks Lease is one year. We plan to use this location for additional corporate offices before moving to our new corporate headquarters in Watertown, MA.

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 Note 2 to the financial statements appearing at the end of this Annual Report on Form 10-K, 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.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We did not hold any cash equivalents or investments as of December 31, 2017. As of December 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 $100,000 related to our borrowings under our 2014 Debt Facility.

Item 8. Financial Statements and Supplementary Data

Our financial statements, together with the report of our independent registered public accounting firm, appear on pages F-1 through F-28 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures.

Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2017. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2017, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's annual report on internal control over financial reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in internal control over financial reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended December 31, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

On March 29, 2018 we entered into a third amendment to our 2014 Debt Facility, which we refer to as our Third Amendment. The Third Amendment reaffirmed our prior commitment of $20 million in funding, or Term Loan A, and extended the interest-only end date for 12 months following the execution of the Third Amendment. In addition, the total borrowing capacity was increased by an additional $5 million, or Term Loan B, subject to the following conditions: (i) the minimum borrowing amount is $250,000 for each incremental borrowing under Term Loan B; (ii) The Term Loans, once repaid, may not be re-borrowed; (iii) we 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 us receiving FDA approval of INVELTYS. Funding under the Term Loan B commitment is available for 12 months following the execution of the Third Amendment. The maturity date of our 2014 Debt Facility was also extended from October 13, 2020 to March 29, 2022.

Part III

Item 10. Directors, Executive Oficers and Corporate Governance

The information required by this Item is incorporated by reference from the information that will be contained in our Proxy Statement for our 2018 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates pursuant to General Instruction G(3) of Form 10-K.

Item 11. Executive Compensation

The information required by this Item is incorporated by reference from the information that will be contained in our Proxy Statement for our 2018 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates pursuant to General Instruction G(3) of Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item is incorporated by reference from the information that will be contained in our Proxy Statement for our 2018 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates pursuant to General Instruction G(3) of Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item is incorporated by reference from the information that will be contained in our Proxy Statement for our 2018 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates pursuant to General Instruction G(3) of Form 10-K.

Item 14. Principal Accounting Fees and Services

The information required by this Item is incorporated by reference from the information that will be contained in our Proxy Statement for our 2018 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates pursuant to General Instruction G(3) of Form 10-K.

Part IV

Item 15. Exhibits, Financial Statement Schedules

(1) **Financial Statements.**

The following documents are included beginning on page F-1 attached hereto and are filed as part of this Annual Report on Form 10-K.

KALA PHARMACEUTICALS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

(2) **Financial Statement Schedules.**

No financial statement schedules have been filed as part of this Annual Report on Form 10-K because they are not applicable, not required or because the information is otherwise included in our financial statements or notes thereto.

(3) **Exhibits**.

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	Description of Exhibit
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on July 25, 2017)
3.2	Amended and Restated By-laws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on July 25, 2017)
4.1	Specimen Stock Certificate evidencing the shares of common stock (incorporated by reference to Exhibit 4.1 to the Registrant's registration statement on Form S-1/A (File No. 333 -218936) filed on July 10, 2017)
4.2	Third Amended and Restated Registration Rights Agreement of the Registrant, as amended (incorporated by reference to Exhibit 10.1 to the Registrant's registration statement on Form S-1 (File No. 333-218936) filed on June 23, 2017)
10.1+	2009 Employee, Director and Consultant Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's registration statement on Form S-1 (File No. 333-218936) filed on June 23, 2017)
10.2+	Form of Stock Option Agreement under the 2009 Employee, Director and Consultant Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's registration statement on Form S-1 (File No. 333-218936) filed on June 23, 2017)
10.3+	2017 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 to the Registrant's registration statement on Form S-1/A (File No. 333-218936) filed on July 10, 2017)
10.4+	2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's registration statement on Form S-1/A (File No. 333-218936) filed on July 10, 2017)
10.5+	Form of Incentive Stock Option Agreement under 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's registration statement on Form S-1/A (File No. 333-218936) filed on July 10, 2017)
10.6+	Forms of Non-Qualified Option Agreement under 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registrant's registration statement on Form S-1/A (File No. 333-218936) filed on July 10, 2017)
10.7†	Exclusive License Agreement, dated November 10, 2009, by and between the Registrant and The Johns Hopkins University, as amended (incorporated by reference to Exhibit 10.7 to the Registrant's registration statement on Form S-1 (File No. 333-218936) filed on June 23, 2017)
10.8†	Settlement and License Agreement, dated October 24, 2014, by and between the Registrant and GrayBug, LLC (incorporated by reference to Exhibit 10.8 to the Registrant's registration statement on Form S-1 (File No. 333-218936) filed on June 23, 2017)
10.9	Lease Agreement, dated September 30, 2013, by and between the Registrant and ARE-MA Region No. 9 LLC, as amended (incorporated by reference to Exhibit 10.9 to the Registrant's registration statement on Form S-1 (File No. 333-218936) filed on June 23, 2017)
10.10*	Loan and Security Agreement, dated November 20, 2014, by and between the Registrant and Square 1 Bank, as amended
10.11+	Amended and Restated Letter Agreement, dated September 10, 2015, by and between the Registrant and Mark Iwicki, as amended by the First Amendment, dated September 28, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's quarterly report on Form 10-Q (File No. 011-38150) filed on November 7, 2017)
10.12*+	Letter Agreement, dated November 6, 2017, by and between the Registrant and Todd Bazemore

Exhibit Number	Description of Exhibit
10.13+	Amended and Restated Letter Agreement, dated May 10, 2016, by and between the Registrant and Kim Brazzell (incorporated by reference to Exhibit 10.13 to the Registrant's registration statement on Form S-1 (File No. 333-218936) filed on June 23, 2017)
10.14+	Form of Indemnification Agreement between the Registrant and each of its Executive Officers and Directors (incorporated by reference to Exhibit 10.14 to the Registrant's registration statement on Form S-1/A (File No. 333-218936) filed on July 10, 2017)
10.15†	Exclusive License Agreement, effective as of May 1, 2017, by and between the Registrant and The Johns Hopkins University (incorporated by reference to Exhibit 10.15 to the Registrant's registration statement on Form S-1 (File No. 333-218936) filed on June 23, 2017)
10.16†	Assignment, dated April 26, 2017, by and between the Registrant and The Johns Hopkins University (incorporated by reference to Exhibit 10.16 to the Registrant's registration statement on Form S-1 (File No. 333-218936) filed on June 23, 2017)
10.17†	Assignment, dated April 26, 2017, by and between the Registrant and The Johns Hopkins University (incorporated by reference to Exhibit 10.17 to the Registrant's registration statement on Form S-1 (File No. 333-218936) filed on June 23, 2017)
10.18*††	Amended and Restated Master Services Agreement, dated October 4, 2017, by and between the Registrant and Alliance Contract Pharma, LLC
10.19†	Commercial Supply Agreement, dated June 27, 2016, by and between the Registrant and Catalent Pharma Solutions, LLC (incorporated by reference to Exhibit 10.19 to the Registrant's registration statement on Form S-1 (File No. 333-218936) filed on June 23, 2017)
10.20†	Manufacturing and Supply Agreement, dated January 10, 2017, by and between the Registrant and Chemo Iberica SA (incorporated by reference to Exhibit 10.20 to the Registrant's registration statement on Form S-1 (File No. 333-218936) filed on June 23, 2017)
10.21*††	Amendment No. 1 to Commercial Supply Agreement, dated February 16, 2018, by and between the Registrant and Catalent Pharma Solutions, LLC
10.22	Lease, dated as of February 28, 2018, by and between the Registrant and 480 Arsenal Group LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 12, 2018)
21.1*	Subsidiaries of the Registrant
23.1*	Consent of Deloitte & Touche LLP
31.1*	Rule 13a-14(a) Certification of Principal Executive Officer
31.2*	Rule 13a-14(a) Certification of Principal Financial Officer
32.1*	Certification of Principal Executive Officer pursuant to 18 U.S.C. §1350
32.2*	Certification of Principal Financial Officer pursuant to 18 U.S.C. §1350
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

* Filed herewith.

† Confidential treatment granted as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

†† Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

\+ Management contract or compensatory plan or arrangement filed in response to Item 15(a)(3) of the Instructions to the Annual Report on Form 10-K.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

KALA PHARMACEUTICALS, INC..

Dated: April 2, 2018

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ Mark Iwicki Mark Iwicki	President, Chief Executive Officer and Chairman of Board of Directors (Principal Executive Officer)	April 2, 2018
/s/ Mary Reumuth Mary Reumuth	Chief Financial Officer (Principal Financial and Accounting Officer)	April 2, 2018
/s/ Gregory Grunberg Gregory Grunberg, M.D.	Director	April 2, 2018
/s/ Paulina Hill Paulina Hill, Ph.D.	Director	April 2, 2018
/s/ Andrew Koven Andrew Koven	Director	April 2, 2018
/s/ Robert Langer Robert Langer, Sc.D.	Director	April 2, 2018
/s/ Robert Paull Robert Paull	Director	April 2, 2018
/s/ Greg Perry Greg Perry	Director	April 2, 2018
/s/ Howard Rosen Howard Rosen	Director	April 2, 2018
/s/ Rajeev Shah Rajeev Shah	Director	April 2, 2018

/s/ Robert Tepper Robert Tepper, M.D.	Director	April 2, 2018

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Kala Pharmaceuticals, Inc.
Waltham, Massachusetts

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Kala Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2017 and 2016, the related consolidated statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2017 and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

April 2, 2018

We have served as the Company's auditor since 2013.

PART I – FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements.

KALA PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash	$ 114,565	$ 45,472
Prepaid expenses and other current assets	648	154
Total current assets	115,213	45,626
Noncurrent assets:		
Property and equipment, net	786	594
Restricted cash	134	109
Total assets	$ 116,133	$ 46,329
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Current portion of long-term debt	$ 6,667	$ 556
Accounts payable	1,202	997
Accrued expenses	6,589	3,993
Total current liabilities	14,458	5,546
Long-term liabilities:		
Long-term debt - less current portion	11,987	9,098
Warrant liability	—	1,039
Other long-term liabilities	9	17
Total long-term liabilities	11,996	10,154
Total liabilities	26,454	15,700
Commitments and Contingencies (Note 14)		
Convertible preferred stock, 0 shares and 170,336,260 shares authorized as of December 31, 2017 and 2016, respectively		
Series Seed convertible preferred stock, $0.001 par value - 0 shares and 11,323,209 shares designated as of December 31, 2017 and 2016, respectively; 0 shares and 11,243,209 shares issued and outstanding as of December 31, 2017 and 2016, respectively	—	11,065
Series A convertible preferred stock, $0.001 par value - 0 shares and 9,583,432 shares designated, issued and outstanding as of December 31, 2017 and 2016, respectively	—	10,736
Series B convertible preferred stock, $0.001 par value - 0 shares and 16,597,221 shares designated as of December 31, 2017 and 2016, respectively; 0 shares and 15,624,999 shares issued and outstanding as of December 31, 2017 and 2016, respectively	—	22,185
Series B-1 convertible preferred stock, $0.001 par value - 0 shares and 4,629,629 shares designated, issued and outstanding as of December 31, 2017 and 2016, respectively	—	6,885
Series C convertible preferred stock, $0.001 par value - 0 shares and 43,034,639 shares designated as of December 31, 2017 and 2016, respectively; 0 shares and 42,782,688 shares issued and outstanding as of December 31, 2017 and 2016, respectively	—	67,520
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 5,000,000 shares and 0 shares authorized as of December 31, 2017 and 2016, respectively; no shares issued or outstanding as of December 31, 2017 or December 31, 2016	—	—
Common stock, $0.001 par value - 120,000,000 and 110,251,951 shares authorized as of December 31, 2017 and 2016, respectively; 24,538,309 and 1,181,429 shares issued and outstanding as of December 31, 2017 and 2016, respectively	25	1
Additional paid-in capital	224,025	4,374
Accumulated deficit	(134,371)	(92,137)
Total stockholders' equity (deficit)	89,679	(87,762)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 116,133	$ 46,329

The accompanying notes are an integral part of these consolidated financial statements.

KALA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2017	2016	2015
Revenue	$ —	$ —	$ 45
Operating expenses:			
Research and development	29,008	25,029	11,382
General and administrative	10,867	7,640	4,609
Total operating expenses	39,875	32,669	15,991
Loss from operations	(39,875)	(32,669)	(15,946)
Other income (expense):			
Interest income	527	147	—
Interest expense	(1,019)	(767)	(604)
Change in fair value of warrant liability	(1,844)	122	(132)
Total other income (expense)	(2,336)	(498)	(736)
Net loss attributable to common stockholders	$ (42,211)	$ (33,167)	$ (16,682)
Net loss per share attributable to common stockholders—basic and diluted	$ (6.11)	$ (28.07)	$ (14.89)
Weighted average shares outstanding—basic and diluted	6,903,239	1,181,429	1,120,268

The accompanying notes are an integral part of these consolidated financial statements

KALA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (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' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance as of 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)
Balance as of 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 expense													2,069		2,069
Net loss														(33,167)	(33,167)
Balance as of 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													23	(23)	—
Conversion of preferred stock upon IPO	(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)	16,101,970	16	118,375		118,391
Issuance of common stock upon IPO, net of underwriters discount and offering costs of $9,495											6,900,000	7	93,998		94,005
Reclassification of preferred warrant liability													2,883		2,883
Exercise of warrants											106,576		379		379
Exercise of stock options											248,334	1	422		423
Stock-based compensation expense													3,571		3,571
Net loss														(42,211)	(42,211)
Balance as of December 31, 2017	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	24,538,309	$ 25	$224,025	$ (134,371)	$ 89,679

The accompanying notes are an integral part of these consolidated financial statements.

KALA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2017	**2016**	**2015**
Cash flows from operating activities:			
Net loss	$ (42,211)	$ (33,167)	$ (16,682)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation	287	297	330
Change in fair value of warrant liability	1,844	(122)	132
Amortization of debt discount	111	106	134
Write-off of deferred offering costs	—	1,789	—
Stock-based compensation	3,571	2,069	638
Loss on disposal of fixed asset	—	—	19
Increase (decrease) in cash from:			
Accounts receivable	—	—	36
Prepaid expenses and other current assets	(494)	(66)	34
Accounts payable	205	(343)	911
Accrued expenses	2,596	2,108	(605)
Other long-term liabilities	(7)	(19)	(36)
Net cash used in operating activities	(34,098)	(27,348)	(15,089)
Cash flows from investing activities:			
Purchases of property and equipment	(480)	(153)	(252)
Net cash used in investing activities	(480)	(153)	(252)
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 from common stock offering, net of underwriters discounts	96,255	—	—
Payment of common stock offering costs	(2,250)	—	—
Proceeds from venture debt	10,000	1,333	5,000
Payment of principal on venture debt facility	(1,111)	(1,333)	—
Payment of venture debt issuance costs	—	(23)	(3)
Payment of Series B-1 issuance costs	—	—	(115)
Payment of Series C issuance costs	—	(402)	—
Payment of deferred offering costs	—	(283)	(1,506)
Proceeds from exercise of warrants	379	—	—
Proceeds from exercise of stock options	423	—	104
Net cash provided by financing activities	103,696	67,214	10,480
Net increase (decrease) in cash and restricted cash	69,118	39,713	(4,861)
Cash and restricted cash at beginning of period	45,581	5,868	10,729
Cash and restricted cash at end of period	114,699	45,581	5,868
Adjustment for restricted cash	(134)	(109)	(109)
Cash at end of period	$ 114,565	$ 45,472	$ 5,759
Supplemental disclosure of non-cash investing and financing activities:			
Conversion of convertible preferred stock into common stock	$ 118,391	$ —	$ —
Reclassification of warrants to additional paid-in capital	2,883	—	—
Deferred offering costs included in accounts payable and accruals	—	—	226
Cashless exercise of warrants	411	—	—
Fair value of warrants issued in connection with venture debt	—	225	—
Cash paid for interest	$ 863	$ 681	$ 442

The accompanying notes are an integral part of these consolidated financial statements.

KALA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1: Nature of business

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. The Company has applied the MPP technology to lotepredol etabonate, or LE, a corticosteroid designed for ocular applications, resulting in two lead product candidates. These product candidates are INVELTYS™ (KPI-121 1.0%), for the treatment of inflammation and pain following ocular surgery, for which the U.S. Food and Drug Administration (the "FDA") has accepted for filing the Company's New Drug Application, or NDA, and KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. The Company is evaluating opportunities for MPP nanosuspensions of LE with less frequent daily dosing regimens for the treatment of inflammation and pain following ocular surgery, for the temporary relief of the signs and symptoms of dry eye disease and for potential chronic treatment of dry eye disease. The Company is also evaluating compounds in its topically applied MPP receptor Tyrosine Kinase Inhibitor program, or rTKI program, that inhibit the vascular endothelial growth factor, or VEGF, pathway, for the potential treatment of a number of retinal diseases. The brand name INVELTYS has been conditionally approved by the FDA.

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

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

Proceeds from the Company's IPO were approximately $94.0 million after deducting underwriting discounts and commissions of $7.3 million and offering costs of $2.2 million. Upon the closing of the IPO, all of the Company's outstanding shares of convertible preferred stock automatically converted into 16,101,970 shares of common stock at the applicable conversion ratio then in effect. All of the Company's outstanding warrants to purchase preferred stock automatically converted into warrants to purchase 202,020 shares of common stock.

Note 2: Summary of Significant Accounting Policies

Principles of consolidation—The accompanying consolidated financial statements include the accounts of Kala Pharmaceuticals, Inc. and its wholly owned subsidiary, Kala Pharmaceuticals Security Corporation, which is a Massachusetts subsidiary created to buy, sell and hold securities. All intercompany transactions and balances have been eliminated.

Basis of Presentation—The accompanying consolidated 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 $42.2 million, $33.2 million and $16.7 million for the years ended December 31, 2017, 2016 and 2015, respectively, and used cash in operations of $34.1 million, $27.3 million and $15.1 million in the years ended December 31, 2017, 2016, and 2015 respectively. The Company has financed its operations to date primarily through the issuance of common stock, 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 $6.7 million due within one year. The Company expects that its cash of $114.6 million as of December 31, 2017 will be sufficient to fund its operating expenses, debt repayments and capital expenditure requirements for at least 12 months from the date these consolidated financial statements were issued. This evaluation is based on relevant conditions and events that are known and reasonably knowable at the date that the consolidated financial statements are issued.

The viability of the Company beyond that point is dependent on its estimated rate of depletion of available capital resources and its ability to raise additional capital to finance its extended 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.

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

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

Use of Estimates—The preparation of consolidated 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 consolidated 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.

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.

Restricted Cash—As of December 31, 2017 and 2016, the Company had restricted cash of $134,000 and $109,000, respectively, 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 consolidated balance sheets.

Deferred Offering Costs—The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with the offering of its common stock as other current assets until the offering is consummated. After consummation of the offering, these costs are recorded in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. 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 $1.8 million directly related to the proposed offering. During the second quarter of 2016, the Company determined that it was likely its offering 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 deferred offering costs of $1.8 million as general and administrative expenses in the year ended December 31, 2016.

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 consolidated 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, 2017, 2016 and 2015, 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 of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's preferred stock warrant liability, prior to conversion to common stock warrants, was carried at fair value determined according to the fair value hierarchy described above (See Note 8) and classified as a Level 3 measurement. The carrying value of accounts payable and accrued expenses approximate their fair value due to the short-term nature of these assets and liabilities. Management believes that the Company's long-term debt (See Note 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 years ended December 31, 2017 and 2016, 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 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 consolidated 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. After the adoption of ASU 2016-09, described in further detail below, 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 assumptions used in calculating the fair value of stock-based payment awards represent management's best estimates. The Company lacks sufficient 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 will continue to do so until 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 Prior to the IPO—For the years ended December 31, 2016 and 2015 and through the consummation of the IPO, 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 the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

Preferred Stock Warrants—Prior to the completion of the IPO, the Company classified 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 consolidated balance sheets as these warrants were free-standing financial instruments that were exercisable for contingently redeemable shares. The warrants were 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 was reported as the change in fair value of warrant liability in the accompanying consolidated statements of operations. The Company continued to adjust the liability for changes in fair value until conversion of the preferred stock warrants to warrants to purchase common stock (see Note 7).

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 consolidated financial statements and tax returns. Deferred tax assets and liabilities are determined based upon the differences between the consolidated 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 consolidated 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.

Tax Incentives

The Company recognizes tax incentives when there is reasonable assurance that the Company will comply with the conditions attached to the tax incentive agreement and the tax incentive will be received. The Company evaluates the conditions of each individual tax incentive as of each reporting period to ensure that the Company has reached reasonable assurance of meeting the conditions of each tax incentive agreement and that it is expected that the tax incentive will be received as a result of meeting the necessary conditions. When tax incentives are related to reimbursements for cost of revenues or operating expenses, the tax incentives are recognized as a reduction of the related expense in the consolidated statements of operations when the related expense has been incurred.

The Company records tax incentive receivables in the consolidated balance sheets in prepaid expenses and other current assets or long-term tax incentive receivable, depending on when the amounts are expected to be received from the funding agency. As of December 31, 2017, the Company had recorded no tax incentives.

Net Loss per Share—Basic net loss per share is computed using the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed using the 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 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 had been recorded pursuant to a change in fair value of the warrant liability during the period, the Company assessed whether the impact of reversing the gain and including the additional securities was dilutive, and if so, adjusted dilutive EPS. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2017, 2016 and 2015.

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 consolidated 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 consolidated 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 assets, there was no net impact to its accumulated deficit or its net loss resulting from the adoption of this standard. Also

under the guidance in ASU 2016-09, an entity may elect to account for forfeitures as they occur or continue to estimate the total number of awards that are vested or expected to vest. The Company elected to account for forfeitures as they occur and applied the accounting change on a modified retrospective basis as a cumulative effect adjustment to accumulated deficit as of the date of adoption, January 1, 2017. The adoption of this standard did not have a material impact on the Company's financial position, results of operations or consolidated statement of cash flows.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows Restricted Cash* ("ASU 2016-18"). This new standard requires companies to include amounts generally described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the consolidated 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 elected to early adopt this guidance as of December 31, 2017. The adoption of this standard did not have a material impact on the consolidated financial statements and related disclosures.

Recently Issued Accounting Pronouncements—In May 2017, the FASB issued ASU Update No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting (*"ASU 2017-09"), which provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The amendments in ASU 2017-09 are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017, with early adoption permitted. The Company is currently evaluating the impact that ASU 2017-09 will have on the Company's consolidated balance sheets, results of operations and consolidated statements of cash flows.

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 of the adoption of ASU 2016-15, but believes its adoption will have no material impact on its consolidated 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 plans to adopt ASU 2016-02 as of January 1, 2018 and expects to recognize substantially all of its leases on the balance sheet by recording a right-to-use asset and corresponding lease liability.

Note 3: Prepaid Expenses and Other Current Assets

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

	December 31, 2017	December 31, 2016
Rent	$ —	$ 58
Insurance	452	55
Other	196	41
Prepaid expenses and other current assets	$ 648	$ 154

Note 4: Property and Equipment, Net

Property and equipment, net, consists of the following (in thousands):

	December 31, 2017	December 31, 2016
Laboratory equipment	$ 2,084	$ 1,729
Leasehold improvements	114	93
Computer hardware and software	87	54
Office equipment	30	23
Furniture and fixtures	11	11
Property and equipment—at cost	2,326	1,910
Less: Accumulated depreciation	(1,540)	(1,316)
Property and equipment—net	$ 786	$ 594

Depreciation expense for the years ended December 31, 2017, 2016 and 2015 was $287,000, $297,000 and $330,000, respectively.

Note 5: Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2017	December 31, 2016
Development costs	$ 3,054	$ 2,280
Compensation and benefits	2,402	1,480
Professional fees	666	171
General and administrative consulting	229	—
Other	238	62
Accrued expenses	$ 6,589	$ 3,993

Note 6: Debt

2014 Debt Facility

In November 2014, the Company entered into a venture debt facility (“2014 Debt Facility”) for a total loan commitment of $10.0 million. On October 13, 2016, the Company entered into a First Amendment to the 2014 Debt Facility the ("First Amendment"), which reaffirmed the initial commitment to a total of $10.0 million of funding (“Term

Loan A") and increased the Company's total borrowing capacity by an additional $10.0 million ("Term Loan B" and together with Term Loan A, "Term Loans"). On September 28, 2017, the Company drew the additional $10.0 million available under Term Loan B. On November 22, 2017, the Company entered into a Second Amendment to the 2014 Debt Facility to account for the formation of the Company's wholly-owned subsidiary. Under the terms of the facility, the borrowings accrue interest at an annual rate equal to 3.00% above the Prime Rate then in effect. The interest rate was 7.50% and 6.50% as of December 31, 2017 and 2016, respectively.

The unpaid principal balance under the 2014 Debt Facility was $18.9 million as of December 31, 2017 and $10.0 million as of December 31, 2016. The unamortized discount was $235,000 and $346,000 as of December 31, 2017 and 2016, respectively. The Company recognized interest expense of $1.0 million, $767,000 and $604,000 related to the 2014 Debt Facility during the years ended December 31, 2017, 2016 and 2015, respectively, which consisted of the amortization of the debt discount of $111,000, $106,000 and $134,000, respectively, and contractual coupon interest of $908,000, $661,000 and $470,000, respectively.

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

In connection with the 2014 Debt Facility and the initial borrowing of $5.0 million under Term Loan A, the Company issued warrants to the lender to purchase 138,889 shares of Series B Preferred Stock at an exercise price of $1.44 per share (the "2014 Warrants"). During 2015 the Company borrowed an additional $5.0 million under Term Loan A and the number of exercisable shares underlying the 2014 Warrants increased to 277,778 shares of Series B Preferred Stock or 53,333 shares of common stock at an exercise price of $7.50 per share on an as-converted basis (see Note 9). 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"), or 48,374 shares of common stock at an exercise price of $8.27 per share on an as-converted basis (see Note 9). Consistent with the warrants issued under the original 2014 Debt Facility, the number of shares of Series C Preferred Stock that become exercisable would increase in proportion to the amount of Term Loan B borrowings. Upon the September 28, 2017 draw down of Term B Loan, the 2016 Warrants became exercisable into 48,374 shares of common stock. The 2016 Warrants were not exercisable into shares as of the First Amendment date or December 31, 2016, as the Company had not borrowed under the Term B Loan during 2016.

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 8), and recorded the estimated fair value of the warrants as a liability separate from the loan balance, resulting in additional debt discount included within long-term debt that is amortized to interest expense over the term of the loan using the effective interest method. The initial fair value of the 2014 Warrants and 2016 Warrants was $140,000 and $225,000, respectively. Upon the Company's IPO on July 25, 2017, all of the underlying preferred stock warrants were converted into warrants for common stock, and the warrant liability was re-measured to fair value and reclassified to additional paid-in capital.

As of December 31, 2017 and 2016, the estimated fair value of the warrant liability associated with the 2014 Warrants was $0 and $274,000, respectively, and the estimated fair value of the warrant liability associated with the 2016 Warrants was $0 and $263,000.

The future annual principal payments due under the 2014 Debt Facility as of December 31, 2017 were as follows (in thousands):

Years Ending December 31,	
2018	$ 6,667
2019	6,667
2020	5,555
Total	$ 18,889

Note 7: Warrants

The Company has issued warrants in connection with debt transactions that were completed prior to 2014, all of which are classified as liabilities as of December 31, 2016 and which were re-measured at fair value at each reporting period prior to the reporting period ending December 31, 2017, as the warrants were exercisable into contingently redeemable shares. As of December 31, 2016, warrants outstanding to acquire Series C Preferred Stock were not exercisable into shares of Series C Preferred Stock. As part of the draw down of Term Loan B on September 28, 2017, warrants to acquire 48,374 shares of common stock became exercisable.

The following table summarizes the preferred warrants outstanding at each of the dates identified:

Issued	Exercisable for	Exercise Price	Expiration Date	Shares Exercisable at December 31, 2017	Shares Exercisable at December 31, 2016
2011 and 2012	Series Seed Preferred Stock	$ 1.00	July 2019	—	80,000 (1)
2013	Series B Preferred Stock	$ 1.44	April 2021	—	694,444 (1)
2014	Series B Preferred Stock	$ 1.44	November 2024	—	277,778 (1)
2016	Series C Preferred Stock	$ 1.59	October 2026	— (2)	— (2)

(1) As of December 31, 2016, the preferred stock warrants to purchase Series Seed Preferred Stock issued in 2011 and 2012, Series B Preferred Stock issued in 2013 and Series B Preferred Stock issued in 2014 were exercisable, and on a converted basis would have represented warrants to purchase common stock of 15,360, 133,327 and 53,333 shares, respectively. As of December 31, 2017 there were no preferred stock warrants outstanding (See Note 1) and all of the underlying preferred stock warrants were converted into warrants for common stock.

(2) As of December 31, 2016, the preferred stock warrants to purchase Series C Preferred Stock were not exercisable and as of December 31, 2017, there were no preferred stock warrants outstanding (See Note 1). Upon the September 2017 $10.0 million draw down of the Term B Loan, 48,374 warrants became exercisable for 48,374 shares of common stock, which for comparative purposes represents 251,951 shares of Series C Preferred Stock on a pre-converted basis.

The following table summarizes the common stock warrants each exercisable into one share of common stock:

Issued	Original Source	Exercise Price	Expiration Date	Exercisable From	Shares Exercisable at December 31, 2017
2013	Series B Preferred Stock	$ 7.50	April 2021	July 2017	82,816
2014	Series B Preferred Stock	$ 7.50	November 2024	July 2017	16,000
2016	Series C Preferred Stock	$ 8.27	October 2026	September 2017	14,512
					113,328

Note 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. Upon the Company's IPO on July 25, 2017, all of the underlying preferred stock warrants became exercisable for common stock instead of preferred stock and the fair value of the warrant liability of $2.9 million, as measured immediately prior to the IPO, was charged to additional paid-in capital with the reclassification of the warrants into equity. There was no warrant liability as of December 31, 2017 and, as such, there were no assets and liabilities measured at fair value on a recurring basis as of December 31, 2017. The assets and liabilities measured at fair value on a recurring basis as of December 31, 2016 and the input categories associated with those assets and liabilities are as follows (in thousands):

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

The Company has historically 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 included the estimated volatility, the estimated fair value of the underlying preferred stock, and to the extent that the number of exercisable shares underlying the warrants were adjustable based on the amount of the Term Loans drawn down or the probability that the Company would draw down on the debt facility. The Company determined the fair values of the warrants as of December 31, 2016 and on an interim basis immediately prior to conversion of preferred stock and warrants into common stock and warrants exercisable for common stock, using the Black-Scholes option-pricing model. The following assumptions were used for the respective measurement date(1):

	2011 and 2012 Series Seed Warrants	2013 Series B Warrants	2014 Series B Warrants	Series C Warrants
December 31, 2016				
Volatility	100.00 %	87.00 %	114.00 %	58.30 %
Risk-free interest rate	1.30 %	1.80 %	2.30 %	2.40 %
Estimated fair value of underlying shares	$ 0.89	$ 1.11	$ 1.11	1.54
Remaining contractual term (years)	2.6	4.3	7.9	9.8
Expected dividend yield	— %	— %	— %	— %
Immediately prior to conversion				
Volatility	119.00 %	112.00 %	114.00 %	116.00 %
Risk-free interest rate	1.40 %	1.60 %	2.10 %	2.20 %
Estimated fair value of underlying shares	$ 13.50	$ 13.50	$ 13.50	$ 13.50
Remaining contractual term (years)	2.0	3.7	7.3	9.2
Expected dividend yield	— %	— %	— %	— %

(1) For purposes of determining the fair value of the warrants to purchase Series C Preferred Stock as of December 31, 2016 and immediately prior to conversion, the Company estimated that there was a 100% probability that it would draw down on the remaining $10.0 million available under the 2014 Debt Facility as of the measurement date, and as such, assumed that the warrants would 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, 2016 and immediately prior to conversion, 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.

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

	Year Ended December 31,	
	2017	2016
Fair value - January 1,	$ 1,039	$ 936
Fair value of 2016 Warrants upon First Amendment	—	225
Change in fair value of warrant liability	1,844	(122)
Reclassification of preferred warrant liability	(2,883)	—
Fair value - December 31,	$ —	$ 1,039

Note 9: Preferred Stock

Adjustment to Conversion Ratios

On July 7, 2017, the Company effected a one-for-5.2083 reverse stock split of the Company's issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for the Company's convertible preferred stock. The par value per share and authorized shares of common and convertible preferred stock were not adjusted as a result of the reverse stock split.

Convertible preferred stock consisted of the following as of December 31, 2016 (in thousands, except share amounts):

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

(1) No fractional shares of Common Stock were issuable upon conversion of the preferred stock. In lieu of any fractional shares to which the holder would otherwise be entitled, the Company paid 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 payments for fractional shares would be made upon such conversion was

determined on the basis of the total number of shares of preferred stock the holder was at the time converting into common stock and the aggregate number of shares of common stock issuable upon such conversion.

Upon the closing of the Company's IPO on July 25, 2017, all outstanding shares of convertible preferred stock converted into 16,101,970 shares of the Company's common stock. Following the closing of the Company's IPO, the Company is authorized to issue 5.0 million shares of undesignated preferred stock in one or more series. As of December 31, 2017, no shares of preferred stock were issued or outstanding.

Series Seed Convertible Preferred Stock

In December 2009, the Company issued an aggregate of 2,000,001 shares of Series Seed Preferred Stock for gross proceeds of $2.0 million or $1.00 per share. In October 2010, the Company issued an aggregate of 2,000,003 shares of Series Seed Preferred Stock to existing investors for gross proceeds of $2.0 million or $1.00 per share. In February 2012, the Company issued an aggregate of 7,243,205 shares of Series Seed Preferred Stock to existing and new investors, which included 6,150,000 shares for gross proceeds of $6.2 million and 1,093,205 shares converted from convertible debt of $1.0 million principal and $93,000 accrued interest. Costs incurred in connection with each of the individual issuances of Series Seed Preferred Stock were $124,000, $39,000 and $15,000 respectively, which have been recorded as a reduction to the carrying amount of the Series Seed Preferred Stock. On July 25, 2017, upon the closing of the Company's IPO, all outstanding shares of Series Seed Convertible Stock converted into 2,158,708 shares of the Company's common stock. As such, there were no outstanding shares of Series Seed Convertible Preferred Stock as of December 31, 2017.

Series A Convertible Preferred Stock

In February 2013, the Company issued 4,791,716 shares of Series A Preferred Stock, at a purchase price of $1.20 per share for gross proceeds of $5.8 million. Additionally, in accordance with the terms of the Series A Preferred Stock Purchase Agreement, investors were granted the right to purchase up to an additional 4,791,716 shares of Series A Preferred Stock, at a price of $1.20 per share, upon the Company meeting certain milestone criteria by December 31, 2013, approval of the Board and approval of the investors holding a majority of the outstanding shares of Series A Preferred Stock. In June 2013, the Board approved waiving one of the milestone events provided for in the Series A Preferred Stock Purchase Agreement. Accordingly, the second tranche of Series A Preferred Stock closed on July 15, 2013 and the Company issued 4,791,716 shares of Series A Preferred Stock for gross proceeds of $5.8 million, or $1.20 per share. Costs incurred in connection with the issuance of the Series A Preferred Stock were $93,000, which have been recorded as a reduction in the carrying amount of the Series A Preferred Stock. On July 25, 2017, upon the closing of the Company's IPO, all outstanding shares of Series A Convertible Stock converted into 1,840,029 shares of the Company's common stock. As such, there were no outstanding shares of Series A Convertible Preferred Stock as of December 31, 2017.

Series B Convertible Preferred Stock

In April 2014, the Company issued 15,624,999 shares of Series B Preferred Stock for gross proceeds of $22.5 million or $1.44 per share which included conversion of the outstanding principal and interest on the 2013 Notes (See Note 7) of $5.1 million, which converted into 3,562,785 shares of Series B Preferred Stock pursuant to the terms of the Notes. Costs incurred in connection with the issuance of the Series B Preferred Stock were $315, which have been recorded as a reduction in the carrying amount of the Series B Preferred Stock. On July 25, 2017, upon the closing of the Company's IPO, all outstanding shares of Series B Convertible Stock converted into 3,000,017 shares of the Company's common stock. As such, there were no outstanding shares of Series B Convertible Preferred Stock as of December 31, 2017.

Series B-1 Convertible Preferred Stock

On August 17, 2015, the Company issued 4,629,629 shares of Series B-1 Senior Convertible Preferred Stock ("Series B-1 Preferred Stock") for gross proceeds of $7.0 million or $1.512 per share. Costs incurred in connection with the issuance of the Series B-1 Preferred Stock were $115,000, which have been recorded as a reduction in the carrying amount of the Series B-1 Preferred Stock. On July 25, 2017, upon the closing of the Company's IPO, all outstanding shares of Series B-1 Convertible Stock converted into 888,894 shares of the Company's common stock. As such, there were no outstanding shares of Series B-1 Convertible Preferred Stock as of December 31, 2017.

Series C Convertible Preferred Stock

On April 5, 2016, the Company issued 42,782,688 shares of Series C Preferred Stock for gross proceeds of $67.9 million or $1.5876 per share. Costs incurred in connection with the issuance of the Series C Preferred Stock were $402,000, which have been recorded as a reduction in the carrying amount of the Series C Preferred Stock. On July 25, 2017, upon the closing of the Company's IPO, all outstanding shares of Series C Convertible Stock converted into 8,214,322 shares of the Company's common stock. As such, there were no outstanding shares of Series C Convertible Preferred Stock as of December 31, 2017.

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' equity (deficit) 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 were as follows:

Voting—Preferred stockholders were 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 was then convertible.

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 were declared or paid through December 31, 2017.

Liquidation Rights— Prior to the IPO, 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 was 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 were 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 were 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 would have been 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 would have been 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 was 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. Following the Company's reverse stock split on July 7, 2017, each share of preferred stock was convertible into 0.1920 shares of common stock. Each share of preferred stock would automatically convert into common stock at the then applicable conversion rate for each series of preferred 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 $30.0 million, 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 did not participate in a Qualified Financing, as defined in the Company's Certificate of Incorporation, as restated from time to time (the "Charter"), effective upon the consummation of the Qualified Financing, a portion of the holder's preferred stock (as determined in accordance with the Charter) would 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 would be subject to any adjustment thereafter.

Note 10: Common Stock

Common Stock

The Company was authorized to issue up to 120,000,000 and 110,251,951 shares of common stock with a $0.001 par value per share as of December 31, 2017 and 2016, respectively. The Company had 24,538,309 and 1,181,429 shares of common stock issued and outstanding as of December 31, 2017 and 2016, respectively.

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.

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.

Reverse Stock Split

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

Reserved Shares

As of December 31, 2017 and 2016, the Company has reserved 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 as follows (see Note 11):

	December 31, 2017	December 31, 2016
Convertible preferred stock	—	16,101,970
2013 Warrant rights to acquire Series B Preferred Stock	—	133,327
2014 Warrant rights to acquire Series B Preferred Stock	—	53,333
2016 Warrant rights to acquire Series C Preferred Stock (1)	—	48,374
2011 Warrant rights to acquire Series Seed Preferred Stock	—	15,360
Warrant rights to acquire Common Stock	113,328	—
2009 stock option plan	2,868,449	3,533,726
2017 stock option plan	2,025,633	—
Total	5,007,410	19,886,090

(1) As of December 31, 2016, warrants outstanding to acquire Series C Preferred Stock were not exercisable into shares of Series C Preferred Stock; however, upon draw down of Term Loan B, the warrants became exercisable for 48,374 shares of common stock, which for comparative purposes represents 251,951 shares of Series C Preferred Stock on a pre-converted basis.

Note 11: Stock-based Compensation

A summary of option activity for employee and non-employee consultant awards under the 2009 Plan and the 2017 Plan for the year ended December 31, 2017 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at January 1, 2017	3,195,469	$ 3.26	8.6	$ 1,200
Granted	973,492	16.88		
Exercised	(248,334)	1.70		
Forfeited	(181,699)	2.80		
Outstanding at December 31, 2017	3,738,928	$ 6.93	8.4	$ 44,578
Vested at December 31, 2017	3,738,928	$ 6.93	8.4	$ 44,578
Options exercisable at December 31, 2017	1,692,918	$ 3.74	7.8	$ 24,963

The assumptions used in determining fair value of the stock options granted in the years ended December 31, 2017, 2016 and 2015 are as follows:

	Year Ended December 31,		
	2017	2016	2015
Expected volatility	102% - 122%	106% - 110%	106% - 115%
Risk-free interest rate	1.81% - 2.29%	1.21% - 1.45%	1.49% - 2.24%
Expected dividend yield	0%	0%	0%
Expected term (in years)	5.04 - 9.82	5.62 - 6.18	5.87 - 9.46

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 expected term of options using the simplified method, as the Company lacks relevant historical data due to the Company's limited operating experience. The estimated volatility is based upon the historical volatility of comparable companies with publicly available share prices. The impact of forfeitures on compensation expense is recorded as they occur.

The weighted average grant-date fair value of options granted during the years ended December 31, 2017, 2016 and 2015 was $13.87, $2.71 and $4.17, respectively. The fair value is being expensed over the vesting period of the options on a straight-line basis as the services are being provided. As of December 31, 2017, there was $15.4 million of unrecognized compensation cost related to the stock options granted, which is expected to be expensed over a weighted-

average period of 3.11 years. Stock-based compensation expense was classified in the consolidated statements of operations as follows (in thousands):

	Year Ended December 31,		
	2017	2016	2015
Research and development	$ 1,267	$ 461	$ 161
General and administrative	2,304	1,608	477
Total	$ 3,571	$ 2,069	$ 638

The Company received cash proceeds from the exercise of stock options of $423,000, $0 and $104,000 during the years ended December 31, 2017, 2016 and 2015, respectively. The total intrinsic value of options exercised for the year ended December 31, 2017, 2016 and 2015 was $4.7 million, $0 and $552,000, respectively.

Note 12: Income Taxes

The Company has had no income tax expense due to operating losses incurred for the years ended December 31, 2017 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.

Tax Reform Language Definition—On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act makes broad and complex changes to the U.S. tax code, including but not limited to, (1) reducing the U.S. federal corporate tax rate from 35 percent to 21 percent; (2) requiring companies to pay a one-time transition tax on certain unrepatriated earnings of foreign subsidiaries; (3) generally eliminating U.S. federal income taxes on dividends from foreign subsidiaries; (4) requiring a current inclusion in U.S. federal taxable income of certain earnings of controlled foreign corporations; (5) eliminating the corporate alternative minimum tax (AMT) and changing how existing AMT credits can be realized; (6) creating the base erosion anti-abuse tax (BEAT), a new minimum tax; (7) creating a new limitation on deductible interest expense; and (8) changing rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017.

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,	
	2017	2016
Federal statutory income tax rate	35.0 %	35.0 %
Effect of:		
Change in valuation allowance	3.5	(42.3)
Impact of change in tax laws	(42.5)	—
State income taxes, net of federal benefit	3.9	4.7
Research and development tax credits	3.2	3.1
Other	(3.1)	(0.5)
Effective income tax rate	— %	— %

Net deferred tax assets as of December 31, 2017 and 2016 consisted of the following (in thousands):

	December 31,	
	2017	2016
Net operating loss carryforwards	$ 33,689	$ 36,280
Research and development tax credit carryforwards	4,470	2,940
Start-up costs and other	2,024	1,807
Total deferred tax assets	40,183	41,027
Depreciation and amortization	(9)	8
Total deferred tax liabilities	(9)	8
Valuation allowance	(40,174)	(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, 2017 and 2016. The valuation allowance decreased by $0.9 million in 2017 due to the tax legislation included in the Tax Act and increased by $14.6 million in 2016 due to an 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, 2017 and 2016, the Company has federal net operating loss carryforwards of $120.9 million and $85.3 million, respectively, which may be available to offset future federal tax liabilities and expire at various dates beginning in 2030 through 2037. At December 31, 2017 and 2016, the Company has state net operating loss carryforwards of $104.0 million and $80.5 million, respectively, which may be available to offset future state income tax liabilities and expire at various dates beginning in 2030 through 2037. As of December 31, 2017 and 2016, the Company also had federal and state research and development credit carryforwards of approximately $4.5 million and $2.9 million, respectively, which are available to reduce future income taxes, if any, from 2030 through 2037 (federal) and 2025 through 2032 (state).

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,

North Carolina, Texas and New Hampshire. All tax years since the date of incorporation remain open to examination by the major taxing jurisdictions (state and federal) to which the Company is subject, as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service (''IRS'') or other authorities if they have or will be used in a future period. The Company is not currently under examination by the IRS or any other jurisdictions for any tax year.

As of December 31, 2017, 2016 and 2015 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, 2017, 2016 and 2015.

Note 13: Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders were calculated as follows (in thousands):

	Year Ended December 31,		
	2017	2016	2015
Numerator:			
Net loss attributable to common stockholders	$ (42,211)	$ (33,167)	$ (16,682)
Denominator:			
Weighted average shares outstanding—basic and diluted	6,903,239	1,181,429	1,120,268
Net loss per share attributable to common stockholders—basic and diluted	$ (6.11)	$ (28.07)	$ (14.89)

The Company's potential dilutive securities, which include stock options, warrants to purchase common stock as of December 31, 2017 and stock options, warrants to purchase preferred stock and convertible preferred stock as of December 31, 2016 and 2015, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share.

Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders are the same.

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

	December 31,		
	2017	2016	2015
Convertible preferred stock (as converted to common stock)	—	16,101,970	7,887,642
Options to purchase common stock	3,738,928	3,195,469	1,546,155
Stock warrants (1)	113,328	250,394	202,020
	3,852,256	19,547,833	9,635,817

(1) Stock warrants outstanding as of December 31, 2016 include warrants to purchase Series C Preferred Stock for which the underlying shares included above of 48,374 are only exercisable upon the Company's draw down of the full amount of Term Loan B of $10.0 million.

Note 14: Commitments and Contingencies

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

On June 30, 2016, the lease was amended to extend the term from January 31, 2017 to January 31, 2019. In connection with the lease agreement, the Company issued a letter of credit to the landlord for $84,000. The Company secured the letter of credit using restricted cash for the full amount of the letter. The restricted cash as of December 31, 2017 and 2016 is included in other noncurrent assets in the accompanying consolidated balance sheets. Total rent expense for the lease for the years ended December 31, 2017, 2016 and 2015, which is recorded on a straight-line basis, was $388,000, $338,000 and $321,000, respectively.

As of December 31, 2017, future minimum commitments due under the lease are as follows (in thousands):

Years Ending December 31,		
2018	$	410
2019		34
Total minimum lease payments	$	444

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

After 2016 and until the first commercial sale of product, the minimum annual payment will be $38,000. If the Company achieves the first commercial sale of the product in the United States, European Union, or Japan, the annual minimum payment will increase to $113,000. The Company is obligated to pay JHU low single-digit running royalties based upon a percentage of net sales of the licensed products. The Company also has an obligation to pay JHU certain one-time development and commercial milestone payments. The Company recorded research and development expenses related to the JHU agreement of $139,000, $169,000 and $152,000 for the years ended December 31, 2017, 2016 and 2015, 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 $10,000. Beginning in 2016, the Company was also obligated to pay an annual payment of $5,000. The agreement terminates in 2018.

The Company's minimum obligations due under its license agreements as of December 31, 2017, are as follows (in thousands):

Year Ended December 31,	
2018	43
2019	38
2020	—
Total minimum license payments	$ 81

The Company entered into a commercial supply agreement with Catalent Pharma Solutions, LLC to manufacture commercial supplies of INVELTYS and KPI-121 0.25%, with annual minimum purchase requirements. Under the minimum unit purchase requirements, if both INVELTYS 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 $1.5 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, 2017, 2016 and 2015, 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 consolidated financial statements.

Note 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 $83,000 to the 401(k) Plan during for the year ended December 31, 2017.

Note 16: Related Parties

The Company has engaged in the following related-party transactions:

A founder, who is also a stockholder and director, served as a consultant to the Company. The individual is employed by a university, which has no relationship to the Company. For the years ended December 31, 2017, 2016 and 2015 the Company paid the individual $35,000, $60,000 and $60,000, respectively, for the consulting services which are included in research and development expense in the accompanying consolidated statements of operations. Immediately prior to the effectiveness of the Company's registration statement on Form S-1 for the Company's IPO in July 2017, the Company terminated the consulting services agreement with the individual.

Note 17: Selected Quarterly Financial Data

Selected quarterly financial data is as follows (in thousands, except per share data):

	Three months ended			
	March 31, 2016	June 30, 2016	September 30, 2016	December 31, 2016
	(in thousands, except per share data)			
Total operating expenses	$ 5,076	$ 9,650	$ 9,747	$ 8,196
Total other income (expense)	(176)	(203)	80	(199)
Net loss attributable to common stockholders	$ (5,252)	$ (9,853)	$ (9,667)	$ (8,395)
Net loss per share attributable to common stockholders—basic and diluted	$ (4.45)	$ (8.34)	$ (8.18)	$ (7.11)

	Three months ended			
	March 31, 2017	June 30, 2017	September 30, 2017	December 31, 2017
	(in thousands, except per share data)			
Total operating expenses	$ 9,571	$ 9,630	$ 9,534	$ 11,140
Total other income (expense)	(188)	(1,356)	(642)	(150)
Net loss attributable to common stockholders	$ (9,759)	$ (10,986)	$ (10,176)	(11,290)
Net loss per share attributable to common stockholders—basic and diluted	$ (8.26)	$ (9.30)	$ (0.56)	(0.46)

Note 18: Subsequent Events

On February 28, 2018, the Company entered into a Lease Agreement (the "Watertown Lease") with 480 Arsenal Group LLC ("the Arsenal Group") for the lease of a portion of the building located at 490 Arsenal Way Watertown, Massachusetts consisting of 66,052 rentable square feet at an initial rate of $53 per square foot and annual increases of 3% for the next 7 years. The initial term of the Watertown Lease is 8 years. The Company expects to occupy the premises by the end of 2018. The Company plans to use the premises as its new corporate headquarters and for research and development.

In connection with the Watertown Lease, the Company issued a letter of credit to the Arsenal Group for $2.0 million. The Company secured the letter of credit using restricted cash for the full amount of the letter.

On March 15, 2018, the Company entered into a Lease Agreement (the "Waverley Oaks Lease") with Duffy Associates, LLC for the lease of a portion of the building located at 465 Waverely Oaks Road Suite 301, Waltham, Massachusetts consisting of 6,294 rentable square feet at a rate of $32 per square foot. The term of the Waverley Oaks Lease is one year. The Company plans to use this location for additional corporate offices before moving to its new corporate headquarters in Watertown, MA.

On March 29, 2018, the Company entered into a third amendment ("the Third Amendment") to the 2014 Debt Facility. The Third Amendment reaffirmed the prior commitment of $20 million in funding, or Term Loan A, and extended the interest-only end date for 12 months following the execution of the Third Amendment. In addition, the total borrowing capacity was increased by an additional $5 million ("Term Loan B") subject to the following conditions: (i) the minimum borrowing amount is $250,000 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 receiving FDA approval of INVELTYS. Funding under the Term Loan B commitment is available for 12 months following the execution of the Third Amendment. The maturity date of the 2014 Debt Facility was also extended from October 13, 2020 to March 29, 2022.

Exhibit 10.10

KALA PHARMACEUTICALS, INC.

LOAN AND SECURITY AGREEMENT

This LOAN AND SECURITY AGREEMENT (this "Agreement") is entered into as of November 20, 2014, by and among Square 1 Bank ("Square 1"), in its capacity as administrative and collateral agent (together with its successors and assigns in such capacity, "Agent") for the lenders hereto as of the date hereof and other financial institutions who hereafter become parties to this Agreement as lenders (each individually a "Lender" and, collectively, the "Lenders"), the Lenders set forth on Schedule 1 hereto and Kala Pharmaceuticals, Inc. ("Borrower").

RECITALS

Borrower wishes to obtain credit from time to time from the Lenders, and the Lenders desire to extend credit to Borrower. This Agreement sets forth the terms on which the Lenders will advance credit to Borrower and Borrower will repay the amounts owing to the Lenders.

AGREEMENT

The parties agree as follows:

1. DEFINITIONS AND CONSTRUCTION.

1.1 Definitions. As used in this Agreement, all capitalized terms shall have the definitions set forth on Exhibit A. Any term used in the Code and not defined herein shall have the meaning given to the term in the Code.

1.2 Accounting Terms. Any accounting term not specifically defined on Exhibit A shall be construed in accordance with GAAP, and all calculations shall be made in accordance with GAAP (except for the calculation of warrant liabilities and stock compensation expenses on Borrower's unaudited financial statements only, which calculations shall be made in accordance with management accounting consistent with past practices). The term "financial statements" shall include the accompanying notes and schedules.

2. LOAN AND TERMS OF PAYMENT.

2.1 Credit Extensions.

(a) Promise to Pay. Borrower promises to pay to the Lenders, in lawful money of the United States of America, the aggregate unpaid principal amount of all Credit Extensions made by the Lenders to Borrower, together with interest on the unpaid principal amount of such Credit Extensions at rates in accordance with the terms hereof.

(b) Term Loan.

(i) Subject to and upon the terms and conditions of this Agreement, the Lenders agree to make, severally and not jointly, according to each Lender's Term Loan Commitment Amount, one or more term loans to Borrower in an aggregate principal amount not to exceed $10,000,000 (each a "Term Loan" and, collectively, the "Term Loans"). Each Term Loan shall be in a minimum amount of $250,000. Borrower may request Term Loans at any time from the date hereof through the Availability End Date. The proceeds

of the Term Loans shall be used for general working capital purposes, and for capital equipment purchases, to pay Lender Expenses and to pay the fees under this Agreement.

(ii) Interest shall accrue from the date of each Term Loan at the rate specified in Section 2.2(a) and, through the Interest-Only End Date, shall be payable monthly in arrears beginning on the first day of the month next following such Term Loan, and continuing on the same day of each month thereafter. Any Term Loans that are outstanding on the Interest-Only End Date shall be payable in 30 equal monthly installments of principal, plus all accrued interest, beginning on the first day of the month immediately following the Interest-Only End Date and continuing on the same day of each month thereafter through the Term Loan Maturity Date, at which time all amounts due in connection with the Term Loans and any other amounts due under this Agreement shall be immediately due and payable. Term Loans, once repaid, may not be reborrowed. Borrower may prepay any Term Loan, subject to the payment of the Prepayment Fee.

(iii) When Borrower desires to obtain a Term Loan, Borrower shall notify Agent (which notice shall be irrevocable) by facsimile transmission to be received no later than 3:30 p.m. Eastern time at least five Business Days prior to the date on which the Term Loan is to be made. Such notice shall be substantially in the form of Exhibit C and signed by an Authorized Officer. Promptly upon receiving such notice, Agent shall notify each Lender of the contents of such notice and each Lender's Pro Rata Share of such Term Loan.

2.2 Interest Rates, Payments, and Calculations.

(a) Interest Rates. Except as set forth in Section 2.2(b), the Term Loans shall bear interest, on the outstanding daily balance thereof, at a variable annual rate equal to the greater of (i) 3.00% above the Prime Rate then in effect, or (ii) 6.25%.

(b) Late Fee; Default Rate. If any payment is not made within 15 days after the date such payment is due, Borrower shall pay Agent (for the benefit of the Lenders) a late fee equal to the lesser of (i) 5% of the amount of such unpaid amount or (ii) the maximum amount permitted to be charged under applicable law. All Obligations shall bear interest, from and after the occurrence and during the continuance of an Event of Default, at a rate equal to five percentage points above the interest rate applicable immediately prior to the occurrence of the Event of Default.

(c) Payments. Agent shall charge all interest, all Lender Expenses, and all Periodic Payments against any of Borrower's deposit accounts. Any interest not paid when due shall be compounded by becoming a part of the Obligations, and such interest shall thereafter accrue interest at the rate then applicable hereunder.

(d) Computation. In the event the Prime Rate is changed from time to time hereafter, the applicable rate of interest hereunder shall be increased or decreased, effective as of the day the Prime Rate is changed, by an amount equal to such change in the Prime Rate. All interest chargeable under the Loan Documents shall be computed on the basis of a 360-day year for the actual number of days elapsed.

2.3 Crediting Payments. Prior to the occurrence of an Event of Default, Agent shall credit a wire transfer of funds, check or other item of payment to such deposit account or Obligation as Borrower specifies. After the occurrence and during the continuance of an Event of Default, Agent shall have the right, in its sole discretion, to immediately apply any wire transfer of funds, check, or other item of payment Agent may receive to conditionally reduce Obligations, but such applications of funds shall not be considered a payment on account unless such payment is of immediately available federal funds or unless and until such check or other item of payment is honored when presented for payment. Notwithstanding anything to the contrary contained herein, any wire transfer or payment received by Agent after 5:30 p.m. Eastern time shall be deemed to have been received by Agent as of the opening of business on the immediately following Business Day. Whenever any payment to Agent under the Loan Documents would otherwise be due (except by reason of acceleration) on a date that is not a Business Day, such payment shall instead be due on the next Business Day, and additional fees or interest, as the case may be, shall accrue and be payable for the period of such extension.

2.4 Fees. Borrower shall pay the following:

(a) Facility Fee. On or before the Closing Date, a fee equal to $50,000 to be paid to Agent (for the benefit of the Lenders), which shall be nonrefundable;

(b) Lender Expenses. On the Closing Date, all Lender Expenses incurred through the Closing Date, and, after the Closing Date, all Lender Expenses, as and when they become due.

(c) Prepayment Fee. In connection with any prepayment of any principal amount of the Term Loans prior to the Term Loan Maturity Date, including following acceleration under Section 9.1, Borrower shall pay to Agent (for the benefit of the Lenders), on the date of such prepayment, a prepayment fee (the "Prepayment Fee") in an amount equal to the principal amount so prepaid multiplied by a percentage determined in accordance with the following schedule:

Period	Applicable Prepayment Percentage
From the Closing Date to (but not including) the first anniversary of the Closing Date	0.90%
From the first anniversary of the Closing Date to (but not including) the second anniversary of the Closing Date	0.60%
From the second anniversary of the Closing Date and thereafter until the Term Loan Maturity Date	0.30%

Borrower acknowledges that the foregoing Prepayment Fee represents a reasonable and fair estimate for the loss that the Lenders may sustain from the prepayment of the Term Loans prior to the Term Loan Maturity Date and further acknowledges that, except as specifically provided herein, Borrower has no right to optionally prepay the Term Loans in whole or in part without paying the foregoing Prepayment Fee. For the avoidance of doubt, no Prepayment Fee shall be payable in connection with any payment of regularly scheduled principal installments of the Term Loans.

2.5 Term. This Agreement shall become effective on the Closing Date and, subject to Section 12.7, shall continue in full force and effect for so long as any Obligations remain outstanding or any Lender has any obligation to make Credit Extensions under this Agreement. Notwithstanding the foregoing, the Lenders shall have the right to terminate their obligation to make Credit Extensions under this Agreement immediately and without notice upon the occurrence and during the continuance of an Event of Default.

3. CONDITIONS OF LOANS.

3.1 Conditions Precedent to Closing. The agreement of Agent and the Lenders to enter into this Agreement on the Closing Date is subject to the condition precedent that Agent and the Lenders shall have received, in form and substance satisfactory to Agent and the Lenders, each of the following items and shall have completed each of the following requirements:

(a) this Agreement;

(b) an officer's certificate of Borrower with respect to incumbency and resolutions authorizing the execution and delivery of this Agreement;

(c) a financing statement (Form UCC-1);

(d) a Loan Advance/Paydown Request Form in a minimum amount of $5,000,000;

(e) payment of the fees and Lender Expenses then due specified in Section 2.4, which may be debited from any of Borrower's accounts with Square 1;

(f) current SOS Reports indicating that, except for Permitted Liens, there are no other security interests or Liens of record in the Collateral;

(g) current financial statements, including audited statements for Borrower's most recently ended fiscal year, together with an unqualified opinion (or an opinion qualified only for going concern solely due to Borrower's projected need for additional funding to continue operations), company prepared consolidated, if applicable, balance sheets, income statements and statements of cash flows for the most recently ended month in accordance with Section 6.2, and such other updated financial information as the Lenders may reasonably request;

(h) current Compliance Certificate in accordance with Section 6.2;

(i) warrants duly executed by Borrower and issued to each Lender;

(j) a Borrower Information Certificate;

(k) a deposit account control agreement with respect to Borrower's account numbers and at Square 1;

(l) [Reserved];

(m) a payoff letter from Lighthouse Capital Partners VI, L.P.;

(n) a copy of Borrower's policies or certificates of insurance including any endorsements showing Agent as loss payee (for the benefit of Lenders) and showing Agent and each Lender as an additional insured;

(o) such other documents or certificates, and completion of such other matters, as Agent and/or any Lender may reasonably request; and

(p) Borrower shall have opened and funded deposit accounts held with Square 1.

3.2 Conditions Precedent to all Credit Extensions. The obligation of the Lenders to make each Credit Extension, including the initial Credit Extension, is contingent upon Borrower's compliance with Section 3.1 above, and is further subject to the following conditions (except that the initial Credit Extension is not subject to the conditions in clause (b)):

(a) timely receipt by Agent of the Loan Advance/Paydown Request Form as provided in Section 2.1;

(b) Borrower shall have transferred substantially all of its Cash assets into operating accounts held with Square 1 and shall otherwise be in compliance with Section 6.6 hereof;

(c) in the Lenders' sole reasonable discretion, there has not been a Material Adverse Effect; and

(d) the representations and warranties contained in Article 5 shall be true and correct in all material respects on and as of the date of such Loan Advance/Paydown Request Form and on the effective date of each Credit Extension as though made at and as of each such date, and no Event of Default shall have occurred and be continuing, or would exist after giving effect to such Credit Extension (provided, however, that those representations and warranties expressly referring to another date shall be true, correct and complete in all material respects as of such date). The making of each Credit Extension shall be deemed to be a representation and warranty by Borrower on the date of such Credit Extension as to the accuracy of the facts referred to in this Section 3.2.

4. CREATION OF SECURITY INTEREST.

4.1 Grant of Security Interest. Borrower grants and pledges to Agent (for the benefit of the Lenders) a continuing security interest in the Collateral to secure prompt repayment of any and all Obligations and to secure prompt performance by Borrower of each of its covenants and duties under the Loan Documents (other than warrants). Except for Permitted Liens or as disclosed in the Schedule, such security interest constitutes a valid, first priority security interest in the presently existing Collateral, and will constitute a valid, first priority security interest in later-acquired Collateral. Borrower also hereby agrees not to sell, transfer, assign, mortgage, pledge, lease, grant a security interest in, or encumber any of its Intellectual Property, except for Permitted Transfers and Permitted Liens. Notwithstanding any termination

of this Agreement or of any filings undertaken related to Agent's or the Lenders' rights under the Code, Agent's Lien on the Collateral shall remain in effect for so long as any Obligations are outstanding.

4.2 Perfection of Security Interest. Borrower authorizes Agent to file at any time financing statements, continuation statements, and amendments thereto that (a) either specifically describe the Collateral or describe the Collateral as all assets of Borrower of the kind pledged hereunder, and (b) contain any other information required by the Code for the sufficiency of filing office acceptance of any financing statement, continuation statement, or amendment, including whether Borrower is an organization, the type of organization and any organizational identification number issued to Borrower, if applicable. Borrower shall have possession of the Collateral, except where expressly otherwise provided in this Agreement or where Agent chooses to perfect its security interest by possession in addition to the filing of a financing statement. Where Collateral is in possession of a third-party bailee, Borrower shall take such steps as Agent reasonably requests for Agent to (i) to the extent required under Section 7.10 below, obtain an acknowledgment, in form and substance reasonably satisfactory to Agent and the Required Lenders, of the bailee that the bailee holds such Collateral for the benefit of Agent, and (ii) to the extent required under Section 6.6 below, obtain "control" of any Collateral consisting of investment property, deposit accounts, letter-of-credit rights or electronic chattel paper (as such items and the term "control" are defined in Revised Article 9 of the Code) by causing the securities intermediary or depositary institution or issuing bank to execute a control agreement in form and substance reasonably satisfactory to Agent and the Required Lenders. Borrower will not create any chattel paper without placing a legend on the chattel paper acceptable to Agent indicating that Agent (for the benefit of the Lenders) has a security interest in the chattel paper. Borrower from time to time, pursuant to additional agreements by Borrower, may deposit with a Lender specific cash collateral to secure specific Obligations; Borrower authorizes the Lenders to hold such specific balances in pledge and to decline to honor any drafts thereon or any request by Borrower or any other Person to pay or otherwise transfer any part of such balances for so long as the specific Obligations are outstanding. Borrower shall take such other actions as Agent reasonably requests to perfect Agent's security interests granted under this Agreement.

5. REPRESENTATIONS AND WARRANTIES.

Borrower represents and warrants to Agent and each Lender as follows:

5.1 Due Organization and Qualification. Borrower and each Subsidiary is duly existing under the laws of the state in which it is organized and qualified and licensed to do business in any state in which the conduct of its business or its ownership of property requires that it be so qualified, except where the failure to do so would not reasonably be expected to cause a Material Adverse Effect.

5.2 Due Authorization; No Conflict. The execution, delivery, and performance of the Loan Documents are within Borrower's powers, have been duly authorized, and are not in conflict with nor constitute a breach of any provision contained in Borrower's Certificate of Incorporation or Bylaws, nor will they constitute an event of default under any material agreement by which Borrower is bound. Borrower is not in default under any

agreement by which it is bound, except to the extent such default would not reasonably be expected to cause a Material Adverse Effect.

5.3 Collateral. Except as set forth on Schedule 5.3, Borrower has rights in or the power to transfer the Collateral, and its title to the Collateral is free and clear of Liens, adverse claims, and restrictions on transfer or pledge except for Permitted Liens and licenses and agreements containing customary anti-assignment provisions so long as such provisions are, or would be, rendered unenforceable or ineffective under applicable law (including, without limitation, Sections 9-406, 9-407 and 9-408 of the Code). Other than movable items of personal property such as laptop computers, all Collateral having an aggregate book value in excess of $100,000 is located solely in the Collateral State, at the locations set forth on Schedule 7.10 and such other locations permitted under Section 7.10. All Inventory is in all material respects of good and merchantable quality, free from all material defects, except for Inventory for which adequate reserves have been made. Except as set forth in the Schedule or as permitted under Section 6.6, none of Borrower's Cash is maintained or invested with a Person other than Square 1 or Square 1's Affiliates.

5.4 Intellectual Property. Except as set forth on Schedule 5.4, Borrower is the sole owner of the Intellectual Property created or purchased by Borrower. Except as set forth on Schedule 5.4, to the best of Borrower's knowledge, each of the Copyrights, Trademarks and Patents created or purchased by Borrower is valid and enforceable, and no part of the Intellectual Property created or purchased by Borrower has been judged invalid or unenforceable, in whole or in part, and no claim has been made to Borrower that any part of the Intellectual Property created or purchased by Borrower violates the rights of any third party except to the extent such claim would not reasonably be expected to cause a Material Adverse Effect.

5.5 Name; Location of Chief Executive Office. Except as disclosed in the Schedule, Borrower has not done business under any name other than that specified on the signature page hereof, and its exact legal name is as set forth in the first paragraph of this Agreement. As of the date hereof, the chief executive office of Borrower is located at the address indicated in Article 10 hereof.

5.6 Litigation. Except as set forth in the Schedule, there are no actions or proceedings pending by or against Borrower or any Subsidiary before any court or administrative agency which would reasonably be expected to have a Material Adverse Effect.

5.7 No Material Adverse Change in Financial Statements. All consolidated and consolidating, if applicable, financial statements related to Borrower and any Subsidiary that are delivered by Borrower to Agent and the Lenders fairly present in all material respects Borrower's consolidated and consolidating, if applicable, financial condition as of the date thereof and Borrower's consolidated and consolidating, if applicable, results of operations for the period then ended. There has not been a material adverse change in the consolidated or in the consolidating, if applicable, financial condition of Borrower since the date of the most recent of such financial statements submitted to Agent and the Lenders.

5.8 Solvency, Payment of Debts. Borrower is able to pay its debts (including trade debts) as they mature; the fair saleable value of Borrower's assets (including goodwill

minus disposition costs) exceeds the fair value of its liabilities; and Borrower is not left with unreasonably small capital after the transactions contemplated by this Agreement.

5.9 Compliance with Laws and Regulations. Borrower and each Subsidiary have met the minimum funding requirements of ERISA with respect to any employee benefit plans subject to ERISA. No event has occurred resulting from Borrower's failure to comply with ERISA that is reasonably likely to result in Borrower's incurring any liability that could have a Material Adverse Effect. Borrower is not an "investment company" or a company "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940. Borrower is not engaged principally, or as one of its important activities, in the business of extending credit for the purpose of purchasing or carrying margin stock (within the meaning of Regulations T and U of the Board of Governors of the Federal Reserve System). Borrower has not violated any statutes, laws, ordinances or rules applicable to it, the violation of which would reasonably be expected to have a Material Adverse Effect. Borrower and each Subsidiary have filed or caused to be filed all tax returns required to be filed, and have paid, or have made adequate provision for the payment of, all taxes reflected therein except those being contested in good faith with adequate reserves under GAAP or where the failure to file such returns or pay such taxes would not reasonably be expected to have a Material Adverse Effect.

5.10 Subsidiaries. Borrower does not own any stock, partnership interest or other equity securities of any Person, except for Permitted Investments.

5.11 Government Consents. Borrower and each Subsidiary have obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all governmental authorities that are necessary for the continued operation of Borrower's business as currently conducted, except where the failure to do so would not reasonably be expected to cause a Material Adverse Effect.

5.12 Inbound Licenses; Other Agreements. Except as disclosed on the Schedule, disclosed in accordance with Section 6.7, Borrower is not a party to, nor is bound by, any material license or other similar agreement important for the conduct of Borrower's business that prohibits or otherwise restricts Borrower from granting a security interest in Borrower's interest in such license or agreement or any other property important for the conduct of Borrower's business, other than this Agreement or the other Loan Documents.

5.13 Full Disclosure. No representation, warranty or other statement made by Borrower in any certificate or written statement furnished to Agent or any Lender in connection with the Loan Documents taken together with all such certificates and written statements furnished to Agent or any Lender contains any untrue statement of a material fact or omits to state a material fact necessary in order to make the statements contained in such certificates or statements not misleading in light of the circumstances in which they were made, it being recognized by Agent and the Lenders that the projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not to be viewed as facts and that actual results during the period or periods covered by any such projections and forecasts may differ from the projected or forecasted results.

6. AFFIRMATIVE COVENANTS.

Borrower covenants that, until payment in full of all outstanding Obligations, and for so long as any Lender may have any commitment to make a Credit Extension hereunder, Borrower shall do all of the following (unless Agent and the Required Lenders provide their prior written consent, which shall not be unreasonably withheld):

6.1 Good Standing and Government Compliance. Borrower shall maintain its and each of its Subsidiaries' corporate existence and good standing in their respective states of formation, shall maintain qualification and good standing in each other jurisdiction in which the failure to so qualify would reasonably be expected to have a Material Adverse Effect, and shall furnish to Agent the organizational identification number issued to Borrower by the authorities of the state in which Borrower is organized, if applicable. Borrower shall meet, and shall cause each Subsidiary to meet, the minimum funding requirements of ERISA with respect to any employee benefit plans subject to ERISA. Borrower shall comply, and shall cause each Subsidiary to comply, with all statutes, laws, ordinances and government rules and regulations to which it is subject, and shall maintain, and shall cause each of its Subsidiaries to maintain, in force all licenses, approvals and agreements, the loss of which or failure to comply with which would reasonably be expected to have a Material Adverse Effect.

6.2 Financial Statements, Reports, Certificates. Borrower shall deliver to Agent and the Lenders: (i) as soon as available, but in any event within 30 days after the end of each calendar month, a company prepared consolidated and consolidating, if applicable, balance sheet, income statement, and statement of cash flows covering Borrower's operations during such period, in a form reasonably acceptable to Agent and the Required Lenders and certified by a Responsible Officer pursuant to a Compliance Certificate; (ii) as soon as available, but in any event within 90 days after the end of each calendar quarter, a company prepared consolidated and consolidating, if applicable, balance sheet, income statement, and statement of cash flows covering Borrower's operations during such period, in a form reasonably acceptable to Agent and the Required Lenders and certified by a Responsible Officer; (iii) as soon as available, but in any event within 180 days after the end of Borrower's fiscal year, audited (or such other level as is required pursuant to the Investment Agreement) consolidated and consolidating, if applicable, financial statements of Borrower prepared in accordance with GAAP, consistently applied, together with an opinion (which is either unqualified, qualified only for going concern solely due to Borrower's projected need for additional funding to continue operations or otherwise consented to in writing by Agent and the Required Lenders) on such financial statements of an independent certified public accounting firm reasonably acceptable to Agent and the Required Lenders; (iv) an annual budget approved by Borrower's Board of Directors as soon as available but not later than the earlier of (A) 60 days after the end of each fiscal year during the term of this Agreement or (B) five days following approval by Borrower's Board of Directors; (v) if applicable, copies of all statements, reports and notices sent or made available generally by Borrower to its security holders or to any holders of Subordinated Debt and all reports on Forms 10-K and 10-Q filed with the Securities and Exchange Commission; (vi) promptly upon receipt of notice thereof, a report of any legal actions pending or threatened against Borrower or any Subsidiary that would reasonably be expected to result in damages or costs to Borrower or any Subsidiary of $250,000 or more; (vii) promptly upon receipt, each management letter prepared by Borrower's independent certified public accounting firm regarding Borrower's management

control systems; (viii) promptly following presentation to Borrower's Board of Directors, and no less frequently than quarterly (or more frequently if requested by Agent or the Required Lenders (such frequency not to exceed six times per year so long as no Event of Default has occurred and is continuing)), clinical program updates in the form provided to Borrower's Board of Directors with such additional information as any Lender may reasonably request from time to time; and (ix) such budgets, sales projections, operating plans or other financial information generally prepared by Borrower in the ordinary course of business as any Lender may reasonably request from time to time.

(a) Within 30 days after the last day of each month, Borrower shall deliver to Agent and the Lenders with the monthly financial statements a Compliance Certificate certified as of the last day of the applicable month and signed by a Responsible Officer in substantially the form of Exhibit D hereto, together with aged listings by invoice date of accounts receivable and accounts payable.

(b) As soon as possible and in any event within three Business Days after becoming aware of the occurrence or existence of an Event of Default hereunder, Borrower shall deliver to Agent and the Lenders a written statement of a Responsible Officer setting forth details of the Event of Default, and the action which Borrower has taken or proposes to take with respect thereto.

(c) Agent (through any of its officers, employees, or agents) shall have the right, upon reasonable prior notice, from time to time during Borrower's usual business hours but no more than once a year (unless an Event of Default has occurred and is continuing), to inspect Borrower's Books and to make copies thereof and to check, test, inspect, audit and appraise the Collateral (and Lenders (through any of their respective officers, employees or agents) shall have the right to join any such inspection) at Borrower's expense in order to verify Borrower's financial condition or the amount of, condition of, or any other matter relating to, the Collateral.

Borrower may deliver to Agent and the Lenders on an electronic basis any certificates, reports or information required pursuant to this Section 6.2, and Agent and the Lenders shall be entitled to rely on the information contained in the electronic files, provided that Agent and the Lenders in good faith believe that the files were delivered by a Responsible Officer. Borrower shall include a submission date on any certificates and reports to be delivered electronically.

6.3 Inventory and Equipment; Returns. Borrower shall keep all Inventory and Equipment in good and merchantable condition, free from all material defects except for Inventory and Equipment (a) sold in the ordinary course of business, and (b) for which adequate reserves have been made, in all cases in the United States and such other locations as to which Borrower gives prior written notice. Returns and allowances, if any, as between Borrower and its account debtors shall be on the same basis and in accordance with the usual customary practices of Borrower, as they exist on the Closing Date. Borrower shall promptly notify Agent and the Lenders of all returns and recoveries and of all written disputes and claims involving inventory having a book value of more than $100,000.

6.4 Taxes. Borrower shall make, and cause each Subsidiary to make, due and timely payment or deposit of all material federal, state, and local taxes, assessments, or contributions required of it by law, including, but not limited to, those laws concerning income taxes, F.I.C.A., F.U.T.A. and state disability, and will execute and deliver to Agent, on demand, proof satisfactory to Agent indicating that Borrower or a Subsidiary has made such payments or deposits and any appropriate certificates attesting to the payment or deposit thereof; provided that Borrower or a Subsidiary need not make any payment if the amount or validity of such payment is contested in good faith by appropriate proceedings and is reserved against (to the extent required by GAAP) by Borrower or such Subsidiary.

6.5 Insurance. Borrower, at its expense, shall (a) keep the Collateral insured against loss or damage, and (b) maintain liability and other insurance, in each case as ordinarily insured against by other owners in businesses similar to Borrower's. All such policies of insurance shall be in such form, with such companies, and in such amounts as reasonably satisfactory to Agent and the Required Lenders. All policies of property insurance shall contain a lender's loss payable endorsement, in a form reasonably satisfactory to Agent and the Required Lenders, showing Agent (for the benefit of the Lenders) as an additional loss payee, and all applicable liability insurance policies shall show Agent and each Lender as an additional insured and specify that the insurer must give at least 20 days' notice to Agent and each Lender before canceling its policy for any reason (except ten days' notice for nonpayment). Upon Agent's or any Lender's request, Borrower shall deliver to Agent and the Lenders certified copies of the policies of insurance and evidence of all premium payments. Proceeds payable under any casualty policy will, at Borrower's option, be payable to Borrower to repair or replace the property subject to the claim, provided that any such repaired or replacement property shall be deemed Collateral in which Agent (for the benefit of the Lenders) has been granted a first priority security interest, provided that, if an Event of Default has occurred and is continuing, all proceeds payable under any such policy shall, at Agent's option, be payable to Agent (for the benefit of the Lenders) to be applied on account of the Obligations.

6.6 Primary Depository. Borrower shall, within one Business Day of the Closing Date, maintain substantially all of its depository and operating accounts with Square 1 and substantially all of its primary investment accounts with Square 1 or Square 1's Affiliates; provided that, for a period of 60 days following the Closing Date, Borrower may maintain at Silicon Valley Bank (a) up to $85,000 to secure a letter of credit issued for the benefit of Borrower's landlord with respect to Borrower's lease of its offices at 100 Beaver Street, Suite 201, Waltham, MA 02453, (b) up to $35,000 to secure credit card reimbursement obligations and (c) up to $300,000 in its operating account. Borrower shall, within 60 days of the Closing Date, maintain all of its depository and operating accounts with Square 1 and its primary investment accounts with Square 1 or Square 1's Affiliates. Prior to maintaining any deposit accounts with Square 1 or any investment accounts with Square 1's Affiliates, Borrower, Agent, and any such Affiliate, as applicable, shall have entered into a deposit account control agreement or a securities account control agreement, as applicable, with respect to any such deposit accounts and investment accounts, in form and substance satisfactory to Agent and the Required Lenders.

6.7 Consent of Inbound Licensors. Within ten days after entering into or becoming bound by any material inbound license or similar agreement, Borrower shall: (a) provide written notice to Agent and the Lenders of the material terms of such license or

agreement with a description of its likely impact on Borrower's business or financial condition; and (b) upon request of Agent, in good faith use commercially reasonable efforts to obtain the consent of, or waiver by, any person whose consent or waiver is necessary for Borrower's interest in such licenses or contract rights to be deemed Collateral and for Agent (for the benefit of the Lenders) to have a security interest in it that would reasonably be expected to otherwise be restricted by the terms of the applicable license or agreement, whether now existing or entered into in the future, provided, however, that the failure to obtain any such consent or waiver shall not constitute a default under this Agreement.

6.8 Creation/Acquisition of Subsidiaries. In the event that any Borrower or any Subsidiary of any Borrower creates or acquires any Subsidiary, Borrower or such Subsidiary shall promptly notify Agent and the Lenders of such creation or acquisition, and Borrower or such Subsidiary shall take all actions reasonably requested by Agent or any Lender to achieve any of the following with respect to such "New Subsidiary" (defined as a Subsidiary formed after the date hereof during the term of this Agreement): (a) if such New Subsidiary is organized under the laws of the United States, to cause such New Subsidiary to become either a co-Borrower hereunder, or a secured guarantor with respect to the Obligations; and (b) to grant and pledge to Agent (for the benefit of the Lenders) a perfected security interest in 100% of the stock, units or other evidence of ownership held by Borrower or its Subsidiaries of any such New Subsidiary which is organized under the laws of the United States, and 65% of the stock, units or other evidence of ownership held by Borrower or its Subsidiaries of any such New Subsidiary which is not organized under the laws of the United States.

6.9 Further Assurances. At any time and from time to time Borrower shall execute and deliver such further instruments and take such further action as may reasonably be requested by Agent or any Lender to effect the purposes of this Agreement.

6.10 Post-Closing. Borrower shall use its commercially reasonable efforts to deliver a fully-executed landlord waiver with respect to Borrower's lease of its offices at 100 Beaver Street, Suite 201, Waltham, MA 02453, in form and substance reasonably satisfactory to Agent and the Required Lenders on or before the date 30 days following the Closing Date.

7. NEGATIVE COVENANTS.

Borrower covenants and agrees that, so long as any credit hereunder shall be available and until the outstanding Obligations are paid in full or for so long as any Lender may have any commitment to make any Credit Extensions, Borrower will not do any of the following without Agent's and the Required Lenders' prior written consent, which shall not be unreasonably withheld:

7.1 Dispositions. Convey, sell, lease, license, transfer or otherwise dispose of (collectively, to "Transfer"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, or move Cash balances on deposit with Square 1 to accounts opened at another financial institution, other than Permitted Transfers.

7.2 Change in Name, Location, Executive Office, or Executive Management; Change in Business; Change in Fiscal Year; Change in Control. Change its

name or the state of Borrower's formation or relocate its chief executive office without 30 days' prior written notification to Agent and the Lenders; replace or suffer the departure of its chief executive officer (or, if Borrower did not have a chief executive officer, its Interim President and Chief Business Officer) or chief financial officer (or, if Borrower did not have a chief financial officer, its Senior Director of Finance) without delivering written notification to Agent and the Lenders within ten days; fail to appoint an interim replacement or fill a vacancy in the position of chief executive officer or chief financial officer for more than 60 consecutive days (it being understood and agreed that (x) Borrower currently does not have a chief executive officer and shall have no obligation to appoint an interim replacement for or fill a vacancy in such position so long as Borrower's Interim President and Chief Business Officer remains in such position and (y) Borrower currently does not have a chief financial officer and shall have no obligation to appoint an interim replacement for or fill a vacancy in such position so long as Borrower's Senior Director of Finance remains in such position); suffer a change on its board of directors which results in the failure of at least one partner from at least one of (a) Polaris Venture Partners or its Affiliates, (b) Third Rock Ventures or its Affiliates, and (c) Lux Capital or its Affiliates to serve as a voting member (other than a change resulting from a partner of such an investor failing to be elected to the board of directors following a bona fide equity financing or series of financings in which such investor's ownership in Borrower is diluted) or suffer the resignation of one or more directors from its board of directors in anticipation of Borrower's insolvency, in either case without the prior written consent of Agent and the Required Lenders which may be withheld in Agent's and the Required Lenders' sole discretion; take action to liquidate, wind up, or otherwise cease to conduct business; engage in any business, or permit any of its Subsidiaries to engage in any business, other than or reasonably related or incidental to the businesses currently engaged in by Borrower; change its fiscal year end; or have a Change in Control.

7.3 Mergers or Acquisitions. Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with or into any other business organization (other than mergers or consolidations of a Subsidiary into another Subsidiary or into Borrower), or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock or property of another Person except where (a) each of the following conditions is applicable: (i) the consideration paid in connection with such transactions (including assumption of liabilities) does not in the aggregate exceed $100,000 during any fiscal year, (ii) no Event of Default has occurred, is continuing or would exist after giving effect to such transactions, (iii) such transactions do not result in a Change in Control, and (iv) Borrower is the surviving entity; or (b) the Obligations are repaid in full concurrently with the closing of any merger or consolidation of Borrower in which Borrower is not the surviving entity; provided, however, that Borrower shall not, without Agent's and the Required Lenders' prior written consent, enter into any binding contractual arrangement with any investment bank, broker, financial advisor or similar Person to attempt to facilitate a merger or acquisition of Borrower, unless (i) no Event of Default exists when such agreement is entered into by Borrower, (ii) such agreement does not give such Person the right to claim any fee, payment or damages from any parties, other than from Borrower or Borrower's investors, in connection with a sale of Borrower's stock or assets pursuant to or resulting from an assignment for the benefit of creditors, an asset turnover to Borrower's creditors (including, without limitation, the Lenders), foreclosure, bankruptcy or similar liquidation, and (iii) Borrower notifies Agent and the Lenders in advance of entering into such an agreement (provided that the failure to give such notification shall not be deemed a breach of this Agreement).

7.4 Indebtedness. Create, incur, assume, guarantee or be or remain liable with respect to any Indebtedness, or permit any Subsidiary so to do, other than Permitted Indebtedness, or prepay any Indebtedness or take any actions which impose on Borrower an obligation to prepay any Indebtedness, except Indebtedness to the Lenders.

7.5 Encumbrances. Create, incur, assume or allow any Lien with respect to its property, or assign or otherwise convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries so to do, except for Permitted Liens, or covenant to any other Person (other than (a) the licensors of in-licensed property with respect to such property, (b) the lessors of specific equipment or lenders financing specific equipment with respect to such leased or financed equipment or (c) Schedule 7.5) that Borrower in the future will refrain from creating, incurring, assuming or allowing any Lien with respect to any of Borrower's property, except for licenses and agreements containing customary anti-assignment provisions so long as such provisions are, or would be, rendered unenforceable or ineffective under applicable law (including, without limitation, Sections 9-406, 9-407 and 9-408 of the Code).

7.6 Distributions. Pay any dividends or make any other distribution or payment on account of or in redemption, retirement or purchase of any capital stock, except that Borrower may (a) repurchase the stock of former employees or directors pursuant to stock repurchase agreements in an aggregate amount not to exceed $100,000 in any fiscal year, so long as an Event of Default does not exist prior to such repurchase or would not exist after giving effect to such repurchase, and (b) repurchase the stock of former employees or directors pursuant to stock repurchase agreements in any amount where the consideration for the repurchase is the cancellation of indebtedness owed by such former employees or directors to Borrower regardless of whether an Event of Default exists.

7.7 Investments. Directly or indirectly acquire or own an Investment in, or make any Investment in or to any Person, or permit any of its Subsidiaries so to do, other than Permitted Investments, or maintain or invest any of its investment property with a Person other than Square 1 and Square 1's Affiliates or permit any Subsidiary to do so unless such Person has entered into a control agreement with Agent (for the benefit of the Lenders), in form and substance reasonably satisfactory to Agent and the Required Lenders, or suffer or permit any Subsidiary to be a party to, or be bound by, an agreement that restricts such Subsidiary from paying dividends or otherwise distributing property to Borrower.

7.8 Transactions with Affiliates. Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower except for transactions that are in the ordinary course of Borrower's business, upon fair and reasonable terms that are no less favorable to Borrower than would be obtained in an arm's-length transaction with a non-affiliated Person and except for transactions permitted under Section 7.9.

7.9 Subordinated Debt. Make any payment in respect of any Subordinated Debt, or permit any of its Subsidiaries to make any such payment, except in compliance with the terms of such Subordinated Debt, or amend any provision affecting Agent's or the Lenders' rights contained in any documentation relating to the Subordinated Debt without Agent's and the Required Lenders' prior written consent.

7.10 Inventory and Equipment. Store Inventory or Equipment with a book value in excess of $100,000 with a bailee, warehouseman, collocation facility or similar third party (other than equipment in transit or held for repair in the ordinary course of Borrower's business) unless the third party has been notified of Agent's security interest and Agent (a) has received an acknowledgment from the third party that it is holding or will hold the Inventory or Equipment for Agent's benefit or (b) is in possession of the warehouse receipt, where negotiable, covering such Inventory or Equipment. Except for Inventory sold in the ordinary course of business and for movable items of personal property having an aggregate book value not in excess of $100,000, and except for such other locations as Agent may approve in writing, Borrower shall keep the Inventory and Equipment only at the locations set forth on Schedule 7.10 and such other locations of which Borrower gives Agent and the Lenders prior written notice and as to which Agent is able to take such actions as may be reasonably necessary to perfect its security interest or to obtain a bailee's acknowledgment of Agent's rights in the Collateral.

7.11 No Investment Company; Margin Regulation. Become or be controlled by an "investment company," within the meaning of the Investment Company Act of 1940, or become principally engaged in, or undertake as one of its important activities, the business of extending credit for the purpose of purchasing or carrying margin stock, or use the proceeds of any Credit Extension for such purpose.

8. EVENTS OF DEFAULT.

Any one or more of the following events shall constitute an Event of Default by Borrower under this Agreement:

8.1 Payment Default. If Borrower fails to pay any of the Obligations when due;

8.2 Covenant Default.

(a) If Borrower fails to perform any obligation under Section 6.2 (financial reporting), 6.4 (taxes), 6.5 (insurance), or 6.6 (primary accounts), or violates any of the covenants contained in Article 7 of this Agreement; or

(b) If Borrower fails or neglects to perform or observe any other material term, provision, condition, or covenant contained in this Agreement, in any of the Loan Documents, or in any other present or future agreement between Borrower and Agent and/or any Lender and as to any default under such other term, provision, condition or covenant that can be cured, has failed to cure such default within ten days after Borrower receives notice thereof or any officer of Borrower becomes aware thereof; provided, however, that if the default cannot by its nature be cured within the ten-day period or cannot after diligent attempts by Borrower be cured within such ten-day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional reasonable period (which shall not in any case exceed 30 days) to attempt to cure such default, and within such reasonable time period the failure to have cured such default shall not be deemed an Event of Default but no Credit Extensions will be made;

8.3 **Material Adverse Change**. If there occurs any circumstance or any circumstances which would reasonably be expected to have a Material Adverse Effect;

8.4 **Attachment**. If any material portion of Borrower's assets is attached, seized, subjected to a writ or distress warrant, or is levied upon, or comes into the possession of any trustee, receiver or person acting in a similar capacity and such attachment, seizure, writ or distress warrant or levy has not been removed, discharged or rescinded within ten days, or if Borrower is enjoined, restrained, or in any way prevented by court order from continuing to conduct all or any material part of its business affairs, or if a judgment or other claim becomes a lien or encumbrance upon any material portion of Borrower's assets, or if a notice of lien, levy, or assessment is filed of record with respect to any material portion of Borrower's assets by the United States Government, or any department, agency, or instrumentality thereof, or by any state, county, municipal, or governmental agency, and the same is not paid within ten days after Borrower receives notice thereof, provided that none of the foregoing shall constitute an Event of Default where such action or event is stayed or an adequate bond has been posted pending a good faith contest by Borrower (provided that no Credit Extensions will be made during such cure period);

8.5 **Insolvency**. If Borrower becomes insolvent, or if an Insolvency Proceeding is commenced by Borrower, or if an Insolvency Proceeding is commenced against Borrower and is not dismissed or stayed within 45 days (provided that no Credit Extensions will be made prior to the dismissal of such Insolvency Proceeding);

8.6 **Other Agreements**. If there is a default or other failure to perform in any agreement to which Borrower is a party with a third party or parties (a) resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of $250,000, (b) in connection with any lease of real property material to the conduct of Borrower's business, if such default or failure to perform results in the right of another party, whether or not exercised, to terminate such lease, or (c) that would reasonably be expected to have a Material Adverse Effect;

8.7 **Judgments**. If a final non-appealable, uninsured judgment or judgments for the payment of money in an amount, individually or in the aggregate, of at least $250,000 shall be rendered against Borrower and shall remain unsatisfied and unstayed for a period of ten days (provided that no Credit Extensions will be made prior to the satisfaction or stay of the judgment); or

8.8 **Misrepresentations**. If any material misrepresentation or material misstatement exists now or hereafter in any warranty or representation set forth herein or in any certificate delivered to Agent or any Lender by any Responsible Officer pursuant to this Agreement or to induce Agent or any Lender to enter into this Agreement or any other Loan Document.

9. **LENDERS' RIGHTS AND REMEDIES**.

9.1 **Rights and Remedies**. Upon the occurrence and during the continuance of an Event of Default, Agent may, and at the written direction of the Required Lenders shall,

without notice of its election and without demand, do any one or more of the following, all of which are authorized by Borrower:

(a) Declare all Obligations, whether evidenced by this Agreement, by any of the other Loan Documents, or otherwise, immediately due and payable (provided that, upon the occurrence of an Event of Default described in Section 8.5 (insolvency), all Obligations shall become immediately due and payable without any action by Agent or the Lenders);

(b) Notify Borrower that Lenders are ceasing advancing money or extending credit to or for the benefit of Borrower under this Agreement and/or under any other agreement between Borrower and Agent and/or any Lender;

(c) Settle or adjust disputes and claims directly with account debtors for amounts, upon terms and in whatever order that Agent reasonably considers advisable;

(d) Make such payments and do such acts as Agent considers necessary or reasonable to protect its security interest in the Collateral. Borrower agrees to assemble the Collateral if Agent so requires, and to make the Collateral available to Agent as Agent may designate. Borrower authorizes Agent to enter the premises where the Collateral is located, to take and maintain possession of the Collateral, or any part of it, and to pay, purchase, contest, or compromise any encumbrance, charge, or lien which in Agent's determination appears to be prior or superior to its security interest and to pay all expenses incurred in connection therewith. With respect to any of Borrower's owned premises, Borrower hereby grants Agent a license to enter into possession of such premises and to occupy the same, without charge, in order to exercise any of Agent's rights or remedies provided herein, at law, in equity, or otherwise;

(e) Set off and apply to the Obligations any and all (i) balances and deposits of Borrower held by a Lender, and (ii) indebtedness at any time owing to or for the credit or the account of Borrower held by a Lender;

(f) Ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, advertise for sale, and sell (in the manner provided for herein) the Collateral. Agent is hereby granted a license or other right, solely pursuant to the provisions of this Section 9.1, to use, without charge, Borrower's labels, patents, copyrights, rights of use of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any property of a similar nature, as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Agent's exercise of its rights under this Section 9.1, Borrower's rights under all licenses and all franchise agreements shall inure to Agent's benefit;

(g) Sell the Collateral at either a public or private sale, or both, by way of one or more contracts or transactions, for cash or on terms, in such manner and at such places (including Borrower's premises) as is commercially reasonable, and apply any proceeds to the Obligations in whatever manner or order Agent deems appropriate. Agent may sell the Collateral without giving any warranties as to the Collateral. Agent may specifically disclaim any warranties of title or the like. This procedure will not be considered adversely to affect the

commercial reasonableness of any sale of the Collateral. If Agent sells any of the Collateral upon credit, Borrower will be credited only with payments actually made by the purchaser, received by Agent, and applied to the indebtedness of the purchaser. If the purchaser fails to pay for the Collateral, Agent may resell the Collateral and Borrower shall be credited with the proceeds of the sale;

(h) Credit bid and purchase at any public sale;

(i) Apply for the appointment of a receiver, trustee, liquidator or conservator of the Collateral, without notice and without regard to the adequacy of the security for the Obligations and without regard to the solvency of Borrower, any guarantor or any other Person liable for any of the Obligations; and

(j) Any deficiency that exists after disposition of the Collateral as provided above will be paid immediately by Borrower.

Agent's compliance with any applicable state or federal law requirements in connection with a disposition of the Collateral will not be considered adversely to affect the commercial reasonableness of any sale of the Collateral.

9.2 Power of Attorney. Effective only upon the occurrence and during the continuance of an Event of Default, Borrower hereby irrevocably appoints Agent (and any of Agent's designated officers or employees) (for the benefit of the Lenders) as Borrower's true and lawful attorney to: (a) send requests for verification of Accounts or notify account debtors of Agent's security interest in the Accounts; (b) endorse Borrower's name on any checks or other forms of payment or security that may come into Agent's possession; (c) sign Borrower's name on any invoice or bill of lading relating to any Account, drafts against account debtors, schedules and assignments of Accounts, verifications of Accounts, and notices to account debtors; (d) dispose of any Collateral; (e) make, settle, and adjust all claims under and decisions with respect to Borrower's policies of insurance; (f) settle and adjust disputes and claims respecting the accounts directly with account debtors, for amounts and upon terms which Agent determines to be reasonable; and (g) file, in its sole discretion, one or more financing or continuation statements and amendments thereto, relative to any of the Collateral; provided that Agent may exercise such power of attorney to sign the name of Borrower on any of the documents described in clause (g) above, regardless of whether an Event of Default has occurred. The appointment of Agent as Borrower's attorney in fact, and each and every one of Agent's rights and powers, being coupled with an interest, is irrevocable until all of the Obligations have been fully repaid and performed, and each Lender's obligation to provide advances hereunder is terminated.

9.3 Accounts Collection. At any time after the occurrence and during the continuation of an Event of Default, Agent may notify any Person owing funds to Borrower of Agent's security interest in such funds and verify the amount of such Account. Borrower shall collect all amounts owing to Borrower for Agent, receive in trust all payments as Agent's trustee, and immediately deliver such payments to Agent (for the benefit of the Lenders) in their original form as received from the account debtor, with proper endorsements for deposit.

9.4 Lender Expenses. If Borrower fails to pay any amounts or furnish any required proof of payment due to third persons or entities, as required under the terms of this Agreement, then Agent may do any or all of the following after reasonable notice to Borrower: (a) make payment of the same or any part thereof; or (b) obtain and maintain insurance policies of the type discussed in Section 6.5 of this Agreement, and take any action with respect to such policies as Agent deems prudent. Any amounts so paid or deposited by Agent shall constitute Lender Expenses, shall be immediately due and payable, shall bear interest at the then applicable rate hereinabove provided, and shall be secured by the Collateral. Any payments made by Agent shall not constitute an agreement by Agent or any Lender to make similar payments in the future or a waiver by Agent of any Event of Default under this Agreement.

9.5 Liability for Collateral; Duty of Agent With Respect to Collateral; Marshaling.

(a) Agent and the Lenders have no obligation to clean up or otherwise prepare the Collateral for sale. All risk of loss, damage or destruction of the Collateral shall be borne by Borrower.

(b) Agent's and each Lender's sole duty with respect to the custody, safekeeping and physical preservation of the Collateral in Agent's or the Lender's possession shall be to deal with it in the same manner as Agent and the Lender, as applicable, deals with similar property for its own account. The powers conferred on Agent and the Lenders hereunder are solely to protect Agent's and the Lenders' interest in the Collateral and shall not impose any duty upon Agent or any Lender to exercise any such powers. Agent and each Lender shall be accountable only for amounts that Agent or the Lender receives as a result of the exercise of such powers, and neither Agent nor any Lender shall be responsible to Borrower for any act or failure to act hereunder, except for its own gross negligence or willful misconduct as finally determined by a non-appealable judgment of a court of competent jurisdiction. In addition, neither Agent nor any Lender shall be liable or responsible for any loss or damage to any Collateral, or for any diminution in the value thereof, by reason of the act or omission of any warehousemen, carrier, forwarding agency, consignee or other bailee selected by it in good faith. Agent may (but shall not be obligated to except at the request of the Required Lenders) pay taxes on behalf of Borrower, satisfy any Liens against the Collateral (other than Permitted Liens), purchase insurance to protect Agent's and the Lenders' interest if Borrower fails to maintain the insurance required hereunder and pay for the maintenance, insurance, protection and preservation of the Collateral and effect compliance with the terms of any Loan Document. Borrower agrees to reimburse Agent, on demand, for all costs and expenses incurred by Agent in connection with such payment or performance and agrees that such amounts shall constitute Obligations. Borrower hereby (i) waives any right under the UCC or any other applicable law to receive notice and/or copies of any filed or recorded financing statements, amendments thereto, continuations thereof or termination statements and (ii) releases and excuses Agent and each Lender from any obligation under the UCC or any other applicable law to provide notice or a copy of any such filed or recorded documents.

(c) Neither Agent nor any Lender shall be under any obligation to marshal any property in favor of Borrower or any other Person or against or in payment of any Obligation.

9.6 No Obligation to Pursue Others. Agent and the Lenders have no obligation to attempt to satisfy the Obligations by collecting them from any other person liable for them, and Agent may release, modify or waive any collateral provided by any other Person to secure any of the Obligations, all without affecting Agent's and the Lenders' rights against Borrower. Borrower waives any right it may have to require Agent or any Lender to pursue any other Person for any of the Obligations.

9.7 Remedies Cumulative. Agent's and the Lenders' rights and remedies under this Agreement, the Loan Documents, and all other agreements shall be cumulative. Agent and the Lenders shall have all other rights and remedies not inconsistent herewith as provided under the Code, by law, or in equity. No exercise by Agent or any Lender of one right or remedy shall be deemed an election, and no waiver by Agent or any Lender of any Event of Default on Borrower's part shall be deemed a continuing waiver. No delay by Agent or any Lender shall constitute a waiver, election, or acquiescence by it. No waiver by Agent or any Lender shall be effective unless made in a written document signed on behalf of Agent and the Required Lenders and then shall be effective only in the specific instance and for the specific purpose for which it was given. Borrower expressly agrees that this Section 9.7 may not be waived or modified by Agent or any Lender by course of performance, conduct, estoppel or otherwise.

9.8 Demand; Protest. Except as otherwise provided in this Agreement, Borrower waives demand, protest, notice of protest, notice of default or dishonor, notice of payment and nonpayment and any other notices relating to the Obligations.

10. NOTICES.

Unless otherwise provided in this Agreement, all notices or demands by any party relating to this Agreement or any other agreement entered into in connection herewith shall be in writing and (except for financial statements and other informational documents which may be sent by first-class mail, postage prepaid) shall be personally delivered or sent by a recognized overnight delivery service, certified mail, postage prepaid, return receipt requested, or by telefacsimile to Borrower, to Agent or to the Lenders, as the case may be, at its address set forth below:

If to Borrower:	Kala Pharmaceuticals, Inc. Attn: Mary Reumuth 100 Beaver Street, Suite 201 Waltham, MA 02453 FAX: (781) 642-0399
With a copy (which will not constitute notice) to:	Wilmer Cutler Pickering Hale and Dorr LLP Attn: Jamie N. Class, Esq. 60 State Street Boston, MA 02446 FAX: (617) 526-5000

If to Agent:	Square 1 Bank Attn: Loan Operations Manager Durham, NC 27701 FAX: (919) 314-3080
If to a Lender:	To such Lender's address on Schedule 1

The parties hereto may change the address at which they are to receive notices hereunder, by notice in writing in the foregoing manner given to the other.

11. CHOICE OF LAW AND VENUE; JURY TRIAL WAIVER.

This Agreement shall be governed by, and construed in accordance with, the internal laws of the State of North Carolina, without regard to principles of conflicts of law. Jurisdiction shall lie in the State of North Carolina. All disputes, controversies, claims, actions and similar proceedings arising with respect to Borrower's account or any related agreement or transaction shall be brought in the General Court of Justice of North Carolina sitting in Durham County, North Carolina or the United States District Court for the Middle District of North Carolina, except as provided below with respect to arbitration of such matters. AGENT, EACH LENDER AND BORROWER EACH ACKNOWLEDGE THAT THE RIGHT TO TRIAL BY JURY IS A CONSTITUTIONAL ONE, BUT THAT IT MAY BE WAIVED. EACH OF THEM, AFTER CONSULTING OR HAVING HAD THE OPPORTUNITY TO CONSULT WITH COUNSEL OF THEIR CHOICE, KNOWINGLY, VOLUNTARILY AND INTENTIONALLY WAIVES ANY RIGHT ANY OF THEM MAY HAVE TO A TRIAL BY JURY IN ANY LITIGATION BASED UPON OR ARISING OUT OF THIS AGREEMENT OR ANY RELATED INSTRUMENT OR LOAN DOCUMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT OR ANY COURSE OF CONDUCT, DEALING, STATEMENTS (WHETHER ORAL OR WRITTEN), OR ACTION OF ANY OF THEM. THESE PROVISIONS SHALL NOT BE DEEMED TO HAVE BEEN MODIFIED IN ANY RESPECT OR RELINQUISHED BY AGENT, ANY LENDER OR BORROWER, EXCEPT BY A WRITTEN INSTRUMENT EXECUTED BY EACH OF THEM. If the jury waiver set forth in this Article 11 is not enforceable, then any dispute, controversy, claim, action or similar proceeding arising out of or relating to this Agreement, the Loan Documents or any of the transactions contemplated therein shall be settled by final and binding arbitration held in Durham County, North Carolina in accordance with the then current Commercial Arbitration Rules of the American Arbitration Association by one arbitrator appointed in accordance with those rules. The arbitrator shall apply North Carolina law to the resolution of any dispute, without reference to rules of conflicts of law or rules of statutory arbitration. Judgment upon any award resulting from arbitration may be entered into and enforced by any state or federal court having jurisdiction thereof. Notwithstanding the foregoing, the parties may apply to any court of competent jurisdiction for preliminary or interim equitable relief, or to compel arbitration in accordance with this Article. The costs and expenses of the arbitration, including without limitation, the arbitrator's fees and expert witness fees, and reasonable attorneys' fees, incurred by the parties to the arbitration may be awarded to the prevailing party, in the discretion of the arbitrator, or may be apportioned between the parties in any manner deemed appropriate by the arbitrator. Unless and until the arbitrator decides that one party is to pay for all (or a share) of

such costs and expenses, both parties shall share equally in the payment of the arbitrator's fees as and when billed by the arbitrator.

12. GENERAL PROVISIONS.

12.1 Successors and Assigns. This Agreement shall bind and inure to the benefit of the respective successors and permitted assigns of each of the parties and shall bind all persons who become bound as a debtor to this Agreement. Borrower may not transfer, pledge or assign this Agreement or any rights or obligations under it without Agent's and each Lender's prior written consent (which may be granted or withheld in Agent's and each Lender's sole discretion). The Lenders have the right without the consent of or notice to Borrower to sell, transfer, assign, pledge, negotiate or grant a participation in (any such sale, transfer, assignment, negotiation or grant of a participation, a "Lender Transfer") all or any part of, or any interest in, the Lenders' obligations, rights and benefits under this Agreement and the other Loan Documents; provided, however, that any such Lender Transfer of its obligations, rights and benefits under this Agreement and the other Loan Documents shall (a) be in minimum increments of $1,000,000 or, if the remaining outstanding principal amount of the obligations owing to such Lender is less than $1,000,000, then the entirety of such lesser amount, and (b) except with respect to a Lender Transfer to the transferring Lender's Affiliate, another Lender or an Affiliate of another Lender, require the prior written consent of Agent which consent shall not be unreasonably withheld or delayed. Borrower and Agent shall be entitled to continue to deal solely and directly with such Lender in connection with the interests so assigned until Agent shall have received and accepted an effective assignment agreement in form satisfactory to Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such transferee as Agent reasonably shall require.

12.2 Indemnification. Borrower shall defend, indemnify and hold harmless Agent, each Lender and their respective officers, employees, and agents (each an "Indemnified Person") against: (a) all obligations, demands, claims, and liabilities claimed or asserted (collectively, "Claims") by any other party in connection with the transactions contemplated by this Agreement; and (b) all losses or Lender Expenses in any way suffered, incurred, or paid by any Indemnified Person as a result of or in any way arising out of, following, or consequential to transactions between Borrower and Agent and/or any Lender whether under this Agreement, or otherwise (including without limitation reasonable attorneys' fees and expenses), except for Claims, losses and/or Lender Expenses caused by an Indemnified Person's gross negligence or willful misconduct.

12.3 Time of Essence. Time is of the essence for the performance of all obligations set forth in this Agreement.

12.4 Severability of Provisions. Each provision of this Agreement shall be severable from every other provision of this Agreement for the purpose of determining the legal enforceability of any specific provision.

12.5 Amendments, Waivers; Integration.

(a) No amendment, modification, termination or waiver of any provision of any Loan Document, and no consent with respect to any departure by Borrower therefrom, shall be effective unless the same shall be in writing and signed by Agent, the Required Lenders (or by Agent with the consent of the Required Lenders) and Borrower; provided that no such amendment, waiver or consent shall, unless in writing and signed by all of the Lenders directly affected thereby (or by Agent with the written consent of all of the Lenders directly affected thereby), in addition to Agent, the Required Lenders (or by Agent with the written consent of the Required Lenders) and Borrower, do any of the following: (i) increase or decrease the amount of any Term Loan Commitment Amount (which shall be deemed to affect all of the Lenders), (ii) reduce the principal of or rate of interest on (other than waiving the imposition of the Default Rate) any Credit Extension or reduce the amount of any fees payable under any Loan Document, (iii) postpone the date fixed for or reduce or waive any scheduled installment of principal or any payment of interest or fees due to any Lender under the Loan Documents, (iv) release or subordinate the Lien on all or substantially all of the Collateral, or consent to a transfer of all or substantially all of the Collateral or Intellectual Property, in each case, except as otherwise may be provided in any Loan Document (which shall be deemed to affect all of the Lenders), (v) release Borrower from, or consent to Borrower's assignment or delegation of, Borrower's obligations under the Loan Documents (which shall be deemed to affect all of the Lenders), except as otherwise may be provided in any Loan Document, (vi) amend or modify the definition of "Required Lenders" or "Pro Rata Share" or any provision providing for the consent or other action by all of the Lenders, or (vii) amend, modify, terminate or waive this Section 12.5(a).

(b) Notwithstanding any provision in Section 12.5(a) to the contrary, (i) Agent may amend Schedule 1 to reflect assignments permitted hereunder and (ii) Agent and Borrower may amend or modify any Loan Document to grant a new Lien, extend an existing Lien over additional property or join additional Persons as credit parties hereunder, in each case for the benefit of Agent and the Lenders.

(c) All prior agreements, understandings, representations, warranties and negotiations between Borrower and the Lenders with respect to the subject matter of this Agreement and the other Loan Documents, if any, are merged into this Agreement and the Loan Documents.

12.6 Counterparts. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, shall be deemed to be an original, and all of which, when taken together, shall constitute but one and the same Agreement. Executed copies of the signature pages of this Agreement sent by facsimile or transmitted electronically in Portable Document Format (PDF), or any similar format, shall be treated as originals, fully binding and with full legal force and effect, and the parties waive any rights they may have to object to such treatment.

12.7 Survival. All covenants, representations and warranties made in this Agreement shall continue in full force and effect so long as any Obligations remain outstanding or any Lender has any obligation to make any Credit Extension to Borrower. The obligations of

Borrower to indemnify Agent and the Lenders with respect to the expenses, damages, losses, costs and liabilities described in Section 12.2 shall survive until all applicable statute of limitations periods with respect to actions that may be brought against Agent and/or any Lender have run.

12.8 Confidentiality. In handling any confidential information, Agent, the Lenders, Borrower and all employees and agents of each such party shall exercise the same degree of care that such party exercises with respect to its own proprietary information of the same types to maintain the confidentiality of any non-public information provided by or on behalf of such party pursuant to the Loan Documents or upon request of such party, except that disclosure of such information may be made (a) in the case of Agent and the Lenders, to the subsidiaries or Affiliates of Agent or any Lender in connection with their present or prospective business relations with Borrower, provided that such subsidiaries or Affiliates are bound by confidentiality obligations substantially the same as those of this Section 12.8, (b) in the case of Agent or any Lender, to prospective transferees or purchasers of any interest in the Credit Extensions, provided that they have entered into a comparable confidentiality agreement in favor of Borrower and have delivered a copy to Borrower, (c) as requested or required by law, regulations, rule or order (including, without limitation, the rules or regulations of any regulatory authority having jurisdiction over such party or its securities or stock exchange on which such party's securities are traded), in legal proceedings, by subpoena, civil investigative demand or judicial order or by other similar order or process, (d) in the case of Agent and the Lenders, as may be required in connection with the examination, audit or similar investigation of Agent or any Lender, (e) as Agent or any Lender may determine in connection with the enforcement of any remedies hereunder or (f) to a Representative of Agent, the Lenders or Borrower, provided that such Representative is bound by either confidentiality obligations substantially the same as those of this Section 12.8 with the party providing it confidential information or other legal or fiduciary obligation to such party. Confidential information hereunder shall not include information that either: (i) is in the public domain or in the knowledge or possession of the receiving party when disclosed to such party, or becomes part of the public domain after disclosure to such receiving party through no fault of such receiving party; or (ii) is disclosed to such receiving party by a third party, provided that the receiving party does not have actual knowledge that such third party is prohibited from disclosing such information.

13. AGENT.

13.1 Appointment and Authority.

(a) Each Lender hereby appoints Square 1 (together with any successor Agent pursuant to Section 13.7) as Agent under the Loan Documents and authorizes Agent to (i) execute and deliver the Loan Documents and accept delivery thereof on its behalf from Borrower, (ii) take such action on its behalf and to exercise all rights, powers and remedies and perform the duties as are expressly delegated to Agent under the Loan Documents, and (iii) exercise such powers as are reasonably incidental thereto. The provisions of this Article 13 are solely for the benefit of Agent and the Lenders, and Borrower shall have no rights as a third-party beneficiary of any of such provisions.

(b) Without limiting the generality of clause (a) above, Agent shall have the sole and exclusive right and authority (to the exclusion of the Lenders) and is hereby authorized to (i) act as the disbursing and collecting agent for the Lenders with respect to all payments and collections arising in connection with the Loan Documents (including in any other bankruptcy, insolvency or similar proceeding), and each Person making any payment in connection with any Loan Document to any Lender is hereby authorized to make such payment to Agent, (ii) file and prove claims and file other documents necessary or desirable to allow the claims of Agent and the Lenders with respect to any Obligations in any bankruptcy, insolvency or similar proceeding, (iii) act as collateral agent for Agent and each Lender for purposes of the perfection, holding and enforcing of all Liens created by the Loan Documents and all other purposes stated therein, together with such powers and discretion as are reasonably incidental thereto and (iv) execute any amendment, consent or waiver under the Loan Documents on behalf of any Lender that has consented in writing to such amendment, consent or waiver; provided, however, that Agent hereby appoints, authorizes and directs each Lender to act as collateral sub-agent for Agent and the Lenders for purposes of the perfection of all Liens with respect to the Collateral, including any deposit account maintained by Borrower with, and cash held by, such Lender, and may further authorize and direct the Lenders to take further actions as collateral sub-agents for purposes of enforcing such Liens or otherwise to transfer the Collateral subject thereto to Agent, and each Lender hereby agrees to take such further actions to the extent, and only to the extent, so authorized and directed. Agent may, upon any term or condition it specifies, delegate or exercise any of its rights, powers and remedies under, and delegate or perform any of its duties or any other action with respect to, any Loan Document by or through any trustee, co-agent, employee, attorney-in-fact and any other Person (including any other Lender). Any such Person shall benefit from this Article 13 to the extent provided by Agent but shall only have obligations to Agent and not to Borrower, any Lender or any other Person, and neither Borrower, any Lender nor any other Person shall have any rights, directly or indirectly, as a third-party beneficiary or otherwise against any such Person.

(c) The Lenders irrevocably authorize Agent to release any Lien on any property granted to or held by Agent under any Loan Document (i) upon all of the Obligations (other than contingent obligations not yet accrued and payable) having been paid in full and so long as no Lender has any commitment to make any Credit Extensions, (ii) that is disposed of as part of or in connection with any Permitted Transfer, (iii) subject to Section 12.5, if approved, authorized or ratified in writing by the Required Lenders or (iv) as expressly provided in any of the other Loan Documents. Upon request by Agent at any time, the Required Lenders will confirm in writing Agent's authority to release its interest in particular types or items of property. In each case as specified in this Section 13.1(c), Agent will, at Borrower's expense, execute and deliver to Borrower such documents as Borrower may reasonably request to evidence the release of items of Collateral from the assignment and security interest granted under the Loan Documents, in each case in accordance with the terms of the Loan Documents and this Section 13.1(c); provided that Borrower shall have delivered to Agent a certificate of a Responsible Officer of Borrower certifying that any such transaction has been consummated in compliance with this Agreement and the other Loan Documents as Agent shall reasonably request.

(d) Under the Loan Documents, Agent (i) is acting solely on behalf of the Lenders, with duties that are entirely administrative in nature, notwithstanding the use of the

defined term "Agent", the terms "agent", "Agent" and "collateral agent" and similar terms in any Loan Document to refer to Agent, which terms are used for title purposes only, (ii) is not assuming any obligation under any Loan Document other than as expressly set forth herein or therein or any role as agent, fiduciary or trustee of or for any Lender or any other Person, and (iii) shall have no implied functions, responsibilities, duties, obligations or other liabilities under any Loan Document. Each Lender, by accepting the benefits of the Loan Documents, hereby waives and agrees not to assert any claim against Agent based on the roles, duties and legal relationships expressly disclaimed in clauses (i) through (iii) above.

13.2 Binding Effect; Use of Discretion.

(a) Each Lender, by accepting the benefits of the Loan Documents, agrees that (i) any action taken by Agent or the Required Lenders (or, if expressly required in any Loan Document, a greater proportion of the Lenders) in accordance with the provisions of the Loan Documents, (ii) any action taken by Agent in reliance upon the instructions of the Required Lenders (or, where so required, such greater proportion), and (iii) the exercise by Agent or the Required Lenders (or, where so required, such greater proportion) of the powers set forth herein or therein, together with such other powers as are reasonably incidental thereto, shall be authorized and binding upon all of the Lenders.

(b) If Agent shall request instructions from the Required Lenders or all of the affected Lenders with respect to any act or action (including failure to act) in connection with any Loan Document, then Agent shall be entitled to refrain from such act or taking such action unless and until Agent shall have received instructions from the Required Lenders or all of the affected Lenders, as the case may be, and Agent shall not incur liability to any Person by reason of so refraining. Agent shall be fully justified in failing or refusing to take any action under any Loan Document (i) if such action would, in the opinion of Agent, be contrary to any requirement of law or any Loan Document, (ii) if such action would, in the opinion of Agent, expose Agent to any potential liability under any requirement of law, or (iii) if Agent shall not first be indemnified to its satisfaction against any and all liability and expense which may be incurred by it by reason of taking or continuing to take any such action. Without limiting the foregoing, no Lender shall have any right of action whatsoever against Agent as a result of Agent acting or refraining from acting under any Loan Document in accordance with the instructions of the Required Lenders or all of the affected Lenders, as applicable.

13.3 Agent's Reliance, Etc. Agent may, without incurring any liability hereunder, (a) consult with any of its Related Persons and, whether or not selected by it, any other advisors, accountants and other experts (including advisors to, and accountants and experts engaged by, Borrower) and (b) rely and act upon any document and information (including those transmitted by electronic transmission) and any telephone message or conversation, in each case believed by it to be genuine and transmitted, signed or otherwise authenticated by the appropriate parties. None of Agent and its Related Persons shall be liable for any action taken or omitted to be taken by any of them under or in connection with any Loan Document, and each Lender and Borrower hereby waives and shall not assert (and Borrower shall cause its Subsidiaries to waive and agree not to assert) any right, claim or cause of action based thereon, except to the extent of liabilities resulting from the gross negligence or willful misconduct of Agent or, as the case may be, such Related Person (each as determined in a final, non-appealable judgment of a court of

competent jurisdiction) in connection with the duties of Agent expressly set forth herein. Without limiting the foregoing, Agent: (i) shall not be responsible or otherwise incur liability for any action or omission taken in reliance upon the instructions of the Required Lenders or for the actions or omissions of any of its Related Persons, except to the extent that a court of competent jurisdiction determines in a final non-appealable judgment that Agent acted with gross negligence or willful misconduct in the selection of such Related Person; (ii) shall not be responsible to any Lender or other Person for the due execution, legality, validity, enforceability, effectiveness, genuineness, sufficiency or value of, or the attachment, perfection or priority of any Lien created or purported to be created under or in connection with, any Loan Document; (iii) makes no warranty or representation, and shall not be responsible, to any Lender or other Person for any statement, document, information, representation or warranty made or furnished by or on behalf of Borrower or any Related Person of Borrower in connection with any Loan Document or any transaction contemplated therein or any other document or information with respect to Borrower, whether or not transmitted or (except for documents expressly required under any Loan Document to be transmitted to the Lenders) omitted to be transmitted by Agent, including as to completeness, accuracy, scope or adequacy thereof, or for the scope, nature or results of any due diligence performed by Agent in connection with the Loan Documents; and (iv) shall not have any duty to ascertain or to inquire as to the performance or observance of any provision of any Loan Document, whether any condition set forth in any Loan Document is satisfied or waived, as to the financial condition of Borrower or as to the existence or continuation or possible occurrence or continuation of any default or Event of Default, and shall not be deemed to have notice or knowledge of such occurrence or continuation unless it has received a notice from Borrower or any Lender describing such default or Event of Default that is clearly labeled "notice of default" (in which case Agent shall promptly give notice of such receipt to all of the Lenders, provided that Agent shall not be liable to any Lender for any failure to do so, except to the extent that such failure is attributable to Agent's gross negligence or willful misconduct as determined by a final non-appealable judgment of a court of competent jurisdiction); and, for each of the items set forth in clauses (i) through (iv) above, each Lender and Borrower hereby waives and agrees not to assert (and Borrower shall cause its Subsidiaries to waive and agree not to assert) any right, claim or cause of action it might have against Agent based thereon. No Lender shall have any right of action whatsoever against Agent as a result of Agent acting or (where so instructed) refraining from acting hereunder or under any of the other Loan Documents in accordance with the instructions of the Required Lenders (or such other number or percentage of the Lenders as shall be expressly provided for herein or in the other Loan Documents).

13.4 Agent Individually. Agent and its Affiliates may make loans and other extensions of credit to, acquire stock of, accept deposits from, and engage in any kind of business with, Borrower or any Affiliate thereof as though it were not acting as Agent and may receive separate fees and other payments therefor. To the extent Agent or any of its Affiliates is or becomes a Lender hereunder, it shall have and may exercise the same rights and powers hereunder and shall be subject to the same obligations and liabilities as any other Lender, and the terms "Lender", "Required Lender" and any similar terms shall, except where otherwise expressly provided in any Loan Document, include, without limitation, Agent or such Affiliate, as the case may be, in its individual capacity as a Lender, or as one of the Required Lenders.

13.5 Lender Credit Decision. Each Lender acknowledges that it shall, independently and without reliance upon Agent, any Lender or any of their Related Persons or

upon any document solely or in part because such document was transmitted by Agent or any of its Related Persons, conduct its own independent investigation of the financial condition and affairs of Borrower and make and continue to make its own credit decisions in connection with entering into, and taking or not taking any action under, any Loan Document or with respect to any transaction contemplated in any Loan Document, in each case based on such documents and information as it shall deem appropriate. Except for documents expressly required by any Loan Document to be transmitted by Agent to the Lenders, Agent shall not have any duty or responsibility to provide any Lender with credit or any other information concerning Borrower, including with respect to its business, prospects, operations, property, financial and other conditions or creditworthiness, or any Affiliate of Borrower, that may come into the possession of Agent (whether in its capacity as Agent or otherwise) or any of its Related Persons.

13.6 Indemnification.

(a) Each Lender agrees to reimburse Agent and each of its Related Persons (to the extent not reimbursed by Borrower) promptly upon demand for its Pro Rata Share of any out-of-pocket costs and expenses (including, without limitation, fees, charges and disbursements of financial, legal and other advisors and any taxes or insurance paid in the name of, or on behalf of, Borrower) incurred by Agent or any of its Related Persons in connection with the preparation, execution, delivery, administration, modification, amendment, consent, waiver or enforcement of, or the taking of any other action (whether through negotiations, through any work-out, bankruptcy, restructuring or other legal or other proceeding (including, without limitation, preparation for and/or response to any subpoena or request for document production relating thereto) or otherwise) in respect of, or legal advice with respect to, its rights or responsibilities under, any Loan Document. Each Lender further agrees to indemnify Agent and each of its Related Persons (to the extent not indemnified by Borrower), ratably according to its Pro Rata Share, from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses or disbursements of any kind or nature whatsoever (including, to the extent not indemnified by the applicable Lender, taxes, interests and penalties imposed for not properly withholding or backup withholding on payments made to or for the account of any Lender) that may be imposed on, incurred by, or asserted against Agent or any of its Related Persons in any matter relating to or arising out of, in connection with or as a result of any Loan Document or any other act, event or transaction related, contemplated in or attendant to any such document, or, in each case, any action taken or omitted to be taken by Agent or any of its Related Persons under or with respect to the foregoing; provided that no Lender shall be liable to Agent or any of its Related Persons under this Section 13.6 to the extent such liability has resulted from the gross negligence or willful misconduct of Agent or, as the case may be, such Related Person, as determined by a final non-appealable judgment of a court of competent jurisdiction.

(b) To the extent required by any applicable requirement of law, Agent may withhold from any payment to any Lender under a Loan Document an amount equal to any applicable withholding tax. If the Internal Revenue Service or any other governmental authority asserts a claim that Agent did not properly withhold tax from amounts paid to or for the account of any Lender for any reason, or if Agent reasonably determines that it was required to withhold taxes from a prior payment to or for the account of any Lender but failed to do so, such Lender shall promptly indemnify Agent fully for all amounts paid, directly or indirectly, by Agent as tax

or otherwise, including penalties and interest, and together with all expenses incurred by Agent. Agent may offset against any payment to any Lender under a Loan Document any applicable withholding tax that was required to be withheld from any prior payment to such Lender but which was not so withheld, as well as any other amounts for which Agent is entitled to indemnification from such Lender under the immediately preceding sentence of this Section 13.6.

13.7 Successor Agent. Agent may resign at any time by delivering notice of such resignation to the Lenders and Borrower, effective on the date set forth in such notice. If Agent delivers any such notice, the Required Lenders shall have the right to appoint a successor Agent. If, after 30 days after the date of the retiring Agent's notice of resignation, no successor Agent has been appointed by the Required Lenders that has accepted such appointment, then the retiring Agent may, on behalf of the Lenders, appoint a successor Agent from among the Lenders, provided that, if Agent shall notify Borrower and the Lenders that no qualifying Person has accepted such appointment, then such resignation shall nonetheless become effective in accordance with such notice. Effective immediately upon its resignation, (a) the retiring Agent shall be discharged from its duties and obligations under the Loan Documents, (b) the Lenders shall assume and perform all of the duties of Agent until a successor Agent shall have accepted a valid appointment hereunder and all payments, communications and determinations provided to be made by, to or through Agent shall instead be made by or to each Lender directly until such time as the Required Lenders appoint a successor Agent as provided for above in this paragraph, (c) the retiring Agent and its Related Persons shall no longer have the benefit of any provision of any Loan Document other than with respect to any actions taken or omitted to be taken while such retiring Agent was, or because such Agent had been, validly acting as Agent under the Loan Documents, and (d) subject to its rights under Section 13.2(b), the retiring Agent shall take such action as may be reasonably necessary to assign to the successor Agent its rights as Agent under the Loan Documents. Effective immediately upon its acceptance of a valid appointment as Agent, a successor Agent shall succeed to, and become vested with, all of the rights, powers, privileges and duties of the retiring Agent under the Loan Documents.

13.8 Setoff and Sharing of Payments. In addition to any rights now or hereafter granted under any applicable requirement of law and not by way of limitation of any such rights, upon the occurrence and during the continuance of any Event of Default and subject to Section 13.9(d), each Lender is hereby authorized at any time or from time to time upon the direction of Agent, without notice to Borrower or any other Person, any such notice being hereby expressly waived, to setoff and to appropriate and to apply any and all balances held by it at any of its offices for the account of Borrower (regardless of whether such balances are then due to Borrower) and any other properties or assets at any time held or owing by that Lender or that holder to or for the credit or for the account of Borrower against and on account of any of the Obligations that are not paid when due. Any Lender exercising a right of setoff or otherwise receiving any payment on account of the Obligations in excess of its Pro Rata Share thereof shall purchase for cash (and the other Lenders or holders shall sell) such participations in each such other Lender's or holder's Pro Rata Share of the Obligations as would be necessary to cause such Lender to share the amount so offset or otherwise received with each other Lender or holder in accordance with their respective Pro Rata Shares of the Obligations. Borrower agrees, to the fullest extent permitted by law, that (a) any Lender may exercise its right to offset with respect to amounts in excess of its Pro Rata Share of the Obligations and may purchase participations in

accordance with the preceding sentence and (b) any Lender so purchasing a participation in the Credit Extensions made or other Obligations held by other Lenders or holders may exercise all rights of offset, bankers' lien, counterclaim or similar rights with respect to such participation as fully as if such Lender or holder were a direct holder of the Credit Extensions and the other Obligations in the amount of such participation. Notwithstanding the foregoing, if all or any portion of the offset amount or payment otherwise received is thereafter recovered from the Lender that has exercised the right of offset, the purchase of participations by that Lender shall be rescinded and the purchase price restored without interest.

13.9 Payments; Non-Funding Lenders; Actions in Concert.

(a) Payments. If Agent receives any payment for the account of any Lender on or prior to 2:00 p.m. (Eastern time) on any Business Day, Agent shall pay to the applicable Lender such payment on the next Business Day. If Agent receives any payment for the account of any Lender after 2:00 p.m. (Eastern time) on any Business Day, Agent shall pay to the applicable Lender such payment on the second Business Day thereafter.

(b) Return of Payments.

(i) If Agent pays an amount to a Lender under this Agreement in the belief or expectation that a related payment has been or will be received by Agent from Borrower and such related payment is not received by Agent, then Agent will be entitled to recover such amount (including interest accruing on such amount at the rate otherwise applicable to such Obligation) from such Lender on demand without setoff, counterclaim or deduction of any kind.

(ii) If Agent determines at any time that any amount received by Agent under any Loan Document must be returned to Borrower or paid to any other Person pursuant to any insolvency law or otherwise, then, notwithstanding any other term or condition of any Loan Document, Agent will not be required to distribute any portion thereof to any Lender. In addition, each Lender will repay to Agent on demand any portion of such amount that Agent has distributed to such Lender, together with interest at such rate, if any, as Agent is required to pay to Borrower or such other Person, without setoff, counterclaim or deduction of any kind.

(c) Non-Funding Lenders.

(i) Unless Agent shall have received notice from a Lender prior to the date of any particular Credit Extension that such Lender will not make available to Agent such Lender's Pro Rata Share of such Credit Extension, Agent may assume that such Lender will make such amount available to it on the date of such Credit Extension in accordance with Section 2.1(b)(i), and Agent may (but shall not be obligated to), in reliance upon such assumption, make available a corresponding amount for the account of Borrower on such date. If and to the extent that such Lender shall not have made such amount available to Agent, such Lender and Borrower severally agree to repay to Agent forthwith on demand such corresponding amount together with interest thereon, for each day from the day such amount is made available to Borrower until the day such amount is repaid to Agent, at a rate per annum equal to the

interest rate applicable to the Obligation that would have been created when Agent made available such amount to Borrower had such Lender made a corresponding payment available. If such Lender shall repay such corresponding amount to Agent, the amount so repaid shall constitute such Lender's portion of the applicable Credit Extension for purposes of this Agreement.

(ii) To the extent that any Lender has failed to fund any Credit Extension or any other payments required to be made by it under the Loan Documents after any such Credit Extension is required to be made or such payment is due (a "Non-Funding Lender"), Agent shall be entitled to set off the funding short-fall against that Non-Funding Lender's Pro Rata Share of all payments received from Borrower. The failure of any Non-Funding Lender to make any Credit Extension or any payment required by it hereunder shall not relieve any other Lender (each such other Lender, an "Other Lender") of its obligations to make such Credit Extension, but neither any Other Lender nor Agent shall be responsible for the failure of any Non-Funding Lender to make such Credit Extension or make any other payment required hereunder. Notwithstanding anything set forth herein to the contrary, a Non-Funding Lender shall not have any voting or consent rights under or with respect to any Loan Document or constitute a "Lender" (or be included in the calculation of the "Required Lenders" hereunder) for any voting or consent rights under or with respect to any Loan Document. At Borrower's request, Agent or a Person reasonably acceptable to Agent shall have the right with Agent's consent and in Agent's reasonable discretion (but Agent or any such Person shall have no obligation) to purchase from any Non-Funding Lender, and each Lender agrees that if it becomes a Non-Funding Lender it shall, at Agent's request, sell and assign to Agent or such Person, all of the Term Loan Commitment Amount (if any) and all of the outstanding Credit Extensions of that Non-Funding Lender for an amount equal to the principal balance of all Credit Extensions held by such Non-Funding Lender and all accrued interest with respect thereto through the date of sale, such purchase and sale to be consummated pursuant to an executed assignment agreement.

(d) **Actions in Concert**. Anything in this Agreement to the contrary notwithstanding, each Lender hereby agrees with each other Lender that no Lender shall take any action to protect or enforce its rights arising out of any Loan Document (including exercising any rights of setoff) without first obtaining the prior written consent of Agent and the Required Lenders, it being the intent of the Lenders that any such action by a Lender to protect or enforce rights under any Loan Document shall be taken in concert and at the direction or with the consent of Agent and the Required Lenders. Nothing contained herein shall be deemed to authorize Agent to authorize or consent to or accept or adopt on behalf of any Lender any plan of reorganization, arrangement, adjustment or composition affecting the Obligations or the rights of any Lender to authorize the Agent to vote in respect of the claim of any Lender or in any such proceeding.

[Signature Page Follows]

[Signature Page to Loan and Security Agreement]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first above written.

BORROWER:

KALA PHARMACEUTICALS, INC.

By: /s/ Mary Reumuth

Name: Mary Reumuth

Title: Senior Director of Finance and Corporate Controller

AGENT:

SQUARE 1 BANK

By: /s/ David B. Kho

Name: David B. Kho

Title: Vice President

LENDERS:

SQUARE 1 BANK

By: /s/ David B. Kho

Name: David B. Kho

Title: Vice President

ALEXANDRIA EQUITIES, LLC,
a Delaware limited liability company

By: Alexandria Real Estate Equities, Inc., a Maryland corporation, managing member

By: /s/ Jennifer Banks

Name: Jennifer Banks

Title: EVP, General Counsel

SCHEDULE 1

LENDERS

Lender	Term Loan Commitment Amount	Closing Date Pro Rata Share	Address
Square 1 Bank	$ 7,000,000	70 %	Square 1 Bank Attn: Loan Operations Manager 406 Blackwell Street, Suite 240 Durham, NC 27701 With a copy to: Square 1 Bank Attn: Phil Gager 101 Main Street, Suite 1210 Cambridge, MA 02142
Alexandria Equities, LLC	$ 3,000,000	30 %	Alexandria Equities, LLC Attn: Corporate Secretary 385 E. Colorado Blvd., Suite 299 Pasadena, CA 91101 Fax: (626) 578-7252 With a copy to: investments@are.com

EXHIBIT A

DEFINITIONS

"Accounts" means all presently existing and hereafter arising accounts, contract rights, payment intangibles and all other forms of obligations owing to Borrower arising out of the sale or lease of goods (including, without limitation, the licensing of software and other technology) or the rendering of services by Borrower and any and all credit insurance, guaranties, and other security therefor, as well as all merchandise returned to or reclaimed by Borrower and Borrower's Books relating to any of the foregoing.

"Affiliate" means, with respect to any Person, any Person that owns or controls directly or indirectly such Person, any Person that controls or is controlled by or is under common control with such Person, and each of such Person's senior executive officers, directors, and general partners.

"Agent" has the meaning assigned in the preamble of this Agreement.

"Agreement" has the meaning assigned in the preamble of this Agreement.

"Authorized Officer" means someone designated as such in the corporate resolution provided by Borrower to Agent in which this Agreement and the transactions contemplated hereunder are authorized by Borrower's board of directors. If Borrower provides subsequent corporate resolutions to Agent after the Closing Date, the individual(s) designated as "Authorized Officer(s)" in the most-recently provided resolution shall be the only "Authorized Officers" for purposes of this Agreement.

"Availability End Date" means the date that is 12 months from the Closing Date.

"Borrower" has the meaning assigned in the preamble of this Agreement.

"Borrower's Books" means all of Borrower's books and records including: ledgers; records concerning Borrower's assets or liabilities, the Collateral, business operations or financial condition; and all computer programs, or tape files, and the equipment containing such information.

"Business Day" means any day that is not a Saturday, Sunday, or other day on which banks in the State of North Carolina are authorized or required to close.

"Cash" means unrestricted cash and cash equivalents.

"Change in Control" means a transaction or series of transactions in which the stockholders of Borrower who were not stockholders immediately prior to the first such transaction own more than 49% of the voting stock of Borrower immediately after giving effect to such transaction or related series of such transactions; provided that, in any event, the following shall not constitute a Change in Control for purposes of this Agreement: (a) an initial public offering of Borrower's common stock (i) that is a QPO under Borrower's Certificate of Incorporation, as the same may be amended from time to time, and (ii) in which Borrower receives aggregate gross proceeds of

not less than $30,000,000; or (b) a bona fide equity financing or series of financings on terms and from investors reasonably acceptable to Agent and the Required Lenders.

"Claims" has the meaning assigned in Section 12.2.

"Closing Date" means the date of this Agreement.

"Code" means the North Carolina Uniform Commercial Code as amended or supplemented from time to time.

"Collateral" means the property described on Exhibit B attached hereto and all Negotiable Collateral to the extent not described on Exhibit B, except to the extent any such property (a) is nonassignable by its terms without the consent of the licensor thereof or another party (but only to the extent such prohibition on transfer is enforceable under applicable law, including, without limitation, § 25-9-406 and § 25-9-408 of the Code), (b) the granting of a security interest therein is contrary to applicable law, provided that, upon the cessation of any such restriction or prohibition, such property shall automatically become part of the Collateral, (c) constitutes the capital stock of a controlled foreign corporation (as defined in the IRC), in excess of 65% of the voting power of all classes of capital stock of such controlled foreign corporations entitled to vote, or (d) property (including any attachments, accessions or replacements) that is subject to a Lien that is permitted pursuant to clauses (a) and (c) of the definition of Permitted Liens, if the grant of a security interest with respect to such property pursuant to this Agreement would be prohibited by the agreement creating such Permitted Lien or would otherwise constitute a default thereunder, provided that such property will be deemed "Collateral" hereunder upon the termination and release of such Permitted Lien.

"Collateral State" means the state where the Collateral is located, which is Massachusetts.

"Compliance Certificate" means a compliance certificate, in substantially the form of Exhibit D attached hereto, executed by a Responsible Officer of Borrower.

"Contingent Obligation" means, as applied to any Person, any direct or indirect liability, contingent or otherwise, of that Person with respect to (a) any indebtedness, lease, dividend, letter of credit or other obligation of another, including, without limitation, any such obligation directly or indirectly guaranteed, endorsed, co-made or discounted or sold with recourse by that Person, or in respect of which that Person is otherwise directly or indirectly liable; (b) any obligations with respect to undrawn letters of credit, corporate credit cards or merchant services issued for the account of that Person; and (c) all obligations arising under any interest rate, currency or commodity swap agreement, interest rate cap agreement, interest rate collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; provided, however, that the term "Contingent Obligation" shall not include endorsements for collection or deposit in the ordinary course of business. The amount of any Contingent Obligation shall be deemed to be an amount equal to the stated or determined amount of the primary obligation in respect of which such Contingent Obligation is made or, if not stated or determinable, the maximum reasonably anticipated liability in respect thereof as determined by such Person in good faith; provided,

however, that such amount shall not in any event exceed the maximum amount of the obligations under the guarantee or other support arrangement.

"Copyrights" means any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret, now or hereafter existing, created, acquired or held.

"Credit Extension" means each Term Loan or any other extension of credit by any Lender, to or for the benefit of Borrower hereunder.

"Equipment" means all present and future machinery, equipment, tenant improvements, furniture, fixtures, vehicles, tools, parts and attachments in which Borrower has any interest.

"ERISA" means the Employee Retirement Income Security Act of 1974, as amended, and the regulations thereunder.

"Event of Default" has the meaning assigned in Article 8.

"GAAP" means generally accepted accounting principles, consistently applied, as in effect from time to time in the United States.

"Indebtedness" means (a) all indebtedness for borrowed money or the deferred purchase price of property or services, including without limitation reimbursement and other obligations with respect to surety bonds and letters of credit, (b) all obligations evidenced by notes, bonds, debentures or similar instruments, (c) all capital lease obligations (as such term is understood under GAAP as in effect on the date hereof), and (d) all Contingent Obligations.

"Indemnified Person" has the meaning assigned in Section 12.2.

"Insolvency Proceeding" means any proceeding commenced by or against any Person or entity under any provision of the United States Bankruptcy Code, as amended, or under any other bankruptcy or insolvency law, including assignments for the benefit of creditors, formal or informal moratoria, compositions, extension generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief.

"Intellectual Property" means:

(a) Copyrights, Trademarks and Patents;

(b) Any and all trade secrets, and any and all intellectual property rights in computer software and computer software products now or hereafter existing, created, acquired or held;

(c) Any and all design rights which may be available to Borrower now or hereafter existing, created, acquired or held;

(d) Any and all claims for damages by way of past, present and future infringement of any of the rights included above, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the intellectual property rights identified above;

(e) All amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents; and

(f) All other intellectual property.

"Interest-Only End Date" means May 31, 2016.

"Inventory" means all present and future inventory in which Borrower has any interest.

"Investment" means any beneficial ownership of (including stock, partnership or limited liability company interest or other securities) any Person, or any loan, advance or capital contribution to any Person.

"Investment Agreement" means, collectively, Borrower's stock purchase and other agreement(s) pursuant to which Borrower most recently issued its preferred stock.

"IRC" means the Internal Revenue Code of 1986, as amended, and the regulations thereunder.

"Lender Expenses" means all reasonable costs or expenses (including reasonable attorneys' fees and expenses, whether generated in-house or by outside counsel) incurred in connection with the preparation, negotiation, administration, and enforcement of the Loan Documents; reasonable Collateral audit fees; and Agent's and the Lenders' reasonable attorneys' fees and expenses (whether generated in-house or by outside counsel) incurred in amending, enforcing or defending the Loan Documents (including fees and expenses of appeal), incurred before, during and after an Insolvency Proceeding, whether or not suit is brought.

"Lender Transfer" has the meaning assigned in Section 12.1.

"Lien" means any mortgage, lien, deed of trust, charge, pledge, security interest or other encumbrance.

"Loan Documents" means, collectively, this Agreement, any note or notes executed by Borrower, and any other document, instrument or agreement entered into in connection with this Agreement, all as amended or extended from time to time.

"Material Adverse Effect" means a material adverse effect on (a) the operations, business or financial condition of Borrower and its Subsidiaries taken as a whole, (b) the ability of Borrower to repay the Obligations or otherwise perform its obligations under the Loan Documents, or (c) Borrower's interest in, or the value, perfection or priority of Agent's security interest in the Collateral.

"Mucus Penetrating Delivery Technology" means microparticle and nanoparticle technologies for delivering pharmaceutical agents, including, without limitation, microparticles and

nanoparticles for use in delivering therapeutic or prophylactic agents to or through mucus, mucin or mucosal barriers or tissues.

"Negotiable Collateral" means all of Borrower's present and future letters of credit of which it is a beneficiary, drafts, instruments (including promissory notes), securities, documents of title, and chattel paper, and Borrower's Books relating to any of the foregoing.

"New Subsidiary" has the meaning assigned in Section 6.8.

"Non-Funding Lender" has the meaning assigned in Section 13.9(c).

"Obligations" means all debt, principal, interest, Lender Expenses and other amounts owed to Agent or any Lender by Borrower pursuant to this Agreement or any other agreement, whether absolute or contingent, due or to become due, now existing or hereafter arising, including any interest that accrues after the commencement of an Insolvency Proceeding and including any debt, liability, or obligation owing from Borrower to others that Agent or any Lender may have obtained by assignment or otherwise. Notwithstanding the foregoing, "Obligations" shall not include any obligations under the Warrants (other than Lender Expenses incurred in connection therewith).

"Other Lender" has the meaning assigned in Section 13.9(c).

"Patents" means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

"Periodic Payments" means all installments or similar recurring payments that Borrower may now or hereafter become obligated to pay to any Lender pursuant to the terms and provisions of any instrument, or agreement now or hereafter in existence between Borrower and Agent and/or any Lender.

"Permitted Indebtedness" means:

(a) Indebtedness of Borrower in favor of the Lenders arising under this Agreement or any other Loan Document;

(b) Indebtedness existing on the Closing Date and disclosed in the Schedule;

(c) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of business;

(d) Indebtedness not to exceed $250,000 in the aggregate at any time secured by a lien described in clause (c) of the defined term "Permitted Liens," provided that such Indebtedness does not exceed at the time it is incurred the lesser of the cost or fair market value of the property financed with such Indebtedness;

(e) Subordinated Debt;

(f) Indebtedness to trade creditors incurred in the ordinary course of business;

(g) Reimbursement obligations with respect to Square 1 letters of credit and credit cards;

(h) Indebtedness permitted under clause (d) of Permitted Investments; and

(i) Extensions, refinancings and renewals of any items of Permitted Indebtedness, provided that the principal amount is not increased or the terms modified to impose more burdensome terms upon Borrower or its Subsidiary, as the case may be.

"Permitted Investment" means:

(a) Investments existing on the Closing Date disclosed in the Schedule;

(b) (i) Marketable direct obligations issued or unconditionally guaranteed by the United States of America or any agency or any State thereof maturing within one year from the date of acquisition thereof, (ii) commercial paper maturing no more than one year from the date of creation thereof and currently having rating of at least A-2 or P-2 from either Standard & Poor's Corporation or Moody's Investors Service, (iii) Square 1's certificates of deposit maturing no more than one year from the date of investment therein, (iv) Square 1's money market or other securities accounts, (v) Investments in regular deposit or checking accounts held with Square 1 or as otherwise permitted by, and subject to the terms and conditions of, Section 6.6 of this Agreement, and (vi) Investments consistent with any investment policy adopted by Borrower's board of directors;

(c) Investments accepted in connection with Permitted Transfers;

(d) Investments (i) of Subsidiaries in or to other Subsidiaries (which are co-Borrowers or secured guarantors and, for Subsidiaries created or acquired after the date hereof, with respect to which Borrower and its Subsidiaries have fully complied with Section 6.8 hereof) or Borrower and Investments by Borrower in Subsidiaries (which are co-Borrowers or secured guarantors and, for Subsidiaries created or acquired after the date hereof, with respect to which Borrower and its Subsidiaries have fully complied with Section 6.8 hereof) and (ii) of Subsidiaries in or to other Subsidiaries (which are not co-Borrowers or secured guarantors) and Investments by Borrower in Subsidiaries (which are not co-Borrowers or secured guarantors) not to exceed $100,000 in the aggregate in any fiscal year;

(e) Investments not to exceed $250,000 outstanding in the aggregate at any time consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plan agreements approved by Borrower's Board of Directors;

(f) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of Borrower's business;

(g) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business, provided that this subparagraph (h) shall not apply to Investments of Borrower in any Subsidiary;

(h) Joint ventures or strategic alliances in the ordinary course of Borrower's business consisting of the non-exclusive licensing of technology, the development of technology or the providing of technical support, provided that any cash Investments by Borrower in another Person do not exceed $100,000 in the aggregate in any fiscal year;

(i) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and

(j) Investments permitted under Section 7.3.

"Permitted Licenses" means the following:

(a) non-exclusive licenses or sublicenses and similar arrangements, partnerships and joint ventures on commercially reasonable terms for the use of the property of Borrower or its Subsidiaries in the ordinary course of business;

(b) exclusive licenses or sublicenses on commercially reasonable terms of Borrower's Mucus Penetrating Delivery Technology for any use (including the treatment of diseases and conditions of the eye) with a third-party proprietary therapeutic product candidate or group of third-party proprietary therapeutic product candidates or with a limited set of third-party proprietary drug targets targeting a specific disease or organ system, provided that any such license (i) does not include rights to any pre-clinical or clinical product candidate or drug target of Borrower (including without limitation where the active pharmaceutical ingredient is loteprednol etabonate or an RTKi developed by Borrower) and (ii) could not result in a legal transfer of title of the licensed property;

(c) exclusive licenses or sublicenses on commercially reasonable terms only as to discrete geographical areas outside of the United States, provided that any such license could not result in a legal transfer of title of the licensed property; and

(d) licenses or sublicenses existing on the Closing Date and disclosed on the Schedule;

provided, in each case, that, consistent with the terms of such license, Borrower's interest in such license would be included in the Collateral and Agent (for the benefit of the Lenders) would obtain a security interest therein.

"Permitted Liens" means the following:

(a) Any Liens existing on the Closing Date and disclosed in the Schedule (excluding Liens to be satisfied with the proceeds of the Credit Extensions) or arising under this Agreement, the other Loan Documents, or any other agreement in favor of Agent;

(b) Liens for taxes, fees, assessments or other governmental charges or levies, either not delinquent or being contested in good faith by appropriate proceedings and for which Borrower maintains adequate reserves;

(c) Liens not to exceed $250,000 in the aggregate at any time (i) upon or in any Equipment (other than Equipment financed by a Credit Extension) acquired or held by Borrower or any of its Subsidiaries to secure the purchase price of such Equipment or indebtedness incurred solely for the purpose of financing the acquisition or lease of such Equipment, or (ii) existing on such Equipment at the time of its acquisition, in each case provided that the Lien is confined solely to the property so acquired and improvements thereon, and the proceeds of such Equipment;

(d) Liens incurred in connection with the extension, renewal or refinancing of the indebtedness secured by Liens of the type described in clauses (a) through (c) above, provided that any extension, renewal or replacement Lien shall be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness being extended, renewed or refinanced does not increase;

(e) Liens securing Subordinated Debt;

(f) Permitted Licenses;

(g) Liens securing reimbursement obligations regarding Square 1 letters of credit and credit cards;

(h) Liens of carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed $25,000.00 and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

(i) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA); and

(j) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Section 8.4 (attachment) or 8.7 (judgments).

"Permitted Transfer" means the conveyance, sale, lease, transfer or disposition by Borrower or any Subsidiary of:

(a) Inventory in the ordinary course of business;

(b) Transfers that constitute Permitted Investments;

(c) Transfers that constitute Permitted Licenses;

(d) worn-out, surplus or obsolete Equipment; and

(e) grants of security interests and other Liens that constitute Permitted Liens.

"Person" means any individual, sole proprietorship, partnership, limited liability company, joint venture, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or governmental agency.

"Prepayment Fee" has the meaning assigned in Section 2.4(c).

"Prime Rate" means the variable rate of interest, per annum, most recently announced by Square 1, as its "prime rate," whether or not such announced rate is the lowest rate available from Square 1.

"Pro Rata Share" means a fraction (expressed as a percentage, carried out to the ninth decimal place), the numerator of which is the original principal amount of a Lender's Credit Extensions to Borrower under this Agreement, and the denominator of which is the aggregate original principal amount of all Credit Extensions to Borrower under this Agreement, and, for clarity, as of the date hereof, means the percentage set forth on Schedule 1 hereto.

"Related Persons" means, with respect to any Person, each Affiliate of such Person and each director, officer, employee, agent, trustee, representative, attorney, accountant and each insurance, environmental, legal, financial and other advisor and other consultants and agents of or to such Person or any of its Affiliates.

"Representative" of Borrower, Agent or any Lender means, collectively, with respect to such party, its directors, officers, employees, agents or advisers (including, without limitation, attorneys, accountants, consultants, bankers and financial advisers).

"Required Lenders" means (a) for so long as all of the Persons that are Lenders on the Closing Date (each an "Original Lender") have not assigned or transferred any of their interests in their respective Credit Extensions, Lenders holding 100% of the aggregate outstanding principal balance of the Credit Extensions, or (b) at any time from and after any Original Lender has assigned or transferred any interest in its Credit Extensions, all Lenders meeting the criteria of at least one of the clauses below:

(i) each Original Lender that has not assigned or transferred any portion of its respective Credit Extensions,

(ii) each assignee of an Original Lender provided (A) such assignee was assigned or transferred and continues to hold 100% of the assigning Original Lender's interest in the Credit Extensions and (B) Agent has consented in writing to such assignee being a Required Lender by virtue of this clause (ii) of clause (b), except that no consent shall be required with respect to a Lender Transfer to the transferring Lender's Affiliate, another Lender or an Affiliate of another Lender, and

(iii) in the event that the Required Lenders under clauses (i) and (ii) of this clause (b) collectively hold less than 66-2/3% of the aggregate outstanding principal

balance of the Credit Extensions, such other Lenders, when aggregated with the Required Lenders under clause (i) or (ii) of this clause (b), holding 66-2/3% or more of the aggregate outstanding principal balance of the Credit Extensions.

For purposes of this definition only, a Lender shall be deemed to include itself, and any Lender that is an Affiliate of such Lender.

"Responsible Officer" means each of the following, if applicable: the Chief Executive Officer, the Chief Operating Officer, the Chief Financial Officer, the Senior Director of Finance, the Interim President and Chief Business Officer and the Controller of Borrower, as well as any other officer or employee identified as an Authorized Officer in the corporate resolution delivered by Borrower to Agent in connection with this Agreement.

"Schedule" means the schedule of exceptions attached hereto and approved by Agent and the Lenders, if any.

"SOS Reports" means the official reports from the Secretaries of State of each Collateral State, the state where Borrower's chief executive office is located, the state of Borrower's formation and other applicable federal, state or local government offices identifying all current security interests filed in the Collateral and Liens of record as of the date of such report.

"Square 1" has the meaning assigned in the preamble of this Agreement.

"Subordinated Debt" means any debt incurred by Borrower that is subordinated in writing to the debt owing by Borrower to the Lenders on terms reasonably acceptable to Agent and the Required Lenders (and identified as being such by Borrower, Agent and the Required Lenders).

"Subsidiary" means any corporation, partnership or limited liability company or joint venture in which (a) any general partnership interest or (b) more than 50% of the stock, limited liability company interest or joint venture of which by the terms thereof ordinary voting power to elect the Board of Directors, managers or trustees of the entity, at the time as of which any determination is being made, is owned by Borrower, either directly or through an Affiliate.

"Term Loan Commitment Amount" means the dollar amount set forth on Schedule 1 hereto, as amended from time to time.

"Term Loan Maturity Date" means December 1, 2018.

"Trademarks" means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower connected with and symbolized by such trademarks.

"Transfer" has the meaning assigned in Section 7.1.

EXHIBIT B

COLLATERAL DESCRIPTION ATTACHMENT TO LOAN AND SECURITY AGREEMENT

DEBTOR **KALA PHARMACEUTICALS, INC.**

SECURED PARTY: **SQUARE 1 BANK, AS AGENT FOR THE LENDERS**

All personal property of Borrower (herein referred to as "Borrower" or "Debtor") whether presently existing or hereafter created or acquired, and wherever located, including, but not limited to:

(a) all accounts (including health-care-insurance receivables), chattel paper (including tangible and electronic chattel paper), deposit accounts, documents (including negotiable documents), equipment (including all accessions and additions thereto), financial assets, general intangibles, goods (including fixtures), instruments (including promissory notes), inventory (including all goods held for sale or lease or to be furnished under a contract of service, and including returns and repossessions), investment property (including securities and securities entitlements), letter of credit rights, money, and all of Debtor's books and records with respect to any of the foregoing, and the computers and equipment containing said books and records;

(b) any and all cash proceeds and/or noncash proceeds of any of the foregoing, including, without limitation, insurance proceeds, and all supporting obligations and the security therefor or for any right to payment. All terms above have the meanings given to them in the North Carolina Uniform Commercial Code, as amended or supplemented from time to time, including revised Division 9 of the Uniform Commercial Code-Secured Transactions.

Notwithstanding the foregoing, the Collateral shall not include any (i) property expressly excluded from Collateral under that certain Loan and Security Agreement dated as of November 20, 2014 by and among Square 1 Bank, as agent, the lenders party thereto, and Kala Pharmaceuticals, Inc. (the "Loan and Security Agreement") or (ii) Intellectual Property (as defined in the Loan and Security Agreement), in any medium, of any kind or nature whatsoever, now or hereafter owned or acquired or received by Borrower, or in which Borrower now holds or hereafter acquires or receives any right or interest (collectively, the "Intellectual Property"); provided, however, that the Collateral shall include all accounts and general intangibles that consist of rights to payment and proceeds from the sale, licensing or disposition of all or any part, or rights in, the foregoing (the "Rights to Payment").

Notwithstanding the foregoing, if a judicial authority (including a U.S. Bankruptcy Court) holds that a security interest in the underlying Intellectual Property is necessary to have a security interest in the Rights to Payment, then the Collateral shall automatically, and effective as of November 20, 2014, include the Intellectual Property to the extent and only to the extent necessary to permit perfection of Agent's security interest in the Rights to Payment, and further provided, however, that Agent's enforcement rights with respect to any security interest in the Intellectual Property shall be absolutely limited to the Rights to Payment only, and Agent shall have no recourse whatsoever with respect to the underlying Intellectual Property.

EXHIBIT C

LOAN ADVANCE / PAYDOWN REQUEST FORM

EXHIBIT D

COMPLIANCE CERTIFICATE

SCHEDULE OF EXCEPTIONS

Permitted Indebtedness (Exhibit A)

1. Irrevocable Standby Letter of Credit No. SVBSF008707, dated January 2, 2014 in the amount of $86,697.37 (Beneficiary: ARE-MA Region No. 9, LLC)

2. Borrower's credit cards with Silicon Valley Bank in an amount up to $35,000 in the aggregate.

Permitted Investments (Exhibit A) — None.

Permitted Licenses (Exhibit A)

1. Exclusive License Agreement between The Johns Hopkins University and Kala Pharmaceuticals, Inc. (formerly known as Hanes Newco, Inc.) dated November 10, 2009, as amended by a First Amendment dated November 19, 2012, as further amended by a Second Amendment dated May 22, 2014, and as again amended by a Third Amendment dated August 26, 2014.

2. Settlement and License Agreement, dated October 24, 2014, by and between The Johns Hopkins University, Kala Pharmaceuticals, Inc., and GrayBug, LLC

3. Side Agreement, dated October 24, 2014, by and between The Johns Hopkins University, Kala Pharmaceuticals, Inc., and GrayBug, LLC

Permitted Liens (Exhibit A)

1. That certain Irrevocable Standby Letter of Credit No. SVBSF008707, dated January 2, 2014 in the amount of $86,697.37 (Beneficiary: ARE-MA Region No. 9, LLC) disclosed above is secured by cash collateral in an amount equal to the dollar value of the letter of credit.

2. Bank Services Pledge Agreement (Cash-Secured), dated December 19, 2013, between Silicon Valley Bank and Kala Pharmaceuticals, Inc. with respect to deposit account no. relating to the letter of credit described in item 1 ("Pledge Agreement for Deposit Account No. ").

3. Borrower's credit cards with Silicon Valley Bank disclosed above are secured by cash collateral in an amount equal to $35,000 in the aggregate.

4. Bank Services Pledge Agreement (Cash-Secured), dated August 27, 2012, between Silicon Valley Bank and Kala Pharmaceuticals, Inc. with respect to deposit account no. relating to the credit cards described in item 3 ("Pledge Agreement for Deposit Account No. ").

Collateral (Section 5.3)

1. Certain property of Borrower is subject to Liens as described in items 1 and 2 of Schedule 7.5 and certain licenses and agreements to which Borrower is a party are subject to restrictions on transfer and/or pledge as described in Schedule 7.5.

Intellectual Property (Section 5.4)

1. Borrower's patent family identified as Kala reference number KP003 is jointly owned by Borrower and The John's Hopkins University. This patent family includes U.S. Provisional Patent Application Serial No. , filed May 3, 2012 (now expired), U.S. Patent Application Serial No.

, filed May 3, 2013, and PCT International Application No. , filed May 3, 2013, and any applications filed in the future claiming benefit of any of the foregoing.

2. Borrower is actively engaged in performing feasibility studies with a number of parties under the terms of feasibility study agreements ("FSA"), wherein Borrower is applying its platform technology to active pharmaceutical ingredients (API) provided by the other party to an FSA. In these arrangements, new inventions created in the course of that work (excluding inventions relating to the platform) are jointly owned by Borrower and the other party, and the parties cannot practice joint inventions without entering into a definitive license agreement.

3. The '433 Patent (as defined in Schedule 5.6) was revoked as described in Schedule 5.6.

Prior Names (Section 5.5)

1. Hanes Newco, Inc.

Litigation (Section 5.6)

1. On November 16, 2011, Vectura Limited ("Vectura") filed an opposition at the European Patent Office (the "Vectura Opposition") against European Patent No. 2061433 (the "'433 Patent") owned by The Johns Hopkins University and licensed to Kala Pharmaceuticals, Inc. Vectura sought to have all granted claims revoked. An Oral Hearing was held at the European Patent Office on April 23, 2013, at which the '433 Patent was revoked. A notice of appeal of the European Patent Office's decision was filed July 16, 2013, and the statement of grounds of appeal was submitted on September 17, 2013. Vectura filed its reply to appeal on February 7, 2014. The appeal is pending, and the Company is awaiting further communication or action by the European Patent Office.

Inbound Licenses; Other Agreements (Section 5.12)

1. Exclusive License Agreement between The Johns Hopkins University and Kala Pharmaceuticals, Inc. (formerly known as Hanes Newco, Inc.) dated November 10, 2009, as amended by a First Amendment dated November 19, 2012, as further amended by a Second Amendment dated May 22, 2014, and as again amended by a Third Amendment dated August 26, 2014.

2. Borrower is prohibited and/or restricted from granting a security interest in the licenses and agreements set forth in item 3 of Schedule 7.5.

Encumbrances (Section 7.5)

1. Deposit Account No. is subject to that certain Pledge Agreement described in item 2 of the Permitted Liens schedule.

2. Deposit Account No. is subject to that certain Pledge Agreement described in item 4 of the Permitted Liens schedule.

3. The following licenses and agreements contain restrictions on transfer and/or pledge:

    a. Exclusive License Agreement between The Johns Hopkins University and Kala Pharmaceuticals, Inc. (formerly known as Hanes Newco, Inc.) dated November 10, 2009, as amended by a First Amendment dated November 19, 2012, as further amended by a Second Amendment dated May 22, 2014, and as again amended by a Third Amendment dated August 26, 2014.

b. Settlement and License Agreement, dated October 24, 2014, by and between The Johns Hopkins University, Kala Pharmaceuticals, Inc., and GrayBug, LLC

c. Side Agreement, dated October 24, 2014, by and between The Johns Hopkins University, Kala Pharmaceuticals, Inc., and GrayBug, LLC

d. Lease Agreement, dated September 30, 2013, between ARE-MA Region No. 9, LLC and Kala Pharmaceuticals, Inc.

Locations (Section 7.10)

1. Michigan
2. California
3. New Jersey
4. Pennsylvania
5. New Hampshire

USA PATRIOT ACT
NOTICE
OF
CUSTOMER IDENTIFICATION

IMPORTANT INFORMATION ABOUT PROCEDURES FOR OPENING A NEW ACCOUNT

To help the government fight the funding of terrorism and money laundering activities, Federal law requires all financial institutions to obtain, verify, and record information that identifies each person who opens an account.

WHAT THIS MEANS FOR YOU: when you open an account, we will ask your name, address, date of birth, and other information that will allow us to identify you. We may also ask to see your driver's license or other identifying documents.

SQUARE 1 BANK

Member FDIC

AUTOMATIC DEBIT AUTHORIZATION

To: **Square 1 Bank, as agent for the Lenders**

Re: **Loan #**

You are hereby authorized and instructed to charge account No. in the name of KALA PHARMACEUTICALS, INC.

for facility fees, principal, interest and other payments due on above-referenced loan as set forth below and credit the loan referenced above.

☒ Debit the Facility Fee as it becomes due according to the terms of the Loan and Security Agreement and any renewals or amendments thereof.

☒ Debit each interest payment as it becomes due according to the terms of the Loan and Security Agreement and any renewals or amendments thereof.

☒ Debit each principal payment as it becomes due according to the terms of the Loan and Security Agreement and any renewals or amendments thereof.

☒ Debit each payment for Lender Expenses as it becomes due according to the terms of the Loan and Security Agreement and any renewals or amendments thereof.

This Authorization is to remain in full force and effect until revoked in writing.

Borrower Signature	**Date**

CLIENT MARKETING AUTHORIZATION

We are excited to have you as a Square 1 Bank client and want to spread the word about your success!

From press releases to mentions on social media sites, and all points in between, Square 1's marketing and communications team is constantly seeking new opportunities to promote our clients and to connect them to prospects, existing customers, and the larger entrepreneurial/venture capital community.

If you complete the authorization below and return it to us, you are authorizing us to reference and/or include your company as part of our marketing and advertising efforts without further review or advance approval by you. Please select all areas that you approve.

☐ All items listed below

☐ List company as a Square 1 Bank customer on social media sites, including Twitter, LinkedIn, Facebook, Square 1 Bank corporate blog, or any other social media site

☐ Press release including your company as a Square 1 Bank client (to include company name and description only; may appear alongside other clients)

☐ Press release including your company as a Square 1 Bank client (**general** press release not focused on your company, but referring to your company as a client, and including your company's name, description, and editorial comments; may appear alongside other clients)

☐ Provide quote for inclusion in a Square 1 Bank press release

☐ Use of company name and logo in Square 1 Bank marketing materials including corporate marketing collateral, website, social media sites, and other advertising campaigns

☐ Provide quotes for inclusion in Square 1 Bank marketing materials including corporate marketing collateral, website, social media sites, and other advertising campaigns

☐ Customer case study/application brief (success story to be posted on website, included in press kits and/or pitched to publications as potential articles)

☐ Willing to participate in a video testimonial highlighting your banking relationship and experiences with Square 1 Bank

☐ Other (please describe):

If you have questions, please contact your Square 1 banker, or our Marketing + Communications department at marketing@square1bank.com.

Please acknowledge your authorization by signing below:

Company Name: **KALA PHARMACEUTICALS, INC.**
Authorized Signer: _____
Name: _____
Title: _____
Date: _____

FIRST AMENDMENT
TO
LOAN AND SECURITY AGREEMENT

This First Amendment to Loan and Security Agreement (the "***Amendment***") is entered into as of October 13, 2016, by and among Pacific Western Bank, a California state chartered bank (as successor in interest by merger to Square 1 Bank) ("***Square***"), in its capacity as administrative and collateral agent (together with its successors and assigns in such capacity, "***Agent***"), the Lenders set forth on Schedule 1 of the Agreement (as defined below) or otherwise a party thereto from time to time, including Square 1 in its capacity as a Lender and Alexandria Equities, LLC, a Delaware limited liability company (each individually a "***Lender***" and, collectively, the "***Lenders***"), and Kala Pharmaceuticals, Inc. ("***Borrower***").

RECITALS

Agent, the Lenders, and Borrower are parties to that certain Loan and Security Agreement dated as of November 20, 2014 (as amended from time to time, the "***Agreement***"). The parties desire to amend the Agreement in accordance with the terms of this Amendment.

NOW, THEREFORE, the parties agree as follows:

1) Section 2.1(b) of the Agreement is hereby amended and restated, as follows:

(b) Term Loans.

(i) Term Loans A. Subject to and upon the terms and conditions of this Agreement, the Lenders agree to make on the date hereof, severally and not jointly, according to each Lender's Term Loan Commitment Amount, term loans to Borrower in the aggregate principal amount of $10,000,000 (each a "Term Loan A" and, collectively, the "Term Loans A"). Each Term Loan A shall be deemed made as of October 13, 2016. The proceeds of the Term Loans A shall be used (A) first, to refinance the aggregate principal amount of all 'term loans' then outstanding under this Agreement (but without the requirement to pay any Prepayment Fee which is hereby waived) and (B) second, for general working capital purposes, for capital equipment purchases, to pay Lender Expenses and to pay the fees under this Agreement. For the avoidance of doubt, the difference between $10,000,000 and the outstanding balance of the existing term loans will be credited to Borrower's account, and no Prepayment Fee will be due in connection with the foregoing refinancing.

(ii) Term Loans B. Subject to and upon the terms and conditions of this Agreement, the Lenders agree to make, severally and not jointly, according to each Lender's Term Loan Commitment Amount, one or more term loans to Borrower in an aggregate principal amount not to exceed $10,000,000 (each a "Term Loan B" and, collectively, the "Term Loans B", and together with the Term Loans A, each a "Term Loan" and collectively, the "Term Loans"). Each Term Loan B shall be in a minimum amount of $250,000. Borrower may request Term Loans B at any time from the Term Loan B Availability Start Date through the Term Loan B Availability End Date. The proceeds of the Term Loans B shall be used for general working capital purposes, for capital equipment purchases, to pay Lender Expenses and to pay the fees under this Agreement.

(iii) Interest shall accrue from the date of each Term Loan at the rate specified in Section 2.2(a) and, through the Interest-Only End Date, shall be payable monthly in arrears beginning on the 13th day of the month next following such Term Loan, and continuing on the same day of each month thereafter. Any Term Loans that are outstanding on the Interest-Only End Date shall be payable in 36 equal monthly installments of principal, plus all accrued interest, beginning on the date that is one month immediately following the Interest-Only End Date and continuing on the same day of each month thereafter through the Term Loan Maturity Date, at which time all amounts due in connection with the Term Loans and any other amounts due under this Agreement shall be immediately due and payable. Term Loans, once repaid, may not be reborrowed. Borrower may prepay any Term Loan, subject to the payment of the Prepayment Fee.

(iv) When Borrower desires to obtain a Term Loan B, Borrower shall notify Agent (which notice shall be irrevocable) by facsimile transmission to be received no later than 3:30 p.m. Eastern time at least five Business Days prior to the date on which the Term Loan B is to be made. Such notice shall be substantially in the form of Exhibit C and signed by an Authorized Officer. Promptly upon receiving such notice, Agent shall notify each Lender of the contents of such notice and each Lender's Pro Rata Share of such Term Loan B.

2) The table in Section 2.4(c) of the Agreement is hereby deleted and replaced with the following table:

Period	Applicable Prepayment Percentage
From October 13, 2016 to (but not including) October 13, 2017	0.90 %
From October 13, 2017 to (but not including) October 13, 2018	0.60 %
From October 13, 2018 and thereafter until the Term Loan Maturity Date	0.30 %

3) Agent's address for notice in Article 10 of the Agreement is hereby amended to read as follows:

Pacific Western Bank
Attn: Loan Operations Manager
Durham, NC 27701
FAX: (919) 314-3080

4) The following defined terms are hereby added to Exhibit A to the Agreement, as follows:

"Term Loan B Availability End Date" means October 13, 2017.

"Term Loan B Availability Start Date" means the receipt by Agent and the Required Lenders of evidence reasonably acceptable to Agent and the Required Lenders that Borrower has received positive results from its second Phase III clinical trial for Borrower's KPI-121 product candidate for the treatment of inflammation and pain following cataract surgery. For purposes of clarity, 'positive' results shall mean (i) achievement of the primary endpoint of proportion of study eyes with complete resolution of anterior chamber cells at day 8 (maintained through day 15) sufficient to support NDA submission and (ii) no significant treatment-related safety findings observed during the course of the trial that would prevent submission of the NDA. An investor who has appointed a member to Borrower's Board of Directors, chosen by Agent and the Required Lenders, must confirm to Agent and the Required Lenders that the aforementioned 'positive' results are sufficient to support an NDA submission.

5) The following defined terms in Exhibit A to the Agreement are hereby amended and restated, as follows:

"Interest-Only End Date" means October 13, 2017.

"Pro Rata Share" means a fraction (expressed as a percentage, carried out to the ninth decimal place), the numerator of which is the original principal amount of a Lender's Credit Extensions to Borrower under this Agreement, and the denominator of which is the aggregate original principal amount of all Credit Extensions to Borrower under this Agreement, and, for clarity, means the percentage set forth on Schedule 1 hereto, as such schedule may be amended from time to time.

"Term Loan Maturity Date" means October 13, 2020.

6) Schedule 1 to the Agreement is hereby deleted and replaced with the new Schedule 1 attached hereto as Appendix I.

7) Item 2 of Section 5.4 of the Schedule of Exceptions to the Agreement is hereby deleted and replaced with the paragraph below:

2. From time to time, Borrower may engage in performing feasibility studies with a number of parties under the terms of feasibility study agreements ("FSA"), wherein Borrower would apply its platform technology to active pharmaceutical ingredients ("API") provided by the other party to such FSA. In such arrangements, new inventions created in the course of that work (excluding inventions relating to the platform) are typically jointly owned by Borrower and the other party, and the parties typically cannot practice joint inventions without entering into a definitive license agreement.

8) Section 5.12 of the Schedule of Exceptions to the Agreement is hereby amended to include the additional agreements listed below:

3. Settlement and License Agreement, dated October 24, 2014, by and between The Johns Hopkins University, Kala Pharmaceuticals, Inc., and GrayBug, LLC

4. Side Agreement, dated October 24, 2014, by and between The Johns Hopkins University, Kala Pharmaceuticals, Inc., and GrayBug, LLC

9) The defined term "Availability End Date" and its definition in Exhibit A to the Agreement are hereby deleted.

10) Unless otherwise defined, all initially capitalized terms in this Amendment shall be as defined in the Agreement. The Agreement, as amended hereby, shall be and remain in full force and effect in accordance with its respective terms and hereby is ratified and confirmed in all respects. Except as expressly set forth herein, the execution, delivery, and performance of this Amendment shall not operate as a waiver of, or as an amendment of, any right, power, or remedy of the Lenders under the Agreement, as in effect prior to the date hereof. Borrower ratifies and reaffirms the continuing effectiveness of all agreements entered into in connection with the Agreement.

11) Borrower represents and warrants that the representations and warranties contained in the Agreement are true and correct in all material respects as of the date of this Amendment; provided, however, that those representations and warranties expressly referring to another date shall be true and correct as in all material respects as of such date; and provided further that representations and warranties that by their terms include a materiality qualification shall be true and correct in all respects.

12) This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

13) As a condition to the effectiveness of this Amendment, Agent shall have received, in form and substance satisfactory to Agent and each Lender, the following:

a) this Amendment, duly executed by Borrower;

b) an officer's certificate of Borrower with respect to incumbency and resolutions authorizing the execution and delivery of this Amendment;

c) a Second Warrant to Purchase Stock issued to Square 1, duly executed by Borrower, in substantially the form attached hereto as Exhibit A;

d) a Second Warrant to Purchase Stock issued to Alexandria Equities, LLC, duly executed by Borrower, in substantially the form attached hereto as Exhibit B;

e) payment of a $20,000 facility fee (for the benefit of the Lenders), which Agent may debit from any of Borrower' s accounts at Square 1;

f) payment of all Lender Expenses, including Agent's and each Lender's expenses for the documentation of this Amendment and any related documents, and any UCC, good standing or intellectual property search or filing fees, which Agent may debit from any of Borrower's accounts at Square 1; and

g) such other documents and completion of such other matters, as Agent and each Lender may reasonably deem necessary or appropriate.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the undersigned have executed this Amendment as of the first date above written.

BORROWER:

KALA PHARMACEUTICALS, INC.

By: /s/ Mary Reumuth
Name: Mary Reumuth
Title: VP Finance and Corporate Controller

AGENT:

PACIFIC WESTERN BANK

By: /s/ John Orlando
Name: John Orlando
Title: Vice President

LENDERS:

PACIFIC WESTERN BANK

By: /s/ John Orlando
Name: John Orlando
Title: Vice President

ALEXANDRIA EQUITIES, LLC
a Delaware limited liability company

By: Alexandria Real Estate Equities Inc., a
Maryland corporation, managing member

By: /s/ Eric S. Johnson
Name: Senior Vice President
Title: RE Legal Affairs

[Signature Page to First Amendment to Loan and Security Agreement]

APPENDIX I

SCHEDULE 1

LENDERS

Lender	Term Loan A Commitment Amount	Term Loan B Commitment Amount	Pro Rata Share	Address
Pacific Western Bank	$ 7,000,000	$ 7,000,000	70%	Pacific Western Bank Attn: Loan Operations Manager 406 Blackwell Street, Suite 240 Durham, NC 27701 With a copy to: Pacific Western Bank 131 Oliver Street, 2nd Floor Boston, MA 02110 Attn: Phil Gager
Alexandria Equities, LLC	$ 3,000,000	$ 3,000,000	30%	Alexandria Equities, LLC Attn: Corporate Secretary 385 E. Colorado Blvd., Suite 299 Pasadena, CA 91101 Fax: (626) 578-7252 With a copy to: investments@are.com

Exhibit A

Form of Square 1 Second Warrant

THIS WARRANT AND THE SHARES ISSUABLE HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES LAWS OF ANY STATE AND MAY NOT BE SOLD, PLEDGED OR OTHERWISE TRANSFERRED EXCEPT IN ACCORDANCE WITH APPLICABLE LAW. THIS WARRANT AND THE SHARES ISSUABLE HEREUNDER MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF THIS WARRANT.

SECOND WARRANT TO PURCHASE STOCK

Corporation:	Kala Pharmaceuticals, Inc.
Warrant No.:	No.
Number of Shares:	Calculated in accordance with Section 1.7
Class of Stock:	Series C Preferred Stock, par value $0.001 per share
Initial Exercise Price:	$1.5876 per share
Issue Date:	, 2016
Expiration Date:	, 2026
Credit Facility:	This Second Warrant to Purchase Stock (this "***Warrant***") is issued in connection with that certain Loan and Security Agreement among Pacific Western Bank, Alexandria Equities, LLC and the Company, dated November 20, 2014, as amended by the First Amendment to Loan and Security Agreement dated on or about the Issue Date, and as further amended from time to time (the "***Loan and Security Agreement***").

THIS SECOND WARRANT CERTIFIES THAT, for good and valuable consideration, the receipt of which is hereby acknowledged, **PACIFIC WESTERN BANK** or its assignee or transferee ("***Holder***") is entitled to purchase up to the aggregate number of fully paid and nonassessable shares of the class of securities (the "***Shares***") of the corporation (the "***Company***") at the initial exercise price per Share (the "***Warrant Price***") all as set forth above and as adjusted pursuant to Section 1.7 and Article 2 of this Warrant, subject to the provisions and upon the terms and conditions set forth in this Warrant. This is one of a series of the Company's warrants in the same form and issued on or about the Issue Date of this Warrant pursuant to the Loan and Security Agreement. Reference is made to Section 5.4 of this warrant, whereby Pacific Western Bank shall transfer this warrant to its parent company, PacWest Bancorp.

ARTICLE 1

EXERCISE

1.1 Method of Exercise. Holder may exercise this Warrant, in whole or in part, by delivering the original of this Warrant and a duly executed Notice of Exercise in substantially the form attached as Appendix 1 to the principal office of the Company. Unless Holder is exercising a cashless exercise set forth in Section 1.2, Holder shall also deliver to the Company a check, wire transfer of same-day funds (to an account designated by the Company) or other form of

payment acceptable to the Company for the aggregate Warrant Price for the Shares being purchased.

1.2 Cashless Exercise. In lieu of payment of the aggregate Warrant Price in the manner specified in Section 1.1 above (but otherwise in accordance with the requirements of Section 1.1), Holder may elect to exercise this Warrant, in whole or in part, and receive such number of Shares as is determined by dividing (a) the aggregate fair market value of the Shares with respect to which this Warrant is being exercised (including the Shares surrendered to the Company in payment of the aggregate Warrant Price) minus the aggregate Warrant Price of the Shares with respect to which this Warrant is being exercised (including the Shares surrendered to the Company in payment of the aggregate Warrant Price) by (b) the fair market value of one Share. The fair market value of the Shares shall be determined pursuant to Section 1.3.

1.3 Fair Market Value. If the Company's common stock is then traded or quoted on a nationally recognized securities exchange, inter-dealer quotation system or over-the-counter market (a "***Trading Market***") and the Class of Stock is common stock, the fair market value of a Share shall be the closing price or last sale price of a share of common stock reported for the Business Day (as defined below) immediately before the date on which Holder delivers this Warrant together with its Notice of Exercise to the Company. If the Company's common stock is then traded or quoted on a Trading Market and the Class of Stock is a series of the Company's convertible preferred stock, the fair market value of a Share shall be the closing price or last sale price of a share of the Company's common stock reported for the Business Day immediately before the date on which Holder delivers this Warrant together with its Notice of Exercise to the Company multiplied by the number of shares of the Company's common stock into which a Share is then convertible. If the Company's common stock is not traded or quoted on a Trading Market, the Board of Directors of the Company shall determine the fair market value of a Share in its reasonable good faith judgment. "***Business Day***" means any day that is not a Saturday, Sunday or a day on which Pacific Western Bank is closed.

1.4 Delivery of Certificate and New Warrant. Within a reasonable time after Holder exercises this Warrant in the manner set forth in Section 1.1 or 1.2 above, the Company shall deliver to Holder a certificate for the Shares acquired by Holder upon such exercise and, if this Warrant has not been fully exercised and has not expired, a new warrant of like tenor representing the Shares neither so acquired nor canceled in payment of the aggregate Warrant Price.

1.5 Replacement of Warrant. On receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of loss, theft or destruction, on delivery of an indemnity agreement reasonably satisfactory in form, substance and amount to the Company or, in the case of mutilation, on surrender and cancellation of this Warrant, the Company at its expense shall, within a reasonable time, execute and deliver to Holder, in lieu of this Warrant, a new warrant of like tenor.

1.6 Repurchase on Sale, Merger, or Consolidation of the Company.

1.6.1 ***Acquisition.*** For the purpose of this Warrant, "***Acquisition***" means any transaction or series of related transactions involving: (i) the sale, lease, exclusive license, or

other disposition of all or substantially all of the assets of the Company, (ii) any merger or consolidation of the Company into or with another person or entity (other than a merger or consolidation effected exclusively to change the Company's domicile), or any other corporate reorganization, in which the stockholders of the Company in their capacity as such immediately prior to such merger, consolidation or reorganization, own less than a majority of the Company's (or the surviving or successor entity's) outstanding voting power immediately after such merger, consolidation or reorganization (or, if such Company stockholders beneficially own a majority of the outstanding voting power of the surviving or successor entity immediately after such merger, consolidation or reorganization, such surviving or successor entity is not the Company); or (iii) any sale or other transfer by the stockholders of the Company of shares representing at least a majority of the Company's then-total outstanding combined voting power.

1.6.2 Exercise Upon Acquisition. Upon the closing of any Acquisition in which the consideration to be received by the Company's stockholders consists of cash, marketable securities, or a combination of both cash and marketable securities (a "***Cash/Public Acquisition***"), this Warrant shall be deemed to have been automatically exercised pursuant to Section 1.2, and thereafter Holder shall participate in the Acquisition on the same terms as other holders of the same class of securities of the Company. For the purpose of this Warrant, "***marketable securities***" means securities meeting all of the following requirements: (i) the issuer thereof is then subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), and is then current in its filing of all required reports and other information under the Act and the Exchange Act; (ii) the class and series of shares or other security of the issuer that would be received by Holder in connection with the Acquisition were Holder to exercise this Warrant on or prior to the closing thereof is then traded in a Trading Market, and (iii) following the closing of such Acquisition, Holder would not be restricted from publicly re-selling all of the issuer's shares and/or other securities that would be received by Holder in such Acquisition were Holder to exercise this Warrant in full on or prior to the closing of such Acquisition, except to the extent that any such restriction (x) arises solely under federal or state securities laws, rules or regulations, and (y) does not extend beyond six (6) months from the closing of such Acquisition.

1.6.3 Assumption of Warrant. Upon the closing of any Acquisition other than a Cash/Public Acquisition, the successor entity shall assume the obligations of this Warrant, and this Warrant shall thereafter be exercisable for the same securities and/or other property as would have been paid for the Shares issuable upon exercise of the unexercised portion of this Warrant as if such Shares were outstanding on and as of the closing of such Acquisition, subject to further adjustment from time to time in accordance with the provisions of this Warrant.

1.7 Adjustment in Underlying Shares.

1.7.1 Solely for purposes of this Section 1.7, capitalized terms used in this Section 1.7 but not defined in this Warrant shall have the meaning given to them in the Loan and Security Agreement.

1.7.2 This Warrant shall be exercisable for the number of Shares equal to the quotient of (a) 4.0% of the difference between (i) the aggregate principal amount of all Term Loans made by Pacific Western Bank pursuant to the Loan and Security Agreement on or before

the date of exercise, it being understood that in the event of any partial exercise of this Warrant, the aggregate principal amount of all Term Loans made by Pacific Western Bank upon any subsequent exercise shall include only the aggregate principal amount of Term Loans made after the date of the most recent prior exercise and (ii) $7,000,000, divided by (b) the Warrant Price, with any resulting fraction rounded down to the nearest whole share, which total number of Shares shall not exceed 176,366 (subject to any adjustment made pursuant to Article 2 hereof).

1.7.3 With respect to any adjustment to the number of shares pursuant to this Section 1.7, all shares subject to this Warrant shall be of the same series and class of stock and bearing the same rights, preferences, and privileges as such series and class of stock denoted in the above caption hereto. The adjustment under this Section 1.7 shall be in addition to any adjustment made pursuant to Article 2 hereof.

1.8 Certain Agreements. As a condition to the issuance of Shares upon any exercise of this Warrant, Holder shall, if the Company so requests in writing, become a party to, by execution and delivery to the Company of a counterpart signature page, joinder agreement, instrument of accession or similar instrument, (i) that certain Fifth Amended and Restated Stockholders Agreement, dated as of April 6, 2016, among the Company and the stockholders party thereto, as such agreement may be amended and/or restated from time to time (the "***Stockholders Agreement***"), and (ii) that certain Third Amended and Restated Registration Rights Agreement, dated as of April 6, 2016, among the Company and the individuals and entities listed on Exhibit A attached thereto, as such agreement may be amended and/or restated from time to time (the "***Registration Rights Agreement***") (each of which has been provided to Holder), in each case, solely with respect to the Shares issued upon such exercise (and the shares of common stock, if any, issued upon conversion of such Shares), solely to the extent that all holders of outstanding shares of the Class of Stock are then parties thereto, and solely to the extent each such agreement is then by its terms in force and effect.

ARTICLE 2

ADJUSTMENTS TO THE SHARES

2.1 Stock Dividends, Splits, Etc. If the Company declares or pays a dividend on the outstanding shares of the Class of Stock payable in common stock, or other securities, then upon exercise of this Warrant, for each Share acquired, Holder shall receive, without additional cost to Holder, the total number and kind of securities to which Holder would have been entitled had Holder owned the Shares of record as of the date the dividend occurred. If the Company subdivides the outstanding shares of the Class of Stock into a greater amount of shares of such Class of Stock, the number of Shares purchasable hereunder shall be proportionately increased and the Warrant Price shall be proportionately decreased. If the Company combines or consolidates, by reclassification or otherwise, the outstanding shares of the Class of Stock into a lesser amount of shares of such Class of Stock, the number of Shares purchasable hereunder shall be proportionately decreased and the Warrant Price shall be proportionately increased.

2.2 Reclassification, Exchange or Substitution. Upon any reclassification, exchange, substitution, or other event that results in all of the outstanding shares of the Class of Stock being reclassified, exchanged, substituted or replaced for, into with or by Company

securities of a different class and/or series, then from and after the consummation of such event, Holder shall be entitled to receive, upon exercise of this Warrant, the number and kind of securities that Holder would have received for the Shares if this Warrant had been exercised immediately before such reclassification, exchange, substitution, or other event. Such an event shall include any conversion of the outstanding or issuable securities of the Company of the same class or series as the Shares to common stock, automatically or by action of the holders thereof, pursuant to the terms of the Company's Amended and Restated Certificate of Incorporation (as amended and/or restated from time to time, the "***Certificate of Incorporation***"), including, without limitation, in connection with a QPO (as defined in the Certificate of Incorporation). The Company or its successor shall promptly issue to Holder a new warrant for such new securities or other property. The new warrant shall provide for adjustments which shall be as nearly equivalent as may be practicable to the adjustments provided for in this Article 2 including, without limitation, adjustments to the Warrant Price and to the number of securities or property issuable upon exercise of the new warrant. The provisions of this Section 2.2 shall similarly apply to successive reclassifications, exchanges, substitutions, or other events.

2.3 Adjustments for Diluting Issuances. Without duplication of any adjustment provided for in this Section 2, the number of shares of common stock issuable upon conversion of the Shares shall be subject to anti-dilution adjustment from time to time in the manner set forth in the Certificate of Incorporation as if the Shares were issued and outstanding on and as of the date of any such required adjustment.

2.4 Certificate as to Adjustments. Upon each adjustment of the Warrant Price, the Company at its expense shall promptly compute such adjustment, and notify Holder in writing setting forth such adjustment and the facts upon which such adjustment is based. The Company shall, upon written request from Holder, furnish Holder with a certificate of its Chief Financial Officer (or person of equivalent responsibility) setting forth the Warrant Price in effect upon the date thereof and the series of adjustments leading to such Warrant Price.

2.5 No Fractional Shares. No fractional Shares shall be issuable upon exercise of this Warrant and the number of Shares to be issued shall be rounded down to the nearest whole Share. If a fractional share interest arises upon any exercise of this Warrant, the Company shall eliminate such fractional share interest by paying Holder in cash the amount computed by multiplying the fractional interest by (a) the fair market value (as determined pursuant to Section 1.3 above) of a full Share, less (b) the then-effective Warrant Price.

ARTICLE 3

REPRESENTATIONS AND COVENANTS OF THE COMPANY

3.1 Representations and Warranties. The Company hereby represents and warrants to Holder as follows:

(a) The initial Warrant Price referenced on the first page of this Warrant is not greater than the price per share at which shares of the Class of Stock were last sold and issued prior to the Issue Date.

(b) All Shares which may be issued upon the exercise of the purchase right represented by this Warrant, when paid for in accordance with the provisions hereof, and all securities, if any, issuable upon conversion of the Shares, shall, upon issuance, be duly authorized, validly issued, fully paid and nonassessable, and free of any liens and encumbrances except for restrictions on transfer provided for herein or under applicable federal and state securities laws.

(c) The Company's capitalization table attached to this Warrant is true and complete, other than failures to be true and complete as are de minimis in effect to Holder, as of the Issue Date.

3.2 Notice of Certain Events. The Company shall provide Holder with not less than 10 days prior written notice of, including a description of the material facts surrounding, any of the following events: (a) declaration of any dividend or distribution upon its common stock, whether in cash, property, stock, or other securities and whether or not a regular cash dividend; (b) offering for subscription pro rata to the holders of the outstanding shares of the Class of Stock any additional shares of stock of any class or series of its stock (other than pursuant to contractual pre-emptive rights); (c) effecting any reclassification or recapitalization of common stock; or (d) effecting an Acquisition or liquidation, dissolution or winding up. The Company will also provide information requested by Holder that is reasonably necessary to enable Holder to comply with Holder's accounting or reporting requirements.

3.3 Information Rights. So long as Holder holds this Warrant, the Company shall deliver to Holder such reports as the Company furnishes to each Major Investor (as defined in the Stockholders Agreement) pursuant to Section 7.1 of the Stockholders Agreement, subject to the limitations set forth therein.

3.4 Registration Under Securities Act of 1933, as amended. The Company agrees that, upon execution and delivery of a counterpart signature to the Registration Rights Agreement, the Shares or, if the Shares are convertible into common stock of the Company, such common stock, shall be "Registrable Securities" solely for the purpose of obtaining "piggyback" registration rights pursuant to Section 4 of the Registration Rights Agreement, and Holder shall be an "Investor" under the Registration Rights Agreement.

ARTICLE 4

REPRESENTATIONS, WARRANTIES AND COVENANTS OF HOLDER

4.1 Representations and Warranties. Holder hereby represents and warrants to the Company as follows:

4.1.1 Purchase for Own Account. This Warrant is made with Holder in reliance upon the Holder's representation to the Company, which by Holder's execution of this Warrant, Holder hereby confirms, that this Warrant, the Shares and the securities issuable, directly or indirectly, upon conversion of the Shares, if any (collectively, the "Securities"), are being acquired for investment for Holder's own account (or the account of its respective Affiliates), not as a nominee or agent, and not with a view to the resale or distribution of any part

thereof in violation of any applicable law, and that Holder has no present intention of selling, granting any participation in or otherwise distributing the Securities to any other person in violation of any applicable law. By executing this Warrant, Holder further represents that Holder does not have any contract, undertaking, agreement or arrangement with any person to sell, transfer or grant participation to such person or to any third person, with respect to any of the Securities.

4.1.2 Disclosure of Information. Holder represents that it has had an opportunity to discuss with the Company the terms and conditions of the offering of this Warrant and the Company's business, properties, prospects and financial condition. The foregoing, however, does not limit or modify the representations and warranties of the Company in Article 3 of this Warrant or the right of the Holder to rely thereon.

4.1.3 Investment Experience. Holder is an investor in securities of companies in the development stage and acknowledges that it is able to fend for itself, can bear the economic risk of its investment, and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in this Warrant and the Securities issuable upon exercise thereof. Holder also represents it has not been organized for the purpose of acquiring this Warrant or the Securities issuable upon exercise thereof.

4.1.4 No Public Market. Holder understands that no public market now exists for this Warrant or the Securities issuable upon exercise thereof, and that the Company has made no assurances that a public market will ever exist for this Warrant or the Shares.

4.1.5 Accredited Investor. Holder is an "accredited investor" within the meaning of Rule 501(a) of Regulation D promulgated under the Securities Act.

4.1.6 Restricted Securities. Holder understands that the Securities are "restricted securities" under applicable U.S. federal and state securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such Securities may be resold without registration under the Securities Act and such other securities laws only in certain limited circumstances. In the absence of any effective registration statement covering the Securities or an available exemption from registration under the Securities Act, the Securities must be held indefinitely. In this connection, such Holder represents that it is familiar with Rule 144 of the Securities Act, as presently in effect, and understands the resale limitations imposed thereby and by the Securities Act, including without limitation the Rule 144 condition that current information about the Company be available to the public. Such information is not now available and the Company has no present plans to make such information available. Holder acknowledges that the Company has no obligation to register or qualify the Securities for resale.

4.2 Market Stand-Off Agreement. Holder agrees that the Shares shall be subject to the same market stand-off provisions as those set forth in Section 12 of the Registration Rights Agreement, as in effect on the Issue Date.

4.3 No Stockholder Rights. Without limiting any provision of this Warrant, Holder agrees that, as a Holder of this Warrant, it will not have any voting rights or other rights as a stockholder until the exercise of this Warrant in accordance with its terms.

ARTICLE 5

MISCELLANEOUS

5.1 Term; Automatic Cashless Exercise Upon Expiration.

5.1.1 This Warrant is exercisable in whole or in part, at any time and from time to time on or before the Expiration Date set forth above; provided, however, that if the Company completes its initial public offering within the 270-day period immediately prior to the Expiration Date, the Expiration Date shall automatically be extended until 270 days after the effective date of the Company's initial public offering.

5.1.2 In the event that, upon the Expiration Date, the fair market value (as determined pursuant to Section 1.3 above) of one Share (or other security issuable upon the exercise hereof) is greater than the Warrant Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to Section 1.2 above as to all Shares (or such other securities) for which it shall not previously have been exercised.

5.2 Legends. Each certificate evidencing the Shares (and each certificate evidencing the securities issuable, directly or indirectly, upon conversion of the Shares, if any) shall be imprinted with a legend in substantially the following form:

> THIS SECURITY HAS NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN THAT CERTAIN SECOND WARRANT TO PURCHASE STOCK ISSUED BY THE ISSUER TO PACIFIC WESTERN BANK DATED , 2016, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED EXCEPT IN ACCORDANCE WITH APPLICABLE LAW.

5.3 Compliance with Securities Laws on Transfer. This Warrant and the Shares issuable upon exercise of this Warrant (and the securities issuable, directly or indirectly, upon conversion of the Shares, if any) may not be transferred or assigned in whole or in part without compliance with applicable federal and state securities laws by the transferor and the transferee (including, without limitation, the delivery of investment representation letters and legal opinions reasonably satisfactory to the Company, as reasonably requested by the Company). The Company shall not require Holder to provide an opinion of counsel if the transfer is to PacWest Bancorp or any other affiliate of Holder or if there is no material question as to the availability of current information as referenced in Rule 144(c), Holder represents that it has complied with Rule 144(d) and (e) in reasonable detail, the selling broker represents that it has complied with Rule 144(f), and the Company is provided with a copy of Holder's notice of proposed sale.

5.4 Transfer Procedure. After receipt by Pacific Western Bank of this warrant, Pacific Western Bank will transfer this warrant in its entirety to its parent company, PacWest

Bancorp. Subject to the provisions of Section 5.3 and this Section 5.4, Holder may transfer all or part of this Warrant or the Shares issuable upon exercise of this Warrant (or the securities issuable, directly or indirectly, upon conversion of the Shares, if any) by giving the Company written notice of the portion of this Warrant and/or Shares (and/or securities issuable, directly or indirectly, upon conversion of the Shares, if any) being transferred setting forth the name, address and taxpayer identification number of the transferee and surrendering this Warrant to the Company for reissuance to the transferee(s) (and Holder, if applicable); provided that, as a condition to such transfer, any subsequent transferee shall agree in writing with the Company to be bound by the terms and conditions of this Warrant, including without limitation Section 4.2 hereof. No surrender or reissuance shall be required for the transfer to PacWest Bancorp or a transfer to any other affiliate of Holder; provided that, for a transfer to any other affiliate of Holder, Holder gives the Company written notice of the portion of this Warrant and/or Shares (and/or securities issuable, directly or indirectly, upon conversion of the Shares, if any) being transferred setting forth the name, address and taxpayer identification number of the transferee. Notwithstanding anything to the contrary set forth herein, Holder shall not be permitted to transfer this Warrant or the Shares issuable upon exercise of this Warrant (or the securities issuable, directly or indirectly, upon conversion of the Shares, if any) to an operating corporation, partnership, limited liability company or similar entity actively engaged, directly or indirectly (including through any partnership, limited liability company, corporation, joint venture or similar arrangement (whether now existing or formed hereafter)), in the research, production, development, manufacture, licensing, distribution, sale, or use of microparticle or nanoparticle technologies for developing therapeutic or prophylactic pharmaceutical agents delivered to or through mucus, mucin, or mucosal tissues or barriers (a "***Competitive Operating Entity***"), except in connection with an Acquisition of the Company by such Competitive Operating Entity.

5.5 Notices. All notices and other communications from the Company to Holder, or vice versa, shall be deemed delivered and effective when given personally or mailed by first- class registered or certified mail, postage prepaid, at such address as may have been furnished to the Company or Holder, as the case may be, in writing by the Company or such Holder from time to time. All notices to Holder shall be addressed as follows:

PacWest Bancorp
Attn: Warrant Administrator
406 Blackwell Street, Suite 240
Durham, NC 27701

All notices to the Company shall be addressed as follows until Holder receives notice of a change in address:

Kala Pharmaceuticals, Inc.
100 Beaver Street
Suite 201
Waltham, MA 02453
Attn: Chief Executive Officer

With a copy (which shall not constitute notice) to:

Wilmer Cutler Pickering Hale and Dorr LLP
Attn: Lia Der Marderosian, Esq.
60 State Street
Boston, MA 02109
Facsimile: (617) 526 5000
Email: Lia.DerMarderosian@wilmerhale.com

5.6 Amendments. This Warrant and any term hereof may be changed, waived, discharged or terminated only by an instrument in writing signed by the party against which enforcement of such change, waiver, discharge or termination is sought.

5.7 Attorneys' Fees. In the event of any dispute between the parties concerning the terms and provisions of this Warrant, the party prevailing in such dispute shall be entitled to collect from the other party all costs incurred in such dispute, including reasonable attorneys' fees.

5.8 Governing Law. This Warrant shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to its principles regarding conflicts of law.

5.9 Counterparts; Facsimile/Electronic Signatures. This Warrant may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail or other transmission method, and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

5.10 Effect of Headings. The descriptive headings in this Warrant have been inserted for convenience only and shall not be deemed to limit or otherwise affect the construction of any provision hereof.

5.11 Entire Agreement. This Warrant constitutes the full and entire understanding and agreement among the parties hereto with respect to the subject matter hereof, and any and all other written or oral agreements relating to such subject matter existing among the parties are expressly canceled.

[Signature Page Follows]

IN WITNESS WHEREOF, the undersigned has executed this Second Warrant to Purchase Stock as of the Issue Date set forth above.

COMPANY:

KALA PHARMACEUTICALS, INC.

By: _____

Name: _____

Title: _____

HOLDER:

PACIFIC WESTERN BANK

By: _____

Name: _____

Title: _____

APPENDIX 1

NOTICE OF EXERCISE

1. The undersigned, pursuant to the terms of the attached warrant (the "Warrant"), hereby elects to purchase: *(check applicable box)*

☐ Shares of **KALA PHARMACEUTICALS, INC.** covered by the Warrant and tenders herewith payment of the purchase price of such Shares in full pursuant to Section 1.1 thereof; or

☐ Shares of **KALA PHARMACEUTICALS, INC.** covered by the Warrant pursuant to the cashless exercise procedure set forth in Section 1.2 thereof.

2. Please issue a certificate or certificates representing the Shares in the name of the undersigned or in such other name as is specified below:

Holder's Name:
Address:

3. By its execution below, Holder hereby makes and affirms each of the representations, warranties and covenants set forth in Section 4 of the Warrant as of the date hereof.

HOLDER:

PACIFIC WESTERN BANK

By: _____

_____
(Print Name of Signatory)

_____
(Title)

_____
(Date)

Exhibit B

Form of Alexandria Equities, LLC Second Warrant

THIS WARRANT AND THE SHARES ISSUABLE HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES LAWS OF ANY STATE AND MAY NOT BE SOLD, PLEDGED OR OTHERWISE TRANSFERRED EXCEPT IN ACCORDANCE WITH APPLICABLE LAW. THIS WARRANT AND THE SHARES ISSUABLE HEREUNDER MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF THIS WARRANT.

SECOND WARRANT TO PURCHASE STOCK

Corporation:	Kala Pharmaceuticals, Inc.
Warrant No.:	No.
Number of Shares:	Calculated in accordance with Section 1.7
Class of Stock:	Series C Preferred Stock, par value $0.001 per share
Initial Exercise Price:	$1.5876 per share
Issue Date:	, 2016
Expiration Date:	, 2026
Credit Facility:	This Second Warrant to Purchase Stock (this "***Warrant***") is issued in connection with that certain Loan and Security Agreement among Pacific Western Bank, Alexandria Equities, LLC and the Company, dated November 20, 2014, as amended by the First Amendment to Loan and Security Agreement dated on or about the Issue Date, and as further amended from time to time (the "***Loan and Security Agreement***").

THIS SECOND WARRANT CERTIFIES THAT, for good and valuable consideration, the receipt of which is hereby acknowledged, **ALEXANDRIA EQUITIES, LLC** or its assignee or transferee ("***Holder***") is entitled to purchase up to the aggregate number of fully paid and nonassessable shares of the class of securities (the "***Shares***") of the corporation (the "***Company***") at the initial exercise price per Share (the "***Warrant Price***") all as set forth above and as adjusted pursuant to Section 1.7 and Article 2 of this Warrant, subject to the provisions and upon the terms and conditions set forth in this Warrant. This is one of a series of the Company's warrants in the same form and issued on or about the Issue Date of this Warrant pursuant to the Loan and Security Agreement.

ARTICLE 1

EXERCISE

1.1 Method of Exercise. Holder may exercise this Warrant, in whole or in part, by delivering the original of this Warrant and a duly executed Notice of Exercise in substantially the form attached as Appendix 1 to the principal office of the Company. Unless Holder is exercising a cashless exercise set forth in Section 1.2, Holder shall also deliver to the Company a check, wire transfer of same-day funds (to an account designated by the Company) or other form of payment acceptable to the Company for the aggregate Warrant Price for the Shares being purchased.

1.2 Cashless Exercise. In lieu of payment of the aggregate Warrant Price in the manner specified in Section 1.1 above (but otherwise in accordance with the requirements of Section 1.1), Holder may elect to exercise this Warrant, in whole or in part, and receive such number of Shares as is determined by dividing (a) the aggregate fair market value of the Shares with respect to which this Warrant is being exercised (including the Shares surrendered to the Company in payment of the aggregate Warrant Price) minus the aggregate Warrant Price of the Shares with respect to which this Warrant is being exercised (including the Shares surrendered to the Company in payment of the aggregate Warrant Price) by (b) the fair market value of one Share. The fair market value of the Shares shall be determined pursuant to Section 1.3.

1.3 Fair Market Value. If the Company's common stock is then traded or quoted on a nationally recognized securities exchange, inter-dealer quotation system or over-the-counter market (a "***Trading Market***") and the Class of Stock is common stock, the fair market value of a Share shall be the closing price or last sale price of a share of common stock reported for the Business Day (as defined below) immediately before the date on which Holder delivers this Warrant together with its Notice of Exercise to the Company. If the Company's common stock is then traded or quoted on a Trading Market and the Class of Stock is a series of the Company's convertible preferred stock, the fair market value of a Share shall be the closing price or last sale price of a share of the Company's common stock reported for the Business Day immediately before the date on which Holder delivers this Warrant together with its Notice of Exercise to the Company multiplied by the number of shares of the Company's common stock into which a Share is then convertible. If the Company's common stock is not traded or quoted on a Trading Market, the Board of Directors of the Company shall determine the fair market value of a Share in its reasonable good faith judgment. "***Business Day***" means any day that is not a Saturday, Sunday or a day on which Pacific Western Bank is closed.

1.4 Delivery of Certificate and New Warrant. Within a reasonable time after Holder exercises this Warrant in the manner set forth in Section 1.1 or 1.2 above, the Company shall deliver to Holder a certificate for the Shares acquired by Holder upon such exercise and, if this Warrant has not been fully exercised and has not expired, a new warrant of like tenor representing the Shares neither so acquired nor canceled in payment of the aggregate Warrant Price.

1.5 Replacement of Warrant. On receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of loss, theft or destruction, on delivery of an indemnity agreement reasonably satisfactory in form, substance and amount to the Company or, in the case of mutilation, on surrender and cancellation of this Warrant, the Company at its expense shall, within a reasonable time, execute and deliver to Holder, in lieu of this Warrant, a new warrant of like tenor.

1.6 Repurchase on Sale, Merger, or Consolidation of the Company.

1.6.1 ***Acquisition.*** For the purpose of this Warrant, "***Acquisition***" means any transaction or series of related transactions involving: (i) the sale, lease, exclusive license, or other disposition of all or substantially all of the assets of the Company, (ii) any merger or consolidation of the Company into or with another person or entity (other than a merger or consolidation effected exclusively to change the Company's domicile), or any other corporate

reorganization, in which the stockholders of the Company in their capacity as such immediately prior to such merger, consolidation or reorganization, own less than a majority of the Company's (or the surviving or successor entity's) outstanding voting power immediately after such merger, consolidation or reorganization (or, if such Company stockholders beneficially own a majority of the outstanding voting power of the surviving or successor entity immediately after such merger, consolidation or reorganization, such surviving or successor entity is not the Company); or (iii) any sale or other transfer by the stockholders of the Company of shares representing at least a majority of the Company's then-total outstanding combined voting power.

1.6.2 Exercise Upon Acquisition. Upon the closing of any Acquisition in which the consideration to be received by the Company's stockholders consists of cash, marketable securities, or a combination of both cash and marketable securities (a "***Cash/Public Acquisition***"), this Warrant shall be deemed to have been automatically exercised pursuant to Section 1.2, and thereafter Holder shall participate in the Acquisition on the same terms as other holders of the same class of securities of the Company. For the purpose of this Warrant, "***marketable securities***" means securities meeting all of the following requirements: (i) the issuer thereof is then subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), and is then current in its filing of all required reports and other information under the Act and the Exchange Act; (ii) the class and series of shares or other security of the issuer that would be received by Holder in connection with the Acquisition were Holder to exercise this Warrant on or prior to the closing thereof is then traded in a Trading Market, and (iii) following the closing of such Acquisition, Holder would not be restricted from publicly re-selling all of the issuer's shares and/or other securities that would be received by Holder in such Acquisition were Holder to exercise this Warrant in full on or prior to the closing of such Acquisition, except to the extent that any such restriction (x) arises solely under federal or state securities laws, rules or regulations, and (y) does not extend beyond six (6) months from the closing of such Acquisition.

1.6.3 Assumption of Warrant. Upon the closing of any Acquisition other than a Cash/Public Acquisition, the successor entity shall assume the obligations of this Warrant, and this Warrant shall thereafter be exercisable for the same securities and/or other property as would have been paid for the Shares issuable upon exercise of the unexercised portion of this Warrant as if such Shares were outstanding on and as of the closing of such Acquisition, subject to further adjustment from time to time in accordance with the provisions of this Warrant.

1.7 Adjustment in Underlying Shares.

1.7.1 Solely for purposes of this Section 1.7, capitalized terms used in this Section 1.7 but not defined in this Warrant shall have the meaning given to them in the Loan and Security Agreement.

1.7.2 This Warrant shall be exercisable for the number of Shares equal to the quotient of (a) 4.0% of the difference between (i) the aggregate principal amount of all Term Loans made by Alexandria Equities, LLC pursuant to the Loan and Security Agreement on or before the date of exercise, it being understood that in the event of any partial exercise of this Warrant, the aggregate principal amount of all Term Loans made by Alexandria Equities, LLC upon any subsequent exercise shall include only the aggregate principal amount of Term Loans

made after the date of the most recent prior exercise and (ii) $3,000,000, divided by (b) the Warrant Price, with any resulting fraction rounded down to the nearest whole share, which total number of Shares shall not exceed 75,585 (subject to any adjustment made pursuant to Article 2 hereof).

1.7.3 With respect to any adjustment to the number of shares pursuant to this Section 1.7, all shares subject to this Warrant shall be of the same series and class of stock and bearing the same rights, preferences, and privileges as such series and class of stock denoted in the above caption hereto. The adjustment under this Section 1.7 shall be in addition to any adjustment made pursuant to Article 2 hereof.

1.8 Certain Agreements. As a condition to the issuance of Shares upon any exercise of this Warrant, Holder shall, if the Company so requests in writing, become a party to, by execution and delivery to the Company of a counterpart signature page, joinder agreement, instrument of accession or similar instrument, (i) that certain Fifth Amended and Restated Stockholders Agreement, dated as of April 6, 2016, among the Company and the stockholders party thereto, as such agreement may be amended and/or restated from time to time (the "***Stockholders Agreement***"), and (ii) that certain Third Amended and Restated Registration Rights Agreement, dated as of April 6, 2016, among the Company and the individuals and entities listed on Exhibit A attached thereto, as such agreement may be amended and/or restated from time to time (the "***Registration Rights Agreement***") (each of which has been provided to Holder), in each case, solely with respect to the Shares issued upon such exercise (and the shares of common stock, if any, issued upon conversion of such Shares), solely to the extent that all holders of outstanding shares of the Class of Stock are then parties thereto, and solely to the extent each such agreement is then by its terms in force and effect.

ARTICLE 2

ADJUSTMENTS TO THE SHARES

2.1 Stock Dividends, Splits, Etc. If the Company declares or pays a dividend on the outstanding shares of the Class of Stock payable in common stock, or other securities, then upon exercise of this Warrant, for each Share acquired, Holder shall receive, without additional cost to Holder, the total number and kind of securities to which Holder would have been entitled had Holder owned the Shares of record as of the date the dividend occurred. If the Company subdivides the outstanding shares of the Class of Stock into a greater amount of shares of such Class of Stock, the number of Shares purchasable hereunder shall be proportionately increased and the Warrant Price shall be proportionately decreased. If the Company combines or consolidates, by reclassification or otherwise, the outstanding shares of the Class of Stock into a lesser amount of shares of such Class of Stock, the number of Shares purchasable hereunder shall be proportionately decreased and the Warrant Price shall be proportionately increased.

2.2 Reclassification, Exchange or Substitution. Upon any reclassification, exchange, substitution, or other event that results in all of the outstanding shares of the Class of Stock being reclassified, exchanged, substituted or replaced for, into with or by Company securities of a different class and/or series, then from and after the consummation of such event, Holder shall be entitled to receive, upon exercise of this Warrant, the number and kind of

securities that Holder would have received for the Shares if this Warrant had been exercised immediately before such reclassification, exchange, substitution, or other event. Such an event shall include any conversion of the outstanding or issuable securities of the Company of the same class or series as the Shares to common stock, automatically or by action of the holders thereof, pursuant to the terms of the Company's Amended and Restated Certificate of Incorporation (as amended and/or restated from time to time, the "***Certificate of Incorporation***"), including, without limitation, in connection with a QPO (as defined in the Certificate of Incorporation). The Company or its successor shall promptly issue to Holder a new warrant for such new securities or other property. The new warrant shall provide for adjustments which shall be as nearly equivalent as may be practicable to the adjustments provided for in this Article 2 including, without limitation, adjustments to the Warrant Price and to the number of securities or property issuable upon exercise of the new warrant. The provisions of this Section 2.2 shall similarly apply to successive reclassifications, exchanges, substitutions, or other events.

2.3 Adjustments for Diluting Issuances. Without duplication of any adjustment provided for in this Section 2, the number of shares of common stock issuable upon conversion of the Shares shall be subject to anti-dilution adjustment from time to time in the manner set forth in the Certificate of Incorporation as if the Shares were issued and outstanding on and as of the date of any such required adjustment.

2.4 Certificate as to Adjustments. Upon each adjustment of the Warrant Price, the Company at its expense shall promptly compute such adjustment, and notify Holder in writing setting forth such adjustment and the facts upon which such adjustment is based. The Company shall, upon written request from Holder, furnish Holder with a certificate of its Chief Financial Officer (or person of equivalent responsibility) setting forth the Warrant Price in effect upon the date thereof and the series of adjustments leading to such Warrant Price.

2.5 No Fractional Shares. No fractional Shares shall be issuable upon exercise of this Warrant and the number of Shares to be issued shall be rounded down to the nearest whole Share. If a fractional share interest arises upon any exercise of this Warrant, the Company shall eliminate such fractional share interest by paying Holder in cash the amount computed by multiplying the fractional interest by (a) the fair market value (as determined pursuant to Section 1.3 above) of a full Share, less (b) the then-effective Warrant Price.

ARTICLE 3

REPRESENTATIONS AND COVENANTS OF THE COMPANY

3.1 Representations and Warranties. The Company hereby represents and warrants to Holder as follows:

(a) The initial Warrant Price referenced on the first page of this Warrant is not greater than the price per share at which shares of the Class of Stock were last sold and issued prior to the Issue Date.

(b) All Shares which may be issued upon the exercise of the purchase right represented by this Warrant, when paid for in accordance with the provisions hereof, and all securities, if any, issuable upon conversion of the Shares, shall, upon issuance, be duly authorized, validly issued, fully paid and nonassessable, and free of any liens and encumbrances except for restrictions on transfer provided for herein or under applicable federal and state securities laws.

(c) The Company's capitalization table attached to this Warrant is true and complete, other than failures to be true and complete as are de minimis in effect to Holder, as of the Issue Date.

3.2 Notice of Certain Events. The Company shall provide Holder with not less than 10 days prior written notice of, including a description of the material facts surrounding, any of the following events: (a) declaration of any dividend or distribution upon its common stock, whether in cash, property, stock, or other securities and whether or not a regular cash dividend; (b) offering for subscription pro rata to the holders of the outstanding shares of the Class of Stock any additional shares of stock of any class or series of its stock (other than pursuant to contractual pre-emptive rights); (c) effecting any reclassification or recapitalization of common stock; or (d) effecting an Acquisition or liquidation, dissolution or winding up. The Company will also provide information requested by Holder that is reasonably necessary to enable Holder to comply with Holder's accounting or reporting requirements.

3.3 Information Rights. So long as Holder holds this Warrant, the Company shall deliver to Holder such reports as the Company furnishes to each Major Investor (as defined in the Stockholders Agreement) pursuant to Section 7.1 of the Stockholders Agreement, subject to the limitations set forth therein.

3.4 Registration Under Securities Act of 1933, as amended. The Company agrees that, upon execution and delivery of a counterpart signature to the Registration Rights Agreement, the Shares or, if the Shares are convertible into common stock of the Company, such common stock, shall be "Registrable Securities" solely for the purpose of obtaining "piggyback" registration rights pursuant to Section 4 of the Registration Rights Agreement, and Holder shall be an "Investor" under the Registration Rights Agreement.

ARTICLE 4

REPRESENTATIONS, WARRANTIES AND COVENANTS OF HOLDER

4.1 Representations and Warranties. Holder hereby represents and warrants to the Company as follows:

4.1.1 Purchase for Own Account. This Warrant is made with Holder in reliance upon the Holder's representation to the Company, which by Holder's execution of this Warrant, Holder hereby confirms, that this Warrant, the Shares and the securities issuable, directly or indirectly, upon conversion of the Shares, if any (collectively, the "Securities"), are being acquired for investment for Holder's own account (or the account of its respective Affiliates), not as a nominee or agent, and not with a view to the resale or distribution of any part

thereof in violation of any applicable law, and that Holder has no present intention of selling, granting any participation in or otherwise distributing the Securities to any other person in violation of any applicable law. By executing this Warrant, Holder further represents that Holder does not have any contract, undertaking, agreement or arrangement with any person to sell, transfer or grant participation to such person or to any third person, with respect to any of the Securities.

4.1.2 Disclosure of Information. Holder represents that it has had an opportunity to discuss with the Company the terms and conditions of the offering of this Warrant and the Company's business, properties, prospects and financial condition. The foregoing, however, does not limit or modify the representations and warranties of the Company in Article 3 of this Warrant or the right of the Holder to rely thereon.

4.1.3 Investment Experience. Holder is an investor in securities of companies in the development stage and acknowledges that it is able to fend for itself, can bear the economic risk of its investment, and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in this Warrant and the Securities issuable upon exercise thereof. Holder also represents it has not been organized for the purpose of acquiring this Warrant or the Securities issuable upon exercise thereof.

4.1.4 No Public Market. Holder understands that no public market now exists for this Warrant or the Securities issuable upon exercise thereof, and that the Company has made no assurances that a public market will ever exist for this Warrant or the Shares.

4.1.5 Accredited Investor. Holder is an "accredited investor" within the meaning of Rule 501(a) of Regulation D promulgated under the Securities Act.

4.1.6 Restricted Securities. Holder understands that the Securities are "restricted securities" under applicable U.S. federal and state securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such Securities may be resold without registration under the Securities Act and such other securities laws only in certain limited circumstances. In the absence of any effective registration statement covering the Securities or an available exemption from registration under the Securities Act, the Securities must be held indefinitely. In this connection, such Holder represents that it is familiar with Rule 144 of the Securities Act, as presently in effect, and understands the resale limitations imposed thereby and by the Securities Act, including without limitation the Rule 144 condition that current information about the Company be available to the public. Such information is not now available and the Company has no present plans to make such information available. Holder acknowledges that the Company has no obligation to register or qualify the Securities for resale.

4.2 Market Stand-Off Agreement. Holder agrees that the Shares shall be subject to the same market stand-off provisions as those set forth in Section 12 of the Registration Rights Agreement, as in effect on the Issue Date.

4.3 No Stockholder Rights. Without limiting any provision of this Warrant, Holder agrees that, as a Holder of this Warrant, it will not have any voting rights or other rights as a stockholder until the exercise of this Warrant in accordance with its terms.

ARTICLE 5

MISCELLANEOUS

5.1 Term; Automatic Cashless Exercise Upon Expiration.

5.1.1 This Warrant is exercisable in whole or in part, at any time and from time to time on or before the Expiration Date set forth above; provided, however, that if the Company completes its initial public offering within the 270-day period immediately prior to the Expiration Date, the Expiration Date shall automatically be extended until 270 days after the effective date of the Company's initial public offering.

5.1.2 In the event that, upon the Expiration Date, the fair market value (as determined pursuant to Section 1.3 above) of one Share (or other security issuable upon the exercise hereof) is greater than the Warrant Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to Section 1.2 above as to all Shares (or such other securities) for which it shall not previously have been exercised.

5.2 Legends. Each certificate evidencing the Shares (and each certificate evidencing the securities issuable, directly or indirectly, upon conversion of the Shares, if any) shall be imprinted with a legend in substantially the following form:

> THIS SECURITY HAS NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN THAT CERTAIN SECOND WARRANT TO PURCHASE STOCK ISSUED BY THE ISSUER TO ALEXANDRIA EQUITIES, LLC DATED , 2016, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED EXCEPT IN ACCORDANCE WITH APPLICABLE LAW.

5.3 Compliance with Securities Laws on Transfer. This Warrant and the Shares issuable upon exercise of this Warrant (and the securities issuable, directly or indirectly, upon conversion of the Shares, if any) may not be transferred or assigned in whole or in part without compliance with applicable federal and state securities laws by the transferor and the transferee (including, without limitation, the delivery of investment representation letters and legal opinions reasonably satisfactory to the Company, as reasonably requested by the Company). The Company shall not require Holder to provide an opinion of counsel if the transfer is to an affiliate of Holder or if there is no material question as to the availability of current information as referenced in Rule 144(c), Holder represents that it has complied with Rule 144(d) and (e) in reasonable detail, the selling broker represents that it has complied with Rule 144(f), and the Company is provided with a copy of Holder's notice of proposed sale.

5.4 Transfer Procedure. Subject to the provisions of Section 5.3 and this Section 5.4, Holder may transfer all or part of this Warrant or the Shares issuable upon exercise of this

Warrant (or the securities issuable, directly or indirectly, upon conversion of the Shares, if any) by giving the Company written notice of the portion of this Warrant and/or Shares (and/or securities issuable, directly or indirectly, upon conversion of the Shares, if any) being transferred setting forth the name, address and taxpayer identification number of the transferee and surrendering this Warrant to the Company for reissuance to the transferee(s) (and Holder, if applicable); provided that, as a condition to such transfer, any subsequent transferee shall agree in writing with the Company to be bound by the terms and conditions of this Warrant, including without limitation Section 4.2 hereof. No surrender or reissuance shall be required if the transfer is to an affiliate of Holder; provided that Holder gives the Company written notice of the portion of this Warrant and/or Shares (and/or securities issuable, directly or indirectly, upon conversion of the Shares, if any) being transferred setting forth the name, address and taxpayer identification number of the transferee. Notwithstanding anything to the contrary set forth herein, Holder shall not be permitted to transfer this Warrant or the Shares issuable upon exercise of this Warrant (or the securities issuable, directly or indirectly, upon conversion of the Shares, if any) to an operating corporation, partnership, limited liability company or similar entity actively engaged, directly or indirectly (including through any partnership, limited liability company, corporation, joint venture or similar arrangement (whether now existing or formed hereafter)), in the research, production, development, manufacture, licensing, distribution, sale, or use of microparticle or nanoparticle technologies for developing therapeutic or prophylactic pharmaceutical agents delivered to or through mucus, mucin, or mucosal tissues or barriers (a "***Competitive Operating Entity***"), except in connection with an Acquisition of the Company by such Competitive Operating Entity.

5.5 Notices. All notices and other communications from the Company to Holder, or vice versa, shall be deemed delivered and effective when given personally or mailed by first- class registered or certified mail, postage prepaid, at such address as may have been furnished to the Company or Holder, as the case may be, in writing by the Company or such Holder from time to time. All notices to Holder shall be addressed as follows:

Alexandria Equities, LLC
385 E. Colorado Blvd., Suite 299
Pasadena, California 91101
Attn: Chief Financial Officer

All notices to the Company shall be addressed as follows until Holder receives notice of a change in address:

Kala Pharmaceuticals, Inc.
100 Beaver Street
Suite 201
Waltham, MA 02453
Attn: Chief Executive Officer

With a copy (which shall not constitute notice) to:

Wilmer Cutler Pickering Hale and Dorr LLP
Attn: Lia Der Marderosian, Esq.
60 State Street
Boston, MA 02109
Facsimile: (617) 526 5000
Email: Lia.DerMarderosian@wilmerhale.com

5.6 Amendments. This Warrant and any term hereof may be changed, waived, discharged or terminated only by an instrument in writing signed by the party against which enforcement of such change, waiver, discharge or termination is sought.

5.7 Attorneys' Fees. In the event of any dispute between the parties concerning the terms and provisions of this Warrant, the party prevailing in such dispute shall be entitled to collect from the other party all costs incurred in such dispute, including reasonable attorneys' fees.

5.8 Governing Law. This Warrant shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to its principles regarding conflicts of law.

5.9 Counterparts; Facsimile/Electronic Signatures. This Warrant may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail or other transmission method, and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

5.10 Effect of Headings. The descriptive headings in this Warrant have been inserted for convenience only and shall not be deemed to limit or otherwise affect the construction of any provision hereof.

5.11 Entire Agreement. This Warrant constitutes the full and entire understanding and agreement among the parties hereto with respect to the subject matter hereof, and any and all other written or oral agreements relating to such subject matter existing among the parties are expressly canceled.

[Signature Page Follows]

IN WITNESS WHEREOF, the undersigned has executed this Second Warrant to Purchase Stock as of the Issue Date set forth above.

COMPANY:

KALA PHARMACEUTICALS, INC.

By: _____

Name: _____

Title: _____

HOLDER:

ALEXANDRIA EQUITIES, LLC

By: _____

Name: _____

Title: _____

APPENDIX 1

NOTICE OF EXERCISE

1. The undersigned, pursuant to the terms of the attached warrant (the "Warrant"), hereby elects to purchase: *(check applicable box)*

☐ Shares of **KALA PHARMACEUTICALS, INC.** covered by the Warrant and tenders herewith payment of the purchase price of such Shares in full pursuant to Section 1.1 thereof; or

☐ Shares of **KALA PHARMACEUTICALS, INC.** covered by the Warrant pursuant to the cashless exercise procedure set forth in Section 1.2 thereof.

2. Please issue a certificate or certificates representing the Shares in the name of the undersigned or in such other name as is specified below:

Holder's Name:
Address:

3. By its execution below, Holder hereby makes and affirms each of the representations, warranties and covenants set forth in Section 4 of the Warrant as of the date hereof.

HOLDER:

ALEXANDRIA EQUITIES, LLC

By: _____

_____
(Print Name of Signatory)

_____
(Title)

_____
(Date)

SECOND AMENDMENT
TO
LOAN AND SECURITY AGREEMENT

This Second Amendment to Loan and Security Agreement (the "***Amendment***") is entered into as of November 22, 2017, by and among Pacific Western Bank, a California state chartered bank (as successor in interest by merger to Square 1 Bank) ("***Square 1***"), in its capacity as administrative and collateral agent (together with its successors and assigns in such capacity, "***Agent***"), the Lenders set forth on Schedule 1 of the Agreement (as defined below) or otherwise a party thereto from time to time, including Square 1 in its capacity as a Lender and Alexandria Venture Investments, LLC, a Delaware limited liability company (each individually a "***Lender***" and, collectively, the "***Lenders***"), and Kala Pharmaceuticals, Inc. ("***Borrower***").

RECITALS

Agent, the Lenders, and Borrower are parties to that certain Loan and Security Agreement dated as of November 20, 2014 (as amended from time to time, the "***Agreement***"). The parties desire to amend the Agreement in accordance with the terms of this Amendment.

NOW, THEREFORE, the parties agree as follows:

1) Agent, the Lenders, and Borrower hereby agree that, notwithstanding the prohibitions on Investments in Section 7.7 of the Agreement, if the MSC Investment Conditions are then being met and no Event of Default then exists, then Borrower may make Investments in an MSC Subsidiary, such Investments shall be treated as Permitted Investments for purposes of the Agreement, and in accordance with Section 6.6 of the Agreement, Borrower shall be permitted to maintain Cash and/or Investments owned by an MSC Subsidiary in one or more accounts outside of Square 1 or Square 1's Affiliates. If, at any time after the incorporation of any MSC Subsidiary, the MSC Investment Conditions are not met, then (i) Borrower shall immediately cause all MSC Subsidiaries to distribute to Borrower all assets held by any MSC Subsidiaries for deposit into a deposit account at Square 1, and (ii) Borrower shall not permit any MSC Subsidiary to hold any assets. Borrower shall not permit any MSC Subsidiary to make any Investments or hold any assets that would cause such MSC Subsidiary to fail to qualify as a Massachusetts security corporation under 830 CMR 63.38B.1 of the Massachusetts tax code and applicable regulations (as the same may be amended, modified or replaced from time to time).

2) Section 6.6 of the Agreement is hereby amended and restated, as follows:

6.6 Primary Depository. Borrower shall maintain all of its depository and operating accounts with Square 1 and its primary investment accounts with Square 1 or Square 1's Affiliates. Notwithstanding the foregoing, Borrower shall be permitted to maintain Cash and/or Investments owned by an MSC Subsidiary in one or more accounts outside of Square 1 or Square 1's Affiliates, without the requirement for control agreements, so long as Borrower maintains at all times the MSC Investment Conditions. Prior to maintaining any deposit accounts with Square 1 or any investment accounts with Square 1's Affiliates, Borrower, Agent, and any such Affiliate, as applicable, shall have entered into a deposit

account control agreement or a securities account control agreement, as applicable, with respect to any such deposit accounts and investment accounts, in form and substance satisfactory to Agent and the Required Lenders.

3) Agent, the Lenders, and Borrower hereby agree that, notwithstanding Section 6.8 of the Agreement, if the MSC Investment Conditions are then being met and no Event of Default then exists, the MSC Subsidiary shall not be required to become a co-Borrower or secured guarantor with respect to the Obligations. Pursuant to Section 6.8 of the Agreement, the Borrower shall grant and pledge to Agent (for the benefit of the Lenders) a perfected security interest in 100% of the stock of the MSC Subsidiary.

4) The following defined terms are hereby added to Exhibit A to the Agreement, as follows:

"MSC Investment Conditions" means that Borrower has on deposit with Square 1 unrestricted cash or cash equivalents in an aggregate amount greater than or equal to 125% of the then outstanding principal and accrued interest on all Credit Extensions.

"MSC Subsidiary" means a wholly owned Subsidiary incorporated in the Commonwealth of Massachusetts or the State of Delaware for the purpose of holding Investments as a Massachusetts security corporation under 830 CMR 63.38B.1 of the Massachusetts tax code and applicable regulations (as the same may be amended, modified or replaced from time to time).

5) Unless otherwise defined, all initially capitalized terms in this Amendment shall be as defined in the Agreement. The Agreement, as amended hereby, shall be and remain in full force and effect in accordance with its respective terms and hereby is ratified and confirmed in all respects. Except as expressly set forth herein, the execution, delivery, and performance of this Amendment shall not operate as a waiver of, or as an amendment of, any right, power, or remedy of the Lenders under the Agreement, as in effect prior to the date hereof. Borrower ratifies and reaffirms the continuing effectiveness of all agreements entered into in connection with the Agreement.

6) Borrower represents and warrants that the representations and warranties contained in the Agreement are true and correct in all material respects as of the date of this Amendment; provided, however, that those representations and warranties expressly referring to another date shall be true and correct as in all material respects as of such date; and provided further that representations and warranties that by their terms include a materiality qualification shall be true and correct in all respects.

7) This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

8) As a condition to the effectiveness of this Amendment, Agent shall have received, in form and substance satisfactory to Agent and each Lender, the following:

a) this Amendment, duly executed by Borrower;

b) payment of all Lender Expenses, including Agent's and each Lender's expenses for the documentation of this Amendment and any related documents, and any UCC, good standing or intellectual property search or filing fees, which Agent may debit from any of Borrower's accounts at Square 1; and

c) such other documents and completion of such other matters, as Agent and each Lender may reasonably deem necessary or appropriate.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the undersigned have executed this Amendment as of the first date above written.

BORROWER:

KALA PHARMACEUTICALS, INC.

By: /s/ Mary Reumuth
Name: Mary Reumuth
Title: Chief Financial Officer

AGENT:
PACIFIC WESTERN BANK

By: /s/ John Orlando
Name: John Orlando
Title: Vice President

LENDERS:

PACIFIC WESTERN BANK

By: /s/ John Orlando
Name: John Orlando
Title: Vice President

ALEXANDRIA VENTURE INVESTMENTS, LLC
a Delaware limited liability company

By: Alexandria Real Estate Equities, Inc., its managing member
By: /s/ Aaron Jacobson
Name: Aaron Jacobson
Title: VP – Corporate Counsel

[Signature Page to Second Amendment to Loan and Security Agreement]

THIRD AMENDMENT
TO
LOAN AND SECURITY AGREEMENT

This Third Amendment to Loan and Security Agreement (the "***Amendment***") is entered into as of March 29, 2018, by and among Pacific Western Bank, a California state chartered bank (as successor in interest by merger to Square 1 Bank) ("***Square 1***"), in its capacity as administrative and collateral agent (together with its successors and assigns in such capacity, "***Agent***"), the Lenders set forth on Schedule 1 of the Agreement (as defined below) or otherwise a party thereto from time to time, including Square 1 in its capacity as a Lender and Alexandria Venture Investments, LLC, a Delaware limited liability company (as successor in interest by name change to Alexandria Equities, LLC) (each individually a "***Lender***" and, collectively, the "***Lenders***"), and Kala Pharmaceuticals, Inc. ("***Borrower***").

RECITALS

Agent, the Lenders, and Borrower are parties to that certain Loan and Security Agreement dated as of November 20, 2014 (as has been and may be further amended from time to time, the "***Agreement***"). The parties desire to amend the Agreement to increase the existing term loan facility and make certain other modifications, all in accordance with the terms of this Amendment.

NOW, THEREFORE, the parties agree as follows:

1) Section 2.1(b) of the Agreement is hereby amended and restated, as follows:

(b) Term Loans.

(i) Term Loans A. Subject to and upon the terms and conditions of this Agreement, the Lenders agree to make on the Third Amendment Date, severally and not jointly, according to each Lender's Term Loan Commitment Amount, term loans to Borrower in the aggregate principal amount of $20,000,000 (each a "Term Loan A" and, collectively, the "Term Loans A"). Each Term Loan A shall be deemed made as of the Third Amendment Date. The proceeds of the Term Loans A shall be used (A) first, to repay the aggregate principal amount of all 'term loans' then outstanding under this Agreement (but without the requirement to pay any Prepayment Fee which is hereby waived solely with respect to such 'term loans') and (B) second, for general working capital purposes, for capital equipment purchases, to pay Lender Expenses and to pay the fees under this Agreement. For the avoidance of doubt, the difference between $20,000,000 and the outstanding balance of the existing term loans will be credited to Borrower's account, and no Prepayment Fee will be due in connection with the foregoing repayment of 'term loans'.

(ii) Term Loans B. Subject to and upon the terms and conditions of this Agreement, the Lenders agree to make, severally and not jointly, according to each Lender's Term Loan Commitment Amount, one or more term loans to Borrower in an aggregate principal amount not to exceed $5,000,000 (each a "Term Loan B" and, collectively, the "Term Loans B", and together with the Term Loans A, each a "Term Loan" and collectively, the "Term Loans"). Each Term Loan B shall be in a minimum amount of $250,000. Borrower may request Term Loans B at any time from the Term Loan B Availability Start Date through the Term Loan B Availability End Date. The proceeds of the Term Loans B shall be used for general working capital purposes.

(iii) Interest shall accrue from the date of each Term Loan at the rate specified in Section 2.2(a) and, through the Interest-Only End Date, shall be payable monthly in arrears beginning on the 29th day

of the month next following such Term Loan, and continuing on the same day of each month thereafter. If the Borrower does not achieve the Extension Criteria, any Term Loans that are outstanding on the Interest-Only End Date shall be payable in 36 equal monthly installments of principal, plus all accrued interest, beginning on the date that is one month immediately following the Interest-Only End Date and continuing on the same day of each month thereafter through the Term Loan Maturity Date, at which time all amounts due in connection with the Term Loans and any other amounts due under this Agreement shall be immediately due and payable. If the Borrower achieves the Extension Criteria, any Term Loans that are outstanding on the Interest-Only End Date shall be payable in 30 equal monthly installments of principal, plus all accrued interest, beginning on the date that is one month immediately following the Interest-Only End Date and continuing on the same day of each month thereafter through the Term Loan Maturity Date, at which time all amounts due in connection with the Term Loans and any other amounts due under this Agreement shall be immediately due and payable. Term Loans, once repaid, may not be reborrowed. Borrower may prepay any Term Loan, subject to the payment of the Prepayment Fee.

(iv) When Borrower desires to obtain a Term Loan B, Borrower shall notify Agent (which notice shall be irrevocable) by facsimile transmission to be received no later than 3:30 p.m. Eastern time at least five Business Days prior to the date on which the Term Loan B is to be made. Such notice shall be substantially in the form of Exhibit C and signed by an Authorized Officer. Promptly upon receiving such notice, Agent shall notify each Lender of the contents of such notice and each Lender's Pro Rata Share of such Term Loan B.

2) Section 2.2(a) of the Agreement is hereby amended and restated, as follows:

(a) Interest Rates. Except as set forth in Section 2.2(b), the Term Loans shall bear interest, on the outstanding daily balance thereof, at a variable annual rate equal to the greater of (i) 3.00% above the Prime Rate then in effect, or (ii) 7.50%.

3) The table in Section 2.4(c) of the Agreement is hereby deleted and replaced with the following table:

Period	Applicable Prepayment Percentage
From the Third Amendment Date to (but not including) the date that is twelve (12) months after the Third Amendment Date	0.90%
From the date that is twelve (12) months after the Third Amendment Date to (but not including) the date that is twenty-four (24) months after the Third Amendment Date	0.60%
From the date that is twenty-four (24) months after the Third Amendment Date and thereafter until the Term Loan Maturity Date	0.30%

4) Section 5.12 of the Agreement is hereby amended by inserting "or" before "disclosed in accordance with Section 6.7".

5) The following defined terms are hereby added to Exhibit A to the Agreement, as follows:

"Extension Criteria" means Agent and the Required Lenders have received evidence reasonably acceptable to Agent and the Required Lenders that Borrower has (A) satisfied the Term Loan B Milestone and (B) received at least Fifty Million Dollars ($50,000,000) in gross proceeds of New Equity on or before March 31, 2019.

"New Equity" means Cash proceeds received after the Third Amendment Date from the sale or issuance of Borrower's equity securities.

"Term Loan B Milestone" means receipt by Borrower of approval from the United States Food and Drug Administration of Borrower's new drug application for INVELTYS (KPI-121 1%).

"Third Amendment Date" means March 29, 2018.

6) The following defined terms in Exhibit A to the Agreement are hereby amended and restated, as follows:

"Interest-Only End Date" means the date that is twelve (12) months after the Third Amendment Date; provided however, that if the Borrower achieves the Extension Criteria, the "Interest-Only End Date" shall instead mean the date that is eighteen (18) months after the Third Amendment Date.

"Term Loan B Availability End Date" means the date that is twelve (12) months after the Third Amendment Date.

"Term Loan B Availability Start Date" means the date of receipt by Agent and the Required Lenders of evidence reasonably acceptable to Agent and the Required Lenders that Borrower has achieved the Term Loan B Milestone, provided that receipt by Agent and the Required Lenders of such evidence must occur no later than the date that is twelve (12) months after the Third Amendment Date.

"Term Loan Maturity Date" means the date that is forty-eight (48) months after the Third Amendment Date.

7) Schedule 1 to the Agreement is hereby deleted and replaced with the new Schedule 1 attached hereto as Appendix I.

8) (a) The Borrower has advised Lender that in connection with the Permitted License with Johns Hopkins University dated November 10, 2009, as amended, Borrower has executed and delivered an Assignment to Johns Hopkins University of certain patent rights dated April 26, 2017 and an Assignment to Johns Hopkins University of certain patent rights dated April 26, 2017. Lender acknowledges that such Assignments constitute Permitted Transfers.

(b) The Borrower has advised Lender that Borrower has executed an Exclusive License Agreement with John Hopkins University as of May 1, 2017 with respect to a license by the John Hopkins University to the Borrower. The Lender hereby agrees that such notice satisfies the requirements of that the Borrower notify Lender of such license under Section 6.7 of the Loan Agreement.

9) Unless otherwise defined, all initially capitalized terms in this Amendment shall be as defined in the Agreement. The Agreement, as amended hereby, shall be and remain in full force and effect in accordance with its respective terms and hereby is ratified and confirmed in all respects. Except as expressly set forth herein, the execution, delivery, and performance of this Amendment shall not operate as a waiver of, or as an amendment of, any right, power, or remedy of the Lenders under the Agreement, as in effect prior to the date hereof. Borrower ratifies and reaffirms the continuing effectiveness of all agreements entered into in connection with the Agreement.

10) Borrower represents and warrants that the representations and warranties contained in the Agreement are true and correct in all material respects as of the date of this Amendment; provided, however, that those representations and warranties expressly referring to another date shall be true and correct as in all material respects as of such date; and provided further that representations and warranties that by their terms include a materiality qualification shall be true and correct in all respects.

11) This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

12) As a condition to the effectiveness of this Amendment, Agent shall have received, in form and substance satisfactory to Agent and each Lender, the following:

a) this Amendment, duly executed by Borrower, Agent, and each Lender;

b) an officer's certificate of Borrower with respect to incumbency and resolutions authorizing the execution and delivery of this Amendment;

c) the First Amendment to Intercreditor Agreement, duly executed by Agent and each Lender;

d) payment of a $50,000 facility fee (for the benefit of the Lenders, to be distributed among them in accordance with each Lender's Pro Rata Share), which Agent may debit from any of Borrower's accounts at Square 1;

e) payment of all Lender Expenses, including Agent's and each Lender's expenses for the documentation of this Amendment and any related documents, and any UCC, good standing or intellectual property search or filing fees, which Agent may debit from any of Borrower's accounts at Square 1; and

f) such other documents and completion of such other matters, as Agent and the Required Lenders may reasonably deem necessary or appropriate (the execution and delivery by the Agent and the Required Lenders of this Amendment to be evidence of the delivery of such documents and the completion of such matters).

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the undersigned have executed this Amendment as of the first date above written.

BORROWER:

KALA PHARMACEUTICALS, INC.

By: /s/ Mary Reumuth
Name: Mary Reumuth
Title: Chief Financial Officer

AGENT:
PACIFIC WESTERN BANK

By: /s/ John Orlando
Name: John Orlando
Title: Vice President

LENDERS:

PACIFIC WESTERN BANK

By: /s/ John Orlando
Name: John Orlando
Title: Vice President

ALEXANDRIA VENTURE INVESTMENTS, LLC
a Delaware limited liability company

By: Alexandria Real Estate Equities, Inc., its managing member
By: /s/ Aaron Jacobson
Name: Aaron Jacobson
Title: VP – Corporate Counsel

APPENDIX I

SCHEDULE 1

LENDERS

Lender	Term Loan A Commitment Amount	Term Loan B Commitment Amount	Pro Rata Share	Address
Pacific Western Bank	$12,000,000	$3,000,000	60%	Pacific Western Bank Attn: Loan Operations Manager 406 Blackwell Street Suite 240 Durham, NC 27701 With a copy to: Pacific Western Bank 131 Oliver Street, 2nd Floor Boston, MA 02110 Attn: Phil Gager
Alexandria Venture Investments, LLC	$8,000,000	$2,000,000	40%	Alexandria Venture Investments, LLC Attn: Corporate Secretary 385 E. Colorado Blvd. Suite 299 Pasadena, CA 91101 Fax: (626) 578-7252 With a copy to: investments@are.com

Exhibit 10.12

11/6/17

100 Beaver Street, Suite 201, Waltham, MA 02453 • Voice 781 996 5252 • Fax 781 642 0399 • www.kalarx.com

November 6, 2017

Mr. Todd Bazemore

Dear Todd:

On behalf of Kala Pharmaceuticals, Inc., a Delaware corporation (the "Company"), I am pleased to offer you the position of Chief Operating Officer, pursuant to the terms of this letter.

1. Position. You will be employed to serve as the Company's Chief Operating Officer. You shall report to the Company's Chief Executive Officer, or if there is no Chief Executive Officer, to the senior executive of the Company, or to such member or members of the Board of Directors of the Company (the "Board") as the Board shall determine from time to time. You are expected to devote your full business time to the performance of your duties and responsibilities for the Company and to materially abide by all Company policies and procedures as in effect from time to time. You are expected to perform the duties of your position, together with such other duties as may reasonably be assigned to you from time to time, consistent with your position as Chief Operating Officer. Moreover, during your employment with the Company, you are expected to conduct your business activities at all times in accordance with the highest legal, ethical and professional standards.

2. Base Salary. You will be paid on a bi-weekly basis at an annual base rate of $405,000 subject to tax and other withholdings as required by law, with salary to be paid in accordance with Company's standard payroll practices. Your base salary will be reviewed annually by the Compensation Committee of the Board.

3. Cash Bonus. You will also be eligible to earn in each calendar year of your employment a performance-based cash bonus with a target of 40% of your annual base salary. Payment of this performance-based bonus shall be based on written Company and personal objectives and criteria established by the Board. The performance-based bonus, if any, will be determined by the Board in its discretion, and will be paid annually after the first of the year (but in no event later than March 15), subject to you being employed by the Company on the preceding December 31st, except as otherwise provided in Section 7. Any bonus for the first fiscal year in which your employment begins shall be prorated, based on the number of days you are employed by the Company during that fiscal year. You will also be paid a sign on bonus of $170,000, less all applicable taxes and withholdings, at the time the Company pays annual bonuses, (but in no event later than March 15, 2018) subject to you being employed by the Company on December 31st, 2017, except as otherwise provided in Section 7.

4. Benefits. You may participate in any and all benefit programs that the Company establishes and makes available to its employees from time to time, provided you are eligible under (and subject to all provisions of) the plan documents governing those programs. The benefit programs made available by the Company, and the rules, terms and conditions for participation in such programs, may be changed by the Company at any time without advance notice. Additionally, the Company will reimburse you for all actual, necessary and reasonable expenses you incur in the course of the Company's business, subject to the Company's expense policy as in effect from time to time and the terms of Exhibit A, attached hereto.

5. Vacation. You are eligible for a maximum of four weeks of vacation per calendar year commencing on your date of employment. The number of vacation days for which you are eligible shall accrue at the rate of 1.67 days per month that you are employed during such calendar year. Any unused

vacation will be treated upon termination of your employment in accordance with the Company's annual vacation accrual policy.

6. Equity Compensation.

(a) If you decide to join the Company, it will be recommended to the Compensation Committee that, at a Compensation Committee meeting no later than the first meeting of the Compensation Committee following your first date of employment, the Compensation Committee approve the grant to you of an option to purchase 172,000 shares of the Company's Common Stock at a price per share equal to the fair market value per share of the Common Stock on the date of grant, as determined by the Compensation Committee. Twenty-five (25%) of the shares subject to the option shall vest twelve (12) months after your first date of employment subject to your continuing employment with the Company, and, except as provided in Section 6(b) and 6(c), no shares shall vest before such date. The remaining shares shall vest monthly over the following thirty-six (36) months in equal monthly amounts subject to your continuing employment with the Company. This option grant shall be subject to the terms and conditions of the Company's equity incentive plan, and your actual stock option agreement, including vesting requirements. No right to any stock is earned or accrued until such time that vesting occurs, nor does the grant confer any right to continue vesting or employment.

(b) Subject to Section 6(c) and 7(c) hereof, if the Company terminates your employment without Cause (as defined below) or you voluntarily terminate your employment for Good Reason (as defined below), then the options and any other equity awards granted to you by the Company, at any time, that vest based solely on your continued service with the Company, will immediately vest as to the portion of the applicable award that would have vested if your employment with the Company had continued for twelve (12) months following such termination and any performance-based grants with the

performance period ending within one year after the termination shall be treated as having satisfied any service requirement with respect thereto and shall vest subject to, and only to the extent of, the satisfaction of the applicable performance goals at the end of the applicable performance period. The period for exercising any options so accelerated shall be as set forth in the applicable stock option plan, certificate or agreement.

(c) Subject to Section 7(c) hereof, if the Company, or its successor, terminates your employment without Cause or you voluntarily terminate your employment for Good Reason in Contemplation of a Change of Control (defined below), or within twelve (12) months following a Change of Control (as defined below), then one hundred percent (100%) of the options and any other equity awards granted to you by the Company, at any time, that vest based solely on your continued service with the Company and that are not then vested, and which have not been exercised, cancelled or forfeited, shall become vested and, if applicable, exercisable in full as of the date of such termination or, if later, the Change of Control and any performance-based grants with the performance period ending within one year after the termination shall be treated as having satisfied any service requirement with respect thereto and shall vest subject to, and only to the extent of, the satisfaction of the applicable performance goals at the end of the applicable performance period. The period for exercising any options so accelerated shall be as set forth in the applicable stock option plan, certificate or agreement.

(d) For purposes of this letter agreement, a "Change of Control" shall mean: (i) a merger or consolidation in which (A) the Company is a constituent party or (B) a subsidiary of the Company is a constituent party, and the Company issues shares of its capital stock pursuant to such merger or consolidation, except in the case of either clause (A) or (B) any such merger or consolidation involving the Company or a subsidiary of the Company in which the beneficial owners of the shares of capital stock of the Company outstanding immediately prior to such merger or consolidation continue

beneficially to own, immediately following such merger or consolidation, at least a majority by voting power of the capital stock of (x) the surviving or resulting corporation or (y) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation; (ii) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Company or a Company subsidiary of all or substantially all the assets of the Company and the Company subsidiaries taken as a whole (except in connection with a merger or consolidation not constituting a Change of Control under clause (i) or where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned Company subsidiary); or (iii) the sale or transfer, in a single transaction or series of related transactions, by the stockholders of the Company of more than 50% by voting power of the then-outstanding capital stock of the Company to any person or entity or group of affiliated persons or entities.

(e) For purposes of this letter agreement, "Contemplation of a Change of Control" means a termination without Cause or for Good Reason that is in connection with and reasonably related to, and occurs within 120 days prior to, a Change of Control.

(f) For purposes of this letter agreement, "Good Reason" shall mean: (1) a material reduction in annual base salary, other than such a reduction that is proportionate to a reduction in salary of all executives of the Company generally; (2) a material breach by the Company of this letter agreement; (3) the relocation of your place of employment more than fifty (50) miles from your then current location without your express written consent; or (4) a material reduction in your job duties, authority, responsibilities, or reporting lines, so as to constitute a de facto demotion; provided that none of the foregoing shall qualify as Good Reason unless, within ninety (90) days of the occurrence of the event you claim so qualifies, you shall have provided the Board with written notice specifying in detail the basis for

such claim and a reasonable opportunity to cure the claimed Good Reason and the Company fails to cure such Good Reason within thirty (30) days of its receipt of your notice; provided further that no termination for Good Reason shall so qualify unless you shall terminate your employment at the Company no more than thirty (30) days following the expiration of the Company's cure period.

7. Severance.

(a) In the event that your employment is terminated by you for Good Reason or by the Company without Cause, you will receive severance of (i) twelve (12) months of your annual base salary then in effect, (ii) any bonus earned for the year prior to the year of termination that has not yet been paid, (iii) a pro-rated portion of any bonus attributable to the year of termination payable at the time that active employees receive their bonus payments for that year but in any event by March 15 of the year following the year of your termination, based on the Company's performance against previously established milestones, and (iv) payment for the cost of up to twelve (12) months of COBRA premiums for continued health benefit coverage. Except as specifically described above, all payments will be made in a lump sum on the Payment Date (as defined below). The payments and benefits provided for in this Section 7(a) shall be subject to Exhibit A attached hereto.

(b) For purposes of this letter agreement, "Cause" shall mean: (a) commission of, or indictment or conviction of, any felony or any other crime involving dishonesty; (b) participation in any fraud, deliberate and substantial misconduct, breach of duty of loyalty or breach of fiduciary duty, in each case, against the Company; (c) intentional and substantial damage to any property of the Company; (d) serious misconduct by you that in the good faith and reasonable judgment of the Board demonstrates gross unfitness to serve as Chief Operating Officer of the Company; (e) willful persistent unsatisfactory job performance that remains uncured for at least sixty (60) days following written notice detailing the

same from the Company; (f) your failure to secure and maintain work visas or other documentation sufficient to allow your service to the Company in the manner contemplated herein; or (g) your material breach of any material provision of this letter agreement or the Non-Competition, Non-Solicitation, Confidentiality and Assignment of Inventions Agreement or any similar agreement to which you are a party, in either case, which breach (if capable of cure) remains uncured for a period of thirty (30) days after written notice to you from the Company. Termination of your employment for Cause will result in no severance pay.

(c) As a condition precedent to the receipt of any severance payments or the accelerated vesting of any equity awards pursuant to this letter agreement or pursuant to any equity award agreement, you will be required to execute a separation agreement and general release of claims in favor of the Company, substantially similar to the form attached hereto as Exhibit B, and any revocation period applicable to such release must expire, within sixty (60) days following your date of termination (the date on which the revocation period expires, the "Payment Date"). Notwithstanding the foregoing, if the 60th day following your date of termination occurs in the calendar year following the year in which your termination occurs, then the Payment Date shall be no earlier than January 1 of such subsequent calendar year.

8. At-Will Employment. This letter agreement shall not be construed as an agreement, either expressed or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at-will, under which both you and the Company remain free to terminate the employment relationship, with or without cause, at any time, with or without notice. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time (provided that any such changes shall be without prejudice to your rights explicitly set forth in this letter agreement), the "at-will" nature of your employment may only be changed

by a written agreement approved by the Board and signed by you and the Company, which expressly states the intention to modify the at-will nature of your employment.

9. Arbitration and Equitable Relief. Should a dispute arise in connection with this letter agreement or your employment with the Company, the parties will first submit the dispute to non-binding mediation. The Company will pay for the mediation and select the mediator. Should the dispute remain unresolved after one day of mediation, the Company and you agree that said dispute or controversy arising out of, in relation to, or in connection with this letter agreement or your employment with the Company, or the making, interpretation, construction, performance or breach of this letter agreement shall be finally settled by binding arbitration in Massachusetts under the then current expedited rules of the American Arbitration Association by one (1) arbitrator mutually selected by the parties or in the event the parties cannot mutually agree, then appointed in accordance with such rules. The arbitrator may grant injunctive or other relief in such dispute or controversy, including awarding reasonable attorneys' fees, filing fees and other costs to the prevailing party in the event of frivolous or unfounded claim(s) brought by the non-prevailing party. The decision of the arbitrator shall be final, conclusive and binding on the parties to the arbitration. Judgment may be entered on the arbitrator's decision in any court of competent jurisdiction. The parties agree that, any provision of applicable law notwithstanding, they will not request and the arbitrator shall have no authority to award, punitive or exemplary damages against any party. Notwithstanding anything in this Section 9 to the contrary, claims may be made in any Massachusetts court of competent jurisdiction by you or the Company for equitable relief to prevent a breach or threatened breach of any confidentiality or non-competition obligations of the other party

10. Indemnification. You shall be entitled to corporate indemnification and insurance coverages, including survival of such protections following termination of your employment, to the same extent provided to other senior officers and directors of the Company.

11. Non-Competition, Non-Solicitation, Confidentiality and Assignment of Inventions Agreement. As a condition of your employment, you are required to sign and comply with the Non-Competition, Non-Solicitation, Confidentiality and Assignment of Inventions Agreement in the form attached as Exhibit C.

12. Section 280G

(a) If any payment or benefit (including payments and benefits pursuant to this Agreement) that you would receive in connection with an Acquisition from the Company or otherwise ("Transaction Payment") would (a) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this Section 12, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then the Company shall cause to be determined, before any amounts of the Transaction Payment are paid to you, which of the following two alternative forms of payment would result in your receipt, on an after-tax basis, of the greater amount of the Transaction Payment notwithstanding that all or some portion of the Transaction Payment may be subject to the Excise Tax: (1) payment in full of the entire amount of the Transaction Payment (a "Full Payment"), or (2) payment of only a part of the Transaction Payment so that you receive the largest payment possible without the imposition of the Excise Tax (a "Reduced Payment"). "Acquisition" shall mean a change in the ownership or control of the Company or a change in the ownership of a substantial portion of the assets of the Company, in each case as determined under Section 280G and the Treasury Regulations thereunder.

(b) For purposes of determining whether to make a Full Payment or a Reduced Payment, the Company shall cause to be taken into account all applicable federal, state and local income and employment taxes and the Excise Tax (all computed at the highest applicable marginal rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of such state and

local taxes). If a Reduced Payment is made, (x) you shall have no rights to any additional payments and/or benefits constituting the Transaction Payment, and (y) reduction in payments and/or benefits shall occur in the manner that results in the greatest economic benefit to you as determined in this paragraph. If more than one method of reduction will result in the same economic benefit, the portions of the Payment shall be reduced pro rata.

(c) The independent registered public accounting firm or law firm engaged by the Company as of the day prior to the effective date of the Acquisition shall make all determinations required to be made under this Section 12. If the independent registered public accounting firm or law firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Acquisition, the Company shall appoint a nationally recognized independent registered public accounting firm or law firm that is reasonably acceptable to you (and such acceptance shall not be unreasonably withheld) to make the determinations required hereunder. The Company shall bear all reasonable expenses with respect to the determinations by such independent registered public accounting firm or law firm required to be made hereunder. The independent registered public accounting firm or law firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and you within fifteen (15) calendar days after the date on which your right to a Transaction Payment is triggered or such other time as reasonably requested by the Company or you. If the independent registered public accounting firm determines that no Excise Tax is payable with respect to the Transaction Payment, either before or after the application of the Reduced Amount, it shall furnish the Company and you with detailed supporting calculations of its determinations that no Excise Tax will be imposed with respect to such Transaction Payment. Any good faith determinations of the accounting firm made hereunder shall be final, binding and conclusive upon the Company and you.

13. Miscellaneous.

(a) You represent that you are not bound by any employment contract, restrictive covenant or other restriction preventing (or that purports to prevent) you from being employed by or carrying out your responsibilities for the Company, or which is in any way inconsistent with the terms of this letter agreement.

(b) The Company reserves the right to conduct background investigations and/or reference checks on all of its potential employees. Your job offer, therefore, is contingent upon a clearance of such a background investigation and/or reference check, if any. You are required to execute authorizations for the Company to obtain consumer reports and/or investigative consumer reports and use them in conducting background checks as a condition to your employment. The Company may obtain background reports from time to time during your employment with the Company, as necessary.

(c) For purposes of federal immigration law, you will be required to provide the Company with documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided to us within three (3) business days of your date of hire, or our employment relationship with you may be terminated.

(d) You represent that you have disclosed to the Company any and all agreements relating to your prior employment that may affect your eligibility to be employed by the Company or limit the manner in which you may be employed. It is the Company's understanding that any such agreements do not prevent you from performing the duties of your position, and you represent that such is the case. You agree not to bring any third party confidential information to the Company, including that of your former employer, and covenant that in performing your duties for the Company you will not in any way utilize any such information.

(e) As an employee of the Company, you are required to comply with all Company policies and procedures. Material violations of the Company's policies may lead to immediate termination of your employment but shall not change the definition of Cause. Further, the Company's premises, including all workspaces, furniture, documents, and other tangible materials, and all information technology resources of the Company (including computers, data and other electronic files, and all internet and email) are subject to oversight and inspection by the Company at any time. Company employees should have no expectation of privacy with regard to any Company premises, materials, resources, or information.

(f) Attorney's Fees. The Company agrees that it will reimburse you up to a maximum amount of $5,000 for the legal fees incurred by you in connection with the review and negotiation of this letter agreement. The payment will be made directly to the law firm retained by you, subject to receipt of an invoice, with such invoice to be provided within sixty (60) days following the date hereof and such reimbursement to be made within thirty (30) days following receipt of the invoice.

(g) Notices. Any notices from one party to the other will be in writing and will be given by addressing the same to the other at the address set forth in this letter agreement. Notices to the Company will be marked "Board of Directors". Notice will be deemed to have been duly given when (a) deposited in the United States mail with proper postage for first class registered or certified mail, return receipt requested, (b) sent by any reputable commercial courier or (c) delivered personally.

(h) Assignment. All of the terms and provisions of this letter agreement shall be binding on and inure to the benefit of and be enforceable by the respective heirs, executors, administrators, legal representatives successor and assigns of the parties hereto (including, in the case of

the Company, any acquirer), except that your duties and responsibilities under this letter agreement are of a personal nature and shall not be assignable or delegable in whole or in part by you.

(i) No Mitigation/No Offset. You shall have no obligation to seek other employment to mitigate any severance or other payments due hereunder. Any amounts earned by you from other employment shall not offset amounts due hereunder.

(j) Modification; Amendment. This letter agreement may not be modified or amended except by a written agreement signed by you and an authorized representative of the Company.

(k) Entire Agreement. This letter agreement contains and constitutes the entire understanding and agreement between the parties hereto with respect to the terms of your employment with the Company and supersedes any and all prior or contemporaneous agreements, discussions and understandings, whether written or oral, relating to the subject matter of this letter agreement or your employment with the Company.

(l) Governing Law. This letter agreement will be governed by, and construed and enforced in accordance with, the laws of the Commonwealth of Massachusetts applicable to contracts made and to be performed therein, without giving effect to the principles thereof relating to the conflict of laws

(m) Counterparts. This letter agreement may be executed in any number of counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

If you agree with the provisions of this offer, please sign the enclosed duplicate of this letter agreement in the space provided below and return it along with your signed Non-Competition, Non-Solicitation, Confidentiality and Assignment of Inventions Agreement to Mary Reumuth via email at mary.reumuth@kalarx.com or fax (781) 642-0399 by 5pm on 11/7/2017 with originals to follow. If you do not accept this offer by 11/7/2017, this offer will be deemed withdrawn.

[Signature page follows.]

Very truly yours,

KALA PHARMACEUTICALS, INC.

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

The foregoing correctly sets forth the terms under which I will be employed by the Company, effective as of 11/20/17. I am not relying on any representations other than those set form above:

By: /s/ Todd Bazemore
Name: Todd Bazemore

November 6, 2017
Date

Enclosures (4)
Duplicate Original Letter Agreement
Exhibit A: Payments Subject to Section 409A
Exhibit B: Form of Separation and Release Agreement
Exhibit C: Non-Competition, Non-Solicitation, Confidentiality and Assignment of Inventions Agreement

EXHIBIT A

Payments Subject to Section 409A

1. Subject to this Exhibit A, any severance payments that may be due under the letter agreement shall begin only upon the date of the your "separation from service" (determined as set forth below) which occurs on or after the termination of your employment. The following rules shall apply with respect to distribution of the severance payments, if any, to be provided to you under the letter agreement, as applicable:

(a) It is intended that each installment of the severance payments under the letter agreement provided under shall be treated as a separate "payment" for purposes of Section 409A. Neither the Company nor you shall have the right to accelerate or defer the delivery of any such payments except to the extent specifically permitted or required by Section 409A.

(b) If, as of the date of your "separation from service" from the Company, you are not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments shall be made on the dates and terms set forth in the letter agreement.

(c) If, as of the date of your "separation from service" from the Company, you are a "specified employee" (within the meaning of Section 409A), then:

(i) Each installment of the severance payments due under the letter agreement that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when your separation from service occurs, be paid within the short-term deferral period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and shall be paid on the dates and terms set forth in the letter agreement; and

(ii) Each installment of the severance payments due under the letter agreement that is not described in this Exhibit A, Section 1(c)(i) and that would, absent this subsection, be paid within the six-

month period following your "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, your death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six months and one day following your separation from service and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of payments if and to the maximum extent that that such installment is deemed to be paid under a separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of your second taxable year following the taxable year in which the separation from service occurs.

2. The determination of whether and when your separation from service from the Company has occurred shall be made and in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of this Exhibit A, Section 2, "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Code.

3. All reimbursements and in-kind benefits provided under this letter agreement shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirements that (i) any reimbursement is for expenses incurred during your lifetime (or during a shorter period of time specified in this letter agreement), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or

before the last day of the calendar year following the year in which the expense is incurred and (iv) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit.

4. The Company makes no representation or warranty and shall have no liability to you or to any other person if any of the provisions of the letter agreement (including this Exhibit) are determined to constitute deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.

Exhibit B

Form of Separation and Release Agreement

[KALA LETTERHEAD](1)

BY [METHOD OF DELIVERY]

[INSERT DATE]

[INSERT EMPLOYEE NAME]
[INSERT EMPLOYEE ADDRESS]

Dear **[INSERT EMPLOYEE NAME]**:

The purpose of this letter agreement is to confirm the terms regarding your separation of employment from Kala Pharmaceuticals, Inc. (the "Company"), effective **[INSERT SEPARATION DATE]**. The Company will provide you with the severance benefits described in Section 2 below if you sign and return this letter agreement (the "Agreement") to the Company by **[Insert Return Date — *At least 21 days after agreement is received by the employee* (but no earlier than the Separation Date)]** and it becomes binding between you and the Company. By signing and returning this Agreement and not revoking your acceptance, you will be entering into a binding agreement with the Company and will be agreeing to the terms and conditions set forth in the numbered paragraphs below, including the release of claims set forth in Section 3. Therefore, you are advised to consult with an attorney before signing this Agreement and you have been given at least twenty-one (21) days to do so. If you sign this Agreement, you may change your mind and revoke your agreement during the seven (7) day period after you have signed it by notifying me in writing. If you do not so revoke, this Agreement will become a binding agreement between you and the Company upon the expiration of the seven (7) day period.

If you choose not to sign and return this Agreement by **[Insert Return Date - Same as Above]** or if you timely revoke your acceptance in writing, you shall not receive any severance benefits from the Company. You will, however, receive payment on your Separation Date, as defined below, for your final wages and any unused vacation time accrued through the Separation Date. You may also, if eligible, elect to continue receiving group medical insurance pursuant to the federal "COBRA" law, 29 U.S.C. § 1161 et seq. Please consult the COBRA

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(1) Please note that the form and/or substance of this agreement may be adjusted to reflect the timing of termination, address changes of law, and or other facts and circumstances.

materials to be provided by the Company under separate cover for details regarding these benefits. Further, pursuant to the Company's 2009 Employee, Director and Consultant Equity Incentive Plan (as amended to date, the "2009 Plan"), you will have up to 90 days after the Separation Date to exercise any vested stock options you may have (as provided for by the 2009 Plan) subject to the terms of the letter agreement between you and the Company dated (the "2017 Letter Agreement"). All unvested stock options will be cancelled on the Separation Date except as otherwise provided in the grants or the employment agreement.

The following numbered paragraphs set forth the terms and conditions that will apply if you timely sign and return this Agreement.

1. **Separation Date**. Your effective date of separation from the Company is **[INSERT SEPARATION DATE](2)** (the "Separation Date"). As of the Separation Date, all salary payments from the Company will cease and any benefits you had as of the Separation Date under Company-provided benefit plans, programs, or practices will terminate, except as required by federal or state law.

2. **Description of Severance Benefits**. If you timely sign and return this Agreement and do not revoke your acceptance, the Company will provide the following severance benefits set forth in the 2017 Letter Agreement as amended from time to time, between you and the Company (the "Severance Benefits"). You will not be eligible for, nor shall you have a right to receive, any payments or benefits from the Company following the Separation Date other than as described in this Section 2 and the 2017 Letter Agreement.

3. **Representation on Action**. You represent that you have not filed or reported any complaints, claims or actions against any of the Released Parties with any state, federal or local agency or court.

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(2) Please note that, if the Separation Date is after the date of this Agreement, the Agreement will need to be modified, as certain return dates will change.

4. **Release**. In consideration of the Severance Benefits, which you acknowledge you would not otherwise be entitled to receive, you hereby fully, forever, irrevocably and unconditionally release, remise and discharge the Company, its affiliates, subsidiaries, parent companies, predecessors, and successors, and all of their respective past and present officers, directors, stockholders, partners, members, employees, agents, representatives, plan administrators, attorneys, insurers and fiduciaries (each in their individual and corporate capacities but in their individual capacities only for matters related to the Company and/or to your employment and/or separation from the Company) (collectively, the "Released Parties") from any and all claims, charges, complaints, demands, actions, causes of action, suits, rights, debts, sums of money, costs, accounts, reckonings, covenants, contracts, agreements, promises, doings, omissions, damages, executions, obligations, liabilities, and expenses (including attorneys' fees and costs), of every kind and nature that you ever had or now have against any or all of the Released Parties, including, but not limited to, any and all claims arising out of or relating to your periods of employment with and/or separations from the Company, including, but not limited to, all claims under Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq., the Americans With Disabilities Act of 1990, the Age Discrimination in Employment Act, 29 U.S.C. § 621 et seq., 42 U.S.C. § 12101 et seq., the Genetic Information Nondiscrimination Act of 2008, 42 U.S.C. § 2000ff et seq., the Family and Medical Leave Act, 29 U.S.C. § 2601 et seq., the Worker Adjustment and Retraining Notification Act ("WARN"), 29 U.S.C. § 2101 et seq., the Rehabilitation Act of 1973, 29 U.S.C. § 701 et seq., Executive Order 11246, Executive Order 11141, the Fair Credit Reporting Act, 15 U.S.C. § 1681 et seq., and the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 et seq., all as amended; all claims arising out of the Massachusetts Fair Employment Practices Act., M.G.L. c. 151B, § 1 et seq., the Massachusetts Wage Act, Mass. Gen. Laws ch. 149, § 148 et seq. (Massachusetts law regarding payment of wages and overtime), the Massachusetts Civil Rights Act, M.G.L. c. 12, §§ 11H and 11I, the Massachusetts Equal Rights Act, M.G.L. c. 93, § 102 et seq. and M.G.L. c. 214, § 1C, the Massachusetts Small Necessities Leave Act, M.G.L. c. 149, § 52D, the Massachusetts Equal Pay Law, M.G.L. c. 149, § 105A et seq., the Massachusetts Maternity Leave Act, M.G.L. c. 149, § 105D, and the

Massachusetts Privacy Act, M.G.L. c. 214, § 1B, all as amended; all claims arising out of the California Fair Employment and Housing Act, Cal. Gov't. Code § 12900 et seq., the California Equal Pay Act, Cal. Lab. Code § 1197.5 et seq., the California Family Rights Act, Cal. Gov't. Code § 12945.1 et seq. and § 19702.3, Cal. Lab. Code § 233 (California's kin care law), Cal. Code Regs. tit. 2, §§ 7291.2—7291.16 (California's pregnancy leave law), California Unruh Civil Rights Act, Cal. Civ. Code § 51 et seq., and Cal. Lab. Code §§ 98.6 and 1102.5 (California whistleblower protection laws), all as amended; all common law claims including, but not limited to, actions in defamation, intentional infliction of emotional distress, misrepresentation, fraud, wrongful discharge, and breach of contract; all federal and state whistleblower claims to the extent permitted by law; all claims to any non-vested ownership interest in the Company, contractual or otherwise, and any claim or damage arising out of your periods of employment with and/or separation from the Company (including a claim for retaliation) under any common law theory or any federal, state or local statute or ordinance not expressly referenced above; provided, however, that nothing in this Agreement prevents you from filing a charge with, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission or a state fair employment practices agency (except that you acknowledge that you may not recover any monetary benefits in connection with any such claim, charge or proceeding and you further waive any rights or claims to any payment, benefit, attorneys' fees or other remedial relief in connection with any such claim, charge or proceeding); and further provided that this Agreement shall not release any rights you may have to indemnification, advancement of legal fees and directors and officers liability insurance coverage (recognizing, however, that such indemnification, advancement and/or coverage is not guaranteed by this Agreement and that this Agreement creates no rights for you to receive such indemnification, advancement or coverage) or any rights to vested equity or vested benefits.

5. **Post-Separation Obligations**. You acknowledge and reaffirm your obligation to keep confidential and not to disclose any and all non-public information concerning the Company that you acquired

during the course of your periods of employment with the Company, including, but not limited to, any non-public information concerning the Company's business affairs, business prospects, and financial condition. You further acknowledge and reaffirm your obligations under the Non-Competition, Non-Solicitation, Confidentiality and Assignment of Inventions Agreement you previously executed for the benefit of the Company, which remains in full force and effect.

6. **Non-Disparagement**. You understand and agree that, in exchange for the consideration set forth in this Agreement, you shall not make any false, disparaging or derogatory statements to any person or entity, including, without limitation, any media outlet, industry group, financial institution or current or former employee, consultant, client or customer of the Company, regarding the Company or any of its directors, officers, employees, agents or representatives or about the Company's business affairs or financial condition. Additionally, the Company will instruct its officers and directors not to make any false, disparaging or derogatory statement about you to any third party. Nothing herein shall be construed as preventing any of you, the Company, or the Company's officers and directors from making truthful disclosures to any governmental entity or in any litigation or arbitration or rebutting false or misleading statements made by others.

7. **Cooperation**. To the extent permitted by law, you agree to cooperate fully with the Company in the defense or prosecution of any claims or actions which already have been brought, are currently pending, or which may be brought in the future against or on behalf of the Company, whether before a state or federal court, any state or federal government agency, or a mediator or arbitrator related to your period of employment with the Company or to matters about which you gained knowledge during your period of employment with the Company (other than matters adverse to you). Your reasonable cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with counsel to prepare its claims or defenses, to prepare for trial or discovery or an administrative hearing or a mediation or arbitration and to act as a witness when requested by the Company at reasonable times designated by the Company, which shall be set to reasonably recognize your

other commitments and limit your travel. You agree that you will, to the extent permitted by law, notify the Company promptly in the event that you are served with a subpoena or in the event that you are asked to provide a third party with information concerning any actual or potential complaint or claim against the Company, in each case with respect to matters related to your period of employment with the Company or matters about which you gained knowledge during your period of employment with the Company. The Company will promptly reimburse you for your reasonable out-of-pocket expenses in connection with cooperation requested by the Company pursuant hereto.

8. **Scope of Disclosure Restrictions** — Nothing in this Agreement or elsewhere prohibits you from communicating with government agencies about possible violations of federal, state, or local laws or otherwise providing information to government agencies or participating in government agency investigations or proceedings. You are not required to notify the Company of any such communications; provided, however, that nothing herein authorizes the disclosure of information you obtained through a communication that was subject to the attorney-client privilege. Further, notwithstanding your confidentiality and nondisclosure obligations, you are hereby advised as follows pursuant to the Defend Trade Secrets Act: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order."

9. **Return of Company Property**. You represent and confirm that you have returned to the Company all Company-owned property in your possession, custody or control, including, without limitation, all keys, files, documents and records (and copies thereof), equipment (including, but not limited to, computer hardware, software and printers, wireless handheld devices, cellular phones, pagers, etc.), Company identification and Company vehicles, and that you have left intact all electronic Company documents, including, without limitation, those that you developed or helped to develop during your employment. You further confirm that you have cancelled all accounts for your benefit, if any, in the Company's name, including, without limitation, credit cards, telephone charge cards, cellular phone and/or pager accounts, and computer accounts. The Company confirms that you may retain your address book to the extent it only contains contact information and the Company shall cooperate with you to transfer your cell phone number to you.

10. **Business Expenses and Final Compensation**. You acknowledge that you have submitted to the Company documentation for all business expenses incurred in conjunction with the performance of your employment and that no other reimbursements are owed to you. You further acknowledge that you have received payment in full for all services rendered in conjunction with your periods of employment by the Company, including, without limitation, payment for all wages, bonuses, equity, commissions, and accrued, unused vacation time, and that no other compensation is owed to you except as provided herein.

11. **Amendment and Waiver**. This Agreement shall be binding upon the parties and may not be modified in any manner, except by an instrument in writing of concurrent or subsequent date signed by duly authorized representatives of the parties hereto. This Agreement is binding upon and shall inure to the benefit of the parties and their respective agents, assigns, heirs, executors, successors and administrators. No delay or omission by the Company in exercising any right under this Agreement shall operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion shall be effective only in that instance and shall not be construed as a bar to or waiver of any right on any other occasion.

12. **Validity**. Should any provision of this Agreement be declared or be determined by any court of competent jurisdiction to be illegal or invalid, the validity of the remaining parts, terms or provisions shall not be affected thereby and said illegal or invalid part, term or provision shall be deemed not to be a part of this Agreement.

13. **Confidentiality**. To the extent permitted by law, you understand and agree that as a condition of the Severance Benefits herein described, the terms and contents of this Agreement, and the contents of the negotiations and discussions resulting in this Agreement, shall be maintained as confidential by you and your agents and representatives and shall not be disclosed except to the extent required by federal or state law or as otherwise agreed to in writing by the Company, provided, however, that nothing herein shall prevent you from making truthful disclosures to any governmental entity or in any litigation or arbitration.

14. **Tax Provision**. In connection with the Severance Benefits to be provided to you pursuant to this Agreement, the Company shall withhold and remit to the tax authorities the amounts required under applicable law, and you shall be responsible for all applicable taxes with respect to such Severance Benefits under applicable law. You acknowledge that you are not relying upon advice or representation of the Company with respect to the tax treatment of any of the Severance Benefits.

15. **Nature of Agreement**. You understand and agree that this Agreement is a severance agreement and does not constitute an admission of liability or wrongdoing on the part of the Company.

16. **Acknowledgments**. You acknowledge that you have been given at least twenty-one (21) days to consider this Agreement, and that the Company is hereby advising you to consult with an attorney of your own choosing prior to signing this Agreement. You understand that you may revoke this Agreement for a period of seven (7) days after you sign this Agreement by notifying me in writing, and the Agreement shall not be effective or enforceable until the expiration of this seven (7) day revocation period. You understand and agree that by

entering into this Agreement, you are waiving any and all rights or claims you might have under the Age Discrimination in Employment Act, as amended by the Older Workers Benefit Protection Act, and that you have received consideration beyond that to which you were previously entitled.

17. **Voluntary Assent**. You affirm that no other promises or agreements of any kind have been made to or with you by any person or entity whatsoever to cause you to sign this Agreement, and that you fully understand the meaning and intent of this Agreement. You state and represent that you have had an opportunity to fully discuss and review the terms of this Agreement with an attorney. You further state and represent that you have carefully read this Agreement, understand the contents herein, freely and voluntarily assent to all of the terms and conditions hereof, and sign your name of your own free act.

18. **Arbitration and Equitable Relief**. Should a dispute arise in connection with, relating to, or concerning this Agreement, the parties obligations thereunder, your employment with or your separation from employment with the Company, the parties will first submit the dispute to non-binding mediation. The Company will pay for the mediation and select the mediator. Should the dispute remain unresolved after one day of mediation, the Company and you agree that said dispute or controversy arising out of, in relation to, or in connection with this Agreement or your employment with the Company, or the making, interpretation, construction, performance or breach of this Agreement shall be finally settled by binding arbitration in Massachusetts under the then current expedited rules of the American Arbitration Association by one (1) arbitrator mutually selected by the parties or in the event the parties cannot mutually agree, then appointed in accordance with such rules. The arbitrator may grant injunctive or other relief in such dispute or controversy. The decision of the arbitrator shall be final, conclusive and binding on the parties to the arbitration. Judgment may be entered on the arbitrator's decision in any court of competent jurisdiction. The parties agree that, any provision of applicable law notwithstanding, they will not request and the arbitrator shall have no authority to award, punitive or exemplary damages against any party. Notwithstanding anything in this Section 18 to the

contrary, claims may be made in any Massachusetts court of competent jurisdiction by you or the Company for equitable relief to prevent a breach or threatened breach of any provision of this Agreement. Both you and the Company expressly waive any right that any party either has or may have to a jury trial of any dispute arising out of or in any way related to your employment with or termination from the Company.

19. **Applicable Law**. This Agreement will be governed by, and construed and enforced in accordance with, the laws of the Commonwealth of Massachusetts applicable to contracts made and to be performed therein, without giving effect to the principles thereof relating to the conflict of laws.

20. **Entire Agreement**. This Agreement contains and constitutes the entire understanding and agreement between the parties hereto with respect to your Severance Benefits and the settlement of claims against the Company and cancels all previous oral and written negotiations, agreements, and commitments in connection therewith. Nothing in this Section 20, however, shall modify, cancel or supersede your obligations set forth in Section 5 above.

[Signature page follows.]

If you have any questions about the matters covered in this Agreement, please call **[INSERT NAME AND TELEPHONE NUMBER]**.

Very truly yours,

Kala Pharmaceuticals, Inc.

By: _____
[INSERT NAME]
[INSERT TITLE]

I hereby agree to the terms and conditions set forth above. I have been given at least twenty-one (21) days to consider this Agreement, and I have chosen to execute this on the date below. I intend that this Agreement will become a binding agreement between me and the Company if I do not revoke my acceptance in seven (7) days.

_____ _____
[INSERT EMPLOYEE NAME] Date

To be returned in a timely manner as set forth on the first page of this Agreement.

Exhibit C

Form of Non-Competition, Non-Solicitation, Confidentiality and Assignment of Inventions Agreement

NON-COMPETITION, NON-SOLICITATION, CONFIDENTIALITY AND ASSIGNMENT OF INVENTIONS AGREEMENT

KALA PHARMACEUTICALS, INC.

November 21, 2017

Todd Bazemore

Dear Todd: This letter is to confirm our understanding with respect to (i) your agreement not to compete with Kala Pharmaceuticals, Inc. or any present or future parent, subsidiary or affiliate thereof (collectively, the "Company"), (ii) your agreement not to solicit certain employees, consultants, customers and business partners of the Company, (iii) your agreement to protect and preserve information and property which is confidential and proprietary to the Company and (iv) your agreement with respect to the ownership of inventions, ideas, copyrights, patents, trademarks or other intellectual property which may be used in the business of the Company (the terms and conditions agreed to in this letter are hereinafter referred to as the "Agreement").

In consideration of and as a condition of the compensation and other benefits of my employment by the Company, and for other good and valuable consideration, the receipt and sufficiency of which are hereby mutually acknowledged, we have agreed as follows:

1. Prohibited Competition.

(a) Certain Acknowledgements and Agreements.

(i) We have discussed, and you recognize and acknowledge, the competitive and proprietary aspects of the business of the Company.

(ii) You further recognize and acknowledge the competitive and proprietary nature of the Company's business operations. You acknowledge and agree that a business will be deemed competitive with the Company if it engages in a line of business in which it performs or plans to perform any of the services, or researches, produces, develops, manufactures, licenses, distributes or sells any products or services, provided or offered by the Company, or if it performs any other services and/or engages in the production, research, development, manufacture, license, distribution or sale of any service or product similar to the Company's services or products, which services or products were performed, produced, researched, developed, manufactured, licensed, distributed, sold or provided, or planned to be performed, produced, researched, developed,

manufactured, licensed, distributed, sold or provided, by the Company during your employment by the Company, or which services or products were designed to perform the same function or achieve the same results as any of the foregoing, whether or not similar, in the Company's Field of Interest.

(iii) You understand and acknowledge that the term "Company's Field of Interest" means the actual or planned research, production, development, manufacture, licensing, distribution, sale or use of microparticle and nanoparticle technologies for delivering pharmaceutical agents, including, without limitation, microparticles and nanoparticles for use in delivering therapeutic or prophylactic agents to or through mucus, mucin, or mucosal barriers or tissues in humans. You acknowledge and agree that the actual or planned business of the Company may change over the course of your employment and that, notwithstanding the foregoing, the term "Company's Field of Interest" shall include any and all services, products or technologies performed, produced, researched, developed, manufactured, licensed, distributed, sold or provided, or planned to be performed, produced, researched, developed, manufactured, licensed, distributed, sold or provided, by the Company at any time during your employment.

(iv) You further acknowledge that, during the course of your performing services for the Company, the Company will furnish, disclose or make available to you Confidential Information (as defined below) related to the Company's business and that the Company may provide you with unique and specialized training. You also acknowledge that such Confidential Information and such training have been developed and will be developed by the Company through the expenditure by the Company of substantial time, effort and money and that all such Confidential Information and training could be used by you to compete with the Company. You also acknowledge that if you become employed or affiliated with any competitor of the Company in violation of your obligations in this Agreement, it is inevitable that you would disclose the Confidential Information to such competitor and would use such Confidential Information, knowingly or unknowingly, on behalf of such competitor. Further, in the course of your employment, you will be introduced to customers and others with important relationships to the Company. You acknowledge that any and all "goodwill" created through such introductions belongs exclusively to the Company, including, without limitation, any goodwill created as a result of direct or indirect contacts or relationships between you and any customers of the Company.

(v) For purposes of this Agreement, "Confidential Information" means confidential, secret and proprietary information and know-how of the Company, whether in written, oral, electronic or other form, including but not limited to, information and facts concerning business plans, customers, future customers, suppliers, licensors, licensees, partners, investors, affiliates or others, training methods and materials, financial information, sales prospects, client lists, inventions, or any other scientific, technical or trade secrets of the Company or of any third party provided to you or the Company under a condition of confidentiality, provided that Confidential Information will not include

information that is in the public domain other than through any fault or act by you. The term "trade secrets," as used in this Agreement, will be given its broadest possible interpretation under the law of the Commonwealth of Massachusetts and will include, without limitation, anything tangible or intangible or electronically kept or stored, which constitutes, represents, evidences or records, any secret scientific, technical, merchandising, production or management information, or any design, process, procedure, formula, invention, improvement or other confidential or proprietary information or documents.

(b) Non-Competition. During the period in which you perform services for or at the request of the Company and for a period of one (1) year following the termination of your performance of services for or at the request of the Company for any reason or for no reason you will not, without the prior written consent of the Company:

(i) For yourself or on behalf of any other, directly or indirectly, either as principal, agent, stockholder, employee, consultant, representative, owner, officer, director, investor, lender or in any other capacity, own, manage, operate or control , or be concerned, connected or employed by, or otherwise associate in any manner with, engage in or have a financial interest in, any business or enterprise in the Company's Field of Interest anywhere in the world, except that nothing contained herein shall preclude you from purchasing stock in any such business or enterprise if such stock is publicly traded, and provided that your holdings do not exceed one percent (1%) percent of the issued and outstanding capital stock of such business or enterprise; or

(ii) Either individually or on behalf of or through any third party, directly or indirectly, solicit, divert or appropriate or attempt to solicit, divert or appropriate any actual or prospective clients, customers, accounts or business partners of the Company which were contacted, solicited or served by the Company during your employment with the Company; or

(iii) Either individually or on behalf of or through any third party, directly or indirectly, interfere with, or attempt to interfere with, the relations between the Company and any vendor or supplier to the Company.

(c) Non-Solicitation. During the period in which you perform services for or at the request of the Company and for a period of eighteen (18) months following the termination of your performance of services for or at the request of the Company for any reason or for no reason you will not, without the prior written consent of the Company:

(i) Either individually or on behalf of or through any third party, directly or indirectly, (A) solicit, entice or persuade or attempt to solicit, entice or persuade any other employees of or consultants to the Company to leave the services of the Company for any reason, or (B) employ or engage, cause to be employed or engaged, or solicit the employment or engagement of any employee of or consultant to the Company while any such person is providing services to the

Company or within six months after any such person ceases providing services to the Company; or

(ii) Either individually or on behalf of or through any third party, directly or indirectly, interfere with, or attempt to interfere with, the relations between any other employees of or consultants to the Company and the Company.

(d) Reasonableness of Restrictions. You further recognize and acknowledge that (i) the types of employment which are prohibited by this Section 1 are narrow and reasonable in relation to the skills which represent your principal salable asset both to the Company and to your other prospective employers and (ii) the specific but broad geographical scope of the provisions of this Section 1 is reasonable, legitimate and fair to you in light of the Company's need to market its services and sell its products in a large geographic area in order to have a sufficient customer base to make the Company's business profitable and in light of the limited restrictions on the type of employment prohibited herein compared to the types of employment for which you are qualified to earn your livelihood.

(e) Survival of Acknowledgements and Agreements; Extension. Your acknowledgements and agreements set forth in this Section 1 will survive the termination of your provision of services to the Company for any reason or for no reason. If you violate any of the provisions set forth in this Section 1, you shall continue to be bound by the restrictions set forth in this Section 1 until a period of one (1) year has expired, in the case of a violation of Section 1(b), or a period of eighteen (18) months, in the case of a violation of Section 1(c), has expired without any violation of such provisions.

2. Protected Information. You will at all times, both during the period while you are performing services for the Company and after the termination of your provision of services to the Company for any reason or for no reason, and except as permitted by Section 5 below, maintain in confidence, and without the prior written consent of the Company, you will not use, except in the course of performance of your duties for the Company or by court order, disclose or give to others, any Confidential Information. In the event you are questioned by anyone not employed by the Company or by an employee of or a consultant to the Company not authorized to receive Confidential Information, in regard to any Confidential Information, or concerning any fact or circumstance relating thereto, you will promptly notify the Company, except as permitted by Section 5 below. Upon the termination of your provision of services to the Company for any reason or for no reason, or if the Company otherwise requests, (i) you will return to the Company all tangible Confidential Information and copies thereof (regardless how such Confidential Information or copies are maintained) and (ii) you will deliver to the Company any property of the Company which may be in your possession, including products, materials, memoranda, notes, records, reports, or other documents or photocopies of the same. The terms of this Section 2 are in addition to, and not in lieu of, any statutory or other contractual obligation that you may have relating to the protection of the Company's Confidential Information. The terms of this Section 2 will survive indefinitely any termination of your provision of services to the Company for any reason or for no reason.

3. Ownership of Ideas, Copyrights and Patents.

(a) Property of the Company. All ideas, discoveries, creations, manuscripts and properties, innovations, improvements, enhancements, processes, know-how, inventions, designs, developments, apparatus, techniques, methods, laboratory notebooks, software, works of authorship and formulae which may be used in the business of the Company, whether patentable, copyrightable or not, which you may conceive, reduce to practice or develop during the period while you are performing services for the Company and for one (1) year thereafter, alone or in conjunction with another or others, whether during or out of regular business hours, whether or not on the Company's premises or with the use of its equipment, and whether at the request or upon the suggestion of the Company or otherwise (all of which are collectively referred to herein as "Inventions"), will be the sole and exclusive property of the Company. You agree not to publish any of the Inventions without the prior written consent of the Company or its designee. Without limiting the foregoing, you also acknowledge that all original works of authorship which are made by you (solely or jointly with others) within the scope of your employment or which relate to the business of the Company or a Company affiliate and which are protectable by copyright are "works made for hire" pursuant to the United States Copyright Act (17 U.S.C. Section 101). You hereby assign to the Company or its designee all of your right, title and interest in and to all Inventions and all related patents, patent applications, copyrights and copyright applications. You further represent that, to the best of your knowledge and belief, none of the Inventions will violate or infringe upon any right, patent, copyright, trademark or right of privacy, or constitute libel or slander against or violate any other rights, of any person, firm or corporation, and that you will use your best efforts to prevent any such violation.

(b) Cooperation. At any time during or after the period during which you are performing services for the Company, you will fully cooperate with the Company and its attorneys and agents in the preparation and filing of all papers and other documents as may be required to protect the Company's rights and interests in and to any of such Inventions, such papers and documents to include, without limitation, any copyright applications, patent applications, trademark applications, declarations, oaths, formal assignments, assignments of priority rights, and powers of attorney with respect to any such Inventions, and such full cooperation to include, without limitation, joining in any proceeding to obtain letters patent, copyrights, trademarks or other legal rights, in each case, in the United States and in any and all other countries, provided that the Company will bear the expense of such preparations and filings, and that any copyright, patent or other legal or intellectual property rights so issued to you personally will be assigned by you to the Company or its designee without charge by you. You further agree that if the Company is unable, after reasonable effort, to secure your signature on any such papers or documents, any executive officer of the Company shall be entitled to execute any such papers or documents as your agent and attorney-in-fact, and you hereby irrevocably designate and appoint each executive officer of the Company as your agent and attorney-in-fact to execute any such papers or documents on your behalf, and to take any and all actions as the Company may deem necessary or desirable in order to protect its rights and interests in any Inventions, under the conditions described in this sentence.

(c) Licensing and Use of Innovations. With respect to any ideas, discoveries, creations, manuscripts and properties, innovations, improvements, enhancements, processes, know-how, inventions, designs, developments, apparatus, techniques, methods, laboratory notebooks, software, works of authorship and formulae, and works of any similar nature (from any source), which you conceived, reduced to practice or developed prior to performing services for the Company, but which you provide to the Company or incorporate in any Company product or system (all of which are collectively referred to herein as "Innovations"), you hereby grant to the Company a royalty-free, fully paid-up, non-exclusive, perpetual and irrevocable license throughout the world to use, modify, create derivative works from, disclose, publish, translate, reproduce, deliver, perform, dispose of, and to authorize others so to do, all such Innovations. You will not include in any Innovations you deliver to the Company or use on its behalf, without the prior written approval of the Company, any material which is or will be patented, copyrighted or trademarked by you or others unless you provide the Company with the written permission of the holder of any patent, copyright or trademark owner for the Company to use such material in a manner consistent with then-current Company policy.

(d) Prior Inventions. Listed on Exhibit 3(d) to this Agreement are any and all Innovations in which you claim or intend to claim any right, title and interest, including, without limitation, patent, copyright or trademark interests which, to the best of your knowledge, will be or may be delivered to the Company in the course of your employment or incorporated into any Company product or system. You acknowledge that your obligation to disclose such information is ongoing during the period that you provide services to the Company.

4. Disclosure to Future Employers. You agree that you will provide, and that the Company, in its discretion, may similarly provide, a copy of the covenants contained in Sections 1, 2 and 3 of this Agreement to any business or enterprise which you may directly or indirectly own, manage, operate, finance, join, control or in which you may participate in the ownership, management, operation, financing, or control, or with which you may be connected as an officer, director, employee, partner, principal, agent, representative, consultant or otherwise.

5. Scope of Disclosure Restrictions. Nothing in this Agreement prohibits the Employee from communicating with government agencies about possible violations of federal, state, or local laws or otherwise providing information to government agencies, filing a complaint with government agencies, or participating in government agency investigations or proceedings. The Employee is not required to notify the Company of any such communications; provided, however, that nothing herein authorizes the disclosure of information the Employee obtained through a communication that was subject to the attorney-client privilege. Further, notwithstanding the Employee's confidentiality and nondisclosure obligations, the Employee is hereby advised as follows pursuant to the Defend Trade Secrets Act: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of repotting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade

secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order."

6. No Conflicting Agreements. You hereby represent and warrant that you have no commitments or obligations inconsistent with this Agreement and you will indemnify and hold the Company harmless against any and all losses, damages, liabilities or expenses arising from any claim based upon circumstances alleged to be inconsistent with such representation and warranty.

7. Name & Likeness Rights. You hereby authorize the Company to use, reuse, and to grant others the right to use and reuse, your name, photograph, likeness (including caricature), voice, and biographical information, and any reproduction or simulation thereof, in any form of media or technology now known or hereafter developed (including, but not limited to, film, video and digital or other electronic media), both during and after your employment, for whatever purposes the Company deems necessary.

8. General.

(a) Notices. All notices, requests, consents and other communications hereunder will be in writing, will be addressed to the receiving party's address set forth above or to such other address as a party may designate by notice hereunder, and will be either (i) delivered by hand, (ii) sent by overnight courier, or (iii) sent by registered mail, return receipt requested, postage prepaid. All notices, requests, consents and other communications hereunder will be deemed to have been given either (i) if by hand, at the time of the delivery thereof to the receiving party at the address of such party set forth above, (ii) if sent by overnight courier, on the next business day following the day such notice is delivered to the courier service, or (iii) if sent by registered mail, on the fifth business day following the day such mailing is made.

(b) Entire Agreement. This Agreement embodies the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior oral or written agreements and understandings relating to the subject matter hereof. No statement, representation, warranty, covenant or agreement of any kind not expressly set forth in this Agreement will affect, or be used to interpret, change or restrict, the express terms and provisions of this Agreement.

(c) Modifications and Amendments. The terms and provisions of this Agreement may be modified or amended only by written agreement executed by the parties hereto.

(d) Waivers and Consents. The terms and provisions of this Agreement may be waived, or consent for the departure therefrom granted, only by written document executed by the party entitled to the benefits of such terms or provisions. No such waiver or consent will be deemed to be or will constitute a waiver or consent with respect to any other terms or provisions of this Agreement, whether or not similar. Each such waiver or consent will be effective only in the specific instance and for the purpose for which it was given, and will not constitute a continuing waiver or consent.

(e) Assignment. The Company may assign its rights and obligations hereunder to any person or entity that succeeds to all or substantially all of the Company's business or assets or any corporation with which, or into which, the Company may be merged. You may not assign your rights and obligations under this Agreement without the prior written consent of the Company, and any such attempted assignment by you without the prior written consent of the Company will be void.

(f) Benefit. All statements, representations, warranties, covenants and agreements in this Agreement will be binding on the parties hereto and will inure to the benefit of the respective successors and permitted assigns of each party hereto. Nothing in this Agreement will be construed to create any rights or obligations except between the Company and you, and no person or entity other than the Company will be regarded as a third-party beneficiary of this Agreement.

(g) Governing Law. This Agreement and the rights and obligations of the parties hereunder will be construed in accordance with and governed by the laws of the Commonwealth of Massachusetts, without giving effect to the conflict of law principles thereof.

(h) Jurisdiction, Venue and Service of Process. Any legal action or proceeding with respect to this Agreement will be brought in the courts of the Commonwealth of Massachusetts or of the United States of America for the District of Massachusetts. By execution and delivery of this Agreement, each of the parties hereto accepts for itself and in respect of its property, generally and unconditionally, the exclusive jurisdiction of the aforesaid courts.

(i) WAIVER OF JURY TRIAL. ANY ACTION, DEMAND, CLAIM OR COUNTERCLAIM ARISING UNDER OR RELATING TO THIS AGREEMENT WILL BE RESOLVED BY A JUDGE ALONE AND EACH OF THE COMPANY AND YOU WAIVE ANY RIGHT TO A JURY TRIAL THEREOF.

(j) Severability. The parties intend this Agreement to be enforced as written. However, (i) if any portion or provision of this Agreement is to any extent declared illegal or unenforceable by a duly authorized court having jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, will not be affected thereby, and each portion and provision of this Agreement will be valid and enforceable to the fullest extent permitted by law and (ii) if any provision, or part thereof, is held to be unenforceable because of the duration of such provision or the geographic area covered thereby, the court making such determination will have the power to reduce the duration and/or geographic area of such provision, and/or to delete specific words and phrases ("blue-penciling"), and in its reduced or blue-penciled form such provision will then be enforceable and will be enforced.

(k) Headings and Captions. The headings and captions of the various subdivisions of this Agreement are for convenience of reference only and will in no way modify or affect the meaning or construction of any of the terms or provisions hereof.

(l) Injunctive Relief. You hereby expressly acknowledge that any breach or threatened breach of any of the terms and/or conditions set forth in Section 1, 2 or 3 of this Agreement will result in substantial, continuing and irreparable injury to the Company. Therefore, in addition to any other remedy that may be available to the Company, the Company will be entitled to injunctive or other equitable relief by a court of appropriate jurisdiction in the event of any breach or threatened breach of the terms of Section 1, 2 or 3 of this Agreement.

(m) No Waiver of Rights, Powers and Remedies. No failure or delay by a party hereto in exercising any right, power or remedy under this Agreement, and no course of dealing between the parties hereto, will operate as a waiver of any such right, power or remedy of the party. No single or partial exercise of any right, power or remedy under this Agreement by a party hereto, nor any abandonment or discontinuance of steps to enforce any such right, power or remedy, will preclude such party from any other or further exercise thereof or the exercise of any other right, power or remedy hereunder. The election of any remedy by a party hereto will not constitute a waiver of the right of such party to pursue other available remedies. No notice to or demand on a party not expressly required under this Agreement will entitle the party receiving such notice or demand to any other or further notice or demand in similar or other circumstances or constitute a waiver of the rights of the party giving such notice or demand to any other or further action in any circumstances without such notice or demand.

(n) Not Employment Contract. You acknowledge that this Agreement does not constitute a contract of employment, does not imply that the Company will continue your employment for any period of time and does not change the at-will nature of your employment.

(o) Counterparts. This Agreement may be executed in two or more counterparts, and by different parties hereto on separate counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

(p) Opportunity to Review. You hereby acknowledge that you have had adequate opportunity to review these terms and conditions and to reflect upon and consider the terms and conditions of this Agreement, and that you have had the opportunity to consult with counsel of your own choosing regarding such terms. You further acknowledge that you fully understand the terms of this Agreement and have voluntarily executed this Agreement.

[Remainder of page intentionally left blank.]

If the foregoing accurately sets forth our agreement, please so indicate by signing and returning to us the enclosed copy of this letter.

Very truly yours,

KALA PHARMACEUTICALS, INC.

By: /s/ Mary Reumuth
Name: Mary Reumuth
Title: CFO

Accepted and Approved:

/s/ Todd Bazemore
Name: Todd Bazemore

11/21/2017
Date

[NON-COMPETITION, NON-SOLICITATION, CONFIDENTIALITY AND ASSIGNMENT OF INVENTIONS AGREEMENT]

EXHIBIT 3(d)

PRIOR INVENTIONS

[None.]

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

AMENDED AND RESTATED MASTER SERVICES AGREEMENT

THIS AMENDED AND RESTATED MASTER SERVICES AGREEMENT (hereinafter referred to as "Agreement") is entered into as of October 4, 2017 (the "Effective Date"), by and between Alliance Contract Pharma, LLC, a Pennsylvania corporation, having its offices at 1510 Delp Drive, Harleysville, PA 19438, (hereinafter referred to as "SUPPLIER") and Kala Pharmaceuticals, Inc., a Delaware corporation having its offices at 100 Beaver Street, Suite 201, Waltham, MA 02453 (hereinafter referred to as "SPONSOR"). SPONSOR and SUPPLIER may be individually referred to herein as a "Party" or may be collectively referred to herein as the "Parties." This Agreement amends and restates, in its entirety, the Master Services Agreement entered into by the parties as of January 28, 2015 and the Amended and Restated Master Service Agreement entered into by the parties as of January 27, 2017 as of the Effective Date.

RECITALS

WHEREAS, SPONSOR desires to appoint SUPPLIER to perform Services (as hereinafter defined) on a non-exclusive basis as more particularly described below, and SUPPLIER desires to perform said Services in accordance with the terms and conditions contained in this Agreement and all referenced documents.

WHEREAS, SUPPLIER and SPONSOR are each duly authorized to execute and deliver this Agreement, and all necessary corporate action and all consents, approvals and other authorizations and all other acts and things necessary to make this Agreement a valid, binding and legal instrument have been done and performed by SUPPLIER and SPONSOR respectively.

NOW, THEREFORE, in consideration of the mutual agreements herein contained, the Parties hereto, intending to be legally bound, hereby agree as follows:

ARTICLE 1 – DEFINITIONS

"Batch" shall mean a defined quantity of Product that has been or is being manufactured in accordance with the Specifications.

"Certificate of Analysis" (abbreviated "COA") shall mean a document prepared by SUPPLIER containing at a minimum the product name, Lot number, test parameters, test specifications, test method, and test results for each Lot of Product supplied to SPONSOR. Each COA shall be signature approved by SUPPLIER.

"Current Good Manufacturing Practices" (abbreviated "GMPs" or "cGMPs") shall mean the standards established by the United States Food and Drug Administration (the "FDA") for current Good Manufacturing Practices, as specified in FDA 21 C.F.R. §820 Quality Systems Regulations (or its successor provisions); the standards established in the European Council Directive 2004/27/EC of 31 March 2004 concerning medicinal products for human use, as amended (or its successor provisions); and other sections so designated by the title "Good Manufacturing Practices"; as applicable to each respective Product to be manufactured and/or supplied by SUPPLIER.

"Equipment" shall mean any equipment, tools, tanks, instruments, patterns, molds, dies, tools, fixtures, and other items to be used by SUPPLIER in connection with this Agreement and which are paid for by SPONSOR or otherwise provided by SPONSOR.

"Facilities" shall mean SUPPLIER's manufacturing facilities at 1510 Delp Drive, Harleysville, PA 19438.

"Lead Time" shall mean the time period that begins on the day SUPPLIER receives a Purchase Order for Product from SPONSOR and ends on the day SUPPLIER is required to deliver the Product to SPONSOR.

"Lot" shall mean a defined quantity of starting material, packaging material or product processed in one process or series of processes so that it could be expected to be homogeneous.

"Product" shall mean the product(s) to be manufactured and supplied by SUPPLIER to SPONSOR under Purchase Order(s) issued under this Agreement and as more specifically detailed in a Project Proposal/SOW attached hereto.

"Purchase Order" shall mean a purchase order issued by SPONSOR to SUPPLIER for the purchase of Product under this Agreement.

"Specifications" shall mean the Product specifications set forth or referenced in the applicable Proposal/SOW. The Specifications shall also include all necessary test protocols, packaging and labeling specifications, bills of material and other documentation required to describe, control, and assure the quality of the manufacture of the Product, regardless of whether the foregoing is included as a part of applicable Proposal/SOW.

"SPONSOR Materials" shall mean any materials to be supplied by SPONSOR to SUPPLIER in order to manufacture Product.

ARTICLE 2 – SERVICES

A. Scope of Services: SUPPLIER shall provide to SPONSOR manufacturing services relating to various cGMP manufacturing, packaging operations, equipment qualification and/or analytical support services as described in one or more Project Proposal/SOW(s) (defined below) (the "Services"). Each Project Proposal/SOW shall be substantially in the form of the initial Project Proposal/SOW attached hereto as Exhibit A. It is anticipated that SUPPLIER will conduct more than one project ("Project") in connection with the Services. Additional Project Proposals/SOWs will be added to this Agreement as separate exhibits, which shall be incorporated herein by reference, to capture additional activities not captured in the original Project Proposal/SOW.

B . Project Proposal/SOWs: Prior to commencing a Project, SUPPLIER shall submit to SPONSOR an individual proposal/statement of work ("Project Proposal/SOW"). The Project Proposal/SOW shall provide the following information: (i) a description of the Project, (ii) the budget and payment schedule, (iii) the timing or schedule for the Project, and (iv) any other relevant information. Such Project Proposal/SOW must be executed by both SPONSOR and SUPPLIER prior to commencement of any work. Only a duly signed Project Proposal/SOW can commit SPONSOR to make the payments herein for any Services performed by SUPPLIER. Work performed without SUPPLIER receiving the aforementioned duly executed documents shall be at its own risk, cost, and expense.

C . Standard of Performance: The Services shall be performed to the reasonable satisfaction of SPONSOR and shall be performed in accordance with generally accepted professional standards and the Specifications set forth herein and in the applicable Project Proposal/SOW. SUPPLIER shall ensure that, as applicable, the individuals/team assigned to work on the Services understand SPONSOR's business; the industry and market within which SPONSOR operates; and basic industry laws, regulations and guidance, including relevant regulations and/or guidance issued by the U.S. Food and Drug Administration ("FDA"), guidance issued by the U.S. Department of Health and Human Services Office of the Inspector General and the PhRMA code. SPONSOR and SUPPLIER shall comply with all applicable cGMPs and all other applicable Federal, state, local laws, standards, requirements, and regulations (and their foreign counterparts) in connection with the performance of the Services. In no event may SUPPLIER change, alter, or otherwise deviate from the Specification set forth in this Agreement unless mutually agreed by the parties in writing.

D. Agreement/Project Proposal/SOW Conflicts: In the event that the terms of any Project Proposal/SOW or any other document conflict with the terms of this Agreement, the terms of this Agreement shall take precedence, unless the applicable Project Proposal/SOW expressly refers to the Parties' intent to alter the terms of this Agreement with respect to such Project Proposal/SOW in which case those specific terms of the applicable Project Proposal/SOW shall take precedence.

Subject to the foregoing, SUPPLIER shall not proceed with Services that reasonably conflict with the terms of this Agreement and shall promptly notify SPONSOR in writing of any such conflict.

E . Reviews: Periodic reviews of SUPPLIER's performance may be conducted by SPONSOR at SPONSOR's sole cost and expense provided that SPONSOR provides SUPPLIER with at least [**] business days' notice prior to such review. SUPPLIER shall reasonably assist in such reviews and shall ensure SPONSOR has adequate access to the Facility in order to conduct such reviews. If any such review reveals any deficiency in SUPPLIER's performance, SUPPLIER shall promptly correct such deficiencies and notify SPONSOR in writing that such deficiencies have been corrected.

F . Right to Request Modifications: SPONSOR may request, during progress of any work hereunder, additions or modifications to any Project Proposal/SOW. Upon such request by SPONSOR, SUPPLIER shall provide SPONSOR with a revised Project Proposal/SOW setting forth such changes including any changes to costs and/or fees; provided that any increase in costs and/or fees must be proportional to the change in scope required by SPONSOR. If acceptable to SPONSOR, the Parties shall execute the revised Project Proposal/SOW and SUPPLIER shall proceed accordingly.

G . SUPPLIER Agents: SUPPLIER shall ensure that all employees and agents of SUPPLIER who are assigned to perform Services under this Agreement are qualified and have sufficient expertise, training, and experience. SUPPLIER shall ensure that such agents are made aware of and are bound to comply with SUPPLIER's obligations contained in this Agreement.

H . Quality Agreement. SUPPLIER and SPONSOR shall execute a written Quality Agreement between the Parties related to the Services to be performed hereunder (the "Quality Agreement"). Upon execution, the Quality Agreement shall be attached hereto and shall be incorporated herein. The Quality Agreement may be updated from time to time upon the mutual written agreement of the Parties. To the extent that any terms of the Quality Agreement are inconsistent with the terms set forth in this Agreement, the terms of this Agreement shall prevail, except for specific quality-related and quality-assurance (e.g. quality reviews/audits) issues for which the Quality Agreement shall prevail.

I . Equipment. Any and all Equipment shall remain SPONSOR's personal property. Such Equipment shall be plainly marked or otherwise adequately identified by SUPPLIER as SPONSOR's property and shall be safely stored. SUPPLIER shall use Equipment only to meet SPONSOR's Purchase Orders, and shall not use Equipment for any other purpose. All Equipment, while in SUPPLIER's custody or control, shall be held at SUPPLIER's risk, shall be kept insured by SUPPLIER at SUPPLIER's expense in an amount equal to the replacement cost with loss payable to SPONSOR and shall be subject to removal at SPONSOR's written request, in which event SUPPLIER shall prepare such Equipment for shipment and redeliver to SPONSOR in the same condition as originally received by SUPPLIER, reasonable wear and tear excepted, all at SPONSOR's expense. SUPPLIER agrees to keep the Equipment at all times in good and efficient working order for use in manufacturing the Products. SUPPLIER shall be responsible for routine maintenance of all Equipment at the expense of the SPONSOR, but SPONSOR shall be responsible for the cost of replacement at the end of their normal useful life.

ARTICLE 3 – ACCEPTANCE; DEFECTS; RECORDS

A. Acceptance. SPONSOR will have [**] days following SPONSOR's receipt of the Products and all applicable Batch Records and release documentation ("Acceptance Period") to ensure that the Products meet the Specifications, requirements, and terms of this Agreement and the applicable Proposal/SOW. If SPONSOR determines that any Products fail to meet the Specifications, requirements, and terms of this Agreement and the applicable Proposal/SOW ("Defective Products"), then SPONSOR may reject the entire Batch of such Defective Products, and SUPPLIER shall promptly, at its own expense and without limiting any remedies otherwise available to SPONSOR, replace the Defective Products with Products conforming to this Agreement. Any replacement Products shall be subject to additional acceptance terms pursuant to this Section. In the event that replacement Products are required due to Defective Products, SPONSOR shall supply SUPPLIER, at SUPPLIER's sole cost and expense, sufficient quantities of SPONSOR Materials in order for SUPPLIER to provide replacement Products. SUPPLIER shall have no obligation under this section to the extent that any Defective Products result due to: (i) defects in the

SPONSOR Materials or (ii) conduct following SPONSOR's receipt of the Products or (iii) events following shipment of Products by the SUPPLIER.

B. Batch Records and Data; Release. Unless otherwise agreed to by the parties in writing during their ordinary course of dealings, after SUPPLIER completes of a Batch, SUPPLIER shall provide SPONSOR with copies of Batch records prepared in accordance with the Specifications; *provided*, that if testing reveals an out-of-Specification result, SUPPLIER shall provide such Batch records promptly following resolution of the out-of Specification result. After SUPPLIER completes a Batch, SUPPLIER shall also provide SPONSOR or its designee with a sample of the Product.

C. Recordkeeping. SUPPLIER shall maintain materially complete and accurate Batch, laboratory data, reports and other technical records relating to the Services in accordance with SPONSOR's requirements, cGMPs and applicable law. Such information shall be maintained for a period of at least [**] years from the relevant finished Product expiration date or longer if required under applicable laws or the Quality Agreement.

ARTICLE 4 – FORECASTS, PURCHASE ORDERS AND DELIVERY

A. Forecasts. SPONSOR shall provide SUPPLIER, at least [**] days prior to the beginning of each [**], with a [**] month non-binding rolling forecast of the estimated quantities of Product believed to be required by SPONSOR. Forecasted quantities become a firm binding order [**] days before delivery date set forth in the forecast. SPONSOR shall use commercially reasonable efforts to ensure that its forecasts are accurate. SUPPLIER shall ensure that it is able to supply at least [**]% of the quantity of Products set forth in SPONSOR's forecasts. In no event will the fees for the Services increase due to ordered quantities of Product exceeding forecasts, provided, however, that SPONSOR shall bear the cost of any unused materials purchased by SUPPLIER in quantities consistent with SPONSOR's forecast or minimum orders as required by vendors which are communicated to SPONSOR in advance of placing the applicable order.

B. Purchase Orders. All Product ordered by SPONSOR shall be in the form of a firm written Purchase Order not less than [**] days prior to expected delivery. The Lead Time for the Product shall not exceed the number of days set forth in the applicable Proposal/SOW. Each Purchase Order shall contain at a minimum, the following information: description of the Product and quantity ordered, price, delivery terms, delivery date, and Purchase Order number for billing purposes. Each Purchase Order issued pursuant to this Agreement shall be binding, except that delivery dates may be moved ahead or back by mutual written agreement of SUPPLIER and SPONSOR. To the extent there are any conflicts between the terms of any Purchase Order and the terms of this Agreement, the terms of this Agreement shall prevail and control. There shall be no minimum purchase requirements except for binding forecasts. Batches will be invoiced upon the completion of manufacturing and release testing. As noted in the table below, the cost per batch is based on the following three tier pricing schedule: (i) upon the completion of manufacturing the first [**] batches in each calendar year (batches [**]) batches will be invoiced at Tier 1 pricing (ii) upon the completion of manufacturing the [**] batches in each calendar year (batches [**]) batches will be invoiced at Tier 2 pricing (iii) all remaining batches manufactured from batch [**] on will be invoiced at Tier 3 pricing.

Pricing Schedule	Total Product Manufactured in each Calendar Year (total number of batches)	Cost per Batch
Tier 1	[**]	[**]
Tier 2	[**]	[**]
Tier 3	[**]	[**]

C. Delivery. Unless expressly provided otherwise in the applicable Purchase Order, shipping terms for the Product shall be EXW Harleysville, PA (Incoterms 2010). SPONSOR shall coordinate shipments of Product from SUPPLIER. The Product will be packaged and shipped per the Specifications. In the event that any delivery of the Product is anticipated to be late, SUPPLIER will promptly notify SPONSOR of the circumstances for the delay. SUPPLIER will make a reasonable effort to minimize the delay. If as a

result of a SUPPLIER issue, SUPPLIER agrees to assume the burden of bearing additional costs associated with overtime production and premium freight for corrective action as a result of delays caused by SUPPLIER or any personnel or service providers engaged by SUPPLIER. SUPPLIER agrees that all Product shipments to SPONSOR shall be in accordance with SPONSOR's instructions and all applicable laws and regulations governing the shipment, labeling, and packaging of the Product.

D . Storage. Product completed by SPONSOR shall be stored by SUPPLIER in the SPONSOR supplied [**]°C chamber (which shall constitute Equipment hereunder) until shipment of the Product.

E . Financial Statements. Within [**] days after the end of each fiscal year, SUPPLIER shall deliver to SPONSOR an annual Going Concern Statement issued by SUPPLIER's external accounting firm. Such Going Concern Statement shall be sufficient for SPONSOR to confirm SUPPLIER's continued ability to perform its obligations under this Agreement in the following twelve (12) month period and shall be consistent with the standards identified by the Financial Accounting Standards Board. SPONSOR may use such statement strictly in order to confirm SUPPLIER's ongoing ability to perform its obligations under this Agreement. SPONSOR shall keep such financial statements confidential, and shall provide such statements only to those of its financial directors, who have a need to know such information in order to confirm SUPPLIER's continued ability to perform its obligations under this Agreement.

ARTICLE 5 – AGREEMENT TERM

The term of this Agreement shall commence on the Effective Date and shall continue for a period of ten (10) years ("Initial Term"). Thereafter, this Agreement will continue until terminated as provided in this Agreement. The Initial Term and any subsequent continuation of the Agreement are referred to collectively as the "Agreement Term"). In the event a Project Proposal/SOW is still in effect upon the expiration of this Agreement, such Project Proposal/SOW shall remain in effect and shall continue to be governed by the terms and conditions of this Agreement unless and until such Project Proposal/SOW is completed or otherwise terminated in accordance with this Agreement.

ARTICLE 6 – COMPLIANCE WITH LAWS; QUALITY CONTROL

A. Compliance with Laws: SPONSOR and SUPPLIER each agree that they shall comply with all applicable federal, state and local laws and regulations in performance of their respective obligations pursuant to this Agreement, including, without limitation and as applicable, laws and regulations related to promotion of pharmaceutical products, fraud and abuse, insider trading, privacy, discrimination, confidentiality, false claims and prohibition of kickbacks. Without limiting the generality of the foregoing:

a . Privacy: SUPPLIER and SPONSOR each agrees, if applicable, to comply with all applicable federal, state and local laws and regulations relating to the privacy of patient health information, including, but not limited to, the Standards for Individually Identifiable Health Information, 42 C.F.R. §§160 and 164 (the "HIPAA Privacy Regulation") promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996.

b . Dissemination of Materials: SUPPLIER acknowledges that SPONSOR is subject to legal and regulatory restrictions concerning the dissemination, distribution or use of materials related to pharmaceutical products. Accordingly, except as required to perform the Services hereunder, SUPPLIER shall not disseminate, distribute or use any materials prepared in the course of performing the Services or otherwise provided to SUPPLIER without the prior express, written permission of SPONSOR. To the extent that the Services require SUPPLIER to distribute materials, such materials must be approved by SPONSOR for the specific purpose(s) for which SUPPLIER is distributing such materials.

c . Adverse Event Reporting: SUPPLIER acknowledges that SPONSOR is required to comply fully and promptly with all regulatory safety reporting requirements regarding its products. In accordance with SPONSOR policies and procedures, SUPPLIER agrees that if in connection with its performance of the Services it receives information relating to adverse events (AE), product complaints (PC), and/or other SPONSOR product-related safety information (e.g.

special safety topics as communicated to SUPPLIER through separate correspondence), SUPPLIER will promptly notify SPONSOR as follows: All AE and PC information received by SUPPLIER must be reported by SUPPLIER within [**] by telephone to SPONSOR at [**] and by email to [**] or such other party designated by SUPPLIER. If AE/PC information is received by SUPPLIER on a non-business day or after regular business hours of a business day, then SUPPLIER must transmit the information by the end of the next business day. However, if more than [**] non-business days occur in a row, it is the responsibility of SUPPLIER to transmit the information by the end of day [**]. Notwithstanding the foregoing, the time period, criteria and method for reporting AE/PC information, including any special safety topics, may be modified by SPONSOR in separate correspondence. SUPPLIER will ensure that the personnel assigned to perform the Services are sufficiently trained to comply with the requirements of this paragraph. If SPONSOR determines that SUPPLIER personnel require additional training, then SPONSOR will provide training to SUPPLIER personnel to enable SUPPLIER personnel to comply with the requirements of this paragraph. SUPPLIER agrees to follow the direction given in such training.

d . Securities: SUPPLIER acknowledges that during the performance of this Agreement it may come into possession of certain material information about SPONSOR or its affiliates that has not yet been disclosed to the public. SUPPLIER agrees to comply with the rules and regulations of the United States Securities and Exchange Commission ("SEC"), including those relating to insider trading in connection with such material, non-public, information about SPONSOR or its affiliates. SUPPLIER is hereby notified that it should not trade in SPONSOR securities on its own behalf or on the behalf of others after receiving or becoming aware of any such material, non-public information.

e . Permits. SUPPLIER has obtained (or before performing the Services will obtain) all governmental permits (including building/construction permits) and licenses required for it to perform the Services and its other obligations under this Agreement.

f . Reporting. SUPPLER shall provide SPONSOR with all applicable records and data necessary to prepare Annual Product Review Reports as required by Applicable Laws and GMPs.

B . Recalls**.** SPONSOR shall have the right to reasonably declare any recall of, or field corrective action to, any Product supplied to SPONSOR under this Agreement. SUPPLIER agrees to cooperate with SPONSOR in connection with any such recall, and shall indemnify SPONSOR for all expenses arising from any such recall to the extent the recall is attributable to a breach of any of SUPPLIER's warranties under this Agreement or is otherwise attributable to a defect in the Product. SUPPLIER shall also credit SPONSOR's account for the Product recovered and returned to it as a result of the recall.

C. Governmental Inquiries. SUPPLIER shall use its best efforts to:

a. Respond fully and accurately to all inquiries directed to it by the FDA or any government agency with respect to the manufacture, testing, and use of the Product.

b. Assist SPONSOR in responding to inquiries directed to SPONSOR by the FDA or any government agency with respect to the manufacture, testing, and use of the Product.

c. Promptly inform SPONSOR of the existence and substance of any inquiry, investigation or inspection initiated by the FDA or any government agency (including Ministry of Health), department or body relating to the Product or its manufacture. The existence of any such inquiry, investigation or inspection shall not alone constitute a breach of this Agreement or excuse any performance due under this Agreement. SUPPLIER shall immediately provide SPONSOR with copies of any and all inspection reports, letters, documents or similar instruments submitted or received from the FDA or other government agency related to the Product or its manufacture, testing or use. To the extent permitted by applicable law, SUPPLIER shall permit SPONSOR to review and reasonably approve any response to be

made by SUPPLIER in connection with any such inquiry, investigation or inspection.

D. Inspection of Manufacturing Facilities.

a. SUPPLIER shall permit SPONSOR and its agents, during business hours and upon notice to SUPPLIER, to inspect the Facilities where the Product is manufactured, handled, stored or tested, as well as all processes relating to the manufacture, handling, storage, or testing of the Product, as well as all manufacturing, handling, storage, and test records regarding the Product.

b. SUPPLIER shall extend the same inspection privileges set forth above to agents of the FDA or any other government agency, as required, and shall promptly notify SPONSOR of any such inspection. SUPPLIER shall provide SPONSOR with copies of any and all inspection reports from the FDA or other relevant government agency regarding the manufacture of the Product within [**] working days of receipt of such reports.

c. SUPPLIER warrants and agrees that it will correct, at its own expense and within a reasonable amount of time from the date of notification, all deficiencies and/or non-conformances found during a SPONSOR, FDA, or other government agency audit; and that it will correct or issue an approved plan, including timetable, to correct all deficiencies and/or non-conformances within no more than [**] days of such notification.

E . Quality Control Testing. SUPPLIER shall perform quality control testing in accordance with the Specifications for release of each Lot of Product to SPONSOR. SUPPLIER shall provide all such testing data to SPONSOR in the form of a COA. Each COA shall be in accordance with the format approved by SPONSOR, certifying that the Product has met all Specifications. Any third party or contract laboratory used for the testing of the Product must be approved in writing by SPONSOR prior to its use for that purpose, such approval not to be unreasonably withheld or delayed.

F. Specifications and Change Control.

a. The Specifications may not be changed without prior written approval of both parties.

b. SUPPLIER shall not make any changes to the manufacturing process, Facilities, or equipment used in the manufacture of the Product without SPONSOR's prior written approval, such approval not to be unreasonably withheld.

c. SPONSOR shall use commercially reasonable efforts to provide SUPPLIER with sufficient written notice of any instructions or requirements of a government regulatory agency that may require a change of the Specifications. SUPPLIER shall immediately notify SPONSOR if any such changes in the Specifications shall render SUPPLIER unable to supply the Product in accordance with the term and conditions of this Agreement.

G. Technical Assistance. SUPPLIER shall provide SPONSOR with certain technical support regarding the Product as reasonably requested by SPONSOR, including, but not limited to, operation of milling and other ancillary equipment, analytical test methods, method development, physical and chemical properties, and use of the Product..

ARTICLE 7 – COMPENSATION

A . Fees: SPONSOR will pay SUPPLIER, as full and complete compensation for performing the Services pursuant to each Project Proposal/SOW the rates/amounts set forth in the applicable Project Proposal/SOW. The Parties agree that the compensation provided hereunder has been established pursuant to arm's length negotiations between the Parties and is consistent with the fair market value of the Services provided by SUPPLIER during the term of this Agreement. Except to the extent that the Services involve promotion of pharmaceutical products, nothing herein shall be construed to require SUPPLIER to purchase, order, recommend, or arrange for, the purchase, order or recommendation of any products manufactured and/or marketed by SPONSOR.

B. Out-of-Pocket Expenses ("OOPs"): SPONSOR shall reimburse SUPPLIER for all OOPs for activities

described in an approved Project Proposal/SOW and which are preapproved in writing by SPONSOR on a case by case basis, but in no event shall SPONSOR reimburse SUPPLIER for any OOPs that exceed the estimates provided in such Project Proposal/SOW. Upon SPONSOR's request all OOP's for which SUPPLIER seeks reimbursement shall be supported with actual SUPPLIER invoices and/or other reasonable documentation.

C . Other Expenses/Travel: Reasonable expenses incurred by SUPPLIER in the course of providing the Services, including but not limited to, round trip economy airfare, auto rental, meals, lodging and long distance telephone charges (collectively, "Travel Expenses"), will be reimbursed to SUPPLIER by SPONSOR in accordance with SPONSOR's travel and expense policy; provided, however, that all Travel Expenses shall be reimbursed only if plans for same are approved by SPONSOR in advance and in writing. SUPPLIER shall itemize all Travel Expenses on its invoices specifically describing each charge incurred, and when and why such charges were incurred. Receipts and bills shall be submitted with the expense report.

D . Submission of Invoices: SUPPLIER will submit invoices to SPONSOR in accordance with the payment schedule set forth in the Project Proposal/SOW. In the event that payment terms are based on hourly fees, SUPPLIER shall submit monthly invoices to SPONSOR which reflect the total number of hours worked for that month, the activities performed for each hour billed, and the individual who performed such activities. SPONSOR may withhold any invoiced amounts that it reasonably disputes in good faith, in which case SPONSOR will so notify SUPPLIER in writing and the Parties agree to work in good faith to resolve any such disputes. SPONSOR will pay any undisputed amounts specified in such invoice within [**] days of receipt of same. SPONSOR will not pay for any services invoiced more than [**] months after such services were performed. All invoices submitted by SUPPLIER shall reference the appropriate SPONSOR authorized Purchase Order number, and shall be emailed to AP@kalarx.com.

E. Payment: SUPPLIER is not entitled to any compensation unless and until the work or work product produced by SUPPLIER meets the Specifications of the applicable Project Proposal/SOW to the reasonable satisfaction of SPONSOR. SUPPLIER is also not entitled to any compensation related to correcting any work or work product that SPONSOR has rejected as not acceptable to SPONSOR in the exercise of its reasonable discretion.

F . Preparation of Project Proposal/SOWs: There will be no compensation under this Agreement for (i) preparation of any Project Proposal/SOW or (ii) work done in connection therewith, in the event SUPPLIER prepares a bid or proposal for SPONSOR regardless of whether SUPPLIER's bid or proposal is accepted by SPONSOR.

G. No Commission: SUPPLIER shall bill SPONSOR without commission or markup on purchases of goods or services, Travel Expenses or other OOPs. SUPPLIER shall not share directly or indirectly in the profits of any third party in connection with SUPPLIER services provided hereunder without the prior written consent of SPONSOR.

H . SUPPLIER Errors: Notwithstanding anything herein to the contrary, SUPPLIER shall not invoice SPONSOR for any additional costs incurred as a result of any SUPPLIER error, including any failure by SUPPLIER to properly price the Services or any required reperformance of the Services.

ARTICLE 8 – RIGHT TO AUDIT

Upon reasonable notice in writing and at reasonable times during SUPPLIER's normal business hours, not more than [**] (or more frequently for cause), SPONSOR shall have the right to audit and examine all contracts, documents, correspondence, books, time sheets, account books and records and other material (except for individual payroll and personnel records and SUPPLIER overhead) that relate to SPONSOR's account. A representative duly authorized by SPONSOR may perform this audit. To the extent SPONSOR utilizes the services of any third party representative (including any certified public accountants) to perform this audit, the selection of such third party representative shall be approved by SUPPLIER, such approval not to be unreasonably withheld by SUPPLIER. The expense of such audit or examination shall be borne by SPONSOR unless the audit shows that

SPONSOR has been overcharged by more than [**] percent ([**]%), in which case SUPPLIER shall pay for the audit. Any such representative and/or certified public accountants conducting the audit shall be required to sign an appropriate non-disclosure agreement, reasonably acceptable to SUPPLIER, prior to participating in any such audit. Any such audit shall include the right to inspect SUPPLIER's timesheet records; provided, however, that such time sheets may be redacted by SUPPLIER to exclude any confidential or proprietary information of SUPPLIER or any of its other clients. The audit rights provided herein shall survive any termination or expiration of this Agreement. The provisions of this Article 8 shall survive the expiration or sooner termination of this Agreement.

ARTICLE 9 –NON EXCLUSIVE AGREEMENT

A. The Parties recognize that this is a non-exclusive Agreement and during the term hereof, SPONSOR may engage other vendors to perform the Services.

ARTICLE 10 – OWNERSHIP/TRADEMARKS/COPYRIGHTS

A. Ownership of Services:

a. SUPPLIER shall retain all right, title and interest in and to any and all materials, work and work product owned or developed by SUPPLIER prior to, or independently from, its engagement hereunder or developed or obtained by SUPPLIER in the general conduct of its business not specifically related to the Services or SPONSOR ("SUPPLIER Property"). SUPPLIER hereby grants SPONSOR a perpetual, irrevocable, royalty free, worldwide, non-exclusive license, with the right to assign or sublicense, in and to any and all SUPPLIER Property to allow SPONSOR to use the results of the Services to develop, market, promote, make, have made, use, sell, offer for sale and import SPONSOR products or any other purpose consistent with this Agreement. SPONSOR shall retain all right, title and interest in and to any and all materials, work and work product owned or developed by SPONSOR prior to, or independently from, its engagement hereunder ("SPONSOR Property"). SPONSOR hereby grants SUPPLIER, during the term of this Agreement, a non-exclusive, non-transferable, limited license to use the SPONSOR Property solely for the benefit of SPONSOR and solely as necessary for performance of the Services.

b. SUPPLIER represents and warrants that all materials, work and work product provided to SPONSOR or used on behalf of SPONSOR pursuant to this Agreement, including without limitation, all SUPPLIER Property, shall either (i) not infringe the copyright or any other intellectual property right of any third party, or (ii) be licensed at no cost to SPONSOR under a third party release under which SUPPLIER has all rights necessary to provide to SPONSOR such materials, work and work product and permit SPONSOR to use such materials, work and work product as contemplated herein. SPONSOR shall have the right, in its discretion, to examine copies of releases obtained by SUPPLIER. SUPPLIER further represents and warrants that SPONSOR shall be free to use such materials, work and work product without interference by, or claims of, third parties subject to any limitations on usage contained in the aforesaid releases, licenses or other documentation and brought to the attention of SPONSOR in writing.

c. Except for SUPPLIER Property as defined in subsection 7.A.a. above, all materials, work and work product whether created by or on behalf of SUPPLIER, SPONSOR, or any combination thereof hereunder, and all draft versions thereof, whether used or unused, (collectively, "Work Product") shall be property of SPONSOR and shall be delivered to SPONSOR at any time upon SPONSOR's request, or no later than the termination of this Agreement. SUPPLIER hereby transfers and assigns to SPONSOR any copyright and all other intellectual property rights in such Work Product, including all of the exclusive rights comprised in such intellectual property rights, whether in patent, copyright, trade secret, know-how, or otherwise. Subject to the provisions of subsection 7.A.b., SUPPLIER shall ensure that all individuals working on such Work Product have assigned to SUPPLIER their rights to such Work Product.

SUPPLIER agrees to execute any documents necessary to assign to SPONSOR SUPPLIER's full interest (including all intellectual property rights) in the Work Product either solely or jointly with others for SPONSOR pursuant to this Agreement. No restrictions will be placed on SUPPLIER by third parties with respect to any Work Product without the prior written consent of SPONSOR.

d. Except for SUPPLIER Property as defined in subsection 7.A.a. above, all information, inventions, discoveries, patent rights, trademarks and copyrights which result from any Services performed by or on behalf of SUPPLIER pursuant to this Agreement ("Inventions"), will be the exclusive property of SPONSOR and SPONSOR shall have and retain all right, title and interest in and to such Inventions. SUPPLIER hereby transfers and assigns to SPONSOR all intellectual property rights in and to such Inventions. SUPPLIER shall promptly disclose in writing to SPONSOR each such Invention and provide to SPONSOR all information known to SUPPLIER reasonably relating to such Invention. Subject to the provisions of subsection 7.A.b., SUPPLIER shall ensure that all individuals contributing to such Inventions have assigned to SUPPLIER their rights to such Inventions. SUPPLIER agrees to sign all necessary documents or take such other actions as SPONSOR may reasonably request in order to perfect and enforce any and all of its rights in such Inventions. All costs and expenses for perfecting and enforcing its rights in such Inventions shall be borne by SPONSOR.

e. SUPPLIER recognizes and agrees that all Work Product and Inventions prepared by or on behalf of SUPPLIER that are subject to copyright protection shall be "works made for hire" for SPONSOR under the terms hereof. All copyrightable works prepared by or on behalf of SUPPLIER in the course of performing the Services hereunder that may not be interpreted as "works made for hire" shall be subject to SUPPLIER granting to SPONSOR a perpetual, royalty free, irrevocable, worldwide, exclusive license with the right to assign or sublicense, in and to any such works. SUPPLIER hereby assigns to SPONSOR all rights, title and interest to all Work Product and Inventions together with all of the goodwill associated therewith, subject to any properly disclosed third party rights approved by SPONSOR in writing. SPONSOR may, in its sole determination, apply for registration, or other protection, of any such Work Product and Inventions worldwide. SUPPLIER shall cooperate with SPONSOR in regard to obtaining the necessary documents for any Work Product or Inventions protection, including the execution of any required documents. SPONSOR shall pay any reasonable expenses incurred in connection with such cooperation

B. The provisions of this Article 10 shall survive the expiration or sooner termination of this Agreement.

ARTICLE 11 – INDEMNIFICATION AND INSURANCE

A . Indemnification of SPONSOR: SUPPLIER agrees to defend, indemnify and hold SPONSOR and its affiliates, and its and their directors, officers, employees or agents harmless against all claims from third parties arising from: (i) any actual or alleged breach of any term of this Agreement; (ii) the actual or alleged negligent or willful actions of SUPPLIER or SUPPLIER's subcontractors; (iii) contractual arrangements entered into by SUPPLIER with third parties; or (iv) any claim that the Services, Products or Work Product infringe on the intellectual property rights of any third party; except in each case to the extent of the negligence or willful misconduct of SPONSOR.

B . Indemnification of SUPPLIER: SPONSOR agrees to defend, indemnify and hold SUPPLIER and its affiliates, and its and their directors, officers, employees or agents harmless against all claims from third parties arising from (i) any breach of any term of this Agreement; or (ii) the negligent or willful actions of SPONSOR; except in each case to the extent of the negligence or willful misconduct of SUPPLIER.

C . Indemnification Procedures: Each Party shall notify the other in writing promptly upon receiving notification of any such suit or claim (except that failure to timely provide such notice will relieve the indemnifying Party of its obligations only to the extent the indemnifying Party is materially prejudiced as a direct result of such delay); the indemnifying Party shall defend such suit or claim on behalf of

the indemnified Party; the indemnifying Party shall have sole control over the defense thereof and any related settlement negotiations; and the indemnified Party shall cooperate and, at the indemnifying Party's request and expense, assist in such defense. Notwithstanding the foregoing, the indemnified Party may participate at its own expense in the defense and any settlement discussions, and in any event, the indemnifying Party shall not settle any suit or claim without the prior written consent of the indemnified Party (such approval not to be unreasonably withheld).

D. Survival: The indemnification provided herein shall survive any termination or expiration of this Agreement.

E. Insurance:

a. Prior to commencement of any work under this Agreement, SUPPLIER shall, at its sole expense, maintain the following insurance on its own behalf, with insurance companies having an A. M. Best rating of "A-VII" or better and furnish to SPONSOR, Certificate(s) of Insurance evidencing same and reflecting the effective date of such coverage as follows:

- Workers' Compensation and Employers Liability: in the state in which the work is to be performed and elsewhere as may be required by law and shall include:

  Bodily injury by Accident: $[**] each

- Commercial General Liability: (including Premises Operations, Products/Completed Operations, Contractual Liability). The policy must be on an occurrence form and include the following limits:

  Each Occurrence: $[**]

  General Aggregate: $[**]

  Product Completed Operations Aggregate: $[**]

  Personal Injury: $[**]

- Commercial Umbrella Liability:

  Occurrence Limit: $[**]

  Aggregate Limit (where applicable); $[**]

  Policy to be in excess of the Commercial General Liability,

  Commercial Automobile Liability and Employers Liability.

- Errors & Omissions Liability Coverage including Medical Malpractice Coverage if engaged in any direct patient care:

  Each Claim Limit: $[**]

  Aggregate Limit: $[**]

b. Such insurance shall include coverage for bodily injury arising from the performance of or failure to perform professional services. Throughout the term of this Agreement, the Errors & Omissions Liability insurance's retroactive date will be no later than the Effective Date. Upon expiration or termination of this Agreement, SUPPLIER will either continue to maintain an active insurance policy, or purchase an extended reporting period coverage for claims first made and reported to the insurance company within [**] months after the termination or expiration of the Agreement.

c. Such insurance shall include coverage for: (i) personal injuries, unless covered, and not in any way excluded or restricted, by SUPPLIER's General Liability insurance: invasion of privacy, defamation, infliction of emotional distress and advertising injury.

d. With the exception of the Workers Compensation/ Employers Liability and Errors and

Omissions Liability, SPONSOR and its subsidiaries are to be named as an Additional Insured to the policies.

e. The insurance requirements above must include a waiver of subrogation in favor of SPONSOR and its subsidiaries (except where not permitted by law).

f. The amount of insurance required shall not be construed to be a limitation of the liability on the part of the SUPPLIER.

g. It is agreed that this insurance will not be cancelled, materially changed or non-renewed without at least [**] days advance written notice to SPONSOR.

F. **LIMITATION OF LIABILITY: EXCEPT FOR A BREACH OF ARTICLE 9, OR ARTICLE 11, OR THE GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OF A PARTY, OR A PARTY'S INDEMNIFICATION OBLIGATIONS HEREUNDER, NO PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY LOST PROFITS, CONSEQUENTIAL DAMAGES (SPECIFICALLY EXCEPTING THOSE CONSEQUENTIAL DAMAGES ARISING FROM EACH PARTY'S OBLIGATION TO INDEMNIFY THE OTHER FOR LIABILITY ARISING OUT OF OR RELATING TO THIRD PARTY CLAIMS IN ACCORDANCE WITH THIS ARTICLE) INCIDENTAL, INDIRECT, SPECIAL, OR OTHER SIMILAR DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT.** The provisions of this Article 11(F) shall survive the expiration or sooner termination of this Agreement.

ARTICLE 12 – CONFIDENTIAL INFORMATION

A. Each Party (each a "Receiving Party") will not, either during or after the term of this Agreement, disclose to any third person or use the results of the Services or any confidential or proprietary information of the other Party (each a "Disclosing Party") or its affiliates for any purpose other than the performance of the Services, without the prior written authorization of Disclosing Party.

B. For purposes of this Article 12, "confidential or proprietary information" includes, without limitation, the results of the Services, the existence and terms of this Agreement, technical data, know-how, unpublished findings, compounds, compositions, formulations, biomaterials, products, technologies, processes, patent applications, commercial or financial trade secrets, marketing methods and plans, pricing information, manufacturing information, product pipelines, written documents, depictions, oral statements, artwork, unpublished information relating to the business or financial condition of a Party and its affiliates or collaborators, and any other information, property and materials developed, created or acquired by a Party in connection with this Agreement or its terms and conditions, which has been or will be disclosed by Disclosing Party or its affiliates. Without limiting the generality of the foregoing, SUPPLIER acknowledges and agrees that the Work Product and all information related to SPONSOR's mucous penetrating product platform technology shall be considered the confidential or proprietary information of SPONSOR.

C. These obligations shall not apply to the following:

a. information which, after disclosure, becomes available to the public by publication or otherwise, other than by breach of this Agreement by the Receiving Party;

b. information that the Receiving Party can establish by prior written record was already known to it or was in its possession at the time of disclosure and was not acquired, directly or indirectly, from Disclosing Party or its affiliates; or

c. information that the Receiving Party obtains from a third party; provided however, that such information was not obtained by said third party, directly or indirectly, from Disclosing Party or its affiliates under an obligation of confidentiality;

D. If Receiving Party is required (by oral questions, interrogatories, requests for information or

documents, subpoena, civil investigation demand or similar process) to disclose any confidential or proprietary information, Receiving Party may comply with such requirement but will provide prompt notice to Disclosing Party of such requirement in advance of any such disclosure, in order for Disclosing Party to seek a protective order or other remedy prior to such disclosure.

E. The Receiving Party's obligations under this Article 12 to preserve the confidentiality of any and all of the confidential or proprietary information disclosed to it by a Disclosing Party shall continue during the term of the Agreement and for a period of [**] years following expiration or termination of this Agreement, or as otherwise required by law; except for any trade secret recognized as such under the Uniform Trade Secret Act for which the Receiving Party's obligations with respect to use and disclosure shall continue until and unless the applicable confidential or proprietary information falls within an exception set forth in Article 12(C).

F. SUPPLIER agrees that any breach of this Article 12 will cause SPONSOR substantial and irreparable harm and, therefore, in the event of any such breach, in addition to other remedies that may be available to it, SPONSOR shall have the right to seek specific performance and other injunctive and equitable relief.

G. SUPPLIER hereby acknowledges and agrees that all of SPONSOR's confidential information, including Sponsor Materials, disclosed hereunder may be subject to United States export controls, under the export administration regulations, 15 C.F.R. parts 730-774. SUPPLIER shall strictly comply with all export controls applicable to SPONSOR's confidential information and Sponsor Materials and SUPPLIER shall not: (a) utilize any of such information or Sponsor Materials for any purpose whatsoever, except as specifically authorized in this Agreement; (b) export, transfer, divert or disclose any of such information or Sponsor Materials; or (c) use, or make any of such information or Sponsor Materials available for use, directly or indirectly, in the design, development, production, stockpiling or use of any chemical or biological weapons.

H. The provisions of this Article 12 shall survive the expiration or sooner termination of this Agreement.

ARTICLE 13 – TERMINATION

A. Termination of the Agreement:

a. This Agreement may be terminated by SPONSOR at any time with or without cause by giving at least ninety (90) days prior written notice to SUPPLIER. SPONSOR remains responsible for payment associated with any firm orders and unused inventory of raw materials for the Products purchased by SUPPLIER, so long as: (i) SUPPLIER purchased such raw materials in quantities consistent with SPONSOR's most recent firm commitment, and (ii) such materials cannot be readily reused by SUPPLIER for its other clients or customers.

b. This Agreement may be terminated by either Party, in whole or in part upon default in performance of the other Party, provided that the defaulting Party shall be given not less than [**] days prior written notice of default and the opportunity to cure the default during such period.

c. Following the Initial Term, this Agreement may be terminated by SUPPLIER upon at least twenty-four (24) months' prior written notice.

d. In the event that SUPPLIER terminates this Agreement as permitted hereunder, then notwithstanding such termination, upon the request of SPONSOR, SUPPLIER shall complete any outstanding work under any Project Proposal/SOWs approved by SPONSOR even if such activity extends beyond the termination date.

B . Termination of Project Proposal/SOWs: Any Project Proposal/SOW may be terminated by SPONSOR, in whole or in part, with or without cause, upon thirty (30) days written notice to the other Party, or such shorter period of time as the Parties may agree to in any particular Project Proposal/SOW. Termination of a specific Project Proposal/SOW does not constitute termination of this Agreement or any other Project Proposal/SOW.

C . Bankruptcy: If either Party to this Agreement becomes insolvent, or a proceeding in bankruptcy, receivership or similar proceeding is filed involving a Party during the Agreement Term (and such proceeding is not dismissed within ninety 90 days), this Agreement may be immediately terminated by

the other Party. In the event that SUPPLIER becomes insolvent, or a proceeding in bankruptcy, receivership or similar proceeding is filed involving SUPPLIER during the Agreement Term (and such proceeding is not dismissed within ninety 90 days), SUPPLIER shall use its best efforts to ensure SPONSOR's supply of Products is uninterrupted, such best efforts including, without limitation, providing training and assistance to any successor of SUPPLIER that begins manufacturing Services and otherwise cooperating with SPONSOR in SPONSOR's efforts to continue the manufacture of the Product as the Facility. In the event that SPONSOR becomes insolvent, or a proceeding in bankruptcy, receivership or similar proceeding is filed involving SPONSOR during the Agreement Term (and such proceeding is not dismissed within ninety 90 days) prepayment of all firm orders may be required prior to production.

D. Effect of Termination: Termination or expiration of this Agreement or any Project Proposal/SOW shall not relieve SPONSOR of any amounts owing hereunder for Services actually rendered prior to the effective date of termination or expiration. Additionally:

a. Any non-cancellable contract made on SPONSOR's prior written authorization (it being understood that SUPPLIER shall not enter into non-cancellable contracts on SPONSOR's behalf without SPONSOR's prior written authorization), and still to be performed as of the effective date of termination or expiration, shall be paid for by SPONSOR unless mutually agreed in writing to the contrary, and if requested by SPONSOR such contract shall, at SPONSOR's election, either be carried to completion by SUPPLIER or assigned to SPONSOR (and SPONSOR shall assume all of the rights and obligations under such contract and SUPPLIER shall be relieved of any further responsibility or liability with respect thereto).

b. Notwithstanding the foregoing, if SPONSOR terminates this Agreement pursuant to Sections 12(A)(b), (C) or otherwise for cause, the provisions of subsection 10.D.a. shall not apply.

c. SUPPLIER shall promptly cease performing any work not necessary for the orderly close out of the affected Purchase Order(s) or for the fulfillment of regulatory requirements.

d. Within [**] days following the termination of this Agreement, SUPPLIER shall deliver to SPONSOR all data and materials provided by SPONSOR to SUPPLIER for the manufacturing and supply activities under the impacted Purchase Order(s).

e. The terms and conditions of Section [3, 6, 8, 10, 11, 12, 13, 14, 16, 17 and 19] shall survive the expiration or termination of this Agreement for any reason.

ARTICLE 14 – REPRESENTATIONS AND WARRANTIES

A . SUPPLIER's Representations: SUPPLIER represents and warrants that: (i) compliance with the terms of this Agreement and performance of the Services do not and will not breach or conflict with any other agreement or arrangement to which SUPPLIER is a party; and (ii) during performance of the Services, SUPPLIER will not disclose to SPONSOR, or induce SPONSOR to use, any confidential or proprietary information of a third party without appropriate consent or license from such third party.

B. Debarment/Other Sanctions: SUPPLIER hereby certifies that it has not and will not use in any capacity the services of any individual, corporation, partnership or association which has been debarred under 21 U.S.C. Sec.335a(a) or (b), or listed in the DHHS/OIG List of Excluded Individuals/Entities or the General Services Administration's Listing of Parties Excluded from Federal Procurement and Non-Procurement Programs. SUPPLIER further certifies that it has not been debarred under 21 U.S.C. Sec.335a(a) or (b), or listed in the DHHS/OIG List of Excluded Individuals/Entities or the General Services Administration's Listing of Parties Excluded from Federal Procurement and Non-Procurement Programs.

ARTICLE 15 – SUBCONTRACTORS

A. SUPPLIER shall not engage any subcontractor to perform any portion of the Services as related

directly to any SPONSOR Materials hereunder without obtaining SPONSOR's prior written consent, which shall not be unreasonably withheld, after SUPPLIER provides SPONSOR with the name of the subcontractor, a description of the services to be provided and the cost of such services. Before allowing any subcontractor or consultant to begin performing Services, SUPPLIER will enter into a binding written agreement with such subcontractor/consultant that protects SPONSOR's rights and interests to at least the same degree as this Agreement. Notwithstanding the foregoing, as of the Effective Date, SPONSOR hereby consents to SUPPLIER's use of the subcontractor(s) set forth in the applicable [SOW/Proposal], subject to the execution by such subcontractor(s), SUPPLIER and SPONSOR of a three (3) way confidentiality agreement in a form reasonably acceptable to SPONSOR. Notwithstanding any of the foregoing, SUPPLIER shall remain solely responsible for activities performed by any subcontractor(s), and the use of a subcontractor shall not relieve SUPPLIER of any obligations hereunder. SUPPLIER, and not SPONSOR, shall be solely responsible for all financial responsibilities with regard to such subcontractor(s), including withholdings, liabilities and contributions in respect of any such subcontractor(s).

ARTICLE 16 – NOTICES

A. All notices required or permitted to be given under this Agreement shall be in writing and shall be given by addressing the communication to the address set forth below. Such notices shall be deemed given on the date of receipt if sent by (i) certified mail, (ii) recognized overnight courier or personal delivery, or (iii) by acknowledgement of receipt if sent by other sources:

SUPPLIER: Stephen L. Schweibenz, President

Alliance Contract Pharma, LLC

1510 Delp Drive

Harleysville, PA 19438

[**]

Email: [**]

SPONSOR: [**]

Kala Pharmaceuticals, Inc.

100 Beaver Street, Suite 201

Waltham, MA 02453

(781) 996-5252

E-mail: [**]

With a copy to: General Counsel

Kala Pharmaceuticals, Inc.

100 Beaver Street, Suite 201

Waltham, MA 02453

(781) 996-5252

Email not permitted; Notice to be sent pursuant to (i) or (ii) above

B. Any Party may from time to time change the address to which notices to it are to be sent by notifying

the other Party, in writing, of the change and the new address pursuant to this Article 16.

C. The provisions of this Article 16 shall survive the expiration or sooner termination of this Agreement.

ARTICLE 17 – DISPUTES; GOVERNING LAW

A. Disputes: Initially, the Parties shall attempt to resolve any disputes informally between the persons listed in Article 17 above or their replacements or superiors. The parties agree that any and all disputes, claims or controversies arising out of or relating to this Agreement that are not resolved by their mutual agreement (a) shall be brought by a party in such party's individual capacity, and not as a plaintiff or class member in any purported class or representative proceeding and (b) shall be submitted to final and binding arbitration before JAMS (formerly Judicial Arbitration and Mediation Services), or its successor, pursuant to the United States Arbitration Act, 9 U.S.C. Sec. 1 et seq. Either party may commence the arbitration process called for in this Section by filing a written demand for arbitration with JAMS, with a copy to the other party. The arbitration will be conducted in accordance with the provisions of JAMS' Comprehensive Arbitration Rules and Procedures in effect at the time of filing of the demand for arbitration. The parties will cooperate with JAMS and with one another in selecting a single arbitrator from JAMS' panel of neutrals, and in scheduling the arbitration proceedings, which shall take place in Boston, Massachusetts and in the English language. The parties agree that they will participate in the arbitration in good faith, and that they will share equally in its costs. The provisions of this Section may be enforced by any court of competent jurisdiction, and the party seeking enforcement shall be entitled to an award of all costs, fees and expenses, including attorneys' fees, to be paid by the party against whom enforcement is ordered.

B. Governing Law: This Agreement shall be governed by, and construed in accordance with, the law of the State of Delaware irrespective of its choice of law rules.

C. The provisions of this Article 17 shall survive the expiration or sooner termination of this Agreement.

ARTICLE 18 - SUPPLIER STAFFING

A. SUPPLIER acknowledges and agrees that the configuration and competence of SUPPLIER staff assigned to SPONSOR is of critical importance to SPONSOR. Any SUPPLIER staff assigned to SPONSOR must be trained, and competent, to perform the Services as required hereunder.

ARTICLE 19 – MISCELLANEOUS

A . Entire Agreement: This Agreement, together with any exhibits attached hereto, and each fully executed Project Proposal/SOW (as amended hereunder), contains the entire understanding between the Parties with respect to the subject matter hereof and supersedes all prior understandings relating thereto. No amendment, modification or waiver of this Agreement or any term hereof may be effected except by an instrument in writing duly executed by the Parties.

B . Independent Contractors: At all times the relationship of the Parties shall be independent contractors with respect to each other. No Party is responsible for withholding, and shall not withhold, FICA or taxes of any kind from any payments it owes to any other Party. Further, as independent contractors, neither Party, nor any of its employees are eligible to participate in, nor are they eligible for coverage under, any other Party's benefit plans, programs, employment policies or procedures, or workmen's compensation insurance.

C . Assignment: This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and assigns. This Agreement may only be assigned by a Party upon the prior written consent of the other Party; provided, however, that SPONSOR may assign this Agreement to an affiliate or a subsidiary or a successor to that area of its business to which this Agreement is related, whether by merger, sale of assets, sale of stock, reorganization or otherwise.

D. Severability: If any provision of this Agreement shall be invalid or unenforceable in any

jurisdiction, such invalidity or unenforceability shall not affect the validity or enforceability of the remainder of this Agreement or the validity or enforceability of this Agreement in any other jurisdiction, and the Parties shall negotiate in good faith to modify such provision so that it is valid and enforceable to the Parties.

E. Counterparts: This Agreement may be executed in one or more counterparts, each of which shall be deemed an original document, and all of which, shall be deemed one instrument. Such counterparts may be exchanged by facsimile (provided that each executed counterpart is transmitted in one complete transmission), or in Portable Document Format (PDF). Where there is an exchange of executed counterparts by facsimile or PDF, each Party shall be bound by the Agreement notwithstanding that original copies of the Agreement may not be exchanged immediately.

F . Excusable Delay: If either Party shall be delayed, interrupted or prevented from the performance of any obligation hereunder by reason of an act of God, fire, flood, war (declared or undeclared), public disaster, strike or labor dispute, governmental enactment, rule or regulation, or any other cause beyond such Party's reasonable control, such Party shall not be liable to the other and the time for performance of such obligation shall be extended for a period equal to the duration of the contingency that occasioned the delay, interruption or prevention. In relation to any Services, if such interruption lasts more than ten (10) days, SPONSOR, in its sole discretion, may exercise its rights under Article 13 of this Agreement.

G. Further Action. Each Party hereto shall take, or cause to be taken, all actions, and do, or cause to be done, all things necessary, proper or advisable under applicable laws and regulations (including without limitation those regulations promulgated by the U.S. Internal Revenue Service), and execute and deliver such further documents as may be reasonably requested by the other Party in connection with the operation of this Agreement.

H . Relationship of the Parties: SUPPLIER has no authority from and will not authorize or bind SPONSOR to any obligation with any third party.

I . SPONSOR Materials. SUPPLIER agrees to use reasonable care in handling the equipment, materials and other property of SPONSOR entrusted to SUPPLIER's care or purchased with SPONSOR funds in performance of this Agreement along with all materials constituting Work Product hereunder (collectively, "SPONSOR Materials"). All SPONSOR Materials shall be and remain SPONSOR's property. Such SPONSOR Materials shall be plainly marked or otherwise adequately identified by SUPPLIER as Sponsor's property and shall be safely stored separate and apart from SUPPLIER's property. Unless otherwise agreed to in writing by SPONSOR on a case-by-case basis, SUPPLIER shall use SPONSOR Materials only for the benefit of SPONSOR under this Agreement and shall not use SPONSOR Materials for any other purpose. All SPONSOR Materials, while in SUPPLIER's custody or control, shall be held at SUPPLIER's risk, shall be kept insured by SUPPLIER at SUPPLIER's expense in an amount equal to the replacement cost with loss payable to SPONSOR and shall be subject to removal at SPONSOR's written request, in which event SUPPLIER shall prepare such SPONSOR Materials for shipment and redeliver to SPONSOR in the same condition as originally received or produced by SUPPLIER, reasonable wear and tear excepted, at SPONSOR's expense (unless otherwise set forth in the applicable Project Proposal/SOW). SUPPLIER agrees to keep the equipment constituting SPONSOR Materials at all times in good and efficient working order for use in performing the Services. SUPPLIER shall be responsible for routine maintenance and calibration of all such equipment, but SPONSOR shall be responsible for the cost of calibration, repairing or replacing such equipment, except to the extent such repairs or replacement are required due to SUPPLIER's breach of this Agreement (including this Section) or SUPPLIER's negligence or willful misconduct. Upon completion of the Services, termination or expiration of this Agreement SUPPLIER will, at SPONSOR's request, return all SPONSOR Materials.

J. Reports. SUPPLIER agrees that at SPONSOR's request, SUPPLIER will submit reports summarizing its work performed pursuant to this Agreement.

K. Section Headings: Article and section headings are intended for the purpose of description only and shall not be used for purposes of interpretation of this Agreement.

L. Survival: The provisions of this Article 19 shall survive the expiration or sooner termination of this Agreement.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement effective as of the Effective Date.

Kala Pharmaceuticals, Inc.		**Alliance Contract Pharma, LLC**	
By:	/s/ Vincent R. Kosewski	By:	/s/ Stephen Schweibenz
Name:	Vincent R. Kosewski	Name:	Stephen Schweibenz
Title:	Sr. VP Mfg & Supply	Title:	President
Date:	October 10, 2017	Date:	October 4, 2017

Project Proposal/SOW:

The following two exhibits (Exhibit A (Revision 03) and Exhibit C (Revision 03)) are attached to this Amended and Restated Master Service Agreement dated October 4, 2017. Included in each of these exhibits are the following activities supporting the manufacturing and packaging of [**] packaged in [**]:

Exhibit A (Revision 03)

ACP will [**].

Exhibit B (Cancelled)

[**]

Exhibit C (Revision 03)

ACP will [**].

KALA PHARMACEUTICALS, INC.
PROJECT PROPOSAL NUMBER: Q100309

STATEMENT OF WORK
API AND COMPONENT RELEASE TESTING / [**]
ENGINEERING BATCH MANUFACTURING
EXHIBIT A (Revision 03) [1]

This Project Proposal/SOW is incorporated into the Amended and Restated Master Services Agreement ("Agreement"), dated October 4, 2017 by and between Alliance Contract Pharma, LLC, ("SUPPLIER" or "ACP") and Kala Pharmaceuticals., Inc. ("SPONSOR" or "Kala"). This Statement of Work describes Services and deliverables to be performed and provided by SUPPLIER pursuant to the Agreement. If any item in this Project Proposal/SOW is inconsistent with the Agreement, the terms of this Project Proposal/SOW will control, but only if this Project Proposal/SOW expressly refers to the Parties' intent to alter the terms of this Agreement with respect to the specific inconsistent item. All capitalized terms used and not expressly defined in this Project Proposal/SOW will have the meanings given to them in the Agreement.

[1] **Note: STATEMENT OF WORK - EXHIBIT A (Revision 03) supersedes the original approved version of EXHIBIT A (dated 27 Jan2017). Reference payment terms listed on page 13 of 13.**

The total cost of the project is $[**]

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 12 pages were omitted. [**]

IV. Project Logistics

1. All shipping charges associated with this project will be at the expense of [**].

2. Unless expressly set forth in this Project Proposal/SOW or agreed to in writing by Kala on a case-by case basis, ACP shall be solely responsible for all costs and expenses in connection with any construction or build-out of ACP's facilities, including any construction or build-out necessary for ACP to perform the Services hereunder.

3. All materials being shipped to ACP must be shipped to the following address: Alliance Contract Pharma, LLC, 1510 Delp Drive, Harleysville, PA 19438 (Reference Q100309 - Exhibit A (Revision 03)).

4. Unless otherwise agreed in writing signed by ACP and Kala, Services hereunder are expressly limited to the terms and conditions contained in this Project Proposal/SOW and the Agreement.

V. Schedule of Payments

The total cost for this project is $[**]. If acceptable, please return an approved copy of this proposal along with a purchase order to initiate this project. The remainder of the cost [**] will be invoiced based on the following payment schedule.

- Initiation of Project (Payment Already Received) [**]

• Pass through costs for the Sourcing of Components to be Billed Monthly [**]	[**]
• Pass through costs for API and Excipient Release Testing to be Billed Monthly [**]	[**]
• Release of Materials and Components [**]	[**]
• Completion of Equipment Return and Qualification Activities [**]	[**]
• Completion of R&D Engineering Batch [**][**]	[**]
• Completion of R&D Engineering Batch [**][**]	[**]
• **As requested by Kala, a change control will be issued to manufacture and perform release testing of additional R&D Engineering Batches. These additional batches will be manufactured and tested as a part of the ongoing [**] batch campaign as outlined in this quotation (additional major cleaning will not be required). This change control will also include, as required, additional costs associated with documentation or testing changes as requested by Kala.**	[**]

IN WITNESS WHEREOF, the Parties hereto have executed this Project Proposal/SOW effective as of the date last signed by a Party hereto.

Kala Pharmaceuticals, Inc.		**Alliance Control Pharma, LLC**	
By:	/s/ Vincent R. Kosewski	By:	/s/ Stephen L. Schweibenz
Name:	Vincent R. Kosewski	Name:	Stephen L. Schweibenz
Title:	Sr. VP Mfg & Supply	Title:	President
Date:	October 5, 2017	Date:	October 4, 2017

KALA PHARMACEUTICALS, INC.
PROJECT PROPOSAL NUMBER: Q100309

STATEMENT OF WORK
[**] VALIDATION BATCH MANUFACTURING
EXHIBIT C (Revision 03)[1]

This Project Proposal/SOW is incorporated into the Amended and Restated Master Services Agreement ("Agreement"), dated October 4, 2017, by and between Alliance Contract Pharma, LLC, ("SUPPLIER" or "ACP") and Kala Pharmaceuticals., Inc. ("SPONSOR" or "Kala"). This Statement of Work describes Services and deliverables to be performed and provided by SUPPLIER pursuant to the Agreement. If any item in this Project Proposal/SOW is inconsistent with the Agreement, the terms of this Project Proposal/SOW will control, but only if this Project Proposal/SOW expressly refers to the Parties' intent to alter the terms of this Agreement with respect to the specific inconsistent item. All capitalized terms used and not expressly defined in this Project Proposal/SOW will have the meanings given to them in the Agreement.

This Project Proposal/SOW previous approved version included a clause stating the proposal was on hold pending the condition of positive completion of clinical trials, as determined by Kala in its sole discretion. This revision serves as written acknowledgement by both parties to commence activities of this Exhibit C (revision 03).

[1] **Note: STATEMENT OF WORK - EXHIBIT C (Revision 03) supersedes the original approved version of EXHIBIT C (dated January 27, 2017). Reference payment terms listed on page 9 of 9.**

The total cost of the project is $[**].

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 10 pages were omitted. [**]

IV. Project Logistics

- All shipping charges associated with this project will be at the expense of [**].
- Unless expressly set forth in this Project Proposal/SOW or agreed to in writing by Kala on a case-by-case basis, ACP shall be solely responsible for all costs and expenses in connection with any construction or build-out of ACP's facilities, including any construction or build-out necessary for ACP to perform the Services hereunder.
- All materials being shipped to ACP must be shipped to the following address: Alliance Contract Pharma, LLC, 1510 Delp Drive, Harleysville, PA 19438 (Reference Q100309).
- Unless otherwise agreed in writing signed by ACP and Kala, Services hereunder are expressly limited to the terms and conditions contained in this Project Proposal/SOW and the Agreement.

V. Schedule of Payments

The total cost of this project is $[**]. If acceptable, please return an approved copy of this proposal along with a purchase order number and an initial payment [**] as detailed below to initiate this project. The remainder of the cost [**] will be invoiced based on the following payment schedule.

- Approval of Validation Protocols [**]
- Completion of Manufacturing Validation Batch [**] [**]
- Completion of Manufacturing Validation Batch [**] [**]
- Completion of Manufacturing Validation Batch [**] [**]
- Completion of Validation Reports [**]
- Pass through costs for Micro Release Testing to be Billed Monthly [**]

IN WITNESS WHEREOF, the Parties hereto have executed this Project Proposal/SOW effective as of the date last signed by a Party hereto.

Kala Pharmaceuticals, Inc.		**Alliance Contract Pharma, LLC**	
By:	/s/ Vincent R. Kosewski	By:	/s/ Stephen L. Schweibenz
Name:	Vincent R. Kosewski	Name:	Stephen L. Schweibenz
Title:	Sr. VP Mfg & Supply	Title:	President
Date:	October 5, 2017	Date:	October 4, 2017

KALA PHARMACEUTICALS, INC.
PROJECT PROPOSAL NUMBER: Q100309

STATEMENT OF WORK

GMP PACKAGING OF [**]
[**]

EXHIBIT D (Revision 01)

This Project Proposal/SOW is incorporated into the Amended and Restated Master Services Agreement ("Agreement"), dated October 4, 2017 by and between Alliance Contract Pharma, LLC, ("SUPPLIER" or "ACP") and Kala Pharmaceuticals., Inc. ("SPONSOR" or "Kala"). This Statement of Work describes Services and deliverables to be performed and provided by SUPPLIER pursuant to the Agreement. If any item in this Project Proposal/SOW is inconsistent with the Agreement, the terms of this Project Proposal/SOW will control, but only if this Project Proposal/SOW expressly refers to the Parties' intent to alter the terms of this Agreement with respect to the specific inconsistent item. All capitalized terms used and not expressly defined in this Project Proposal/SOW will have the meanings given to them in the Agreement.

Included in Exhibit D is the GMP packaging of the following batches of [**]:

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 10 pages were omitted. [**]

IV. Project Logistics

1. All shipping charges associated with this project will be at the expense of [**].

2. [**].

3. Unless expressly set forth in this Project Proposal/SOW or agreed to in writing by Kala on a case-bycase basis, ACP shall be solely responsible for all costs and expenses in connection with any construction or build-out of ACP's facilities, including any construction or build-out necessary for ACP to perform the Services hereunder.

4. All materials being shipped to ACP must be shipped to the following address: Alliance Contract Pharma, LLC, 1510 Delp Drive, Harleysville, PA 19438 (Reference 0100309 – Exhibit D (Revision 00)).

5. Unless otherwise agreed in writing signed by ACP and Kala, Services hereunder are expressly limited to the terms and conditions contained in this Project Proposal/SOW and the Agreement.

V. Schedule of Payments

The total cost for this project is $[**]. If acceptable, please return an approved copy of this proposal along with a purchase order to initiate this project. The remainder of the cost [**] will be invoiced based on the following payment schedule.

- Initiation of Project [**]
- Pass through costs for the Sourcing of Components to be Billed Monthly [**] [**]
- Pass through costs for Excipient and Component Release Testing to be Billed Monthly [**] [**]
- Completion of Packaging - Campaign [**] [**]
- Completion of Packaging - Campaign [**] [**]
- Completion of Packaging - Campaign [**] [**]
- Completion of Packaging - Campaign [**] (the first [**] resupply batch) [**]
- **The Cost for Each Additional [**] Resupply Batch ([**]/batch)**
  (Due upon the completion of packaging) **[**]**

IN WITNESS WHEREOF, the Parties hereto have executed this Project Proposal/SOW effective as of the date last signed by a Party hereto.

Kala Pharmaceuticals, Inc.		**Alliance Contract Pharma, LLC**	
By:	/s/ Vincent R. Kosewski	By:	/s/ Dennis DiBiagio
Name:	Vincent R. Kosewski	Name:	Dennis DiBiagio
Title:	Sr. VP Mfg & Supply	Title:	VP, Operations
Date:	Nov. 9, 2017	Date:	November 8, 2017

Exhibit 10.21

EXECUTION VERSION

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

FIRST AMENDMENT TO THE COMMERCIAL SUPPLY AGREEMENT

This First Amendment to Commercial Supply Agreement (the "**First Amendment**") is made as of **February 16, 2018** ("**First Amendment Effective Date**") by and between Kala Pharmaceutical Inc. a Delaware corporation with offices located at 100 Beaver Street, #201, Waltham, Massachusetts 202453 USA ("**Client**") and Catalent Pharma Solutions, LLC, a Delaware corporation with offices located at 14 Schoolhouse Road, Somerset, New Jersey 08873 ("**Catalent**"). Each of Client and Catalent may be referred to as a Party, and collectively as the Parties.

WHEREAS, the Parties entered into a Commercial Supply Agreement dated June 27, 2016 (the "**Agreement**"), pursuant to which Catalent provides services to Client; and

WHEREAS, the Parties wish to amend certain terms of the Agreement;

NOW, THEREFORE, in consideration of the mutual promises contained herein, and for good and valuable consideration, the receipt and sufficiency thereof are hereby acknowledged, the Parties do hereby agree as follows:

1. All capitalized terms used herein but not otherwise defined have the same meaning as set forth in the Agreement.

2. The Parties hereby agree to amend and replace Attachment C with the revised Attachment C, attached hereto.

3. This First Amendment may be executed in counterparts, each of which is deemed an original, but all of which constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties hereto have duly executed this First Amendment as of the First Amendment Effective Date.

Kala Pharmaceuticals, Inc.	**Catalent Pharma Solutions, LLC**
By: /s/ Vincent R. Kosewski	By: /s/ Roy Satchell
Name: Vincent R. Kosewski	Name: Roy Satchell
Title: Sr. VP Mfgr & Supply	Title: SVP R&D
By: /s/ Hongming Chen	
Name: Hongming Chen, ScD	
Title: Chief Scientific Officer	

ATTACHMENT C

UNIT PRICING, FEES AND MINIMUM REQUIREMENT

Commercial pricing for 1st year surgical products at smaller batches:

KPI-121, 1% Surgical Product	**Sterile Topical Eye Drops: 3.2 mL fill in 5 cc multidose bottle in [**] L batches**	**[**]**	**[**]**	**[**]**
		[**]	**[**]**	**[**]**
		[**]	**[**]**	**[**]**

- [**] batches per campaign
- No split batches at the [**]L scale, batch can be run to fill either trade or physician samples

Commercial Unit Pricing after scale up				
Product	**Dosage Form / Unit Strength**	**Annual Unit Tiers**	**Bulk Price**	**Fully Packaged[1]**
KPI-121, 1% Surgical Product	**Sterile Topical Eye Drops: 3.2 mL fill in 5 cc multidose bottle in [**] L batches**	**[**]**	**[**]**	**[**]**
		[**]	**[**]**	**[**]**
		[**]	**[**]**	**[**]**
KPI-121, 0.25% Dry Eyes Product	**Sterile Topical Eye drops/8.2 mL fill in a 10 cc multidose bottle in [**]L Batches**	**[**]**	**[**]**	**[**]**
		[**]	**[**]**	**[**]**
		[**]	**[**]**	**[**]**

- Minimum yield criteria will not apply at this scale
- Development of scaled-up process, and scaled up PV batches, will be conducted by 1 year after small scale PV batches are completed

Sublotting for finished Products				
Product	**Sublotting Samples[2]**		**Bulk Price**	**Fully Packaged[1]**
KPI-121, 1% Surgical Product	Sterile Topical eye drops - Sample -11.5 mL in 5 cc multidose bottle	**Sublotting Fee/Batch**	**[**]**	**[**]**
KPI-121, 0.25% Dry Eyes Product	**Sterile Topical Eye drops - Sample - 2.7mL in a 10ml cc multidose bottle**			

[1] Packaging will consist of wrap around label, individual carton and insert

[2] The minimum for a sublotted batch will be [**] percent ([**]%) of total units in a Batch.

- One unit (**"Unit"**) is one multi-dose bottle of 5cc or 10cc containing 1.5ml, 2.7ml, 3.2 mL or 8.2mL of Product.
- [**].

MINIMUM REQUIREMENT		
Minimum Requirement Year	**Aggregate Product Minimum Requirement**	
	1% Surgical Product, Units (MM)	0.25% Dry Eyes Product, Units (MM)
Minimum Requirement Year 1*	[**]	[**]
Minimum Requirement Year 2	[**]	[**]
Minimum Requirement Year 3	[**]	[**]
Minimum Requirement Year 4	[**]	[**]
Minimum Requirement Year 5	[**]	[**]
Minimum Requirement Year 6	[**]	[**]
Minimum Requirement Year 7	[**]	[**]
Minimum Requirement Year 8	[**]	[**]

*Any Units purchased by Client for resale shall count towards the Minimum Requirement, even if purchased by Client prior to Minimum Requirement Year 1.

Exhibit 21.1

Subsidiaries of the Registrant

Name	Jurisdiction of Organization
Kala Pharmaceuticals Security Corporation	Massachusetts

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-219403 on Form S-8 of our report dated April 2, 2018, relating to the consolidated financial statements of Kala Pharmaceuticals, Inc. and subsidiaries appearing in this Annual Report on Form 10-K of Kala Pharmaceuticals, Inc. for the year ended December 31, 2017.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
April 2, 2018

Exhibit 31.1

CERTIFICATIONS

I, Mark Iwicki, certify that:

1. I have reviewed this Annual Report on Form 10-K of Kala Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

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

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

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

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

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

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

Date: April 2, 2018

/s/ Mark Iwicki
Mark Iwicki
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATIONS

I, Mary Reumuth, certify that:

1. I have reviewed this Annual Report on Form 10-K of Kala Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

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

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

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

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

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

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

Date: April 2, 2018

/s/ Mary Reumuth
Mary Reumuth
Chief Financial Officer
(principal financial and accounting officer)

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of Kala Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Mark Iwicki, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of her knowledge on the date hereof:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 2, 2018

/s/ Mark Iwicki
Mark Iwicki
President and Chief Executive Officer
(principal executive officer)

Exhibit 32.2

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

In connection with the Annual Report on Form 10-K of Kala Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Mary Reumuth, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge on the date hereof:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 2, 2018

/s/ Mary Reumuth
Mary Reumuth
Chief Financial Officer
(principal financial and accounting officer)