

PROSPECTUS



654,610 Shares of Common Stock

This prospectus relates to the possible resale, from time to time, by the selling stockholders identified in this prospectus of up to 654,610 shares of our common stock, par value \$0.01 per share (the “Common Stock”), that are issuable upon exercise of presently issued and outstanding warrants to purchase common stock that were issued to the selling stockholders in a private placement on November 22, 2022 (the “Private Placement”).

The selling stockholders may offer the shares from time to time as each selling stockholder may determine through public or private transactions or through other means described in the section entitled “Plan of Distribution” or a supplement to this prospectus. Each selling stockholder may also sell shares under Rule 144 under the Securities Act of 1933, as amended, if available, rather than under this prospectus.

The registration of these shares does not necessarily mean that any holders will sell any of their shares or exercise their warrants. We are not offering for sale any shares of our Common Stock pursuant to this prospectus. We will not receive any proceeds from the sale of these shares. We will, however, receive cash proceeds equal to the total exercise price of warrants that are exercised for cash.

Our Common Stock is listed on The Nasdaq Capital Market under the symbol “KPRX.” On December 27, 2022, the closing price for our Common Stock, as reported on The Nasdaq Capital Market, was \$2.45 per share.

You should read this prospectus, together with additional information described under the headings “Incorporation of Certain Information by Reference” and “Where You Can Find More Information,” carefully before you invest in our common stock.

Investing in our securities involves a high degree of risk. See “Risk Factors” beginning on page 21 of this prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus, for a discussion of information that should be considered in connection with an investment in our securities.

Neither the U.S. Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is December 28, 2022

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS	i
PROSPECTUS SUMMARY	1
THE OFFERING	20
RISK FACTORS	21
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	54
MARKET FOR COMMON STOCK	56
DIVIDEND POLICY	56
USE OF PROCEEDS	57
SELLING STOCKHOLDERS	58
PLAN OF DISTRIBUTION	61
DETERMINATION OF OFFERING PRICE	63
DESCRIPTION OF OUR CAPITAL STOCK	64
LEGAL MATTERS	67
EXPERTS	67
WHERE YOU CAN FIND MORE INFORMATION	67
INCORPORATION OF CERTAIN INFORMATION BY REFERENCE	68

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we have filed with the Securities and Exchange Commission (the “SEC”) pursuant to which the selling stockholders named herein may, from time to time, offer and sell or otherwise dispose of the securities covered by this prospectus. You should not assume that the information contained in this prospectus is accurate on any date subsequent to the date set forth on the front cover of this prospectus or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus is delivered or securities are sold or otherwise disposed of on a later date. It is important for you to read and consider all information contained in this prospectus, including the Information Incorporated by Reference herein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you under the captions “Where You Can Find More Information” and “Incorporation of Information by Reference” in this prospectus.

Neither we nor the selling stockholders have authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus. This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any of our securities other than the securities covered hereby, nor does this prospectus constitute an offer to sell or the solicitation of an offer to buy any securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about, and to observe, any restrictions as to the offering and the distribution of this prospectus applicable to those jurisdictions.

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market share, is based on information from our own management estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. Our management estimates have not been verified by any independent source, and we have not independently verified any third-party information. In addition, assumptions and estimates of our and our industry’s future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in “Risk Factors.” These and other factors could cause our future performance to differ materially from our assumptions and estimates. See “Special Note Regarding Forward-Looking Statements.”

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to the registration statement of which this prospectus is a part were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

We have proprietary rights to trademarks used in this prospectus, including Kiora®. Solely for our convenience, trademarks and trade names referred to in this prospectus may appear without the “®” or “™” symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent possible under applicable law, our rights or the rights to these trademarks and trade names. We do not intend our use or display of other companies’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies. Each trademark, trade name, or service mark of any other company appearing in this prospectus is the property of its respective holder.

PROSPECTUS SUMMARY

The following summary highlights information contained elsewhere in this prospectus. It may not contain all of the information that is important to you. You should read the entire prospectus carefully, especially the discussion regarding the risks of investing in our securities under the heading “Risk Factors” and our financial statements and the related notes in our Amended Annual Report on Form 10-K/A for the fiscal year ended December 31, 2021 filed with the SEC on July 7, 2022 and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 filed with the SEC on November 9, 2022, before investing in our securities. All references to “Company” “we,” “our” or “us” refer solely to Kiora Pharmaceuticals, Inc. and its subsidiaries and not to the persons who manage us or sit on our Board of Directors.

Overview

We are a clinical-stage specialty pharmaceutical company developing therapies for the treatment of ophthalmic diseases. We were formed as a Delaware corporation on December 26, 2004 under the name of EyeGate Pharmaceuticals, Inc., and changed our name to Kiora Pharmaceuticals, Inc. effective November 8, 2021. We were originally incorporated in 1998 under the name of Optis France S.A. in Paris, France.

Our lead product is KIO-301 with an initial focus on patients with later stages of disease progression due to Retinitis Pigmentosa (any and all sub-forms). KIO-301 is a potential vision-restoring small molecule that acts as a “photoswitch” specifically designed to restore vision in patients with inherited and age-related degenerative retinal diseases. The molecule is specifically designed to restore the eyes’ ability to perceive and interpret light in visually impaired patients. It selectively enters viable downstream retinal ganglion cells (no longer receiving electrical input due to degenerated rods and cones) and is intended to turn them into light sensing cells, capable of signaling the brain as to the presence or absence of light. We initiated a Phase 1b clinical trial in the third quarter of 2022. KIO-301 (formerly known as B-203) was acquired through the Bayon Therapeutics, Inc. (“Bayon”) transaction which closed October 21, 2021.

KIO-101 is a product that focuses on patients with Ocular Presentation of Rheumatoid Arthritis (“OPRA”). KIO-101 is a next-generation, non-steroidal, immunomodulatory, small-molecule inhibitor of Dihydroorotate Dehydrogenase (“DHODH”) with what we believe to be best-in-class picomolar potency and a validated immune modulating mechanism designed to overcome the off-target side effects and safety issues associated with commercially available DHODH inhibitors. In a 14-Day GLP intravenous (IV) repeated dose toxicity study in rats, no adverse or test item related effects were observed in any of the tested parameters (mortality, clinical observations, ophthalmoscopy, body weight and food consumption, hematology and coagulation, clinical biochemistry, organ weight, pathology and histopathology) at the highest doses tested (1.0 mg/kg). In the fourth quarter of 2021, we reported topline safety and tolerability data from a Phase 1b proof-of-concept (“POC”) study evaluating KIO-101 in patients with ocular surface inflammation. As a further sign of safety, there were zero clinically significant laboratory (including liver enzymes) findings observed in both healthy patients and those with ocular surface inflammation. We initiated a Phase 2 clinical trial in the second half of 2022. KIO-101 (formerly known as PP-001) was acquired through the acquisition of Panoptes Pharma Ges.m.b.H “Panoptes” in the fourth quarter of 2020.

In addition, we are developing KIO-201, for patients with Persistent Corneal Epithelial Defects and patients recovering from surgical wounds, such as those undergoing photorefractive keratectomy (“PRK”) surgery. KIO-201 is a modified form of the natural polymer hyaluronic acid, designed to protect the ocular surface to permit re-epithelialization of the cornea and improve and maintain ocular surface integrity. KIO-201 has unique properties that help hydrate and protect the ocular surface.

Market Opportunity

Retinitis Pigmentosa Market Overview

More than 3.4 million patients globally are estimated to have an inherited retinal disease leading to significant or permanent vision loss. Retinitis Pigmentosa (“RP”), the largest family of these inherited diseases, had a global prevalence of 2.3 million in 2019. RP is a group of hereditary progressive disorders that may be inherited as autosomal recessive, autosomal dominant or X-linked recessive traits. About half of all RP cases are isolated (that is, they have no family history of the condition). RP may appear alone or in conjunction with one of several other rare disorders. Patients with RP have a progressive loss of photoreceptors (rods and cones) and therefore patients with late-stage RP have a substantial loss of peripheral and central visual function.

RP affects about 1 in 3,500 people worldwide. Thus, with a population of about 328 million in the United States as of December 2019, about 93,700 people in the U.S. have RP. With a worldwide population presently estimated at over 7.05 billion, it can be estimated that approximately 2 million people around the world have RP. Multiple products in development for RP have received Orphan Drug Designation in the U.S., including KIO-301, as described further below.

While no approved therapies are available for the treatment of RP, current therapeutics in development primarily rely on genetic approaches to introduce light sensing channels into viable downstream cells, a field termed optogenetics. KIO-301 is a small molecule photoswitch, that confers light sensitivity to downstream cells, specifically the Retinal Ganglion Cells (“RGC”s), potentially triggering the same phototransduction signaling as if the photoreceptors were present and viable.

Our Solution: KIO-301

KIO-301 is a novel small molecule with the potential to confer light sensitivity to patients with degenerated retinas due to either inherited or age-related diseases, which has received Orphan Drug Designation from the U.S. FDA. Many retinal diseases result in the death of the retinal photoreceptors, the light sensing cells in the retina. However, downstream retinal neurons, such as the bipolar and RGCs remain viable for long periods after photoreceptor death. KIO-301 selectively enters these cells and non-covalently resides on the intracellular domains of potassium and HCN voltage gated ion channels. As KIO-301 has an azobenzene core, visible light causes a rapid and reversible change in the isomeric state of the molecule, transforming from a linear molecule to an orthogonal molecule. When this happens, the voltage gated ion channels and current efflux are blocked, causing cellular depolarization and signaling to the brain as to the presence of light. When light is no longer touching the molecule, it reverts back to its linear state, allowing ion efflux from the cells and thus promoting repolarization and a turning “off” of the brain signaling.

This novel mechanism of action enables potential application to multiple diseases. RP is a group of inherited eye diseases that cause photoreceptor cell death. In the U.S., RP is considered an orphan disease with a prevalence of <200,000. This prevalence enables consideration for KIO-301 to qualify for Orphan Drug Designation (“ODD”) in the treatment of RP, conferring increased regulatory collaboration with the FDA and market exclusivity if clinical trials demonstrate safety and efficacy. On March 17, 2022, we were granted Orphan Drug Designation by the U.S. FDA for the active ingredient in KIO-301. Currently, no therapeutics are approved to treat patients with RP.

A possible market expansion from RP would be to evaluate KIO-301 in patients with Geographic Atrophy (“GA”), the late stage of age-related dry macular degeneration. There are about 1,000,000 patients in the U.S. with GA and to date, no therapeutics are approved to treat this disease.

Ocular Presentation of Rheumatoid Arthritis Market Overview:

Patients with systemic autoimmune diseases including Rheumatoid Arthritis (“RA”), are known to suffer from ocular presentation of their underlying autoimmune conditions. Secondary to inflammation and associated pathologies in the joint synovium, the eye carries significant morbidity and impact on eye health and quality of life. These ocular presentations can include signs and symptoms similar to keratoconjunctivitis sicca (“KCS”), episcleritis, scleritis, peripheral ulcerative keratitis (“PUK”), anterior uveitis, as well as retinal vasculitis. In patients with OPRA, the surface of the eye often has significant irritation accompanied by symptoms of soreness, grittiness, light sensitivity and dryness. Patients with RA suffer from ocular signs and symptoms at a rate reported to be 2-3X that of the general population. Furthermore, in those OPRA patients, up to 50% report moderate to severe signs and symptoms. Today, there are approximately 1.8 million RA patients in the USA. Approximately 1/3 rd of these patients present with OPRA (~0.5 million in the USA), with >90% seeking prescription medication to address these ophthalmic manifestations. Unfortunately, currently available ocular surface anti-inflammatory medicines are usually not sufficient to treat OPRA as they are broad and not targeted to the underlying pathophysiology.

As noted above, KIO-101 is a member of a family of DHODH inhibitors, known to be disease modifying agents in certain autoimmune diseases. RA, as well as OPRA, are t-cell mediated auto-inflammatory diseases and whilst rheumatologists are helping the systemic manifestations of this disease with approved targeted t-cell modulators, including DHODH inhibitors, ophthalmologists do not have the same toolbox of treatments designed specifically to help patients with ocular presentation.

Our Solution: KIO-101

KIO-101 is a third-generation small molecule DHODH inhibitor. We are using the term ‘third-generation’ to refer to the fact that the first-generation drug approved was leflunomide (a DHODH inhibitor) and the second-generation drug approved was teriflunomide (the active metabolite of leflunomide and also a DHODH inhibitor). Thus, KIO-101 would be a third-generation drug currently in development. DHODH is extensively exploited as potential drug targets for immunological disorders, oncology, and infectious diseases. DHODH is a key enzyme in the de novo pyrimidine synthesis pathway. This enzyme is located in the mitochondria and catalyzes the conversion of dihydroorotate (“DHO”) to orotate as the fourth step in the de novo synthesis of pyrimidines that are ultimately used in the production of nucleotides.

Nucleotides are required for cell growth and replication. Nucleotides are the activated precursors of nucleic acids and are necessary for the replication of the genome and the transcription of the genetic information into RNA. Nucleotides also serve as an energy source for a more select group of biological processes (ATP and GTP). They also play a role in the formation of glycogen, signal-transduction pathways, and as components of co-enzymes (NAD and FAD). An ample supply of nucleotides in the cell is essential for all cellular processes.

There are two pathways for the biosynthesis of nucleotides: salvage and de novo. The main difference is where the nucleotide bases come from. In the salvage pathway, the bases are recovered (salvaged) from RNA and DNA degradation. In the de novo pathway, the bases are assembled from simple precursor molecules (made from scratch).

One critical requirement of fast-growing or proliferating cells, such as the expansion of activated B and T-cells, cancer cells, and pathogen infected host cells, is the requirement of an abundance of nucleotide bases. These metabolic activities will predominately utilize the de novo pathway for nucleotide biosynthesis. A key advantage of DHODH inhibition is the selectivity towards metabolically activated cells (with a high need for RNA and DNA production), which should mitigate any negative impact on normal cells. Depletion of cellular pyrimidine pools through the selective inhibition of DHODH has been shown to be a successful approach for therapeutic development.

Currently, two first generation DHODH inhibitors have been approved in the U.S. and abroad and are marketed by Sanofi as leflunomide (Arava®) and the active metabolite teriflunomide (Aubagio®). These oral tablets are approved for the treatment of rheumatoid and psoriatic arthritis and multiple sclerosis (“MS”), respectively. These diseases are autoimmune disorders. One potential explanation for the therapeutic effects of Arava® in arthritis is the reduction in the numbers or reactivity of activated T-cells, which are involved in the pathogenesis of arthritis. The generally accepted view of human MS pathogenesis implicates peripheral activation of myelin-specific autoreactive T-cells that lead to inflammatory disease in the central nervous system (“CNS”). By blocking the de novo pyrimidine synthesis pathway via DHODH inhibition, it is suggested that Aubagio® reduces T-cell proliferation in the periphery. Arava® and Aubagio® are formulated as oral drugs and it is established that leflunomide will be metabolized in the liver to the active metabolite teriflunomide. Hepatotoxicity was reported as a major side effect after oral administration, possibly as a result of the extent of liver metabolism. Moreover, it was shown that apart from DHODH, a series of protein kinases are inhibited by Arava® and Aubagio®.

Ocular Wound Healing Market Overview:

Normal corneal epithelial wound healing relies on rapid migration and proliferation of epithelial cells from the wound edge and the limbus, followed by extracellular matrix deposition and remodeling. Persistent corneal epithelial defects (PCED) are corneal wounds, caused by injury or disease, that do not heal within the normal time frame (usually 7 – 14 days) but persist for weeks or even months. Several underlying disease states may result in PCED, including previous herpes simplex or herpes zoster infection, neurotrophic keratitis, diabetes, and severe dry eye states. Nonhealing corneal epithelial defects may also occur after ocular surgery or other physical injuries and/or trauma to the cornea. PCEDs require intervention as they can lead to infections, stromal ulceration, corneal scarring, and opacification and result in vision loss.

There is an unmet medical need for a simple treatment that could aid in the healing of PCEDs. Current methods of addressing PCEDs include debridement and patching, applying a bandage contact lens, human amniotic membrane, autologous serum, suturing the lids via a tarsorrhaphy, or in severe cases applying a conjunctival graft over the cornea. These methods are invasive, costly, and/or merely cover the wound; none have proven universally effective for healing PCEDs and often result in a recurrence of the defect.

There are multiple surgical procedures involving the ocular surface that have long recovery, whereby acceleration of that period would benefit the patients. Photorefractive keratectomy (“PRK”) surgery is an efficacious alternative to patients seeking surgical correction of refractive errors who are not suitable candidates for LASIK due to inadequate corneal thickness, larger pupil size, history of KCS, or anterior basement membrane disease. PRK surgery involves controlled mechanical removal of corneal epithelium with subsequent excimer laser photoablation of the underlying Bowman’s layer and anterior stroma, including the subepithelial nerve plexus.

The military prefers PRK as a refractive procedure due to the stability of the PRK incision and the absence of risk for flap dislocation during military active duty. Although this procedure yields desirable visual acuity results, common complications of the procedure include post-operative pain secondary to the epithelial defects, risk of corneal infection prior to re-epithelialization of the large epithelial defect, corneal haze formation, decreased contrast sensitivity, and slower visual recovery. The number of laser vision correction procedures is on the rise, estimated in 2021 at over 2.1 million in the USA, according to the literature. Whilst PRK comprises a fraction of these procedures, there are about 160,000 surgeries performed annually in the USA. These surgeries are heavily consolidated to a few corporate umbrellas, such as TLC Laser Eye Centers, enabling a targeted commercial campaign once a therapeutic is approved.

Keratoconus is an orphan disease of the ocular surface, affecting approximately 165,000 patients in the US alone. Keratoconus progression involves the structure of the cornea which bulges outward, directly affecting vision. Whilst the etiology of the disease is unknown, there are multiple approaches to helping these patients, involving the use of vision correction prothesis such as contact lenses and glasses, to surgical approaches involving collagen cross-linking the corneal surface to provide more rigidity and slow progression. One of these corneal cross-linking approaches, termed epi-off, involves the removal of about 8 mm of the epithelium on the cornea and a riboflavin solution is applied to the exposed corneal stroma. This procedure is not free of side effects, which often include as corneal infections, subepithelial haze, sterile infiltrates, reactivation of herpetic keratitis, and endothelial damage. Thus, accelerating the re-epithelialization would carry significant value.

Our Solution: KIO-201

KIO-201 is a synthetic modified hyaluronic acid (“HA”) capable of coating the ocular surface and designed to resist degradation under conditions present in the eye. This prolongs residence time of the bandage on the ocular surface, thereby addressing one of the limitations of current non-cross-linked hyaluronic acid formulations. Additionally, cross-linking allows the product’s viscosity to be modified to meet optimum ocular needs. The improved viscoelasticity and non-covalent muco-adhesive interfacial forces improve residence time in the tear film, thus providing a coating that aids re-epithelialization of the ocular surface via physical protection. If KIO-201 is approved by the FDA, we expect that it will be the only wound healing prescription eye drop available in the U.S. based on HA.

KIO-201 exhibits significant shear thinning properties. This feature allows the modified HA to act as a more concentrated, viscous barrier at low shear rates in a resting tear film, but also as a lower resistance fluid (therefore thinned) during high shear events such as blinking. This property enables better residence time and a more favorable ocular surface coating with less optical blur. We have demonstrated in animal studies that KIO-201 remains on the ocular surface for up to two hours and further demonstrated in a human clinical study that KIO-201 does not cause blurriness while on the ocular surface. This enhances ocular surface protection and patient comfort, while maintaining good visual function.

KIO-201 has been shown to provide a mechanical barrier that aids in the management of corneal epithelial defects and re-epithelialization in both preclinical studies and in clinical ophthalmic veterinary use. As such, PRK surgery was chosen for the initial clinical trials as the subject population which is best suited to demonstrate this effect. PRK is an efficacious alternative to patients seeking surgical correction of refractive errors who are not suitable candidates for laser in situ keratomileusis (“LASIK”) due to inadequate corneal thickness, larger pupil size, history of keratoconjunctivitis sicca (“KCS”), or anterior basement membrane disease. KIO-201 has demonstrated statistical significance in a pivotal clinical study for its ability to accelerate wound healing against the current standard-of-care, a bandage contact lens. KIO-201 is currently being evaluated in a Phase 2 trial for Persistent Corneal Epithelial Defects in addition to the corneal surgical wounds.

Our Strategy

Our goal is to develop products for treating disorders of the eye. The key elements of this strategy in the near term are to:

- Development of Core Assets
 - Complete Phase 1b clinical study of KIO-301 in patients with later stage Retinitis Pigmentosa.
 - Continue clinical development of KIO-101 for the treatment of the ocular manifestations of autoimmune diseases (e.g., rheumatoid arthritis). In the fourth quarter of 2021, we announced topline safety and tolerability data in our Phase 1b study ocular surface inflammation trial, which further supports our current Phase 2 study for ocular manifestations of autoimmune diseases.
 - Complete Phase 2 clinical trial of KIO-201 for patients with PCEDs.
 - Initiate Phase 3b clinical trial for KIO-201 for patients with surgical wounds, including PRK surgery.

- Expand Portfolio through Collaborations
 - Pursue strategic collaborations to further the Company's existing assets with respect to new indication potential and more detailed mechanism of action, which can result in new intellectual property.

Our Development Pipeline

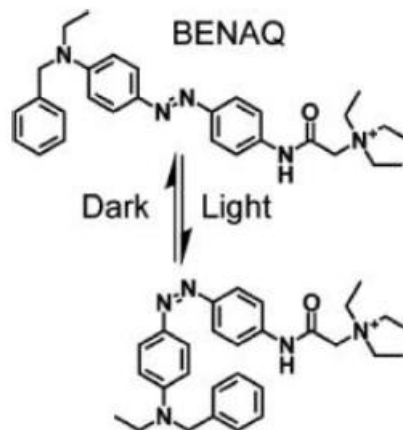
	Indication	Product Formulation	Development Stage				Anticipated Near-Term Milestones
			Pre-clinical	Phase 1	Phase 2	Phase 3	
Posterior Segment	Retinitis Pigmentosa (Mutation Agnostic)	KIO-301 IVT	Granted Orphan Drug Designation - March 2022				Initiated Phase 1b; Enrollment Ongoing
	Ocular Presentation of Rheumatoid Arthritis	KIO-101 Eye Drop					Submitted for Ethics Approval in Q4 2022
Anterior Segment	Persistent Corneal Epithelial Defects	KIO-201 Eye Drop					Phase 2 Trial in Process Expect Orphan Drug Designation in Q1 2023
	Corneal Surgical Wounds	KIO-201 Eye Drop					Expect to initiate Phase 3b in 2023

Preclinical and Clinical Development

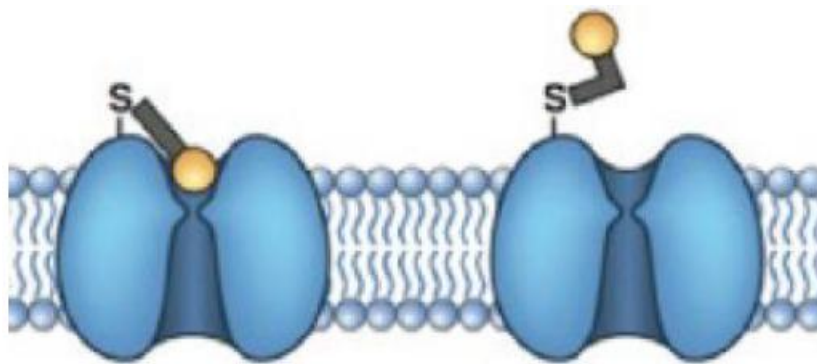
KIO-301: Retinitis Pigmentosa

Mechanism of Action

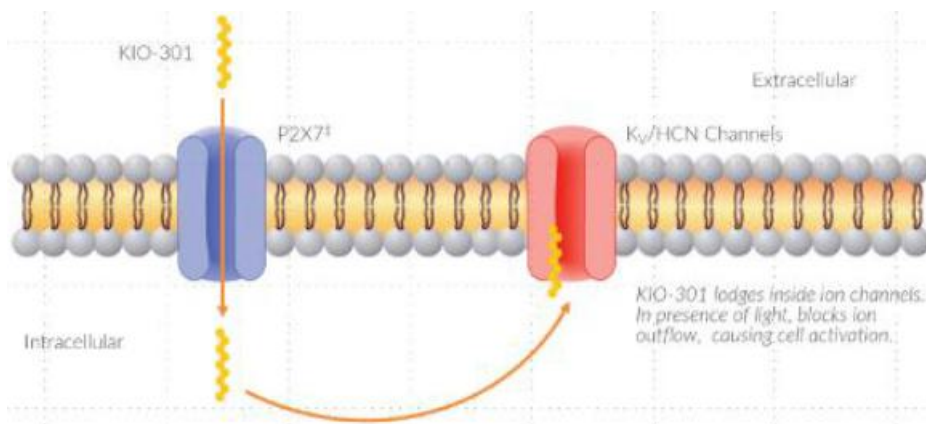
KIO-301 is a covalently modified azobenzene derivative coupled to a quaternary ammonium that undergoes wavelength-dependent cis-trans photoisomerization as shown in the figure below:



Depicted below, this photoisomerization causes light-dependent neuronal depolarization due to blockade of voltage-gated ion channels:



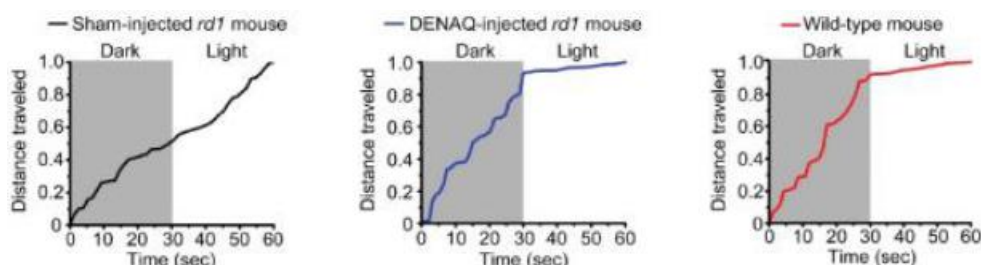
The mechanism of action of KIO-301 on degenerated retinas was obtained from 3- to 6-month-old retinal degeneration (rd1) mice, which lose nearly all rods and cones within 1 month of life. The effect of normal light on the action potential firing by RGCs was recorded using a multielectrode array (MEA). Whilst light did not elicit a change in the firing of untreated rd1 retinas, when treated with KIO-301, these degenerated retinas produced a robust and clear electrical response when exposed to light.



Pharmacology

The *ex vivo* treatment of rd1 mouse retina with KIO-301 found that the EC₅₀ to be 9.5 μ M. The photosensitization action of KIO-301 treatment appears to be specific for regions of the retina with photoreceptor degeneration as it resulted in light sensitive RGCs from degenerated retinas of various strains of blind mice, rats and dogs, but exhibited no effect on healthy retinas from wild-type animals.

An earlier generation and analog of KIO-301, known as DENAQ, was shown to enable innate and learned behavioral light responses in blind mice. Investigators used a visual-cued fear conditioning assay in rd1 mice. Mice were trained with a small electric foot shock when a light in their cage was turned on. This training induced a learned fear response to light (“freezing” behavior). Investigators used 3 groups of animals for these studies (all pre-trained to this fear response): WT mice and rd1 mice (prior to retinal degeneration) injected with either DENAQ or sham at 6 hours before training. On day 1 (training day), animals were exposed to either paired (3 trials of 10 sec light stimuli, each co-terminating with a 2 sec shock) or unpaired stimuli (the same light and shock stimuli interleaved rather than overlapping). On day 2 (recall day), the authors presented the light stimulus alone. Sample recall trial movement traces of individual sham-injected rd1 mice (left, black), DENAQ-injected rd1 mice (middle, blue) and WT mice (right, red), all of whom had been exposed to paired conditioning during day 1, are shown in below:



These results demonstrate that the light perception conferred by DENAQ allows for visual learning, first enabling mice to associate light with a fearful stimulus on day 1, and then mediating the recall of the memory on day 2.

KIO-301 uptake in RGCs being mediated by P2X receptors is further supported by the finding that the non-selective P2X receptor antagonist TNP-ATP and PPADS inhibited the photosensitization produced by KIO-301. The selective P2X7 receptor blocker A740003, reduced KIO-301-mediated photosensitization by ~50%. These findings are further supported by MEA of synaptically-isolated retinal RGCs obtained from mice 1-hour after intravitreal injection with an analog of KIO-301 alone or with P2X receptor antagonists. The analog selectively photosensitized rd1 RGCs but not wild-type (WT) RGCs. P2X receptor antagonists significantly reduced the photosensitization of rd1 RGCs when co-administered with the KIO-301 analog, but had no effect if the analog was preloaded (analog administered prior to P2X receptor antagonist) in the RGCs.

Clinical Development Plan

We initiated a first-in-man Phase 1b clinical trial to evaluate the safety, tolerability and efficacy of KIO-301 in patients with advanced Retinitis Pigmentosa. This single site, open label trial will evaluate a single intravitreal injection with dose escalation upon safety reviews.

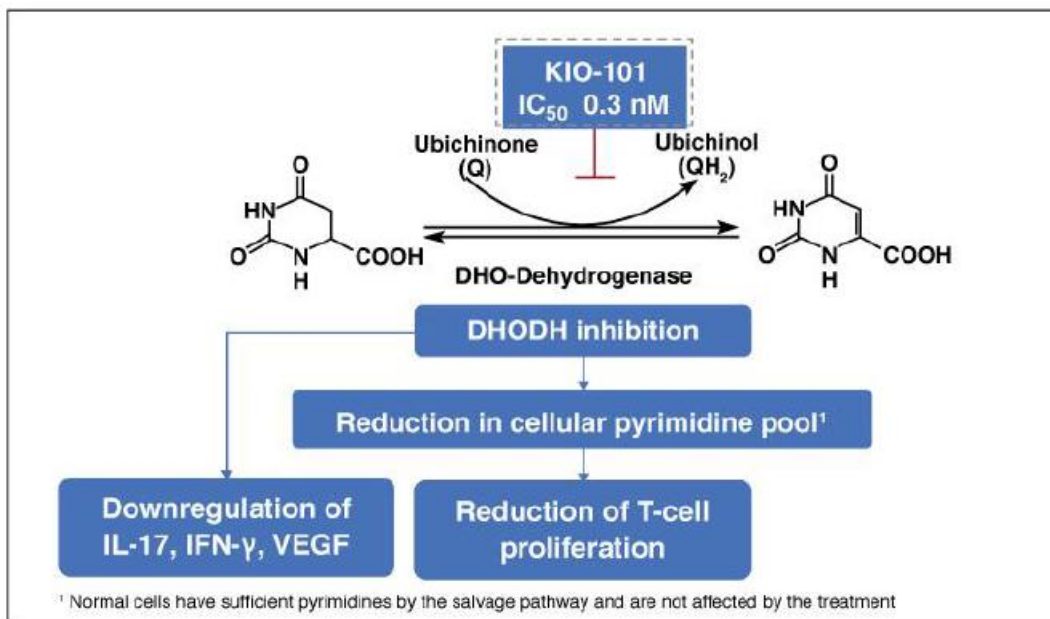
KIO-101: Ocular Presentation of Rheumatoid Arthritis (OPRA)

Mechanism of Action

KIO-101 is a promising novel third generation DHODH inhibitor, with a half-maximal inhibitory concentration IC₅₀-value of 0.3 nM. Based on internal work completed, we believe this means that 1,000-fold more potent than teriflunomide (IC₅₀ DHODH 415 nM). Furthermore, KIO-101 suppresses the expression of key pro-inflammatory cytokines such as IL-17, IFN- γ , VEGF and others, potentially as a consequence of inhibiting DHODH. IL-17 and IFN- γ are the hallmark cytokines expressed by Th1 and Th17 T-cells, respectively, and play a crucial role in initiating the inflammatory processes in several ocular diseases, including dry eye disease (including the association with autoimmune conditions such as rheumatoid arthritis) and non-infectious uveitis. KIO-101 is structurally and mechanistically different from Arava®, a drug currently approved by the FDA for the treatment of rheumatoid arthritis. The IC₅₀ of KIO-101 on selected tyrosine kinases, such as PI3K, AKT and JAK, is more than 10,000-fold above the IC₅₀ of KIO-101 for DHODH. In general, side effects are not expected and have not been observed to date in animal and human studies after KIO-101 administration.

8

The postulated mode of action of KIO-101 is depicted below.



Phase 1b:

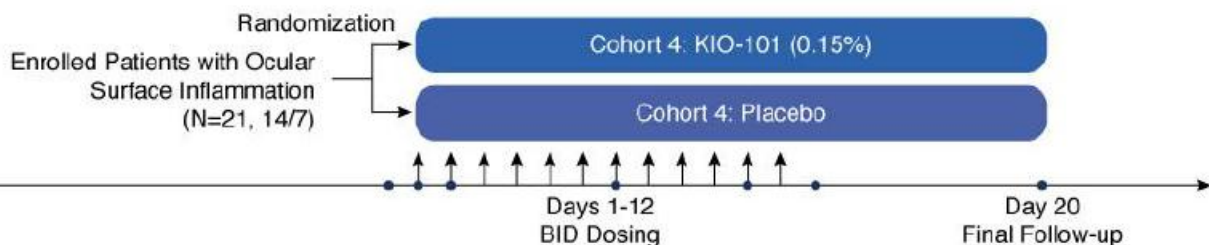
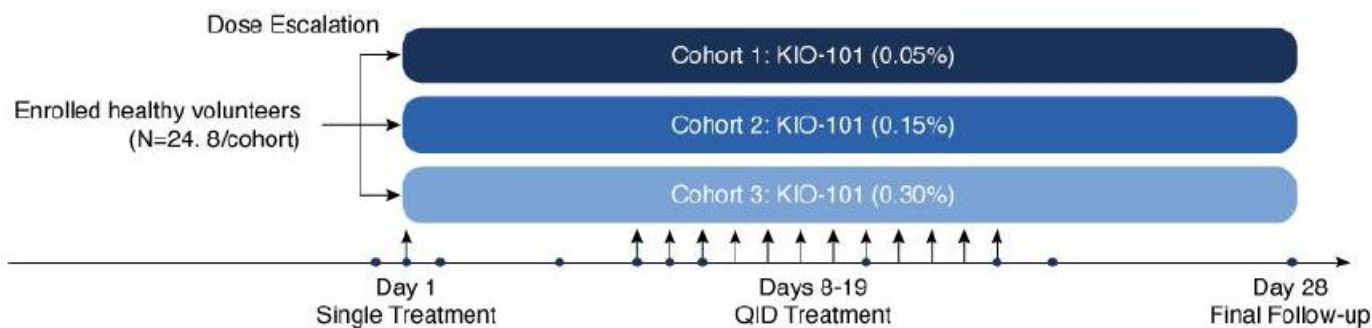
The results of a Phase 1b study of KIO-101 eye drops in adults with and without ocular surface inflammation were reported in the fourth quarter of 2021.

Design

The first part of this single center, randomized, double-masked study was to explore safety and tolerability of KIO-101 in a healthy population and the second part was to investigate a potential efficacy signal in patients with ocular surface inflammation and hyperemia. Part 1 (cohorts 1 through 3) consisted of healthy volunteers receiving dose escalating concentrations of KIO-101 as noted on the figure below. Specifically, healthy volunteers were repeatedly treated with ascending doses of KIO-101 (0.05%, 0.15%, 0.30%) and placebo eyedrops. Subjects receiving 0.05% and 0.15% eyedrops showed excellent tolerability. Both doses can be used for future studies in patients having an infection or inflammation on the ocular surface. No Severe Adverse Events (“SAE”s) or severe ocular Adverse Events (“AE”s) were reported in any patients. In the 0.3% group, two patients withdrew for epistaxis and further dosing in the entire 0.3% group was stopped. No lab abnormalities in these two or any patients were observed and further toxicology studies are ongoing, including the 0.3% dose.

In the second part (cohort 4) of this study, 21 patients diagnosed with ocular surface inflammation, a key driver of ocular surface disease including dry eye disease, were evaluated. These patients were treated twice daily (BID) for 12 days with 0.15% of KIO-101 (n=14) or vehicle (n=7). The key inclusion criteria were conjunctival hyperemia score >2 (on the Efron scale of 0-5) and an Ocular Surface Disease Index (OSDI) score of > 22. Primary endpoints included safety and tolerability. Secondary and exploratory endpoints included pharmacokinetics of KIO-101 as well as change from baseline in OSDI, conjunctival hyperemia, tear break up time (“TBUT”), corneal staining (Fluorescein), and conjunctival staining (Lissamine Green), ocular discomfort, lid edema, lid erythema.

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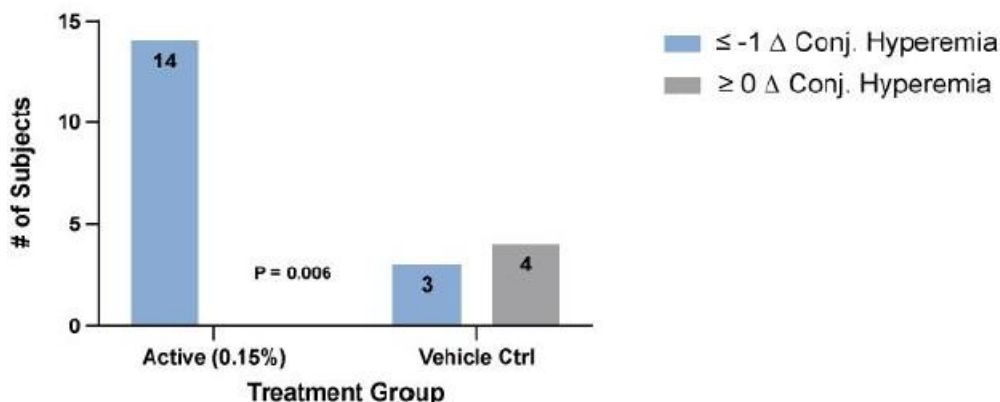


↑ Dosing Days
 ● Follow-Up Days

Study Results

The results demonstrated favorable safety and tolerability of KIO-101, as well as statistically significant improvements in conjunctival hyperemia, a key inclusion criterion for the 21 patients enrolled with ocular surface inflammation and a recognized clinical sign in patients with ocular surface inflammation. At Day 13, 100% of patients treated with KIO-101 (14/14) saw a reduction >1 from baseline, measured on the Efron scale (0-5), versus only 42.8% with vehicle control (3/7) ($p < 0.006$). The mean reduction in conjunctival hyperemia score from baseline to Day 13 demonstrated statistically significant difference in active treatment vs. vehicle control groups (-1.055 vs. -0.604; $p = 0.0316$). This apparent drug effect on conjunctival hyperemia was lost when patients were assessed at the Day 20 post-treatment follow-up, which occurred 8 days after the last dose was administered, further supporting a potential positive drug effect. There was a numerical trend favoring KIO-101 in ocular surface disease index (“OSDI”), but no statistically significant differences were observed in TBUT, corneal staining, conjunctival staining nor other exploratory endpoints. A larger sample size and dosing period longer than two weeks will likely be necessary to effectively evaluate a statistical drug effect on these additional efficacy endpoints.

C4-Baseline:D13 Δ Conj. Hyperemia



No Severe Adverse Events (SAEs) or severe ocular Adverse Events (AEs) were reported. In the 0.3% group, 2 patients withdrew for epistaxis (nose bleeds) and dosing was stopped, with no lab abnormalities in these 2 or any patients observed. In cohort 4, no difference was observed in the frequency of ocular AEs in active vs. control.

Clinical Development Plan

We initiated a Phase 2 clinical trial with KIO-101 eye drops in the second half of 2022 in patients with ocular manifestations of systemic autoimmune conditions, including but may not be limited to dry eye disease associated with rheumatoid arthritis or other autoimmune diseases.

KIO-101: Non-Infectious Posterior Uveitis

Phase 1a/2b Safety Study:

A first in human clinical study to evaluate the safety of intravitreally applied KIO-101 in patients with chronic, non-infectious uveitis was conducted and the final study report was completed in 2021.

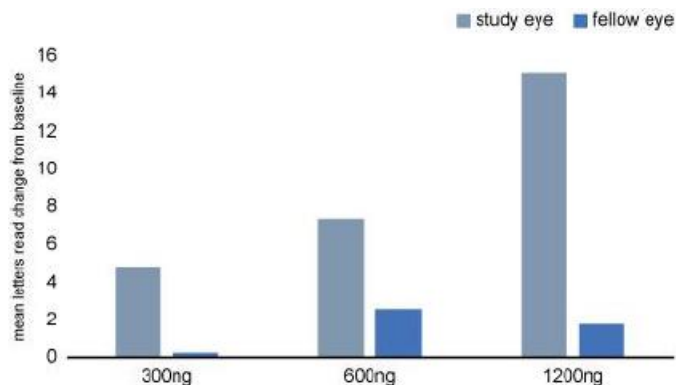
Design

KIO-101 was applied as a single, intravitreal injection of 300, 600 and 1,200 ng per eye. The primary objective of the study was to assess the safety and tolerability of ascending doses of KIO-101 in patients. The secondary objectives were to assess improvement of intraocular inflammation and to evaluate the pharmacokinetics of KIO-101 in patients. For this study, KIO-101 was formulated as a sterile, aqueous solution for intravitreal injection.

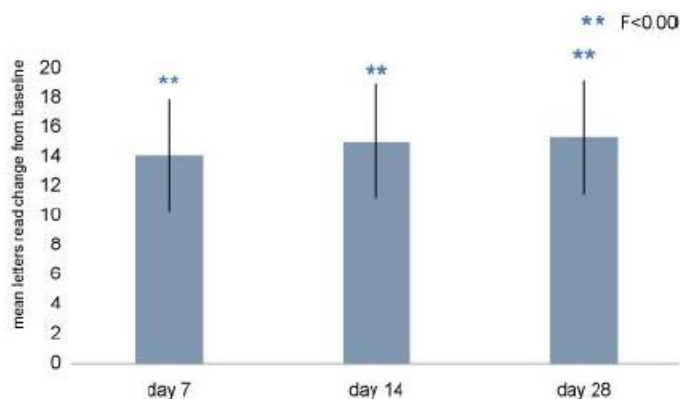
The purpose of this study was to assess safety, pharmacokinetic (“PK”), and efficacy data of 12 treated patients. KIO-101 showed an excellent safety profile and promising efficacy signals in improvement of inflammatory parameters and visual acuity in uveitis patients.

Study Results

The assessment of the evaluated efficacy parameters shows a clear dose dependent treatment effect in improvement of visual acuity at day 14 post dosing. As shown below, the mean change in letters read from baseline for patients treated in cohorts 1, 2, and 3 (300, 600, and 1,200 ng per eye).



Upon analyzing only the highest dose group (1,200 ng per eye, cohort 3), a fundamental mean improvement of visual acuity is seen in the patients, which started within the first week post injection (Day 7) and lasted beyond the last study visit (Day 28). The figure below shows the mean letters read change from baseline to study Days 7, 14, and 28 for patients treated in cohort 3.



Apart from improved visual acuity, improvements in vitreous haze and reduction in macular edema were observed in the patients treated with KIO-101. We have no current plan to develop KIO-101 further for this indication.

KIO-201: PRK Surgical Recovery Pivotal Study

Pivotal Study:

In the fourth quarter of 2019, we reported positive topline results from our corneal wound repair pivotal clinical trial of KIO-201 for the corneal re-epithelialization in patients having undergone PRK surgery. As shown below, this pivotal study demonstrated that KIO-201 accelerates corneal wound healing versus standard of care in post PRK surgical recovery.

Design

The prospective, controlled study randomized 234 patients undergoing bilateral PRK surgery and was designed to assess safety and efficacy by comparing KIO-201 to the current standard-of-care, a bandage contact lens (“BCL”). The primary endpoint was the proportion of study eyes achieving complete wound closure on Day 3 (and remaining closed). This assessment was evaluated by an independent masked reading center, using digital slit-lamp photographs of fluorescein staining in all treated eyes, and a protocol-driven method to quantify the outcomes.

The enrolled patients were randomized into one of two study groups, with patients receiving the same treatment in both eyes:

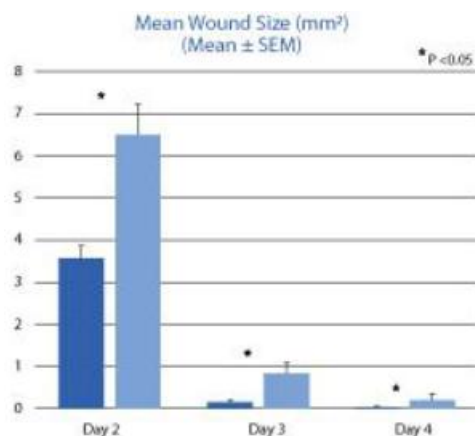
- Arm 1 (n=117) was comprised of KIO-201 four times daily (QID) for two weeks after surgery.

- Arm 2 (n=117) was comprised of BCL administered QID.



Study Results

KIO-201 demonstrated superiority for the primary endpoint with a p-value of 0.0203. The statistical significance measurement was based on the number of patients in each arm that achieved complete corneal defect closure three days post refractive surgery. At Day 3, 80.2% of eyes receiving the KIO-201 treatment regimen were completely healed, compared with 67.0% for BCL. Additionally, at Day 2, the average wound size for all eyes treated with KIO-201 was 3.61 mm², compared to 6.66 mm² for eyes treated with BCL, which is 46% smaller than the standard-of-care as noted in the graph below. As described further, the use of KIO-201 resulted in smaller wounds in the acute healing phase after PRK surgery compared to the standard of care (bandage contact lenses, BCL). This data gives confidence that patients will be able to resume normal activities earlier when treated with KIO-201 compared to BCL.



Clinical Development Plan

We are currently assessing the requirements on a registration clinical trial as well as evaluating the market opportunity. We expect to kickoff further clinical work in 2023.

KIO-201: Punctate Epitheliopathies with a Focus on Dry Eye

Follow-On Pilot Study:

In the first quarter of 2020, we reported positive topline results from the follow-on clinical trial of KIO-201 evaluating the potential to help clinicians better manage patients with dry eye.

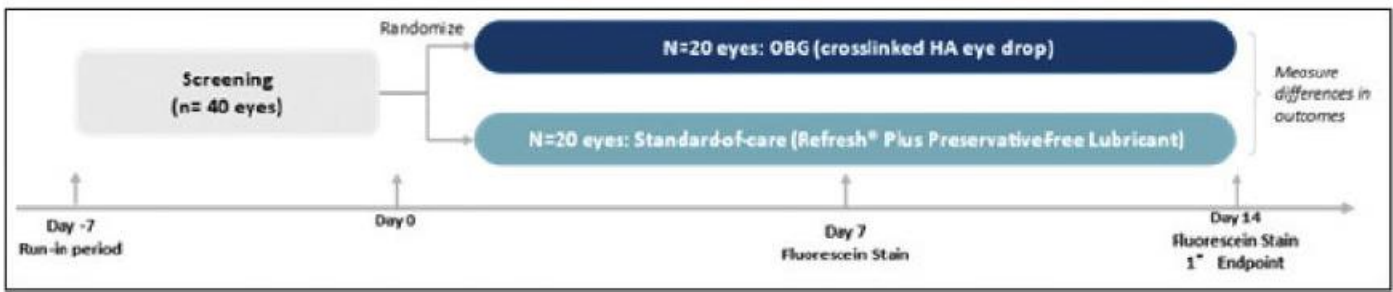
Design

This positive controlled, investigator masked study enrolled 20 patients, or 40 eyes, with dry eye. This study confirmed the ability of KIO-201 eye drops to demonstrate improvement of the ocular surface for several important ophthalmic endpoints. KIO-201 eye drops showed an improvement in central corneal region staining, high order ocular aberrations (“HOA”) and best corrected visual acuity (“BCVA”), outperforming the positive control, Allergan’s Refresh Plus Preservative-Free (“Refresh Plus”) lubricant eye drop.

Prior to randomization there was a one-week run in period where all patients took Refresh eye drops only in both eyes. Patients with a corneal staining score of ≥ 4 , using the NEI scale, and a TBUT of ≤ 7 seconds at Day 0, or at the end of the 7-day run-in period, then entered the 14-day treatment phase. To be randomized at Day 0, both eyes had to qualify and have similar scores for staining and TBUT. The patient acted as their own control and one eye was treated with Refresh Plus eye drops and the other eye was treated with KIO-201 eye drops.

The twenty enrolled patients had one eye randomized to the KIO-201 treatment group and the other eye randomized to the Refresh Plus treatment group, for a total of 40 eyes randomized:

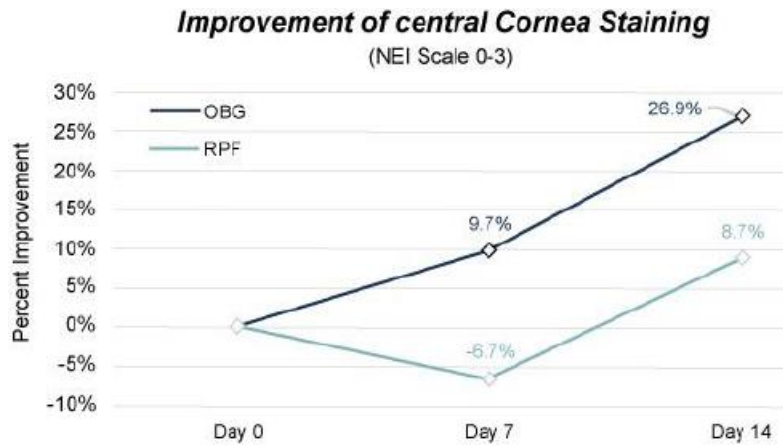
- Arm 1 (n=20 eyes) received KIO-201 eye drops four times daily for four weeks.
- Arm 2 (n=20 eyes) received Refresh Plus eye drops four times daily for four weeks.



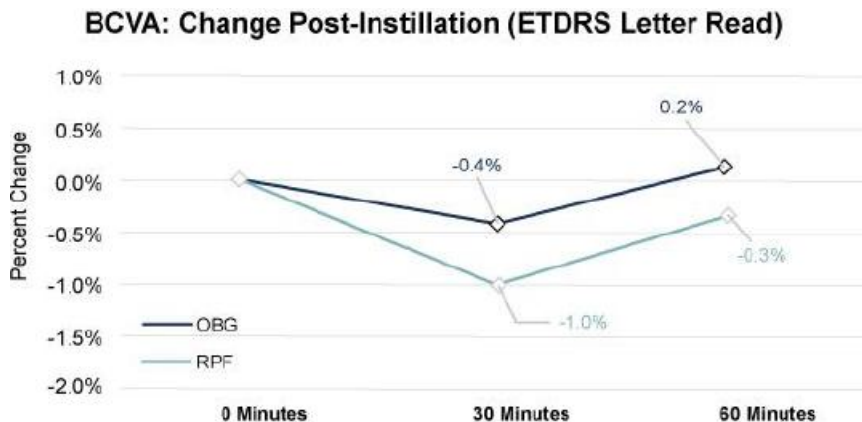
The primary endpoint was based on corneal epithelial healing as measured by fluorescein staining. Punctate epithelial erosions are a sign of epithelial compromise (corneal barrier disruption) which is characterized by a breakdown of the epithelium of the cornea and an increased permeability to fluorescein dye. Thus, fluorescein dye is used to clinically evaluate the severity of corneal barrier disruption. The National Eye Institutes (“NEI”) scale was used, which divides the cornea into five different regions. Each region was scored on a scale from 0 to 3 for a total maximum score of 15 (a higher score represented a more severe disruption of the corneal barrier). To be randomized into the study, each eye had to have a minimum total score of 4.

Study Results

At all visits, all corneal regions were assessed, but of particular interest due to vision quality involvement and corneal sensitivity, is the central region of the cornea. All 20 patients randomized had a minimum scoring for the whole cornea (i.e., all 5 regions) of at least 4 (maximum score = 15) in both eyes, and 16 of these patients also had a minimum score of at least 1 (maximum score = 3) in the central region of the cornea in both eyes. KIO-201 demonstrated a positive treatment effect as compared to Refresh Plus at both Day 7 and Day 14. The overall improvement (i.e., reduction in staining) at Day 14 was approximately 27% from baseline versus only approximately 9% for the positive control, Refresh Plus eye drops. KIO-201 also showed improvement more quickly than Refresh Plus eye drops with an approximately 10% reduction in staining versus an increase in staining of approximately 7% for the Refresh Plus treatment group.



The uniqueness of KIO-201 is the combination of the high viscosity profile with a high shear rate. This means that with blinking or other sources of shearing or energy that the viscosity of KIO-201 temporarily drops. Thus, this clinical study was also used to confirm that KIO-201 does not result in blurriness of vision while on the eye. After all endpoint assessments were completed, one drop of KIO-201 and one drop of Refresh Plus was instilled onto each eye. This was completed in a masked fashion based on randomization of each eye per drop. BCVA measurements were taken at 30 and 60 minutes to determine if instillation of either KIO-201 or Refresh Plus caused blurriness or a change in vision. At all assessment time points there was essentially no change in BCVA for KIO-201 or Refresh Plus, but KIO-201 did perform better than Refresh Plus. At 30 minutes post instillation, KIO-201 saw a negative change of 0.4% versus a negative change of 1.0% for Refresh Plus. At 60 minutes, KIO-201 had a positive effect of 0.2% versus a negative effect of 0.3% for Refresh Plus. We have no current plan to develop KIO-201 further for this indication.



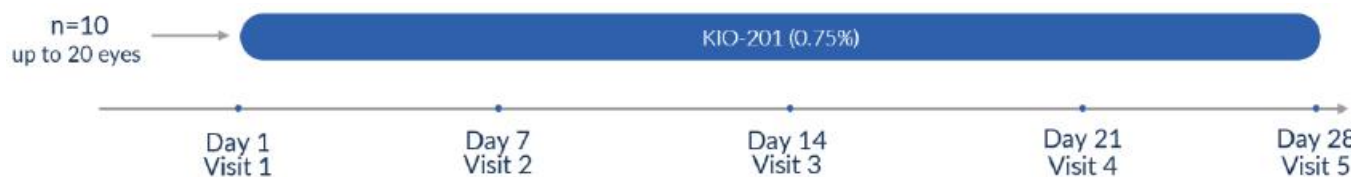
KIO-201: Persistent Corneal Epithelial Defects

Phase 2 Study:

In the first quarter of 2022, we initiated a clinical trial of KIO-201 evaluating the potential to help patients with Persistent Corneal Epithelial Defects (PCEDs). We expect results from this study in early-mid 2023.

Design

This single site clinical trial was designed to enroll up to 10 patients (20 eyes), with PCEDs, as defined by a duration of at least 14 days while on conventional therapies. The primary endpoint of the study is safety and tolerability with key secondary endpoints including assessing the number of patients with healing (defined by lesions being <0.5mm²).



Clinical Development Plan

PCED qualifies as a rare disease, of which we applied for Orphan Drug Designation for KIO-201 in Q4 2022. We expect to receive ODD in Q1 2023 and with the results from the aforementioned clinical trial, we plan to meet with the FDA to discuss next steps.

Intellectual Property and Proprietary Rights

Overview

We are building an intellectual property portfolio for our KIO-101, KIO-201, and KIO-301 platforms and any other product candidates that we may develop, as well as other devices and product candidates for treatment of ocular indications in the U.S. and abroad. We currently seek, and intend to continue to seek, patent protection in the U.S. and internationally for our product candidates, methods of use, and processes for manufacture, and for other technologies, where appropriate. Our current policy is to actively seek to protect our proprietary position by, among other things, filing patent applications in the U.S. and abroad relating to proprietary technologies that are important to the development of our business. We also rely on, and will continue to rely on, trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our technology.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for the technologies that we consider important to our business, our ability to defend our patents, and our ability to preserve the confidentiality of our trade secrets and operate our business without infringing the patents and proprietary rights of third parties.

Patent Portfolio

Our patent portfolio includes drug delivery device patents directed to KIO-101 as composition-of-matter, formulations thereof and its therapeutic uses in the treatment of ocular disorders and diseases and more. In addition, KIO-301 holds a patent portfolio consisting of platform enabling IP, composition-of-matter, methods of use, and formulations thereof. These issued patents will expire between 2023 and 2036. 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 owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant new drug application or NDA. See “Government Regulation — Patent Term Restoration and Marketing Exclusivity” below.

We hold seven U.S. patents and 40 international patents. A summary of owned and licensed patent families by program are noted below:

Kiara Owned

Patent Family	Program	Key Claims	Status	Expiration Date (US)
PT001	KIO-100	Composition of matter covering KIO-100 and derivatives	Patents granted in US and other major markets	Oct. 25, 2025
PT002	KIO-100	Method of inhibiting DHOD with KIO-100 or derivatives	Patents granted in US and other major markets	Jan. 5, 2031
PT003	KIO-100	Method of treating disease caused by viral infection using KIO-100 or derivatives	Patents granted in US and other major markets	Apr. 11, 2034
PT004	KIO-100	Method of treating adenoviral conjunctivitis using KIO-100	Patents granted in several major markets; pending in US and others	Expected 2035
PT005	KIO-100	Method of treating uveitis by intravitreal injection of KIO-100	Patents pending in US and other major markets	Expected 2039
PT007	KIO-100	Ophthalmic composition of KIO-100 with albumin	Patents pending in US and other major markets	Expected 2039
PT008	KIO-100	Method of treating various ocular conditions with the ophthalmic composition	Patents pending in US and other major markets	Expected 2039
PT007	KIO-100	Composition of matter covering polymorphs of KIO-100, methods of preparing, pharmaceutical compositions, and method of treating disease	Filed March 2022	Expected 2043
PT008	KIO-100	Composition of matter covering salts of KIO-100, pharmaceutical compositions, and method of treating disease	Filed March 2022	Expected 2043
EG1017	KIO-200	Ocular composition of thiolated HA crosslinked with PEGDA with antibiotic incorporated	Patent granted in US	Oct. 17, 2034
EG1032	KIO-200	Method of treating ocular disease with composition	Patent granted in US	Oct. 17, 2034
EG1032	KIO-200	Ocular compositions covering KIO-201 with antibiotic incorporated	Patent allowed in US; pending in other major markets	Expected 2040
EG1033	KIO-200	Contact lenses incorporating a covalently attached cationic monomer and an anionic therapeutic	Pending PCT	Expected 2041
EG1034	KIO-200	Ocular compositions covering KIO-201 with poorly-soluble therapeutics incorporated	Pending PCT	Expected 2041
BAY002	KIO-300	Formulations of KIO-300 and related compounds	Pending PCT	Expected 2041

Kiara Licensed

Patent Family	Program	Key Claims	Status	Expiration Date (US)
U-3405	KIO-200	Composition of matter covering thiolated ECM proteins Method of administering in situ crosslinked thiolated HA-containing gels	Patents granted in US (2), EP, CA	May 15, 2023 May 15, 2023
U-3656	KIO-200	Composition of matter covering CMHA-S and other thiolated GAGs, crosslinked CMHA-S (KIO-201) Composition of matter covering CMHA and DM-GAGs	Patents granted in US (2), AU, JP, ZA, CA	Aug. 9, 2027 Feb. 28, 2025
BK-2009-005	KIO-300	Composition of matter covering KIO-300 and related compounds Method for conferring light sensitivity to a cell in the eye using KIO-300 or related compounds	Patents granted in US (3)	Jan. 22, 2030 Oct. 29, 2029 Oct. 29, 2029

License Agreements

We are a party to seven license agreements as described below. These license agreements require us to pay or receive royalties or fees to or from the licensor based on revenue or milestones related to the licensed technology.

On July 2, 2013, we (through our subsidiary, Kiora Pharmaceuticals, GmbH) entered into a patent and know-how assignment agreement with 4SC Discovery GmbH (“4SC”) transferring to us all patent rights and know-how to the compound KIO-101. We are responsible for paying royalties of 3.25% on net sales of KIO-101.

On July 2, 2013, we (through our subsidiary, Kiora Pharmaceuticals, GmbH) entered into an out-license agreement with 4SC granting 4SC the exclusive worldwide right to commercialize the compound KIO-101 for rheumatoid arthritis and inflammatory bowel disease, including Crohn’s Disease and Ulcerative Colitis. We are eligible to receive milestone payments totaling up to 155 million euros, upon and subject to the achievement of certain specified developmental and commercial milestones. We have not received any milestones from 4SC. In addition, we are eligible to receive royalties of 3.25% on net sales of KIO-101.

On September 12, 2013, we (through our subsidiary, Jade Therapeutics, Inc.) entered into an agreement with Lineage Cell Therapeutics, Inc. (“Lineage”), formerly known as BioTime, Inc. granting to us the exclusive worldwide right to commercialize cross-linked thiolated carboxymethyl hyaluronic acid (“modified HA”) for ophthalmic treatments in humans. The agreement requires us to pay an annual fee of \$30,000 and a royalty of 6% on net sales of KIO-201 to Lineage based on revenue relating to any product incorporating the modified HA technology. The agreement expires when patent protection for the modified HA technology lapses in August 2027.

On November 17, 2014, we (through our subsidiary Kiora Pharmaceuticals GmbH) entered into an intellectual property and know-how licensing agreement with Laboratoires Leurquin Mediolanum S.A.S. (“Mediolanum”) for the commercialization of KIO-101 (the “Mediolanum agreement”) in specific territories. Under the Mediolanum agreement, we out-licensed rights to commercialize KIO-101 for uveitis, dry eye and viral conjunctivitis in Italy, and France. This Agreement was amended on December 10, 2015 to also include Belgium and The Netherlands. Under the Mediolanum Agreement, Mediolanum is obligated to pay up to approximately \$20.0 million EUROS in development and commercial milestones and a 7% royalty on net sales of KIO-101 in the territories through the longer of the expiry of the valid patents covering KIO-101 or 10 years from the first commercial sale. The royalty is reduced to 5% after patent expiry.

On September 26, 2018, we entered into an intellectual property licensing agreement (the “SentrX Agreement”) with SentrX, a veterinary medical device company that develops and manufactures veterinary wound care products. Under the SentrX Agreement, we in-licensed the rights to trade secrets and know-how related to the manufacturing of KIO-201. The SentrX Agreement enables us to pursue a different vendor with a larger capacity for manufacturing and an FDA-inspected facility for commercialization of a product for human use. Under the SentrX Agreement, SentrX is eligible to receive milestone payments totaling up to \$4.75 million, upon and subject to the achievement of certain specified developmental and commercial milestones. The term of the agreement is until the Product is no longer in the commercial marketplace.

On May 1, 2020, we (through our subsidiary, Bayon Therapeutics, Inc.) entered into an agreement with the University of California (“UC”) granting to us the exclusive rights to its pipeline of photoswitch molecules. The agreement requires us to pay an annual fee to UC of \$5,000, as well as payments to UC upon the achievement of certain development milestone and royalties based on revenue relating to any product incorporating KIO-301. The Company is obligated to pay royalties on net sales of two percent (2%) of the first \$250 million of net sales, one and a quarter percent (1.25%) of net sales between \$250 million and \$500 million, and one half of one percent (0.5%) of net sales over \$500 million. The agreement expires on the date of the last-to-expire patent included in the licensed patent portfolio which is January 2030.

On May 1, 2020, we (through our subsidiary, Bayon Therapeutics, Inc.) entered into an agreement with Photoswitch Therapeutics, Inc. (“Photoswitch”) granting to us access to certain patent applications and IP rights with last-to-expire patent terms of January 2030. The agreement calls for payments to Photoswitch upon the achievement of certain development milestones and upon first commercial sale of the product.

Recent Developments

Public Offering

On July 22, 2022, we entered into an Underwriting Agreement with Ladenburg Thalmann & Co. Inc., as underwriter, pursuant to which we issued and sold, on July 26, 2022 in a firm commitment underwritten public offering (the “Public Offering”), (i) 592,392 shares of Common Stock, (ii) 1,280 shares of Series E Convertible Preferred Stock, (iii) 30,095,697 Class A Warrants, and (iv) 30,095,697 Class B Warrants. Upon exercise, the warrants will convert on a 40 for 1 basis into a total of 1,504,785 common shares. The net proceeds to us, after deducting the underwriting discount and commissions and estimated offering expenses payable by us, were approximately \$5.3 million. Each of the Class A Warrants and Class B Warrants have an exercise price of \$8.00 per share of underlying common stock. The securities were offered by us pursuant to a Registration Statement on Form S-1 (File No. 333-264641), which was initially filed with the Securities and Exchange Commission (the “Commission”) on May 3, 2022, amended on July 13, 2022, July 19, 2022 and July 21, 2022, and declared effective by the Commission on July 21, 2022.

Each Class A Warrant and Class B Warrant became exercisable following approval by our stockholders of the exercise of those warrants at the stockholder meetings held on September 15, 2022 and September 23, 2022 and the consummation of the reverse stock split as described below. The Class A Warrants will expire on the one-year anniversary of their initial exercise date, and the Class B Warrants will expire on the five-year anniversary of their initial exercise date.

Reverse Stock Split

On September 23, 2022, we filed with the Secretary of State of the State of Delaware a Certificate of Amendment to our Restated Certificate of Incorporation (the “Certificate of Amendment”), which was approved by our stockholders at our 2022 Annual Meeting of Stockholders held on September 23, 2022 and by our Board of Directors.

The Certificate of Amendment effected a 1-for-40 reverse stock split of our Common Stock, in which each forty (40) shares of Common Stock issued and outstanding as of 12:01 a.m. Eastern Time on September 27, 2022 (the effective time of the reverse stock split) was combined and converted into one share of Common Stock. While the reverse stock split decreased the number of outstanding shares of Common Stock, it did not change the total number of shares of Common Stock authorized for issuance by us, nor did it change the par value of the Common Stock. The reverse stock split-adjusted shares of Common Stock began trading on The Nasdaq Capital Market at the open of the market on September 27, 2022 under the new CUSIP number 49721T 309. No change was made to the trading symbol for the Common Stock, “KPRX”, in

connection with the reverse stock split.

In connection with the reverse stock split, proportional adjustments were made to (i) the number of shares of Common Stock underlying our outstanding stock options and warrants, (ii) the exercise price or conversion price (as applicable) of our outstanding stock options and warrants, and (iii) the number of shares reserved for issuance under our equity incentive plan. All share and per share amounts in this prospectus have been adjusted retroactively to reflect the reverse stock split.

Private Placement and Warrant Inducement

On November 17, 2022, we entered into warrant exercise inducement offer letters (“Inducement Letters”) with the selling stockholders pursuant to which the selling stockholders agreed to exercise for cash all of their Class A Warrants to purchase 654,610 shares of our Common Stock originally issued in the Public Offering in exchange for our agreement to issue new warrants (the “Inducement Warrants”) on substantially the same terms as the Class A Warrants, except as described below, to purchase up to 654,610 shares of Common Stock (such issuance, the “Private Placement”). Each Inducement Warrant is exercisable at a price per share of common stock of \$5.97. Each Inducement Warrant will initially be exercisable six months following its date of issuance, and will expire on the 18 month anniversary of their initial exercise date.

We received aggregate gross proceeds of approximately \$3.12 million from the exercise of the Class A Warrants by the selling stockholders and the sale of the Inducement Warrants. We engaged Ladenburg Thalmann & Co. Inc. as our exclusive placement agent in connection with the inducement transactions and paid Ladenburg a fee equal to 8% of gross proceeds from the exercise of the Class A Warrants.

The Inducement Warrants and the shares of Common Stock issuable upon the exercise of the Inducement Warrants, were and will be in each case sold and issued without registration under the Securities Act in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and Rule 506 promulgated under the Securities Act as sales to accredited investors, and in reliance on similar exemptions under applicable state laws.

We also agreed to file a registration statement covering the resale of the shares of Common Stock issued or issuable upon the exercise of the Inducement Warrants no later than 30 calendar days following the date of the Inducement Letters. This prospectus relates to the resale of 654,610 shares of Common Stock underlying the Inducement Warrants issued in the Private Placement.

Related-Party Transactions

We incurred expenses of approximately \$0.125 million for services to a related party vendor Ora, Inc. who is providing us with clinical study services for KIO-301. Aron Shapiro, one of our directors, is an executive at Ora, Inc. This amount was included in accounts payable at September 30, 2022 and was subsequently paid.

Our Corporate Information

Kiora Pharmaceuticals, Inc. was formed in Delaware on December 26, 2004 under the name EyeGate Pharmaceuticals, Inc. On November 8, 2021, we completed a merger of our wholly owned Delaware subsidiary, Kiora Pharmaceuticals, Inc. (incorporated in October 2021) into EyeGate Pharmaceuticals, Inc., which merger resulted in the amendment of our restated certificate of incorporation to change our name to “Kiora Pharmaceuticals, Inc.” effective November 8, 2021 (the “Name Change”). In connection with the name change, we changed our symbol on the Nasdaq Capital Market to “KPRX” and began using a new CUSIP number effective at the market open on November 8, 2021. We were originally incorporated in 1998 under the name of Optis France S.A. in Paris, France. We have four wholly owned subsidiaries: Jade Therapeutics, Inc., Kiora Pharmaceuticals, GmbH (formerly known as Panoptes Pharma Ges.m.b.H), Bayon Therapeutics, Inc., and Kiora Pharmaceuticals Pty Ltd (formerly known as Bayon Therapeutics Pty Ltd). Our former subsidiary, EyeGate Pharma S.A.S. was dissolved effective December 31, 2020. Our principal executive offices are located at 1371 East 2100 South, Suite 200, Salt Lake City, Utah, 84105, and our telephone number is (781) 788-8869. Our website address is www.kiorapharma.com. Our website and the information contained in, or accessible through, our website will not be deemed to be incorporated by reference into this prospectus and does not constitute part of this prospectus. You should not rely on any such information in making your decision whether to purchase our securities.

THE OFFERING

We are registering for resale by the selling stockholders named herein an aggregate of 654,610 shares of our Common Stock as described below.

Securities being offered:	654,610 shares of our Common Stock underlying Inducement Warrants issued to the selling stockholders in the Private Placement.
Use of proceeds	We will not receive any of the proceeds from the sale or other disposition of shares of our Common Stock by the selling stockholders. We may receive proceeds upon any exercise for cash of outstanding Inducement Warrants, in which case such proceeds will be used for working capital and other general corporate purposes. See “Use of Proceeds” on page 57.
Risk factors	Investing in our securities involves a high degree of risk. See “Risk Factors” beginning on page 21 of this prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus, for a discussion of information that should be considered in connection with an investment in our securities.
Nasdaq Capital Market symbol	Our Common Stock is listed on The Nasdaq Capital Market under the symbol “KPRX.” On December 27, 2022, the last reported sale price of our Common Stock on The Nasdaq Capital Market was \$2.45.

RISK FACTORS

Summary of Risk Factors

Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this prospectus and the documents incorporated by reference herein before making an investment decision regarding our securities.

- We have incurred significant operating losses since our inception, which have caused management to determine there is substantial doubt regarding our ability to continue as a going concern. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.
- 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.
- 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.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- The coronavirus pandemic could adversely impact our business, including clinical trials.
- We depend heavily on the success of KIO-101, KIO-201 and KIO-301. If we are unable to successfully obtain marketing approval for KIO-101, KIO-201 or KIO-301, or experience significant delays in doing so, or if after obtaining marketing approvals, we fail to commercialize KIO-101, KIO-201 or KIO-301, our business will be materially harmed.
- If clinical trials of KIO-101, KIO-201, KIO-301, or any other product candidate that we develop fail to demonstrate safety and efficacy to the satisfaction of the FDA or foreign regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be delayed or unable to complete, the development and commercialization of KIO-101, KIO-201, KIO-301 or any other product candidate.
- Even if KIO-101, KIO-201, KIO-301 or any other product candidate that we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for our product candidates may be smaller than we estimate.
- If we are unable to establish sales, marketing and distribution capabilities, we may not be successful in KIO-101, KIO-201, KIO-301 or any other product candidates that we may develop if and when they are approved.
- We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.
- Even if we are able to commercialize KIO-101, KIO-201, KIO-301 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.

21

- 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.
- If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.
- We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.
- Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.
- If we are not able to obtain required regulatory approvals, we will not be able to commercialize KIO-101, KIO-201, KIO-301 or any other product candidate that we may develop, and our ability to generate revenue will be materially impaired.
- We incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.
- 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 identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely satisfy the requirements applicable to public companies, which may adversely affect investor confidence in us, and, as a result, the market price of our common stock.

22

Risk Factors

Investing in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties and all other information contained in or incorporated by reference in this prospectus. All of these risk factors are incorporated by reference herein in their entirety. Our business, financial condition or results of operations could be materially adversely affected by the materialization of any of these risks. The trading price of our securities could decline due to the materialization of any of these risks, and you may lose all or part of your investment. This prospectus and the documents incorporated herein by reference also contain forward-looking statements that involve risks and uncertainties. Actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks described herein and in the documents incorporated herein by reference.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant operating losses since our inception, which have caused management to determine there is substantial doubt regarding our ability to continue as a going concern. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net loss was approximately \$11.085 million for the nine months ended September 30, 2022, \$13.771 million for the year ended December 31, 2021, \$6.862 million for the year ended December 31, 2020 and \$131.965 million from the period of inception (December 26, 2004) through September 30, 2022. To date, we have financed our operations primarily through private placements and public offerings of our securities, and payments from our license agreements. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and, beginning in 2008, clinical trials. We are still in the development stage of our product candidates and we have not completed development of any drugs. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. Our recurring losses from operations have caused management to determine there is substantial doubt regarding our ability to continue as a going concern, and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statements as of and for the year ended December 31, 2021 with respect to this uncertainty.

We anticipate that our expenses will continue to be significant with the clinical trials for the ongoing development of our KIO-101, KIO-201 and KIO-301 products.

Our expenses will also increase if and as we:

- seek marketing approval for KIO-101, KIO-201 and KIO-301, whether alone or in collaboration with third parties;
- continue the research and development of KIO-101, KIO-201 and KIO-301 and any of our other product candidates;
- seek to develop additional product candidates;
- in-license or acquire the rights to other products, product candidates or technologies;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- establish sales, marketing and distribution capabilities and scale up and validate external manufacturing capabilities to commercialize any products for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;

23

- hire additional clinical, quality control, scientific and management personnel;
- expand our operational, financial and management systems and personnel, including personnel to support our clinical development, manufacturing and planned future commercialization efforts and our operations as a public company; and
- increase our insurance coverage as we expand our clinical trials and commence commercialization of KIO-101, KIO-201 and KIO-301.

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

- we are required by the U.S. FDA or foreign equivalents to perform studies or clinical trials in addition to those currently expected; and
- there are any delays in enrollment of patients in or completing our clinical trials or the development of KIO-101, KIO-201, KIO-301 or any other product candidates that we may develop.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue unless and until we obtain marketing approval for, and commercialize KIO-101, KIO-201, KIO-301 or other product candidates that we may develop, which may never occur. This will require us to be successful in a range of challenging activities, including:

- establishing collaboration, distribution, or other marketing arrangements with third parties to commercialize KIO-101, KIO-201 and KIO-301 in markets outside the U.S.;
- achieving an adequate level of market acceptance of our product candidates;
- protecting our rights to our intellectual property portfolio related to our product candidates; and
- ensuring the manufacture of commercial quantities of KIO-101, KIO-201 and KIO-301.

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 depress 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.

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 continuing the clinical development of our KIO-101, KIO-201 and KIO-301 products. In the future, we expect to raise additional financial resources for the continued clinical development of KIO-101, KIO-201, KIO-301 and other product candidates we may develop. In addition, if we obtain regulatory approval for any of our product candidates, we would need to devote substantial financial resources to commercialization efforts, including product manufacturing, marketing, sales, and distribution. Accordingly, we will 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.

24

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

- the progress, costs and outcome of our clinical trials for our product candidates and of any clinical activities required for regulatory review of our product candidates outside of the U.S.;
- the costs and timing of process development and manufacturing scale up and validation activities associated with our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates in the U.S., and in other jurisdictions;
- the costs and timing of commercialization activities for our product candidates if we receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities;
- subject to receipt of marketing approval, the amount of revenue received from commercial sales of our product candidates;
- our ability to establish collaborations on favorable terms, if at all, particularly manufacturing, marketing and distribution arrangements for our product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the extent to which we in-license or acquire rights to other products, product candidates or technologies for the treatment of ophthalmic diseases.

As of September 30, 2022, we had unrestricted cash and cash equivalents of approximately \$4.8 million. We believe that as of September 30, 2022, we had sufficient cash to fund planned operations into April 2023, however, the acceleration or reduction of cash outflows by management can significantly impact the timing needed for raising additional capital to complete development of our products. To continue development, we will need to raise additional capital through debt and/or equity financing or access additional funding through U.S. or foreign grants. Although we completed our initial public offering and subsequent public offerings, registered direct offerings and private placements, additional capital may not be available on terms favorable to us, if at all. Accordingly, no assurances can be given that management will be successful in these endeavors. These conditions raise substantial doubt about our ability to continue as a going concern.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. Our commercial revenues, if any, will be derived from sales of KIO-101, KIO-201, KIO-301 or any other products that we successfully develop, none of which we expect to be commercially available for several years, if at all. In addition, if approved, any product candidate that we develop or any product that we in-license may not achieve commercial success. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. 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.

A material amount of our assets represents intangible assets, and our net income would be reduced if our intangible assets become impaired.

As of September 30, 2022, intangible assets, net, represented approximately \$10.7 million, or 61% of our total assets. Goodwill in the amount of \$4.0 million was written off during the year ended December 31, 2021. Indefinite-lived intangible assets are subject to an impairment analysis at least annually based on fair value. Intangible assets relate primarily to in process research and development and patents acquired by us as part of our acquisitions of other companies and are subject to an impairment analysis whenever events or changes in circumstances exist that indicate that the carrying value of the intangible asset might not be recoverable. If market and economic conditions or business performance deteriorate, the likelihood that we would record an impairment charge would increase, which impairment charge could materially and adversely affect our financial condition and operating results.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely satisfy the requirements applicable to public companies, which may adversely affect investor confidence in us, and, as a result, the market price of our common stock.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with GAAP. Our management is likewise required, on a quarterly basis, to evaluate the effectiveness of our internal controls and to disclose any changes and material weaknesses identified through such evaluation in those internal controls. A material weakness is a deficiency, or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis.

We have previously identified the following material weaknesses:

- We did not design or maintain an effective control environment commensurate with our financial reporting requirements. We lacked a sufficient number of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately. Additionally, the limited personnel resulted in our inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, among other things, our insufficient segregation of duties in our accounting function. This material weakness further contributed to the material weakness below.
- We did not design and maintain formal accounting policies, processes, and controls to analyze, account for and disclose significant and unusual transactions, including business combinations, accounting for stock-based compensation, analysis of goodwill and indefinite-lived asset impairment and contingent consideration.
- For our systems, some of the former finance staff-maintained IT access to systems and controls.

As a result of these material weaknesses, our management concluded that our internal control over financial reporting was not effective as of September 30, 2022. These material weaknesses contributed to a material misstatement of our indefinite-lived assets and related impairment, goodwill, goodwill impairment, contingent consideration, change in fair value of contingent consideration, additional paid-in capital, accumulated deficit, and related financial disclosures included in our previously issued consolidated financial statements as of and for the years ended December 31, 2021 and 2020, and the quarterly periods ended March 31, 2021, June 30, 2021 and September 30, 2021. Additionally, we have identified and are investigating apparent payroll irregularities that occurred in June 2022, and have retained an independent firm to review our internal control over financial reporting in light of such irregularities.

To respond to these material weaknesses, we have devoted, and plan to continue to devote, significant effort and resources to the remediation and improvement of our internal control over financial reporting. While we have processes to identify and appropriately apply applicable accounting requirements, we plan to enhance these processes to better evaluate our research and understanding of the nuances of the complex accounting standards that apply to our consolidated financial statements. Our plans currently include providing enhanced access to accounting literature, research materials and documents and increased communication among our personnel and third-party professionals with whom we consult regarding complex accounting applications. The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects.

Any failure to maintain such internal control could adversely impact our ability to report our financial position and results from operations on a timely and accurate basis. If our consolidated financial statements are not accurate, investors may not have a complete understanding of our operations. Likewise, if our consolidated financial statements are not filed on a timely basis, we could be subject to sanctions or investigations by the stock exchange on which our ordinary shares and other securities are listed, the SEC or other regulatory authorities. In either case, there could result a material adverse effect on our business. Ineffective internal controls could also cause investors to lose confidence in our reported financial information which could have a negative effect on the trading price of our stock.

We can give no assurance that the measures we have taken and plan to take in the future will remediate the material weaknesses identified or that any additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls. In addition, even if we are successful in strengthening our controls and procedures, in the future those controls, and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements.

We may face litigation and other risks because of the material weakness in our internal control over financial reporting.

Based on management's evaluation and the Audit Committees consultation with our financial and legal advisors, we concluded that it was appropriate to restate our previously issued audited consolidated financial statements as of December 31, 2021 and 2020. We determined that material weaknesses in our internal controls over financial reporting contributed to the need to restate our consolidated financial statements.

As a result of this material weakness, the restatement, the change in accounting for the goodwill and contingent consideration, and other matters raised or that may in the future be raised by the SEC, we face the potential for litigation or other disputes which may include, among others, claims invoking the federal and state securities laws, contractual claims or other claims arising from the restatement and material weakness in our internal control over financial reporting and the preparation of our consolidated financial statements. As of the date of this prospectus, we have no knowledge of any such litigation or dispute. However, we can provide no assurance that such litigation or dispute will not arise in the future. Any such litigation or dispute, whether successful or not, could have a material adverse effect on our business, results of operations and financial condition or our ability to complete a business combination.

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, government or other third-party funding, collaborations, strategic alliances, licensing arrangements and marketing and distribution arrangements. We do not have any committed external source of funds. 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 cannot raise funds on acceptable terms, we may not be able to grow our business or respond to competitive pressures.

If we raise additional funds through government or other third-party funding, 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 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 a clinical-stage company with a limited operating history. Our operations to date have been limited to organizing and staffing our company, acquiring rights to intellectual property, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking preclinical studies, and conducting clinical trials of KIO-101, KIO-201 and KIO-301. We have not yet demonstrated our ability to successfully complete development of a product candidate, obtain marketing approvals, manufacture at commercial scale, or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization.

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

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

Foreign currency exchange rate fluctuations may have a negative impact on our financial results.

We are subject to the risks of fluctuating foreign currency exchange rates, which could have an adverse effect on the costs and expenses of our foreign subsidiary. As a result, currency fluctuations among the United States dollar, euro, Australian dollar and the other currencies in which we do business have caused and will continue to cause foreign currency translation and transaction gains and losses. We have not used forward exchange contracts to hedge our foreign currency exposures. In the future, we may undertake to manage foreign currency risk through hedging methods, including foreign currency contracts. We recognize foreign currency gains or losses arising from our operations in the period incurred. We cannot guarantee that we will be successful in managing foreign currency risk or in predicting the effects of exchange rate fluctuations upon our future operating results because of the number of currencies involved, the variability of currency exposure and the potential volatility of currency exchange rates. We cannot predict with any certainty changes in foreign currency exchange rates or the degree to which we can address these risks.

Risks Related to the Discovery and Development of Our Product Candidates

We depend heavily on the success of KIO-101, KIO-201 and KIO-301. If we are unable to successfully obtain marketing approval for KIO-101, KIO-201 and KIO-301, or experience significant delays in doing so, or if after obtaining marketing approvals, we fail to commercialize KIO-101, KIO-201 and KIO-301, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the development of KIO-201, and we expect to invest additional financial resources on its

continued development as well as the development of KIO-101 and KIO-301 in the future. There remains a significant risk that we will fail to successfully develop either product candidate.

We cannot accurately predict when or if KIO-101, KIO-201 or KIO-301 will prove effective or safe in humans or whether it will receive marketing approval. Our ability to generate product revenues, which may never occur, will depend heavily on our obtaining marketing approval for and commercializing KIO-101, KIO-201 and KIO-301.

The success of KIO-101, KIO-201 and KIO-301 will depend on several factors, including the following:

- obtaining favorable results from clinical trials;
- applying for and receiving marketing approvals from applicable regulatory authorities for KIO-101, KIO-201 and KIO-301;
- making arrangements with third-party manufacturers for commercial quantities of KIO-101, KIO-201 and KIO-301 and receiving regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities;
- establishing sales, marketing and distribution capabilities and launching commercial sales of KIO-101, KIO-201 and KIO-301, if and when approved, whether alone or in collaboration with others;
- acceptance of KIO-101, KIO-201 and KIO-301, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies, including the existing standard-of-care;
- maintaining a continued acceptable safety profile of KIO-101, KIO-201 and KIO-301 following approval;
- obtaining and maintaining coverage and adequate reimbursement from third-party payors;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and
- protecting our rights in our intellectual property portfolio related to KIO-101, KIO-201 and KIO-301.

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 KIO-101, KIO-201 and KIO-301, which would materially harm our business.

If clinical trials of KIO-101, KIO-201, KIO-301 or any other product candidate that we develop fail to demonstrate safety and efficacy to the satisfaction of the FDA or foreign regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be delayed or unable to complete, the development and commercialization of KIO-101, KIO-201, KIO-301 or any other 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 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 products.

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 KIO-101, KIO-201, KIO-301 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;
- any third-party contractors may fail to comply with regulatory requirements or meet their contractual 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;
- 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; and
- 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 the trials.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully

complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not favorable or are only modestly favorable 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;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our pre-clinical 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 KIO-101, KIO-201 and KIO-301, or our other product candidates that we may 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 U.S. In addition, some of our competitors may have ongoing clinical trials for product candidates that treat the same indications as KIO-101, KIO-201 and KIO-301, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Our inability to 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 of our product candidates, we may need to abandon or limit our development of such product candidates.

If KIO-101, KIO-201, KIO-301 or any of our other product candidates are associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in clinical or early-stage testing for treating ophthalmic disease have later been found to cause side effects that prevented further development of the compound.

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. To the extent our contemplated trials are unsuccessful, we may not be able to raise additional funds for subsequent trials or pursuing other indications.

Risks Related to the Commercialization of Our Product Candidates

Even if KIO-101, KIO-201, KIO-301 or any other product candidate that we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community necessary for commercial success and the market opportunity for our product candidates may be smaller than we estimate.

If KIO-101, KIO-201, KIO-301 or any other product candidate that we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community.

Our assessment of the potential market opportunity for KIO-101, KIO-201 and KIO-301 is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. 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. If the actual market for KIO-101, KIO-201 and KIO-301 is smaller than we expect, 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, we may not be successful in KIO-101, KIO-201, KIO-301 or any other product candidates that we may develop if and when they are approved.

We do not have a sales or marketing infrastructure. To achieve commercial success for any product for which we have obtained marketing approval and have not licensed the commercialization rights, we will need to establish sales, marketing, and distribution capabilities, either ourselves or through collaborations or other arrangements with third parties.

In the future, we plan to build sales and marketing infrastructure to market or co-promote KIO-101, KIO-201 and KIO-301 products and possibly other product candidates that we develop, if and when they are approved. 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. If the commercial launch of KIO-101, KIO-201, or any other product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize 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 physicians or persuade adequate numbers of physicians 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 and marketing organization.

We expect to enter into arrangements with third parties to perform consulting, sales, marketing, and distribution services in markets outside the U.S. We may also enter into arrangements with third parties to perform these services in the U.S. if we do not establish our own sales, marketing, and distribution capabilities in the U.S. or if we determine that such third-party arrangements are otherwise beneficial. Our product revenues and our profitability, if any, under any such third-party sales, marketing or distribution arrangements are likely to be lower than if we were to market, sell and distribute our product candidates. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. 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 KIO-101, KIO-201, KIO-301 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.

The development and commercialization of new drug products is highly competitive. We face competition with respect to KIO-101, KIO-201, KIO-301 and our other current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. 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 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 product candidates. Our competitors also may obtain FDA or foreign 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 the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If KIO-101, KIO-201, KIO-301 or any other product candidate that we may develop achieves marketing approval, we expect that it will be priced at a premium over competitive products.

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.

Even if we are able to commercialize KIO-101, KIO-201, KIO-301 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 KIO-101, KIO-201, KIO-301 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 our product candidates 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 any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or similar regulatory authorities outside the U.S. 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 U.S. 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 or any products that we may in-license, if they are approved for sale in the U.S. or in other countries, will be considered medically reasonable and necessary for a specific indication, that they will be considered cost-effective by third-party payors, that coverage 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.

Our strategy of obtaining rights to product candidates and approved products through in-licenses and acquisitions may not be successful.

We may expand our product pipeline through opportunistically in-licensing or acquiring the rights to other products, product candidates or technologies. The future growth of our business may depend in part on our ability to in-license or acquire the rights to approved products, additional product candidates or technologies. However, we may be unable to in-license or acquire the rights to any such products, product candidates or technologies from third parties. The in-licensing and acquisition of pharmaceutical products is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire products, product candidates or technologies that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to in-license or acquire the rights to the relevant product, product candidate or technology on terms that would allow us to make an appropriate return on our investment. Furthermore, we may be unable to identify suitable products, product candidates or technologies within our area of focus. If we are unable to successfully obtain rights to suitable products, product candidates or technologies, our ability to pursue this element of our strategy could be impaired.

Product liability lawsuits against us 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 the product candidates that we develop in human clinical trials and will 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.

While we obtain insurance for each clinical trial we perform, we may not be adequately insured to cover all liabilities that we may incur. We will 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 product candidate that receives 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 may enter into collaborations with other 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 commercialize KIO-101, KIO-201 and KIO-301 in markets outside the U.S. We also may enter into arrangements with third parties to perform these services in the U.S. if we do not establish our own sales, marketing and distribution capabilities in the U.S. 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. 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. To date, the only agreements we entered into were our Licensing Agreements with Bausch Health Companies ("BHC"), which were terminated effective March 14, 2019. 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.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If we do not receive the funding we expect under any future collaboration agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this prospectus and the documents incorporated by reference 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 deemphasize 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 additional 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 and biotechnology companies for the development and potential commercialization of therapeutic products. 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 U.S., 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.

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 have relied on third parties, such as contract research organizations ("CROs") to conduct our completed trials of our product candidates, and do not plan to independently conduct clinical trials of our product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our clinical trials. These agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that would delay our product development activities.

36

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

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

We contract with third parties for the manufacture of KIO-101, KIO-201 and KIO-301 for clinical trials and expect to continue to do so in connection with the commercialization of KIO-101, KIO-201, KIO-301 and for clinical trials and commercialization of any other product candidates that we may develop. 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 currently own or operate manufacturing facilities for the production of clinical or commercial quantities of KIO-101, KIO-201, KIO-301 or any other of our product candidates. We rely, and expect to continue to rely, on third parties to manufacture clinical and commercial supplies of KIO-101, KIO-201 and KIO-301, preclinical and clinical supplies of our other product candidates that we may develop, and commercial supplies of products if and when any of our product candidates receives marketing approval. Our current and anticipated future dependence upon others for the manufacture of KIO-101, KIO-201, KIO-301 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.

We currently rely exclusively on third-party manufacturers to assemble and prepare KIO-101, KIO-201 and KIO-301 on a purchase order basis. We do not currently have any contractual commitments for commercial supply of bulk drug substance for KIO-101, KIO-201 and KIO-301, or fill-finish services. We also do not currently have arrangements in place for redundant supply or a second source for bulk drug substance for KIO-101, KIO-201 and KIO-301, or for fill-finish services. The prices at which we are able to obtain supplies of KIO-101, KIO-201, KIO-301 and fill-finish services may vary substantially over time and adversely affect our financial results.

If our third-party manufacturers for KIO-101, KIO-201 or KIO-301 fail to fulfill our purchase orders or should become unavailable to us for any reason, we believe that there are a limited number of potential replacement manufacturers, and we likely would incur added costs and delays in identifying or qualifying such replacements. We could also incur additional costs and delays in identifying or qualifying a replacement manufacturer for fill-finish services if our existing third-party manufacturer should become unavailable for any reason. We may be unable to establish any agreements with such replacement manufacturers or to do so on acceptable terms. Even if we could transfer manufacturing to a different third party, the shift would likely be expensive and time consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need FDA approval before using or selling any products manufactured at that facility.

In connection with our application for a license to market KIO-101, KIO-201, KIO-301 or other product candidates in the U.S., 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.

37

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

- KIO-101, KIO-201, KIO-301 and any other product candidates that we may 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 (“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 U.S. 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.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to our proprietary technology and products. We and our licensors have sought to protect our proprietary position by filing patent applications in the U.S. and abroad related to our novel technologies and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Maintaining patents in the U.S. is an expensive process and it is even more expensive to maintain patents and patent applications in foreign countries. As a result, it is possible that we and our licensors will fail to maintain such patents thereby reducing the rights of our portfolio.

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 and our licensors’ patent rights are highly uncertain. Our and our licensors’ pending and future patent applications may not result in patents being issued which protect our technology or products 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 U.S. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty 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. As a result, the issuance, scope, validity, enforceability, and commercial value of our owned or licensed patent rights are highly uncertain. We currently have 34 pending patents. Our pending and future patent applications may not result in patents being issued which protect our technology or products, 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 U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products 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.

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, 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.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate 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 products. 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 owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

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

Third parties may initiate legal proceedings alleging that we are infringing 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, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the medical device, biotechnology, and

pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the U.S. Patent and Trademark Office. 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 KIO-101, KIO-201, KIO-301 or any other product candidate, or our commercialization thereof, does not and will not infringe or otherwise violate any third party's intellectual property.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our 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. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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.

We are party to licensing agreements that impose, and, for a variety of purposes, we will likely 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.

Under certain of our existing licensing agreements, we are obligated to pay royalties or make specified milestone payments on net product sales to the extent they are covered by the agreements. We also are obligated under certain of our existing license agreements to pay maintenance and other fees. We also have diligence and development obligations under certain of those agreements that we are required to satisfy. 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 the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

We may be 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.

Some of our employees were previously employed at universities or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees 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. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. 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 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise 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 some of 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. 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 U.S. 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 KIO-101, KIO-201, KIO-301 or any other product candidate that we may develop, and our ability to generate 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 KIO-101, KIO-201, KIO-301 or any other product candidate.

The activities associated with the development and commercialization of our product candidates, including KIO-101, KIO-201 and KIO-301, including 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 U.S. and similar regulatory authorities outside the U.S. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market KIO-101, KIO-201, KIO-301 or any other product candidate from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs and consultants to assist us in this process.

The process of obtaining marketing approvals, both in the U.S. and abroad, is expensive and may take many years, especially if additional clinical trials are required, if approval is obtained at all. 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, purity, and potency. 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 KIO-101, KIO-201, KIO-301 or any other product candidate that we may develop is not safe, effective or pure, 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. 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.

The regulatory process can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved.

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

In order to market and sell KIO-101, KIO-201, KIO-301 and any other product candidate that we may develop in other jurisdictions, we or our 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. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U.S., it is required that the product be approved for reimbursement before the product can be sold in that country. We or these third parties may not obtain approvals from regulatory authorities outside the U.S. 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 U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

Even if we, or any collaborators we may have in the future, obtain marketing approvals for KIO-101, KIO-201, KIO-301 or our other product candidates, the terms of those approvals, ongoing regulations and post-marketing restrictions may limit how we, or they, 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 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 they obtain marketing approval. Promotional communications with respect to prescription products 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 KIO-101, KIO-201, KIO-301 or any other product candidate that we may develop receives marketing approval, the accompanying label may limit the approved use of our product, which could limit sales of the product.

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, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, 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 physicians, 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 prescription products 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 adverse 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
- injunctions or the imposition of civil or criminal penalties.

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

Healthcare providers, physicians and third-party payors in the U.S. and elsewhere will play a primary role in the recommendation and prescription of any product candidates, including KIO-101, KIO-201 and KIO-301, 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;

43

- 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 physicians 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 physicians 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.

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

In the U.S. 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 any product candidate, including KIO-101, KIO-201 and KIO-301, for which we obtain marketing approval or that we may in-license. The pharmaceutical industry has been a particular focus of these efforts and has 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 approved product.

44

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") changed the way Medicare covers and pays for pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could limit coverage of and reduce the price that we receive for any approved products. While the MMA applies only to product 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 MMA or other healthcare reform measures may result in a similar reduction in payments from private payors.

In March 2010, former President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively "PPACA"). Among the provisions of PPACA 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 PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2030 unless additional Congressional action is taken. In January 2013, former President Obama signed into law 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. In addition, it is possible that changes in administration and policy could result in additional proposals and/or changes to health care system legislation.

Additionally, there has been heightened governmental scrutiny in the U.S. of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At both the federal and state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that these and 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 approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

The pricing of prescription pharmaceuticals is also subject to governmental control outside the U.S. 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 candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

If we or our third-party manufacturers 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 our third-party manufacturers 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 and flammable 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 workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, this insurance may not provide adequate coverage against potential liabilities.

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 our 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.

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 Brian Strem, our Chief Executive Officer, as well as the other principal members of our management, scientific and clinical team and a number of third-party consultants. Although we have entered into an employment agreement with Dr. Strem, he may terminate his 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 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. The availability of qualified personnel in the markets in which we operate has declined in recent years and competition for such labor has increased, especially under the economic upheaval experienced throughout the COVID-19 pandemic. 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 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 may experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing, and distribution. To manage our potential 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 the limited experience of our management team in managing a company with such potential 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.

We may fail to realize any benefits and incur losses related to any acquisition.

The success of our strategic acquisitions will depend, in part, on our ability to successfully integrate the acquired businesses with our existing business, including our recent acquisitions of Panoptes Pharma Ges.m.b.H and Bayon Therapeutics, Inc. It is possible that the integration process could result in the loss of key employees, the disruption of ongoing business or inconsistencies in standards, controls, procedures, and policies that adversely affect our ability to maintain relationships with clients, customers and employees or to achieve the anticipated benefits of the acquisition. Successful integration may also be hampered by any differences between the operations and corporate culture of the two organizations. If we experience difficulties with the integration process, the anticipated benefits of the acquisition may not be realized fully, or at all, or may take longer to realize than expected.

Risks Related to Our Common Stock

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, 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.

47

The issuance of additional equity securities may negatively impact the trading price of our common stock.

We have issued equity securities in the past, will issue equity securities in this offering and expect to continue to issue equity securities to finance our activities in the future. In addition, outstanding options and warrants to purchase our common stock may be exercised and additional options and warrants may be issued, resulting in the issuance of additional shares of common stock. The issuance by us of additional equity securities would result in dilution to our stockholders, and even the perception that such an issuance may occur could have a negative impact on the trading price of our common stock.

A significant number of additional shares of our common stock may be issued upon the conversion of existing securities, which issuances would substantially dilute existing stockholders and may depress the market price of our common stock.

As of December 20, 2022, there were 1,796,472 shares of common stock outstanding, 7 shares of Series D Convertible Preferred Stock that are convertible into 52 shares of common stock, 1,597,606 shares of common stock underlying outstanding warrants, and 79,538 shares of common stock underlying outstanding options. The issuance of any such shares of common stock would substantially dilute the proportionate ownership and voting power of existing security holders, and their issuance, or the possibility of their issuance, may depress the market price of our common stock.

General Risk Factors

The coronavirus pandemic could adversely impact our business, including clinical trials.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread globally. As the COVID-19 pandemic continues, we could experience disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling patients in clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as clinical trial sites and hospital staff supporting the conduct of clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with groups of people;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global manufacturing and shipping that may affect the transport of clinical trial materials and materials, including testing equipment and personal protective equipment, used at our facilities;
- changes in local regulations as part of a response to the COVID-19 coronavirus outbreak which may require us to change the ways in which clinical trials are conducted, which may result in unexpected costs;

48

- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- delay in the timing of interactions with the FDA due to absenteeism by federal employees or by the diversion of their efforts and attention to approval of other therapeutics or other activities related to COVID-19.

The global outbreak of the COVID-19 coronavirus continues to rapidly evolve. The extent to which COVID-19 may impact our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the emergence of new variants, travel restrictions and social distancing in the U.S. and other countries, business closures or business disruptions and the effectiveness of actions taken in the U.S. and other countries to contain and treat the disease.

Laws and regulations governing international operations may preclude us from developing, manufacturing, and selling certain products outside of the U.S. and require us to develop and implement costly compliance programs.

We must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate, including our operations in Austria and Australia. The Foreign Corrupt Practices Act (“FCPA”) prohibits any U.S. individual or business from paying, offering, authorizing payment, or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA 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. Various laws, regulations and executive orders also restrict the use and dissemination outside of the U.S., 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. Our foreign operations 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 U.S., which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA’s accounting provisions.

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

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach 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 and the further development of our product candidates could be delayed.

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 restated certificate of incorporation and our amended and restated 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:

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

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

- the success of competitive products or technologies;

- results of clinical trials of KIO-101, KIO-201, KIO-301 or any other product candidate that we may develop;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the U.S. 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, 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;
- reduction in stock price could indicate impairment of the goodwill and intangible assets;
- 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 KIO-101, KIO-201 or KIO-301. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management’s attention and resources.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2021, we had federal net operating loss carryforwards of approximately \$72.4 million, state net operating loss carryforwards of approximately \$51.9 million and aggregate federal and state research and development tax credit carryforwards of approximately \$2.5 million and \$0.503 million, respectively, available to reduce future taxable income. Certain of these federal and state net operating loss carryforwards and federal and state tax credit carryforwards will expire at various dates through 2041, if not utilized. Federal net operating losses generated as of December 31, 2017 will carry-forward until 2037 and net operating losses generated during the year ended December 31, 2018 and later will be carried forward indefinitely until utilized, but their utilization will be limited to 80% of taxable income. Utilization of these net operating loss and tax credit carryforwards may be subject to a substantial limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and comparable provisions of state, local and foreign tax laws due to changes in ownership of our company that have occurred previously or that could occur in the future. Under Section 382 of the Code and comparable provisions of state, local and foreign tax laws, if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change by value in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research and development tax credits, to reduce its post-change income may be limited. We have not completed a study to determine whether our initial public offering, subsequent public and private offerings, and other transactions that have occurred may have triggered an ownership change limitation. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we generate taxable income, our ability to use our pre-change net operating loss and tax credits carryforwards to reduce U.S. federal and state taxable income may be subject to limitations, which could result in increased future tax liability to us. In addition, the Tax Cuts and Jobs Act (“TCJA”) enacted on December 22, 2017 limits the amount of net operating losses that we are permitted to deduct in any taxable year to 80% of our taxable income in such year. The TCJA also eliminates the ability to carry back net operating losses to prior years, but allows net operating losses generated after 2017 to be carried forward indefinitely. As such, there is a risk that due to such items, our existing net operating losses could expire or be unavailable to offset future income. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

We are a smaller reporting company and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are a smaller reporting company (“SRC”) and a non-accelerated filer, which allows us to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not SRCs or non-accelerated filers, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, reduced disclosure obligations, including disclosures regarding executive compensation, in our Annual Report and our periodic reports and proxy statements and providing only two years of audited consolidated financial statements in our Annual Report and our periodic reports. We will remain an SRC until (a) the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day our most recently completed second fiscal quarter exceeds \$250 million or (b) in the event we have over \$100 million in annual revenues, the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day our most recently completed second fiscal quarter exceeds \$700 million. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of 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 and may decline.

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

As a public company, we incur significant legal, accounting, and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, FINRA rules 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 need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain a non-accelerated filer, 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 have engaged in a process to document and evaluate our internal control over financial reporting. In this regard, we will need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan to continue 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. As we have identified 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 consolidated financial statements.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains, and the documents incorporated herein by reference contain, forward-looking statements that involve risks and uncertainties. The forward-looking statements are contained principally in the sections of this prospectus and the documents incorporated herein by reference under the captions "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "seek," "aim," "think," "optimistic," "strategy," "goals," "sees," "new," "guidance," "future," "continue," "drive," "growth," "long-term," "develop," "possible," "emerging," "opportunity," "pursue," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the timing and success of preclinical studies and clinical trials conducted by us and our development partners;
- the ability to obtain and maintain regulatory approval of our product candidates, and the labeling for any approved products;
- the scope, progress, expansion, and costs of developing and commercializing our product candidates;
- the size and growth of the potential markets for our product candidates and the ability to serve those markets;
- our expectations regarding our expenses and revenue, the sufficiency of our cash resources and needs for additional financing;
- the rate and degree of market acceptance of any of our product candidates;
- our expectations regarding competition;
- our anticipated growth strategies;
- our ability to attract or retain key personnel;
- our ability to establish and maintain development partnerships;
- our expectations regarding federal, state and foreign regulatory requirements;
- regulatory developments in the U.S. and foreign countries;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- the anticipated trends and challenges in our business and the market in which we operate;
- the impact of the evolving COVID-19 pandemic and the global response thereto; and
- our use of proceeds from this offering.

Any forward-looking statement made by us in this prospectus speaks only as of the date on which it is made. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

55

MARKET FOR COMMON STOCK

Our common stock is listed on The Nasdaq Capital Market under the symbol “KPRX”. On December 27, 2022, the last reported sale price of our common stock as reported by The Nasdaq Capital Market was \$2.45 per share. As of such date, we had approximately 53 stockholders of record.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain future earnings, if any, and all currently available funds for use in the operation of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our Board of Directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the Board of Directors deems relevant, and subject to the restrictions contained in our current or future financing instruments.

56

USE OF PROCEEDS

We will receive no proceeds from the sale of shares of Common Stock by the selling stockholders.

The shares of Common Stock covered by this prospectus are issuable upon exercise of the Inducement Warrants issued to the selling stockholders. The exercise price of the outstanding Inducement Warrants is \$5.97 per share. The exercise price and number of shares of Common Stock issuable upon exercise of the Inducement Warrants may be adjusted in certain circumstances, including stock splits or dividends, mergers, or reclassifications or similar events. Upon any exercise of outstanding Inducement Warrants, the applicable selling stockholder will pay us the exercise price.

To the extent we receive proceeds from the cash exercise of outstanding Inducement Warrants, we intend to use the proceeds for working capital and other general corporate purposes.

57

SELLING STOCKHOLDERS

The table below sets forth information concerning the resale of our shares by the selling stockholders. The selling stockholders acquired the Inducement Warrants in the Private Placement, and the shares of Common Stock being registered hereunder are issuable pursuant to the exercise of those Inducement Warrants. The total number of shares of Common Stock sold under this prospectus may be adjusted to reflect adjustments due to stock dividends, stock distributions, splits, combinations or recapitalizations with regard to the Common Stock and warrants. Unless otherwise stated below in the footnotes, to our knowledge, neither the selling stockholders, nor any affiliate of such stockholders: (i) has held any position or office with us during the three years prior to the date of this prospectus; or (ii) is a broker-dealer, or an affiliate of a broker-dealer.

The Selling Stockholders may exercise their Inducement Warrants at any time following the six-month anniversary of the issuance of the Inducement Warrants in their sole discretion. Set forth below is the name of each selling stockholder and the amount and percentage of Common Stock owned by such selling stockholder (including shares which such stockholder has the right to acquire within 60 days, including upon exercise of warrants) prior to the offering, the shares to be sold in the offering, and the amount and percentage of Common Stock to be owned by each selling stockholder (including shares which such stockholder has the right to acquire within 60 days, including upon exercise of warrants) after the offering assuming all shares are sold. The footnotes provide information about persons who have voting and dispositive power with respect to shares held by the selling stockholder.

We have registered 654,610 shares of our Common Stock underlying Inducement Warrants issued to the selling stockholders in connection with the Private Placement. See “Prospectus Summary” above.

The following table is based on information provided to us by the selling stockholders and is as of December 20, 2022. Each selling stockholder may sell all or some of the shares of Common Stock it is offering, and may sell, unless indicated otherwise in the footnotes below, shares of our Common Stock otherwise than pursuant to this prospectus. The tables below assume that each selling stockholder sells all of the shares offered by it in offerings pursuant to this prospectus, and does not acquire any additional shares. We are unable to determine the exact number of shares that will actually be sold or when or if these sales will occur.

58

Name of Selling Stockholders	Shares Beneficially Owned Pre-Offering (1)	Common Stock Offered in this Offering	Number of Shares Post-Offering	% of Shares Post-Offering (2)
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Bigger Capital Fund, LP (3)	263,452	85,938	177,514	4.99%
Boothbay Absolute Return Strategies, LP (4)	41,400		20,700	1.14 %
Boothbay Diversified Alpha Master Fund LP (5)	21,000	10,550	10,550	*
District 2 Capital Fund LP (6)	180,814	60,938	119,876	4.99 %
FGP Protective Opportunity Fund (7)	178,750	56,875	121,875	6.35 %
Intracoastal Capital LLC (8)	172,771	53,125	119,646	6.24 %
Iroquois Capital Investment Group, LLC (9)	10,000	5,000	5,000	*
Iroquois Master Fund, Ltd. (10)	40,000	20,000	20,000	1.10 %
Lincoln Park Capital Fund, LLC (11)	365,625	121,875	243,750	9.99 %
Lind Global Fund II LP (12)	135,858	62,500	73,358	3.92 %
Walleye Opportunities Master Fund Ltd. (13)	370,035	121,875	248,160	9.99 %
Warberg WF X LP (14)	108,278	35,234	73,044	3.91 %
TOTAL	1,888,083	654,610	1,233,473	

* Less than one percent of shares outstanding.

- (1) Beneficial ownership includes shares of Common Stock as to which a person or group has sole or shared voting power or dispositive power. Shares of Common Stock registered hereunder, as well as shares of common stock subject to options, warrants or convertible preferred stock that are exercisable or convertible within 60 days of December 20, 2022, are deemed outstanding for purposes of computing the number of shares beneficially owned and percentage ownership of the person or group holding such shares of Common Stock, options, warrants or convertible securities, but are not deemed outstanding for computing the percentage of any other person. For purposes of this table only, the shares of common stock underlying the Inducement Warrants are included under the column “Shares Beneficially Owned Pre-Offering”, notwithstanding that the Inducement Warrants may not be exercised until six months following their issuance.
- (2) Percentages are based on 1,796,472 shares of Common Stock outstanding as of December 20, 2022.
- (3) Consists of (i) 84,337 shares of common stock, (ii) 85,938 Inducement Warrants, and (iii) other warrants to purchase an aggregate of 93,177 shares of common stock that are exercisable within 60 days of December 20, 2022. The beneficial ownership percentage reflects a beneficial ownership limitation in such warrants that prohibits their exercise if it would result in the holder beneficially owning more than 4.99% of our common stock. Michael Bigger, Managing Member of the GP of Bigger Capital Fund, LP, may be deemed to have voting control and investment discretion over securities held by Bigger Capital Fund, LP.
- (4) Consists of (i) 20,700 Inducement Warrants, and (ii) other warrants to purchase an aggregate of 20,700 shares of common stock that are exercisable within 60 days of December 20, 2022. Boothbay Absolute Return Strategies LP, a Delaware limited partnership (the “Fund”), is managed by Boothbay Fund Management, LLC, a Delaware limited liability company (the “Adviser”). The Adviser, in its capacity as the investment manager of the Fund, has the power to vote and the power to direct the disposition of all securities held by the Fund. Ari Glass is the Managing Member of the Adviser. Each of the Fund, the Adviser and Mr. Glass disclaim beneficial ownership of these securities, except to the extent of any pecuniary interest therein.
- (5) Consists of (i) 10,550 Inducement Warrants, and (ii) other warrants to purchase an aggregate of 10,550 shares of common stock that are exercisable within 60 days of December 20, 2022. Boothbay Diversified Alpha Master Fund LP, a Cayman Islands limited partnership (the “Fund”), is managed by Boothbay Fund Management, LLC, a Delaware limited liability company (the “Adviser”). The Adviser, in its capacity as the investment manager of the Fund, has the power to vote and the power to direct the disposition of all securities held by the Fund. Ari Glass is the Managing Member of the Adviser. Each of the Fund, the Adviser and Mr. Glass disclaim beneficial ownership of these securities, except to the extent of any pecuniary interest therein.

- (6) Consists of (i) 55,318 shares of common stock, (ii) 60,938 Inducement Warrants, and (iii) other warrants to purchase an aggregate of 64,558 shares of common stock that are exercisable within 60 days of December 20, 2022. The beneficial ownership percentage reflects a beneficial ownership limitation in such warrants that prohibits their exercise if it would result in the holder beneficially owning more than 4.99% of our common stock. Michael Bigger, Managing Member of the GP of District 2 Capital Fund, LP, may be deemed to have voting control and investment discretion over securities held by District 2 Capital Fund, LP.
- (7) Consists of (i) 56,875 Inducement Warrants, and (ii) other warrants to purchase an aggregate of 121,875 shares of common stock that are exercisable within 60 days of December 20, 2022. Gregory Pepin, Investment Manager of FGP Protective Opportunity Fund, may be deemed to have voting control and investment discretion over securities held by FGP Protective Opportunity Fund.
- (8) Consists of (i) 54,996 shares of common stock, (ii) 53,125 Inducement Warrants, and (iii) other warrants to purchase an aggregate of 64,650 shares of common stock that are exercisable within 60 days of December 20, 2022. Mitchell P. Kopin (“Mr. Kopin”) and Daniel B. Asher (“Mr. Asher”), each of whom are managers of Intracoastal Capital LLC (“Intracoastal”), have shared voting control and investment discretion over the securities reported herein that are held by Intracoastal. As a result, each of Mr. Kopin and Mr. Asher may be deemed to have beneficial ownership (as defined under Section 13(d) of the Exchange Act) of the securities reported herein that are held by Intracoastal.
- (9) Consists of (i) 5,000 Inducement Warrants, and (ii) other warrants to purchase an aggregate of 5,000 shares of common stock that are exercisable within 60 days of December 20, 2022. Richard Abbe is the managing member of Iroquois Capital Investment Group LLC. Mr. Abbe has voting control and investment discretion over securities held by Iroquois Capital Investment Group LLC.
- (10) Consists of (i) 20,000 Inducement Warrants, and (ii) other warrants to purchase an aggregate of 20,000 shares of common stock that are exercisable within 60 days of December 20, 2022. Richard Abbe is the managing member of Iroquois Master Fund, Ltd. Mr. Abbe has voting control and investment discretion over securities held by Iroquois Master Fund, Ltd.
- (11) Consists of (i) 121,875 shares of common stock, (ii) 121,875 Inducement Warrants, and (iii) other warrants to purchase an aggregate of 121,875 shares of common stock that are exercisable within 60 days of December 20, 2022. The beneficial ownership percentage reflects a beneficial ownership limitation in such warrants that prohibits their exercise if it would result in the holder beneficially owning more than 9.99% of our common stock. Lincoln Park Capital LLC (“LPC”) is the Managing Member of Lincoln Park Capital Fund LLC (“LPC Fund”). Rockledge Capital Corporation (“RCC”) and Alex Noah Investors, Inc. (“Alex Noah”) are the Managing Members of LPC. Joshua Scheinfeld is the president and sole shareholder of RCC, as well as a principal of LPC. Jonathan Cope is the president and sole shareholder of Alex Noah, as well as a principal of LPC. As a result of the foregoing, Mr. Scheinfeld and Mr. Cope have shared voting and shared investment power over the shares of common stock held directly by LPC Fund. Pursuant to Section 13(d) of the Exchange Act and the rules thereunder, each of LPC, RCC, Mr. Scheinfeld, Alex Noah, and Mr. Cope may be deemed to be a beneficial owner of the shares of common stock beneficially owned directly by LPC Fund. Each of LPC, RCC, Mr. Scheinfeld, Alex Noah, and Mr. Cope disclaims beneficial ownership of the shares of Common Stock of the Issuer held directly by LPC Fund.
- (12) Consists of (i) 62,500 Inducement Warrants, and (ii) other warrants to purchase an aggregate of 73,358 shares of common stock that are exercisable within 60 days of December 20, 2022. Jeff Easton, the managing member of Lind Global Partners, LLC, the general partner of Lind Global Fund II, LP, may be deemed to have voting control and investment discretion over securities held by Lind Global Fund II, LP.
- (13) Consists of (i) 126,285 shares of common stock, (ii) 121,875 Inducement Warrants, and (iii) other warrants to purchase an aggregate of 121,875 shares of common stock that are exercisable within 60 days of December 20, 2022. The beneficial ownership percentage reflects a beneficial ownership limitation in such warrants that prohibits their exercise if it would result in the holder beneficially owning more than 9.99% of our common stock. William England, the Chief Investment Officer of Walleye Capital, LLC, the Manager of Walleye Opportunities Master Fund Ltd., may be deemed to have voting control and investment discretion over securities held by Walleye Opportunities Master Fund Ltd.
- (14) Consists of (i) 37,810 shares of common stock, (ii) 35,234 Inducement Warrants, and (iii) other warrants to purchase an aggregate of 35,234 shares of common stock that are exercisable within 60 days of December 20, 2022. Daniel Warsh, Manager of Warberg WF X LP, may be deemed to have voting control and investment discretion over securities held by Warberg WF X LP.

PLAN OF DISTRIBUTION

The selling stockholders, which for this purpose includes donees, pledgees, transferees or other successors-in-interest selling shares of Common Stock or interests in shares of Common Stock received after the date of this prospectus from the selling stockholders as a gift, pledge, dividend, distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of Common Stock or interests in shares of Common Stock on any stock exchange, market or trading facility on which the shares are traded, or in private transactions. These sales or other dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.

The selling stockholders may use any one or more of the following methods when selling our shares or interests in our shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which a broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- on any national securities exchange or quotation service on which the shares may be listed or quoted at the time of sale;
- privately negotiated transactions;
- short sales effected after the date the registration statement of which this prospectus is a part is declared effective by the SEC;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- broker-dealers may agree with a selling stockholder to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted by applicable law.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of our shares owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of Common Stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act, amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders may also transfer our shares in other circumstances, in which case the transferees, pledgees or other successors will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of our shares of Common Stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of our shares in the course of hedging the positions they assume. The selling stockholders may also sell shares of our Common Stock short and deliver these securities to close out their short positions, or loan or pledge the Common Stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling stockholders from the sale of the Common Stock offered by them will be the purchase price of the Common Stock less discounts or commissions, if any. The selling stockholders reserve the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of Common Stock to be made directly or through agents. We will not receive any of the proceeds from sales of shares by the selling stockholders.

The selling stockholders may also resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided that they meet the criteria and conform to the requirements of that rule, or under Section 4(a)(1) of the Securities Act, if available, rather than by means of this prospectus.

In connection with the sale of shares of Common Stock covered by this prospectus, broker-dealers may receive commissions or other compensation from the selling stockholders in the form of commissions, discounts or concessions. Broker-dealers may also receive compensation from purchasers of the shares of Common Stock for whom they act as agents or to whom they sell as principals or both. Compensation as to a particular broker-dealer may be in excess of customary commissions or in amounts to be negotiated. In connection with any underwritten offering, underwriters may receive compensation in the form of discounts, concessions or commissions from a selling stockholder or from purchasers of the shares for whom they act as agents. Underwriters may sell the shares of Common Stock to or through dealers, and such dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for whom they may act as agents. Any underwriters, broker-dealers, agents or other persons acting on behalf of a selling stockholder that participate in the distribution of the shares of Common Stock may be deemed to be “underwriters” within the meaning of the Securities Act, and any profit on the sale of the shares of Common Stock by them and any discounts, commissions or concessions received by any of those underwriters, broker-dealers, agents or other persons may be deemed to be underwriting discounts and commissions under the Securities Act. The aggregate amount of compensation in the form of underwriting discounts, concessions, commissions or fees and any profit on the resale of shares by the selling stockholders that may be deemed to be underwriting compensation pursuant to Financial Industry Regulatory Authority, Inc., rules and regulations will not exceed applicable limits.

The selling stockholders and any underwriters, broker-dealers or agents that participate in the sale of the Common Stock or interests therein may be “underwriters” within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares may be underwriting discounts and commissions under the Securities Act. Selling stockholders who are “underwriters” within the meaning of Section 2(a)(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act and may be subject to certain statutory liabilities, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Exchange Act.

To the extent required, the shares of our Common Stock to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agent, dealer or underwriter, and any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the Common Stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the Common Stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. In addition, to the extent applicable, we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act. All of the foregoing may affect the marketability of the Common Stock and the ability of any person or entity to engage in market-making activities with respect to our Common Stock.

We will pay all expenses of the registration of the Common Stock for resale by the selling stockholders, including, without limitation, filing fees and expenses of compliance with state securities or “blue sky” laws; provided, however, that the selling stockholders will pay all underwriting discounts and selling commissions, if any, and any related legal expenses incurred by them.

DETERMINATION OF OFFERING PRICE

The prices at which the shares of Common Stock covered by this prospectus may actually be sold will be determined by the prevailing public market price for shares of Common Stock, by negotiations between the selling stockholders and buyers of our Common Stock in private transactions or as otherwise described in “Plan of Distribution.”

DESCRIPTION OF OUR CAPITAL STOCK

General

Our authorized capital stock consists of 50,000,000 shares of common stock, par value \$0.01 per share, and 10,000,000 shares of preferred stock, par value \$0.01 per share, of which 3,750 are designated as Series A Convertible Preferred Stock, 10,000 are designated as Series B Convertible Preferred Stock, 10,000 are designated as Series C Convertible Preferred Stock, 20,000 are designated as Series D Convertible Preferred Stock, and 1,280 are designated as Series E Convertible Preferred Stock, which we refer to as our Series E Preferred Stock. The following description summarizes some of the terms of our restated certificate of incorporation and second amended and restated bylaws, but does not purport to be complete and is qualified in its entirety by the provisions of our restated certificate of incorporation and second amended and restated bylaws, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.

There were 1,796,472 shares of our common stock, no shares of our Series A Convertible Preferred Stock, Series B Convertible Preferred Stock, Series C Convertible Preferred Stock or Series E Preferred Stock, and 7 shares of our Series D Convertible Preferred Stock (convertible into an aggregate of 52 shares of common stock) outstanding as of December 20, 2022, assuming no exercise of outstanding options or warrants. There were approximately 53 holders of record of our common stock as of December 20, 2022. This number does not include beneficial owners whose shares are held in street name.

As of December 20, 2022, there were 79,538 shares of common stock subject to outstanding options and 1,597,606 shares of common stock subject to outstanding warrants.

Common Stock

Voting Rights. Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of the stockholders, including the election of directors. Except as otherwise provided by law or our restated certificate of incorporation or bylaws, all matters other than the election of directors submitted to the stockholders at any meeting shall be decided by the affirmative vote of a majority of the outstanding shares of common stock present in person or represented by proxy at the meeting and entitled to vote thereon. Directors are elected by a plurality of the votes cast at the meeting. Our restated certificate of incorporation and second amended and restated bylaws do not provide for cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends. Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of our outstanding shares of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds. At present, we have no plans to issue dividends.

Liquidation. In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Other Rights and Preferences. Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of 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.

Fully Paid and Nonassessable. All of our outstanding shares of common stock are fully paid and nonassessable.

Forum Selection. Our restated 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 (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our restated certificate of incorporation or our bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act, Securities Act, or, in each case, the rules and regulations thereunder, or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Provisions in our restated certificate of incorporation provide that our board of directors is authorized to issue preferred stock in one or more series, to establish the number of shares to be included in each such series and to fix the designation, powers, preferences and rights of such shares and any qualifications, limitations or restrictions thereof. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of our company without further action by the stockholders and may adversely affect the voting and other rights of the holders of common stock. The issuance of preferred stock with voting and conversion rights may adversely affect the voting power of the holders of common stock, including the loss of voting control to others. At present, we have no plans to issue any additional preferred stock.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock. The ability of our board of directors, without action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings. Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board or chief executive officer (or president, if there is no chief executive officer), or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals. Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent. Our restated certificate of incorporation and amended and restated bylaws eliminate the right of stockholders to act by written consent without a meeting.

Staggered Board. Our board of directors is divided into three classes. The directors in each class serve for a three-year term, one class being elected each year by our stockholders. This system of electing and removing directors may tend to discourage a third-party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors. Our restated certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds (2/3) of the total voting power of all of our outstanding voting stock then entitled to vote in the election of directors.

65

Stockholders Not Entitled to Cumulative Voting. Our restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute. We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed to be “interested stockholders” from engaging in a “business combination” with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Amendment of Charter Provisions. The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least 66 2/3% of the total voting power of all of our outstanding voting stock.

The provisions of Delaware law, our restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Transfer Agent and Registrar

The transfer and warrant agent and registrar for our common stock is VStock Transfer, LLC.

Listing

Shares of our common stock are quoted on The Nasdaq Capital Market under the symbol “KPRX.”

66

LEGAL MATTERS

Certain legal matters with respect to the validity of the securities offered by this prospectus will be passed upon for us by Burns & Levinson LLP, Boston, MA.

EXPERTS

The consolidated balance sheets of Kiora Pharmaceuticals, Inc. as of December 31, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years then ended, have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report, which is incorporated herein by reference, which report includes an emphasis of matter paragraph regarding the correction of a misstatement and an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern. Such financial statements have been incorporated herein by reference in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the securities being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

We are subject to the information requirements of the Exchange Act and, in accordance therewith, file annual, quarterly and special reports, proxy statements and other information with the SEC. These documents may be accessed through the SEC's electronic data gathering, analysis and retrieval system, or EDGAR, via electronic means, including the SEC's home page on the Internet (www.sec.gov).

We post on our public website (www.kiorapharma.com) our Annual Report 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 Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our website and the information contained on that site, or connected to that site, are not incorporated into and are not a part of this prospectus.

67

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference the information and reports we file with it under File No. 001-36672, which means that we can disclose important information to you by referring you to those publicly available documents. The information incorporated by reference is an important part of this prospectus, and information that we file later with the SEC will automatically update and supersede the information already incorporated by reference. We are incorporating by reference the documents listed below:

- [Our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on April 15, 2022 \(as amended by Amendment No. 1 filed with the SEC on July 7, 2022\);](#)
- [Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 filed with the SEC on July 8, 2022;](#)
- [Our Quarterly Reporting on Form 10-Q for the quarter ended June 30, 2022 filed with the SEC on August 12, 2022;](#)
- [Our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 filed with the SEC on November 9, 2022;](#)
- Our Current Reports on Form 8-K filed with the SEC on [January 11, 2022](#), [February 1, 2022](#), [February 14, 2022](#), [February 28, 2022](#), [March 23, 2022](#), [April 26, 2022](#), [May 23, 2022](#), [May 31, 2022](#), [June 21, 2022](#), [July 26, 2022](#), [August 4, 2022](#), [August 25, 2022](#), [September 16, 2022](#), [September 23, 2022](#), [September 26, 2022](#), [October 13, 2022](#), and [November 21, 2022](#) (in each case, except for information contained therein which is furnished rather than filed);
- The description of our common stock contained in our registration statement on Form 8-A12B filed with the SEC on [July 28, 2015](#) and amended on [July 30, 2015](#); and
- All future documents filed by us with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act, including all filings made after the date of the filing of this registration statement and prior to the effectiveness of this registration statement, prior to the termination of the offering of the underlying securities; provided, however, that we are not incorporating by reference any additional documents or information furnished and not filed with the SEC.

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus is modified or superseded for purposes of the prospectus to the extent that a statement contained in this prospectus or in any other subsequently filed document that also is or is deemed to be incorporated by reference herein modifies or supersedes such statement.

Upon request, we will provide, without charge, to each person, including any beneficial owner, to whom a copy of this prospectus is delivered a copy of the documents incorporated by reference into this prospectus. You may request a copy of these filings, and any exhibits we have specifically incorporated by reference as an exhibit in this prospectus, at no cost by writing or telephoning us at the following address:

Kiora Pharmaceuticals, Inc.
1371 East 2100 South, Suite 200
Salt Lake City, Utah 84105
Telephone: (781) 788-8869

68

This prospectus is part of a registration statement we filed with the SEC. We have incorporated exhibits into this registration statement. You should read the exhibits carefully for provisions that may be important to you.

You should rely only on the information incorporated by reference or provided in this prospectus or any prospectus supplement. We have not authorized anyone to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus or in the documents incorporated by reference is accurate as of any date other than the date on the front of this prospectus or those documents.

69



654,610 Shares of Common Stock

PROSPECTUS

December 28, 2022
