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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022
OR

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

For the transition period from to
Commission File No. 001-36672

KIORA PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**98-0443284**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

332 Encinitas Blvd.
Suite 102
Encinitas, CA 92024
(Address of Principal Executive Offices, including zip code)
(781) 788-8869
(Registrant's telephone number, including area code)

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value	KPRX	The NASDAQ Capital Market

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act ☐ Yes ☒ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act ☐ Yes ☒ No

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of June 30, 2022 was approximately $6,117,599. Shares of the registrant's common stock held by each officer and director and each person known to the registrant to own 10% or more of the outstanding voting power of the registrant have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not a determination for other purposes.

At March 20, 2023, there were 1,919,270 shares of the registrant's common stock outstanding.

KIORA PHARMACEUTICALS, INC.

ANNUAL REPORT ON FORM 10-K
For the Year Ended December 31, 2022

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains statements that are not statements of historical fact and are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. The forward-looking statements are principally, but not exclusively, contained in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about management's confidence or expectations, and our plans, objectives, expectations, and intentions that are not historical facts. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "goals," "sees," "estimates," "projects," "predicts," "intends," "think," "potential," "objectives," "optimistic," "strategy," 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 pre-clinical 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 United States (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; and
- the impact of the evolving COVID-19 pandemic and the global response thereto.

We discuss many of these risks in detail under the heading "Item 1A. Risk Factors" beginning on page of 23 this Annual Report on Form 10-K. You should carefully review all of these factors, as well as other risks described in our public filings, and you should be aware that there may be other factors, including factors of which we are not currently aware, that could cause these differences.

Also, these forward-looking statements represent our estimates and assumptions only as of the date of this report. We may not update these forward-looking statements, even though our situation may change in the future, unless we have obligations under the federal securities laws to update and disclose material developments related to previously disclosed information.

Kiora Pharmaceuticals, Inc. is referred to herein as "we," "our," "us," and "the Company."

PART I

ITEM 1. BUSINESS

Overview

We are a clinical-stage specialty pharmaceutical company developing and commercializing 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 vision loss due to retinitis pigmentosa (RP, 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, including RP. The molecule is designed to restore the eyes' ability to perceive and interpret light in visually impaired patients through selectively entering viable downstream retinal ganglion cells (no longer receiving electrical input due to degenerated rods and cones) and turning 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 and dosed the first patient in November 2022. On March 17, 2022, we were granted orphan drug designation (ODD) by the United States Food and Drug Administration (FDA) for the active pharmaceutical ingredient (API) in KIO-301. KIO-301 (formerly known as B-203) was acquired through the Bayon Therapeutics, Inc. (Bayon) transaction which closed October 21, 2021.

KIO-101 focuses on treating the ocular manifestation of patients with autoimmune diseases, including rheumatoid arthritis and, as such, is termed the Ocular Presentation of Rheumatoid Arthritis and Other Autoimmune Diseases (OPRA+). KIO-101 is a next-generation, non-steroidal, immuno-modulatory, small-molecule inhibitor of dihydroorotate dehydrogenase (DHODH). We believe KIO-101 to be best-in-class with 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 good laboratory practice (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 top-line 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 expect to initiate a Phase 2 clinical trial in the first quarter of 2023. KIO-101 (formerly known as PP-001) was acquired through the acquisition of Panoptes Pharma GmbH (Panoptes) in the fourth quarter of 2020.

We are developing KIO-201 for patients with persistent corneal epithelial defects (PCED). PCED is an orphan disease and as such, we are currently seeking orphan drug designation (ODD). KIO-201 is also being evaluated for patients recovering from surgical wounds, such as those undergoing the laser vision correction procedure, photorefractive keratectomy (PRK). 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. We are currently evaluating KIO-201 in a Phase 2 clinical trial in patients with PCEDs and released top-line data in Q1 2023. We expect to release full data in Q2 2023. We are in planning stages of a Phase 3b trial for patients recovering from PRK and plan to initiate the study before the end of 2023.

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. RP is the largest family of these inherited diseases. RP affects about 1 in 3,500 people worldwide. Thus, with a population of about 330 million in the U.S. as of February 2021, about 96,250 people in

the U.S. would be expected to have RP. With a worldwide population presently estimated at over 7.7 billion, it can be estimated that approximately 2.3 million people around the world have RP.

RP is a group of hereditary progressive disorders that may be inherited as autosomal recessive, autosomal dominant or X-linked recessive traits. Maternally inherited variants of RP transmitted via the mitochondrial DNA can also exist. 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.

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 (RGCs), 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 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 hyperpolarization-activated, cyclic nucleotide-gated (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 fewer than 200,000. This prevalence enables consideration for KIO-301 to qualify for orphan drug designation 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 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 U.S. Approximately one-third of these patients present with OPRA+ (more than 0.5 million in the U.S.), with more than 90% seeking prescription medication to address these ophthalmic manifestations. Unfortunately, today's

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 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. 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 Surgery Market Overview

There are multiple surgical procedures involving the ocular surface that have long recovery, whereby acceleration of that period would benefit the patients. PRK surgery is an efficacious alternative to patients seeking surgical correction of refractive errors who are not suitable candidates for Laser-Assisted In Situ Keratomileusis (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-epithelization 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 U.S., according to the National Organization for Rare Disorders (NORD). Whilst PRK comprises a fraction of these procedures, there are about 160,000 surgeries performed annually in the U.S according to NORD. 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 U.S. alone according to NORD. 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 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 HA 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-epithelization 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-epithelization in both preclinical studies and in clinical ophthalmic veterinary use. As such, PRK surgery was chosen 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 LASIK due to inadequate corneal thickness, larger pupil size, history of 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.

A possible market expansion from PRK surgical recovery would be to evaluate KIO-201 in patients with keratoconus, an ocular disease that affects the structure of the cornea and can cause blindness. Currently patients undergo a mechanical reshaping of the cornea, however this approach causes significant damage to the epithelial layer. As KIO-201 has demonstrated the ability to accelerate wound healing to the ocular surface,

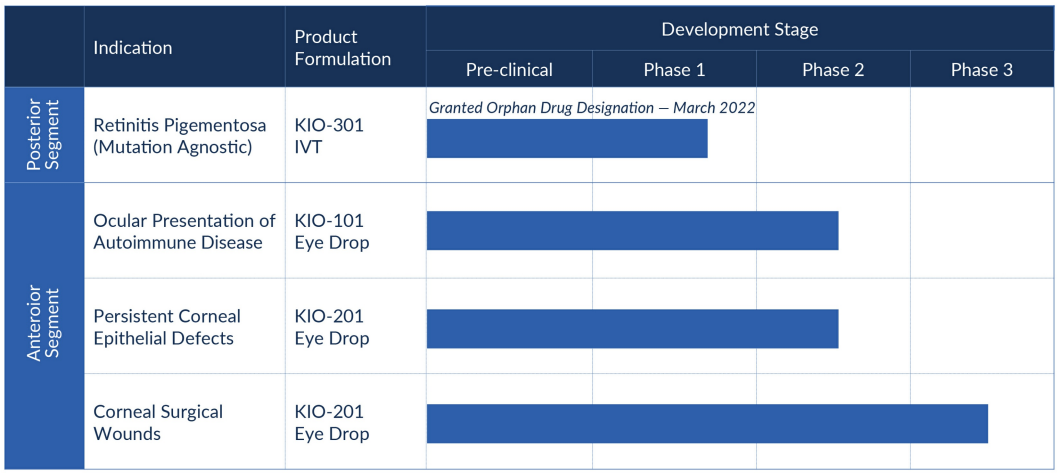
the underlying mechanism of action would be a congruent fit. There are about 170,000 patients in the U.S. with keratoconus according to NORD.

Our Strategy

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

- Develop Core Assets
  - Continue clinical development of KIO-301 in a Phase 1b clinical study in patients with mid to late stage retinitis pigmentosa.
  - Continue clinical development of KIO-101 in a Phase 2 clinical study for the treatment of the ocular manifestations of autoimmune diseases (e.g., rheumatoid arthritis). In the first quarter of 2023, we received approval to initiate a Phase 2 study, slated to start enrollment in the second quarter of 2023.
  - Continue clinical development of KIO-201 in patients with PCEDs and advance our late stage program for patients undergoing surgical vision correction including PRK and certain types of keratoconus surgical procedures. These programs will benefit from discussions with the FDA regarding clinical trial designs and approvable endpoints.
- 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



Clinical Development

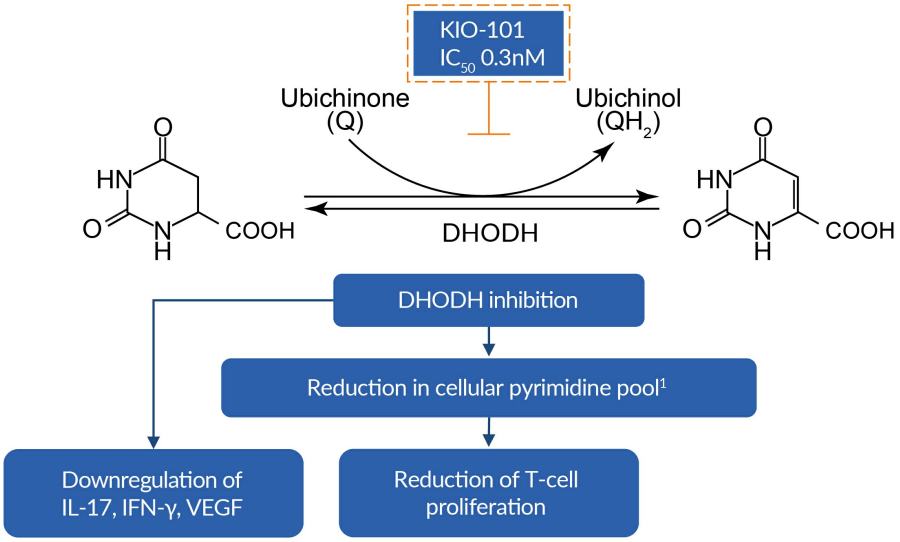
KIO-101: Ocular Presentation of Rheumatoid Arthritis and Other Autoimmune Diseases (OPRA+)

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-g, VEGF and others, potentially as a consequence of inhibiting DHODH. IL-17 and IFN-g 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-noninfectious 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.

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



[1] Normal cells have sufficient pyrimidines by the salvage pathway and are not affected by the treatment

Phase 1b Study:

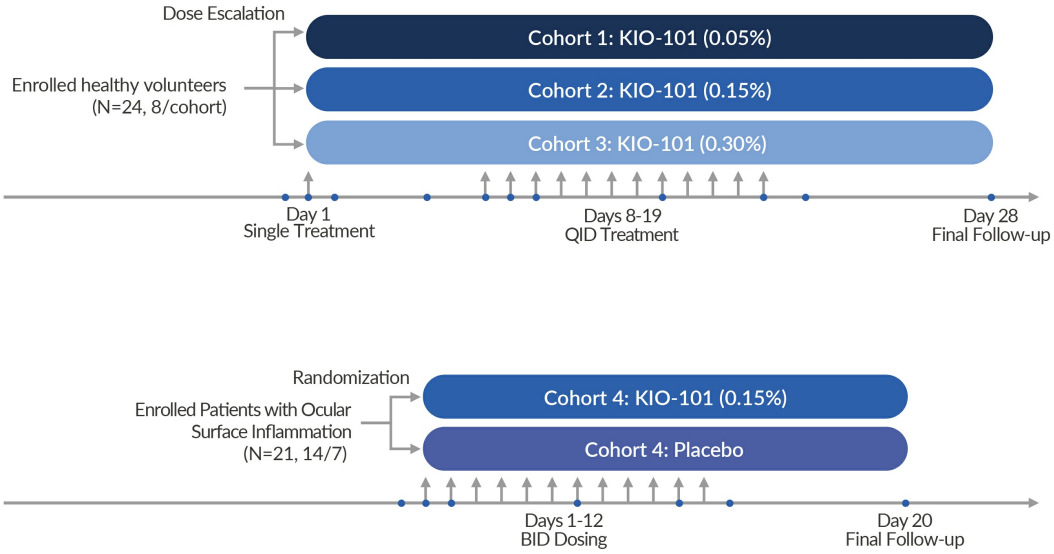
The results of a Phase 1b study of KIO-101 eye drops in adults with and without ocular surface inflammation were reported in Q4 2021.

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 (SAEs) or severe ocular Adverse Events (AEs) 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 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), conjunctival staining (lissamine green), ocular discomfort, lid edema, and lid erythema.



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% (Figure 1 below) 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 OSDI, but no statistically significant differences were observed in TBUT, corneal staining, conjunctival staining, or 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.

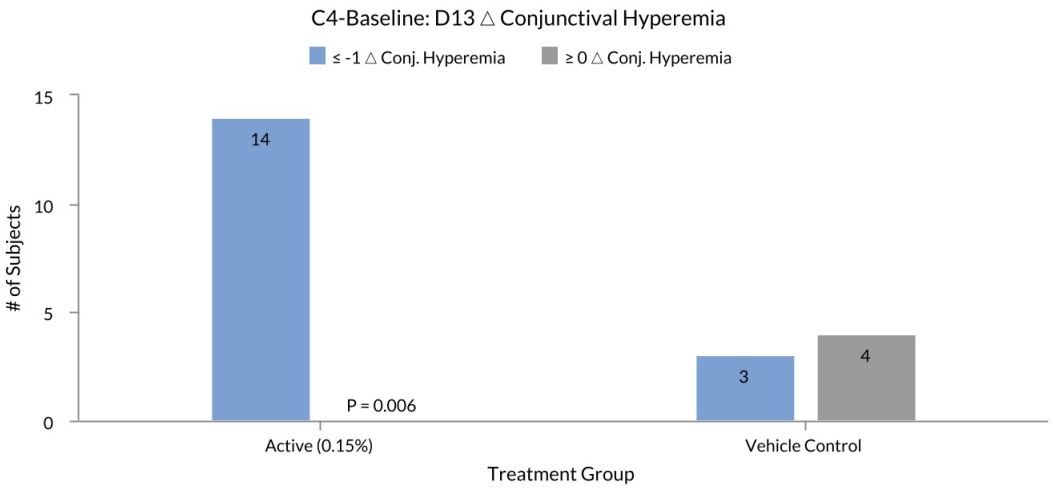


Figure 1: Percent of patients with reduction of >1

No SAEs or severe ocular 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 received conditional approval to initiate a Phase 2 clinical trial with KIO-101 eye drops in Q4 2022. In February 2023 we received investigational new drug application approval for a Phase 2 study of KIO-101 for the treatment of OPRA+ and expect to initiate enrollment in Q2 2023. The study will enroll approximately 120 patients in a multi-center, controlled, randomized, double-masked trial assessing the safety and efficacy of KIO-101 eye drops in patients living with autoimmune disease who have signs and symptoms of ocular surface disease.

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. Figure 2 shows 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).

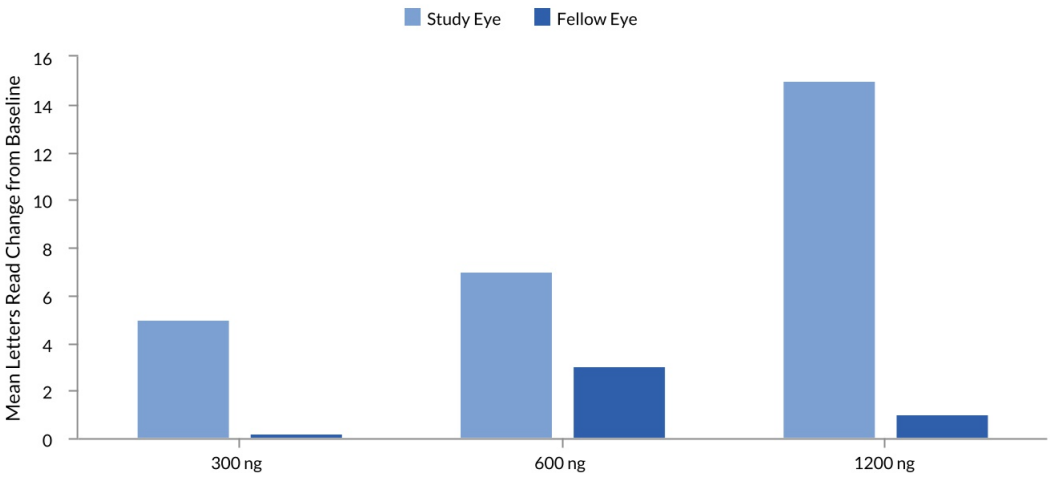


Figure 2: Improvement of visual acuity in cohorts 1, 2, and 3 at Day 14 post dose

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). Figure 3 shows the mean letters read change from baseline to study Days 7, 14, and 28 for patients treated in cohort 3.

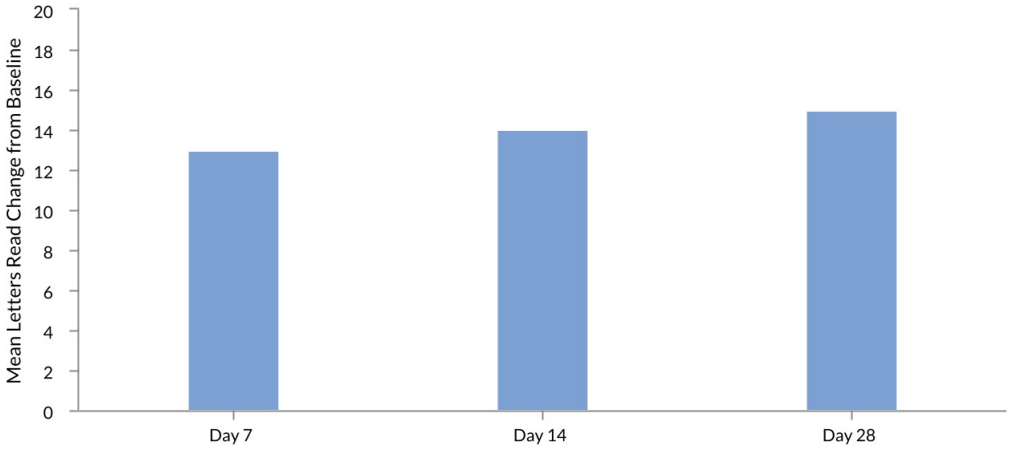


Figure 3: Improvement of visual acuity in cohort 3 on study Days 7, 14, and 28

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:

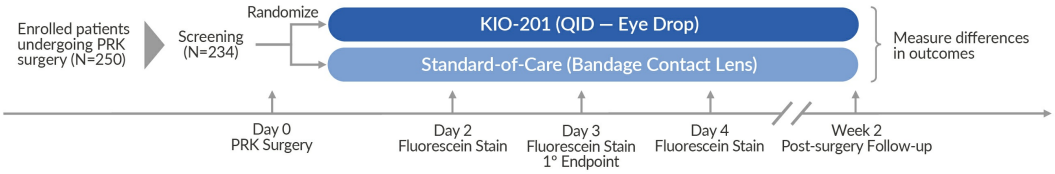
In Q4 2019, we reported positive topline results from our corneal wound repair pivotal clinical trial of KIO-201 for the corneal re-epithelialization in patients having undergone PRK surgery.

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:

- Cohort 1 (n=117) was comprised of KIO-201 QID for two weeks after surgery.
- Cohort 2 (n=117) was comprised of BCL administered four times daily.



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 mm^2, compared to 6.66 mm^2 for eyes treated with BCL, which is 46% smaller than the standard-of-care as noted in Figure 4. 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 (BCL). This data gives confidence that patients will be able to resume normal activities earlier when treated with KIO-201 compared to BCL.

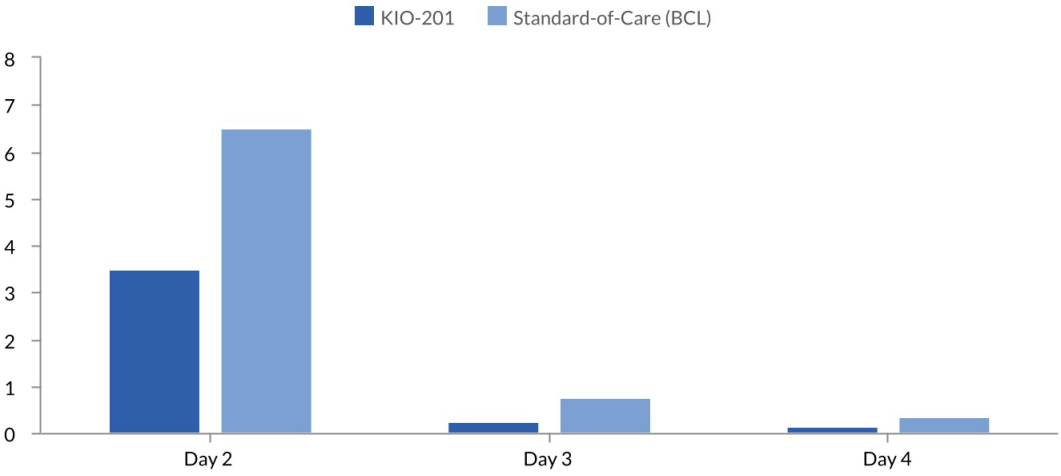


Figure 4: Mean wound size (mm ^{2})

Clinical Development Plan

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

KIO-201: Persistent Corneal Epithelial Defects

Phase 2 Study:

In Q1 2022, we initiated a clinical trial of KIO-201 evaluating the potential to help patients with 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 <0.5mm^2).

Clinical Development Plan

PCED qualifies as a rare disease, and therefore we applied for orphan drug designation as part of our clinical development plan for KIO-201 in Q4 2022. We expect to receive ODD in 2023 and with the results from the aforementioned clinical trial, we plan to meet with the FDA to discuss next steps.

KIO-301: Retinitis Pigmentosa

Phase 1b Study:

In Q4 2022, we initiated a clinical trial of KIO-301 in patients with later stage Retinitis Pigmentosa. We expect results from this study in late 2023.

Design

This is a Phase 1b open-label, single ascending dose clinical trial for people living with retinitis pigmentosa. The study will enroll six patients and evaluate 12 eyes. The first cohort of three patients will include individuals with no or bare light perception due to the progression of RP. The second cohort will include

patients able to detect hand motion and count fingers. Dose escalations will be performed in each patient's contralateral eye. The primary endpoints are safety and tolerability, with secondary efficacy endpoints including objective and subjective evaluations, such as object identification and contrast assessment, navigation, perimetry, functional MRI and other ophthalmic and quality-of-life assessments. This multi-site study is being conducted at The Royal Adelaide Hospital (RAH) in Adelaide, South Australia as well as multiple private ophthalmology clinics in Adelaide, South Australia.

Clinical Development Plan

Retinitis pigmentosa is a rare inherited disease where patients typically present with loss of low light/night vision, followed by reduced visual field (loss of peripheral vision) and eventually loss of central vision. In Q1 2022, we received ODD from the FDA. We will assess the results from the Phase 1b clinical trial and determine next steps in the development of KIO-301 in late 2023.

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 patents covering KIO-101 including composition-of-matter, formulations thereof and its therapeutic uses in the treatment of ocular disorders and diseases and more. In addition, we hold a patent portfolio covering KIO-301 consisting of composition-of-matter, methods of use, and formulations thereof patents. Our KIO-201 portfolio of patents covers composition-of-matter and methods of use claims. 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.

Globally, we hold 26 active and valid patents.

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, 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 million 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 2% of the first $250 million of net sales, 1.25% of net sales between $250 million and $500 million, and 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.

Confidential Information and Inventions Assignment Agreements

We currently require, and will continue to require, each of our employees and consultants to execute confidentiality agreements upon the commencement of such individual's employment, consulting, or collaborative relationships with us. These agreements provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not disclosed to third parties except in specific circumstances.

In the case of employees, the agreements provide that all inventions resulting from such individual's work performed for us, utilizing our property, or relating to our business and conceived or completed by the individual during employment shall be our exclusive property to the extent permitted by applicable law. Our consulting agreements also provide for assignment to us of any intellectual property resulting from services performed by a consultant for us.

Sales and Marketing

If KIO-101, KIO-201 or KIO-301, is approved by the FDA for commercial sale, we may enter into agreements with third parties to sell KIO-101, KIO-201, or KIO-301, or we may choose to market these directly to physicians in the U.S. or globally through our own sales and marketing force and related internal commercialization infrastructure. If we market KIO-101, KIO-201, or KIO-301 directly, we will need to incur significant additional expenses and commit significant additional management resources to establish and train an internal sales and marketing force to market and sell KIO-101, KIO-201, or KIO-301.

Manufacturing

We currently do not have an in-house manufacturing capability for our products and as a result, we will depend heavily on third-party contract manufacturers to produce and package our products. We currently do not have any contractual relationships with third-party manufacturers. We intend to rely on third-party suppliers that we have used in the past for the manufacturing of various components that comprise our KIO-101, KIO-201, KIO-301 and other contemplated clinical trials.

Competition

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

Our potential competitors include large pharmaceutical and biotechnology companies, and specialty pharmaceutical and generic drug companies. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The key competitive factors affecting the success of each of our product candidates, if approved for marketing, are likely to be its efficacy, safety, method of administration, convenience, price, level of generic competition, and the availability of coverage and adequate reimbursement from government and other third-party payors.

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

approval for their products more rapidly than we may obtain approval for ours, 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 seeking to encourage the use of generic products. Generic products currently being used for the indications that we may pursue, and additional products are expected to become available on a generic basis over the coming years. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic products.

Government Regulation

FDA Approval Process

In the U.S., pharmaceutical products are subject to extensive regulation by the FDA. The Food Drug and Cosmetic Act (FDCA) and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable FDA or other requirements may subject a company to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending applications, a clinical hold, warning letters, recall or seizure of products, partial or total suspension of production, withdrawal of the product from the market, injunctions, fines, civil penalties, or criminal prosecution.

FDA approval is required before any new drug can be marketed in the U.S. The process required by the FDA before a new drug product may be marketed in the U.S. generally involves:

- completion of pre-clinical laboratory and animal testing and formulation studies in compliance with the FDA's good laboratory practice or GLP, regulation;
- submission to the FDA of an Investigational New Drug or IND, for human clinical testing which must become effective before human clinical trials may begin in the U.S.;
- approval by an independent Institutional Review Board or IRB, at each site where a clinical trial will be performed before the trial may be initiated at that site;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed product candidate for each intended use;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is manufactured to assess compliance with the FDA's current Good Manufacturing Practice or CGMP regulations;
- submission to the FDA of a new drug application or NDA, which must be accepted for filing by the FDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- payment of user fees, if applicable; and
- FDA review and approval of the NDA.

The pre-clinical and clinical testing and approval process requires substantial time, effort, and financial resources. Pre-clinical tests include laboratory evaluation of product chemistry, formulation, manufacturing and control procedures, and stability, as well as animal studies to assess the toxicity and other safety characteristics of the product. The results of pre-clinical tests, together with manufacturing information, analytical data, and a proposed clinical trial protocol and other information, are submitted as part of an IND to the FDA. Some pre-clinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. A clinical hold may occur at any time during the life of an IND and may affect one or more specific studies or all studies conducted under the IND.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCPs. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, research subject selection and exclusion criteria, and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the results of the clinical trials must be submitted at least annually. In addition, timely safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. An IRB, at each institution participating in the clinical trial, must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed, and otherwise comply with IRB regulations.

Sponsors of clinical trials generally must register and report the key parameters of certain clinical trials, at the National Institutes of Health-maintained website ClinicalTrials.gov. For purposes of an NDA submission and approval, human clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

- *Phase 1:* The product is initially introduced into healthy human patients and tested for safety, dose tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness.
- *Phase 2*: The product is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted indications, and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more extensive clinical trials.
- *Phase 3*: These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product appears to be effective and has an acceptable safety profile, trials are undertaken in large patient populations to further evaluate dosage, to obtain additional evidence of clinical efficacy and safety in an expanded patient population at multiple, geographically-dispersed clinical trial sites, to establish the overall risk-benefit relationship of the product, and to provide adequate information for the labeling of the product.
- *Phase 4*: In some cases, the FDA may conditionally approve an NDA for a product candidate on the sponsor's agreement to conduct additional clinical trials to further assess the product's safety and effectiveness after NDA approval. Such post-approval trials are typically referred to as Phase 4 studies.

The results of product development, pre-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of user fees. A waiver of such fees may be obtained under certain limited circumstances. The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease. A rare disease or condition is defined by the regulatory agency as one affecting fewer than 200,000 individuals in the U.S. or more than 200,000 individuals where there is no reasonable expectation that the product development cost will be recovered from product sales in the U.S. The request form for orphan drug designation must be filed before submitting an NDA and does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. On March 17, 2022, we were granted orphan drug designation by the FDA for the active pharmaceutical ingredient in KIO-301. On August 9, 2022, we submitted an application to the FDA for orphan drug designation for KIO-201. The FDA requested more information, which was provided in December 2022, and we are now awaiting a response.

If a product with orphan drug designation subsequently receives the first FDA approval for the disease for which it was studied, the sponsor will be entitled to seven years of product marketing exclusivity. This means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited and rare circumstances, for seven years. If a competitor obtains approval of the same drug, as defined by the FDA, or if KIO-301 is determined to be contained within a competitor's product for the same indication or disease, the competitor's exclusivity could block the approval of KIO-301 in the designated orphan indication for seven years, unless superior safety or efficacy of our drug is demonstrated.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to product/device listing, recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion, and reporting of adverse experiences with the product.

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

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

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

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of the use of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of fourteen years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA, plus the

time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for extension must be made prior to expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. 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 NDA.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA, or supplement to an approved NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Manufacturing Requirements

We and our third-party manufacturers must comply with applicable FDA regulations relating to FDA CGMP regulations. The CGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, extensive records and reports, and returned or salvaged products. The manufacturing facilities for our products must meet CGMP requirements to the satisfaction of the FDA pursuant to a pre-approval inspection before we can use them to manufacture our products. We and our third-party manufacturers and certain key component suppliers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, including untitled letters, warning letters, determinations of product adulteration, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, and civil and criminal penalties. Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restrictions through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval. Such perceived problems concerning safety or efficacy may arise in the context of clinical studies continued as a result of our post-marketing obligations, reports we or FDA receive from patients and healthcare providers, or literature published by third parties regarding our products or similar products.

Third-Party Payor Coverage and Reimbursement

Reimbursement is expected to use standard approaches for ophthalmology. The commercial success of KIO-101, KIO-201, and KIO-301, if and when commercialized, and our other product candidates will depend, in part, upon the availability of coverage and reimbursement from third-party payors at the federal, state, and private levels, including U.S. Government Payor programs, such as Medicare and Medicaid, private health care insurance companies, and managed care plans that have attempted to control costs by limiting coverage and the amount of reimbursement for particular procedures or drug treatments. The U.S. Congress and state legislatures from time to time propose and adopt initiatives aimed at cost containment, which could impact our

ability to sell our products profitably. Ongoing federal and state government initiatives directed at lowering the total cost of health care will likely continue to focus on healthcare reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid payment systems.

We expect that the pharmaceutical industry will continue to experience pricing pressures due to these initiatives and the trend toward managed healthcare and the increasing influence of managed care organizations. Our results of operations could be adversely affected by current and future healthcare reforms.

Some third-party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for KIO-101, KIO-201, KIO-301, or any other product candidate that we may develop and operate profitably.

Other Regulatory Requirements

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the applicable regulatory agency will have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development, and production efforts, which could harm our business, operating results, and financial condition.

Employees and Human Capital Resources

As of December 31, 2022, we had twelve full-time employees. None of our employees are represented by a collective bargaining agreement and we have never experienced any work stoppage. We believe that we maintain good relations with our employees. Our employees are highly skilled, and many hold advanced degrees and have experience with drug development. Our future performance depends significantly upon the continued service of our key scientific, technical, and senior management personnel and our continued ability to attract and retain highly skilled employees. We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, development programs that enable continued learning and growth, and a robust employment package that promotes well-being across all aspects of their lives. In addition to salaries, these programs include potential annual discretionary bonuses, equity awards, healthcare and insurance benefits, paid time off, family leave, and flexible work schedules, among other benefits. We have taken proactive steps throughout the COVID-19 pandemic to protect the health and safety of our employees. We may take further actions, in compliance with all appropriate government regulations, that we determine to be in the best interest of our employees.

Business Segment and Geographical Information

Operating segments are identified as components of an enterprise for which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance. We view our operations and manage our business in one operating segment. We operate in one geographic segment.

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. In connection with the name change, we changed our symbol on the Nasdaq Capital Market to “KPRX” and began using a new CUSIP number for shares of our common stock (49721T101) effective at the market open on November 8, 2021. Following the reverse stock

split effective September 27, 2022, we began using a new CUSIP number for shares of our common stock (49721T309). 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 GmbH), 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 332 Encinitas Blvd., Suite 102, Encinitas, California, 92024, and our telephone number is (781) 788-8869.

Available Information and Website

We maintain an internet website at www.kiorapharma.com and make available free of charge through our website 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 Sections 13(a) and 15(d) of the Exchange Act. We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the United States Securities and Exchange Commission, or the SEC. You can review our electronically filed reports and other information that we file with the SEC on the SEC's web site at http://www.sec.gov. We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors, and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. The information on our website is not incorporated by reference into this Annual Report on Form 10-K and should not be considered to be a part of this Annual Report on Form 10-K. Our website address is included in this Annual Report on Form 10-K as an inactive technical reference only.

Reverse Stock Split

On September 23, 2022, we filed a Certificate of Amendment to our Restated Certificate of Incorporation (the "Amendment") with the Secretary of State of the State of Delaware to effect a one-for-forty (1-for-40) reverse stock split of our outstanding common stock. The Amendment became effective at 12:01 a.m. Eastern Time on September 27, 2022. The Amendment was approved by our stockholders at our 2022 Annual Meeting of Stockholders held on September 23, 2022, and by our board of directors.

The Amendment provided that, at the effective time of the Amendment, every forty (40) shares of our issued and outstanding common stock automatically combined into one issued and outstanding share of common stock, without any change in par value per share. The reverse stock split affected all shares of our common stock outstanding immediately prior to the effective time of the Amendment. As a result of the reverse stock split, proportionate adjustments were made to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all stock options, and restricted stock awards issued by us and outstanding immediately prior to the effective time of the Amendment, which resulted in a proportionate decrease in the number of shares of our common stock reserved for issuance upon exercise or vesting of such stock options, and restricted stock awards, and, in the case of stock options, a proportionate increase in the exercise price of all such stock options. In addition, the number of shares reserved for issuance under our equity compensation plans immediately prior to the effective time of the Amendment was reduced proportionately. The reverse stock split did not affect the number of shares or par value of common stock authorized for issuance under our Restated Certificate of Incorporation, which remained at 50,000,000 shares.

No fractional shares were issued as a result of the reverse stock split. Stockholders of record who would otherwise have been entitled to receive a fractional share received a cash payment in lieu thereof. The reverse stock split affected all stockholders proportionately and did not affect any stockholder's percentage ownership of our common stock (except to the extent that the reverse stock split results in any stockholder owning only a fractional share). As a result of the reverse stock split, the number of our outstanding shares of common stock as of September 27, 2022 decreased from 43,163,123 (pre-split) shares to 1,079,045 (post-split) shares.

All share and per share amounts in the accompanying financial statements, related footnotes, and management's discussion and analysis have been adjusted retroactively to reflect the reverse stock split as if it had occurred at the beginning of the earliest period presented. While the number of warrants outstanding did not change, the underlying shares did and are presented reflecting the split. Our common stock began trading on The Nasdaq Capital Market on a split-adjusted basis when the market opened on September 27, 2022.

ITEM 1A. RISK FACTORS

Summary of Risk Factors

Below is a summary of the principal factors that make an investment in our common stock 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 Annual Report on Form 10-K and our other filings with the SEC before making an investment decision regarding our common stock.

- 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.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- 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.
- 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 a material weakness in our internal control over financial reporting. If we are unable to remediate this material weakness, 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 requirements applicable to public companies, which may adversely affect investor confidence in us, and, as a result, the market price of our common stock.

Risk Factors

The following factors should be reviewed carefully, in conjunction with the other information contained in this Annual Report on Form 10-K. As previously discussed, our actual results could differ materially from our forward-looking statements. Our business faces a variety of risks. These risks include those described below and may include additional risks and uncertainties not presently known to us or that we currently deem immaterial. If any of the events or circumstances described in the following risk factors occur, our business operations, performance, and financial condition could be adversely affected and the trading price of our common stock could decline.

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 $13.6 million for the year ended December 31, 2022, $13.8 million for the year ended December 31, 2021 and $134.5 million from the period of inception (December 26, 2004) through December 31, 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 pre-clinical 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, 2022, 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, 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;
- 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 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.

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 December 31, 2022, we had cash and cash equivalents of $6.0 million. We believe we will have sufficient cash to fund planned operations into July 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. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities or any other adjustments that might be necessary should we be unable to continue as a going concern.

Identifying potential product candidates and conducting pre-clinical 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.

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 subsidiaries. As a result, currency fluctuations among the U.S. 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 a significant portion of our efforts and financial resources in 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 pre-clinical 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, pre-clinical 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 preclinical studies or clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant pre-clinical 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, KIO-301, 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, KIO-301, 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, pre-clinical 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 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. 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 Annual Report on Form 10-K also apply to the activities of our collaborators.

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

difficult to attract new collaborators and our perception in the business and financial communities could be harmed.

If we are not able to establish 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.

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, pre-clinical 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 receive 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, 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.

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 or CGMP regulations;
- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and

- the possible termination or non-renewal 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 41 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 pre-clinical 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 infringed 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;
- 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.

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, in light of the rising cost of prescription drugs and biologics, there has been heightened governmental scrutiny in the U.S. of pharmaceutical pricing practices. 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. In some cases, the legislation and regulations are 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 M. 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. 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.

We regularly explore opportunities to grow our business, including through acquiring companies. The success of our strategic acquisitions will depend, in part, on our ability to successfully integrate the acquired businesses with our existing business. 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 vendors, 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.

We could face delisting from Nasdaq in the event we do not meeting its minimum bid price rules.

On February 23, 2022, we received a written notification (the "Notice Letter") from Nasdaq indicating that we were not in compliance with Nasdaq Listing Rule 5450(a)(1), as the closing bid price for our Common Stock was below the $1.00 per share requirement for the last 30 consecutive business days. The Notice Letter stated that we have 180 calendar days, or until August 22, 2022 (the "Initial Compliance Period"), to regain compliance with the minimum bid price requirement. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we can regain compliance if the closing bid price of our Common Stock is at least $1.00 for a minimum of 10 consecutive business days.

On August 23, 2022, Nasdaq notified us in writing (the "Extension Letter") that while we had not regained compliance with the Bid Price Rule, we were eligible for an additional 180-day compliance period, or until February 20, 2023, to regain compliance with the Bid Price Rule. Nasdaq's determination was based on our having met the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on The Nasdaq Capital Market, with the exception of the Bid Price Rule, and on our written notice to Nasdaq of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary.

On October 12, 2022, we received a letter from Nasdaq notifying us that the closing bid price of our common stock had been at $1.00 per share or greater for the last 10 consecutive business days and we had regained compliance with the Bid Price Rule and this matter had been closed.

In the event that we lose compliance with Listing Rule 5450(a)(1) again and do not regain compliance prior to the expiration of the compliance period, we will receive written notification that our securities are subject to delisting. At that time, we may appeal the delisting determination to a hearings panel pursuant to the procedures set forth in the applicable Nasdaq Listing Rules. A delisting of our Common Stock would have an adverse effect on the market liquidity of our Common Stock and, as a result, the market price for our Common Stock could become more volatile. Further, a delisting also could make it more difficult for us to raise additional capital. We intend to monitor the closing bid price of our common stock and may conduct a reverse stock split, if necessary, to regain compliance with the Nasdaq bid price rule.

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 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;

- 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 sickness of employees or their families or the desire of employees to avoid contact with groups of people;
- 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;

The global outbreak of the COVID-19 coronavirus continues to 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 Australia and Austria. 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, 2022, we had federal net operating loss carryforwards of approximately $80.5 million, state net operating loss carryforwards of approximately $52.6 million, and aggregate federal and state research and development tax credit carryforwards of approximately $2.5 million and $0.5 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, Financial Industry Regulatory Authority (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. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements.

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

As of December 31, 2022, intangible assets, net, represented approximately $10.7 million, or 58% of our total assets. Goodwill is generated in our acquisitions when the cost of an acquisition exceeds the fair value of the net tangible and identifiable intangible assets we acquire. Goodwill and 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 (IPR&D) 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We currently have three facilities, including our principal executive office located at 332 Encinitas Blvd., Suite 102, Encinitas, CA, 92024; our office located at 1371 East 2100 South, Suite 200, Salt Lake City, UT, 84105; and our office located at Reisnerstraße 34/1, 1030 Wien, Austria. Our office located at 271 Waverley Oaks Road, Suite 108, Waltham, MA, 02452 was closed on March 31, 2022. We conduct our operations using third-party manufacturing facilities and trial sites. We believe our current facilities are adequate for our needs for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

While we are not currently a party to any legal proceedings, from time to time we may be a party to a variety of legal proceedings that arise in the normal course of our business.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASE OF EQUITY SECURITIES

Market Information

Our common stock currently trades on The Nasdaq Capital Market under the symbol “KPRX”. Our common stock began trading on the OTCQB Venture Marketplace on February 13, 2015, in connection with our initial public offering under the symbol “EYEG”. Prior to that time, there was no established public trading market for our common stock. On July 31, 2015, our common stock began trading on The Nasdaq Capital Market. In connection with our name change, we changed our symbol on The Nasdaq Capital Market to “KPRX” effective as of November 8, 2021.

There were 47 holders of record of our common stock as of March 20, 2023. This number does not include beneficial owners whose shares were held in street name.

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.

Recent Sales of Unregistered Securities

On November 17, 2022, the Company entered into warrant exercise inducement offer letters with some of the Class A Warrant holders who agreed to exercise for cash all of their Class A Warrants to purchase 654,609 shares of common stock originally issued in the Public Offering in exchange for the Company's agreement to issue new warrants (the “Inducement Warrants”) on substantially the same terms as the Class A Warrants to purchase up to 654,609 shares of Common Stock. Each Inducement Warrant is exercisable at a price per share of common stock of $5.97.

ITEM 6. RESERVED

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward-Looking Statements

The following section of this Annual Report on Form 10-K entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” contains statements that are not statements of historical fact and are forward-looking statements within the meaning of federal securities laws. These statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the 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. Factors that may cause our actual results to differ materially from those in the forward-looking statements include those factors described in “Item 1A. Risk Factors” beginning on page 23 of this Annual Report on Form 10-K. You should carefully review all of these factor

s, as well as the comprehensive discussion of forward-looking statements on page 2 of this Annual Report on Form 10-K.

Business Overview

We are a clinical-stage specialty pharmaceutical company developing and commercializing products 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. At that time, the name of the French corporation was changed to EyeGate Pharma S.A.S. and became a subsidiary of EyeGate Pharmaceuticals, Inc. EyeGate Pharma S.A.S. was dissolved effective December 30, 2020. We have four wholly-owned subsidiaries: Jade Therapeutics, Inc., Kiora Pharmaceuticals, GmbH (formerly known as Panoptes Pharma GmbH), Bayon Therapeutics, Inc., and Kiora Pharmaceuticals Pty Ltd (formerly known as Bayon Therapeutics Pty Ltd).

Our lead product is KIO-301 with an initial focus on patients with later stages of vision loss due to retinitis pigmentosa (RP, 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 designed to restore the eyes’ ability to perceive and interpret light in visually impaired patients through selectively entering 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 third quarter of 2022 and dosed the first patient in November 2022. On March 17, 2022, we were granted orphan drug designation by the FDA for the API in KIO-301. KIO-301 (formerly known as B-203) was acquired through the Bayon transaction which closed October 21, 2021.

KIO-101 focuses on patients with OPRA+. KIO-101 is a next-generation, non-steroidal, immuno-modulatory and small-molecule inhibitor of DHODH. We believe KIO-101 to be best-in-class with 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 good laboratory practice intravenous 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 top-line safety and tolerability data from a Phase 1b proof-of-concept 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 expect to initiate a Phase 2 clinical trial in the first quarter of 2023. KIO-101 (formerly known as PP-001) was acquired through the acquisition of Panoptes Pharma GmbH in the fourth quarter of 2020.

We are developing KIO-201, for patients with persistent corneal epithelial defects. PCED is an orphan disease and as such, we are currently seeking orphan drug designation. KIO-201 is also being evaluated for patients recovering from surgical wounds, such as those undergoing the laser vision correction procedure, PRK. 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. We are currently evaluating KIO-201 in a Phase 2 clinical trial in patients with PCEDs and released top-line data in Q1 2023. We expect to release full data in Q2 2023. We are in planning stages of a Phase 3b trial for patients recovering from PRK and plan to initiate the study before the end of 2023.

In May 2020, we were granted a loan (the “Loan”) from Silicon Valley Bank in the amount of $0.3 million pursuant to the Paycheck Protection Program (the “PPP”) under Division A, Title I of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which was enacted in March 2020. The Loan could have been prepaid by us at any time prior to maturity with no prepayment penalties. Funds from the Loan were only permitted to be used for payroll costs, costs used to continue group health care benefits, mortgage payments, rent, utilities, and interest on other debt obligations incurred before February 15, 2020 (“Qualifying Expenses”).

We used the entire Loan amount for Qualifying Expenses. Under the terms of the PPP, certain amounts of the Loan could be forgiven if they are used for Qualifying Expenses as described in the CARES Act. In April 2021, we were notified by the Small Business Administration (SBA) that this Loan was forgiven in full.

Throughout our history, we have not generated significant revenue. We have never been profitable, and from inception through December 31, 2022, our losses from operations have aggregated $134.5 million. Our Net Loss was approximately $13.6 million and $13.8 million for the twelve months ended December 31, 2022, and 2021, respectively. We expect to incur significant expenses and increasing operating losses for the foreseeable future as we continue the development and clinical trials of and seek regulatory approval for our KIO-101, KIO-201, and KIO-301 product candidates, and any other product candidates we advance to clinical development. If we obtain regulatory approval for KIO-101, KIO-201, and KIO-301, we expect to incur significant expenses to create an infrastructure to support the commercialization of KIO-101, KIO-201, and KIO-301 including sales, marketing, and distribution functions.

The continued spread of the COVID-19 pandemic could adversely impact our clinical studies. See “Item 1A. Risk Factors” above. The extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the emergence of new variants, and the effectiveness of actions to contain and treat COVID-19. We cannot presently predict the scope and severity of any potential disruptions to our business, including to our ongoing and planned clinical studies. Any such shutdowns or other business interruptions could result in material and negative effects to our ability to conduct our business in the manner and on the timelines presently planned, which could have a material adverse impact on our business, results of operation, and financial condition. As of the date of this report, there have been no material adverse effects to our ongoing business operations from COVID-19.

We will need additional financing to support our continuing operations. We will seek to fund our operations through public or private equity, debt financings, license and development agreements, or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. These conditions raise substantial doubt about our ability to continue as a going concern. We will need to generate significant revenue to achieve profitability, and we may never do so.

Financial Overview

Revenues

To date, we have recognized collaboration revenue from U.S. and foreign government grants made to Jade and Panoptes, as well as from license agreements as performance obligations toward milestones that were met. We expect to continue to incur significant operating losses as we fund research and clinical trial activities relating to our therapeutic assets, consisting of our photoswitch, DHODH, and modified HA-based products, or any other product candidate that we may develop. There can be no guarantee that the losses incurred to fund these activities will succeed in generating revenue.

Research and Development Expenses

We expense all research and development expenses as they are incurred. Research and development expenses primarily include:

- non-clinical development, pre-clinical research, and clinical trial and regulatory-related costs;
- expenses incurred under agreements with sites and consultants that conduct our clinical trials;
- expenses related to generating, filing, and maintaining intellectual property; and
- employee-related expenses, including salaries, bonuses, benefits, travel, and stock-based compensation expense.

We expect our research and development expenses to increase for the near future as we advance KIO-101, KIO-201, KIO-301, and any other product candidate through clinical development, including the conduct of our planned clinical trials. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We are unable to estimate with any certainty the costs we will incur in the continued development of our KIO-101, KIO-201, KIO-301, and any other product candidate that we may develop. Clinical development timelines, the probability of success and development costs can differ materially from expectations.

We may never succeed in achieving marketing approval for our product candidates.

The costs of clinical trials may vary significantly over the life of a project owing to, but not limited to, the following:

- per patient trial costs;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the cost of comparative agents used in trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidate.

We do not expect our product candidates to be commercially available, if at all, for the next several years.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation. Our general and administrative expenses consisted primarily of payroll expenses for our full-time employees. Other general and administrative expenses include professional fees for auditing, tax, patent costs, and legal services.

We expect that general and administrative expenses will remain consistent for the near future until commercialization of our photoswitch, DHODH, and modified HA-based products, which could lead to an increase in these expenses.

Other Income, Net

Other income, net consists primarily of warrant liability fair value changes, interest income we earn on interest-bearing accounts, and interest expense incurred on our outstanding financing arrangements.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the

expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Business Combinations

We applied the provisions of Accounting Standards Codification (ASC) Topic 805, "Business Combinations," in the accounting for our acquisitions of Bayon and Panoptes. It required us to recognize the assets acquired and the liabilities assumed at their acquisition date fair values, which were determined using market, income, and cost approaches, or a combination. Goodwill as of the respective acquisition date was measured as the excess of consideration transferred over the net of the acquisition date fair value of the assets acquired and the liabilities assumed. Goodwill is generally the result of expected synergies of the combined company or an assembled workforce. Indefinite-lived intangible assets acquired were in-process research and development. The fair value for these intangible assets was determined using the income approach. Under the income approach, fair value reflects the present value of the projected cash flows that are expected to be generated by the products incorporating the in-process research and development, if successful.

Goodwill and Intangible Assets

Goodwill represents the excess of the purchase price over the estimated fair value of the identifiable assets acquired and liabilities assumed in a business combination. The Company evaluates goodwill for impairment annually or when a triggering event occurs that could indicate a potential impairment. The evaluation for impairment includes assessing qualitative factors or performing a quantitative analysis to determine whether it is more-likely-than-not that the fair value of net assets is below the carrying amount. The goodwill was related to the 2021 acquisition of Bayon and 2020 acquisition of Panoptes, which represents the excess of the purchase price over the estimated fair value of the net assets acquired. For the year ended December 31, 2021, we incurred a $4.0 million impairment loss related to goodwill. As of December 31, 2022 and 2021, goodwill was $0.

Intangible assets acquired in a business combination are recognized separately from goodwill and are initially recognized at fair value at the acquisition date. The Company tests intangible assets for impairment as of December 31 of each year or more frequently if indicators of impairment are present. The authoritative accounting guidance provides an optional qualitative assessment for any indicators that indefinite-lived intangible assets are impaired. If it is determined that it is more likely than not that the indefinite-lived intangible assets are impaired, the fair value of the indefinite-lived intangible assets is compared with the carrying amount and impairment is recorded for any excess of the carrying amount over the fair value of the indefinite-lived intangible assets.

The Company performed an annual evaluation of it's indefinite-lived intangible assets for impairment as of August 31, 2022 with a quantitative analysis. As of December 31, 2022 the Company also performed a qualitative update analysis for impairment and based on this analysis, the fair value of these products was greater than their carrying value. The Company considered the development timelines for its program and noted no qualitative factors that would indicate potential impairment of its indefinite-lived intangible assets.

Accrued Research and Development Expenses

As part of the process of preparing the consolidated financial statements, we are required to estimate and accrue research and development expenses. This process involves the following:

- communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost;
- estimating and accruing expenses in our consolidated financial statements as of each balance sheet date based on facts and circumstances known to us at the time; and
- periodically confirming the accuracy of our estimates with selected service providers and making adjustments, if necessary.

Examples of estimated research and development expenses that we accrue include:

- fees paid to contract research organizations and investigative sites in connection with clinical studies;
- fees paid to contract manufacturing organizations in connection with non-clinical development, pre-clinical research, and the production of clinical study materials; and
- professional service fees for consulting and related services.

We base our expense accruals related to non-clinical development, pre-clinical studies, and clinical trials on our estimates of the services received and efforts expended pursuant to contracts with organizations/consultants that conduct and manage clinical studies on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts may depend on many factors, such as the successful enrollment of patients, site initiation, and the completion of clinical study milestones. Our service providers invoice us as milestones are achieved and monthly in arrears for services performed. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. To date, we have not experienced significant changes in our estimates of accrued research and development expenses after a reporting period.

However, due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical studies and other research activities.

Refunds for Research and Development

We, through our Kiora Pharmaceuticals, GmbH and Kiora Pharmaceuticals Pty Ltd. subsidiaries, are eligible to receive certain refundable tax incentives associated with our research and development expenses in Austria and Australia. These refunds are realized in the form of a cash payment when received, following the incurred research & development expenses. We record the refundable payment as a tax receivable and a reduction in expense in the period in which the research and development expenses are incurred.

Contingent Consideration

We initially value contingent consideration related to business combinations using a probability-weighted calculation of potential payment scenarios discounted at rates reflective of the risks associated with the expected future cash flows. Key assumptions used to estimate the fair value of contingent consideration include the probability of success, discount rate, and updated timing of payment. After the initial valuation, we will use our best estimate to measure contingent consideration at each subsequent reporting period. Gains and losses are recorded in operating expenses within the consolidated statements of operations and comprehensive loss.

Stock-Based Compensation

We have issued options to purchase our common stock and restricted stock. Stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service/vesting period. Determining the appropriate fair value model and calculating the fair value of stock-based payment awards require the use of highly subjective assumptions, including the expected life of the stock-based payment awards and stock price volatility.

We estimate the grant date fair value of stock options and the related compensation expense, using the Black-Scholes option valuation model. This option valuation model requires the input of subjective assumptions including: (1) expected life (estimated period of time outstanding) of the options granted, (2) volatility, (3) risk-free rate, and (4) dividends. In general, the assumptions used in calculating the fair value of stock-based payment awards represent management's best estimates, but the estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future.

Recent Accounting Pronouncements

Refer to Note 1. Business, Presentation and Recent Accounting Pronouncements, in the Notes to the audited consolidated financial statements of Part IV, Item 15. Exhibits, Financial Statement Schedules of this Form 10-K for detailed information regarding the status of recently issued accounting pronouncements.

Other Information

Net Operating Loss Carryforwards

As of December 31, 2022, the Company has federal and state net operating loss carryforwards of approximately $80.5 million and $52.6 million, respectively, to offset future federal and state taxable income. Federal NOL carryforwards as of December 31, 2017 totaling $46.1 million, and state NOL carryforwards as of December 31, 2022 totaling $52.6 million will expire at various dates through 2042. Federal NOL carryforwards generated during the years ended December 31, 2018 and forward totaling $34.4 million will carry forward indefinitely, but their utilization will be limited to 80% of taxable income. The Company has foreign net operating loss carryforwards of $10.7 million as of December 31, 2022, which can be carried forward indefinitely. As of December 31, 2022, the Company also has federal and state research and development tax credit carryforwards of approximately $2.5 million and $0.5 million, respectively, to offset future income taxes, which expire at various times through 2042.

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, our registered direct offering, our follow-on public offerings, and other transactions that have occurred over the past three years 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 TCJA enacted on December 22, 2017, limits the amount of NOLs 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 NOLs to prior years but allows NOLs generated after 2017 to be carried forward indefinitely. As such, there is a risk that due to such items, our existing NOLs could expire or be unavailable to offset future income.

Results of Operations

Comparison of Years Ended December 31, 2022 and 2021

The following table summarizes the results of our operations for the years ended December 31, 2022 and 2021:

	Year Ended December 31,		
	2022	2021	Change
Operating Expenses:			
Research and Development	3,448,925	5,350,264	(1,901,339)
General and Administrative	8,277,993	5,323,649	2,954,344
Goodwill Impairment	—	4,037,811	(4,037,811)
Change in Fair Value of Contingent Consideration	582,605	(475,956)	1,058,561
Total Operating Expenses	12,309,523	14,235,768	(1,926,245)
Operating Loss Before Other Income	(12,309,523)	(14,235,768)	1,926,245
Other (Expense) Income, Net	(1,387,097)	272,480	(1,659,577)
Loss Before Income Tax Benefit (Expense)	(13,696,620)	(13,963,288)	266,668
Income Tax Benefit (Expense)	113,010	192,603	(79,593)
Net Loss	$ (13,583,610)	$ (13,770,685)	$ 187,075

Research and Development Expenses

Research and development expenses decreased by $1.9 million due to reduced development costs for KIO-101 and KIO-201 of approximately $1.1 million, decreased personnel costs of approximately $1.0 million and an increase in the research refundable credit of $1.0 million. These net decreases were partially offset by an increase in development costs related to KIO-301 of $1.3 million.

The following table summarizes our research and development expense by program:

	Year Ended December 31,		
	2022	2021	Change
External research and development expense by program			
KIO-101	1,622,602	2,160,530	(537,928)
KIO-201	102,754	652,107	(549,353)
KIO-301	1,349,382	16,096	1,333,286
Unallocated research and development expense			
Personnel	1,868,131	2,883,229	(1,015,098)
R&D Credit	(1,541,609)	(517,625)	(1,023,984)
Other Research	47,665	155,927	(108,262)
Total research and development expense	$ 3,448,925	$ 5,350,264	$ (1,901,339)

General and Administrative Expenses

General and administrative expenses increased by $3.0 million due to increases in professional fees of $1.5 million, executive severance of $1.0 million, corporate costs of $0.3 million and travel related costs of $0.3 million.

Goodwill Impairment Loss

Goodwill impairment loss decreased by $4.0 million due to the write-off of goodwill in 2021.

Change in Fair Value of Contingent Consideration

The change in fair value of contingent consideration increased $1.1 million. The change in fair value of contingent consideration is primarily due to a change in the probability of success related to a new indication that was added for KIO-201 (PCED) which increased the probability of success for the Jade milestone payment. Additionally, in March 2022 KIO-301 was granted orphan drug designation which increased the probability of success rate for the Bayon milestone payment.

Other (Expense) Income, Net

Other (expense) income increased by $1.7 million due to a change in fair value of warrant liability. The change in fair value of the warrant liability between issuance and reclassification to equity was approximately $1.4 million in expense and was primarily due to a change in our stock price..

Income Tax Benefit (Expense)

Income tax benefit (expense) decreased by $0.1 million.

Liquidity and Capital Resources

Since becoming a public company in 2015, we have financed our operations from several registered offerings and private placements of our securities, payments from license agreements, and U.S. and foreign government grants. From inception through December 31, 2022, we have raised a total of approximately $127.2 million from such sales of our equity and debt securities, both as a public company and prior to our IPO, as well as approximately $14.9 million in payments received under our license agreements and government grants and $0.3 million received pursuant to the Loan under the PPP, which was fully forgiven in April of 2021.

On January 6, 2021, we completed a private placement of 38,278 shares of common stock and warrants to purchase up to 38,278 shares of common stock to an affiliate of Armistice Capital, LLC, with a combined purchase price per share and warrant of $209.00. The total net proceeds from the private placement were approximately $8.0 million. The warrants have an exercise price of $209.00 per share, subject to adjustments as provided under the terms of the warrants, and will be exercisable on the six-month anniversary of their issuance date. The warrants are exercisable for five years from the issuance date.

On August 11, 2021, we completed a registered direct offering for 116,721 shares of common stock with a purchase price of $92.10 per share. We also completed a concurrent private placement of unregistered warrants to purchase up to an aggregate of 58,361 shares of common stock at an exercise price of $89.60 per share that are exercisable immediately upon issuance and will expire five and one-half years following the date of issuance. In addition, the Company issued to the placement agent warrants to purchase up to 5,836 shares of Common Stock at an exercise price of $115.124 per share, which expire five years following the date of issuance. The total net proceeds to us from the offering were approximately $9.8 million.

On June 18, 2022, in connection with our acquisition of Panoptes Pharma Ges.m.b.H in December 2020 (“Panoptes Acquisition”), we issued an aggregate of 10,087 shares of common stock to former shareholders of Panoptes, which had been held back for a period of eighteen months following the closing of the Panoptes acquisition to satisfy post-closing adjustment and indemnification obligations pursuant to the terms of the Share Purchase Agreement between us and the former shareholders of Panoptes.

On July 22, 2022, we entered into an underwriting agreement to issue and sell stock and warrants in a public offering. On July 25, 2022, the underwriter fully exercised the option granted by us to purchase stock and warrants. On July 26, 2022, the Public Offering closed, and we issued and sold (i) 592,392 shares of common stock, (ii) 1,280 shares of Series E Convertible Preferred Stock convertible into up to 160,000 shares of common 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 public offering price of $8.00 per share of common stock, Class A Warrant and Class B Warrant or $1,000 per preferred share, 5,000 Class A Warrants and 5,000 Class B Warrants resulted in net proceeds to us of approximately $5.3 million net of underwriting discount and commissions of $0.4 million and expense of $0.3 million.

On November 17, 2022, we entered into warrant exercise inducement offer letters with some of the Class A warrant holders who agreed to exercise for cash, at a discounted exercise price of $4.77 per share, all of their Class A Warrants to purchase 654,609 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 to purchase up to 654,609 shares of common stock. Each Inducement Warrant is exercisable six months following its date of issuance at a price per share of common stock of $5.97 and will expire on the 18 month anniversary of their initial exercise date. We received aggregate gross proceeds of

approximately $3.1 million from the exercise of the Class A Warrants by the selling stockholders and the sale of the Inducement Warrants.

At December 31, 2022, we had unrestricted cash and cash equivalents totaling approximately $6.0 million.

Comparison of Years Ended December 31, 2022 and 2021

The following table sets forth the primary sources and uses of cash for the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
	2022	**2021**
Net Cash Used in Operating Activities	$ (10,428,133)	(10,675,390)
Net Cash Provided by (Used in) Investing Activities	6,375	(157,020)
Net Cash Provided by Financing Activities	8,620,921	17,582,926

Operating Activities

During the year ended December 31, 2022, we recorded a net loss of $13.6 million and adjusted primarily for non-cash expense for stock-based compensation in the amount of $0.5 million, an increase in the change in fair value of contingent consideration of $0.6 million, an increase in the change in fair value of warrant liability of $1.4 million and a decrease in accounts payable of $0.8 million and accrued expenses of $0.6 million, which was partially offset by an increase in tax credits receivable of $0.9 million. During the year ended December 31, 2021, we recorded a net loss of $13.8 million and adjusted primarily for goodwill impairment loss of $4.0 million, non-cash expense for stock-based compensation in the amount of $0.8 million, which was partially offset by an increase in tax credits receivable of $0.4 million, a decrease in the change in fair value of contingent consideration of $0.5 million, and a decrease in accounts payable of $0.3 million.

Investing Activities

During the year ended December 31, 2022, net cash provided by investing activities related to proceeds from the sale of equipment. During the year ended December 31, 2021, net cash used related to the acquisition of Bayon, as well as the purchase of office furniture and fixtures.

Financing Activities

During the year ended December 31, 2022, we received net proceeds of $5.4 million from the completion of a public offering, as well as net proceeds of $2.7 million from the completion of a warrant inducement transaction. During the year ended December 31, 2021, we received net proceeds of $9.8 million from the completion of a registered direct offering, as well as net proceeds of $8.0 million from the completion of a private placement.

Funding Requirements and Other Liquidity Matters

Our KIO-101, KIO-201, and KIO-301 product pipeline is still in various stages of clinical development. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- seek marketing approval for our KIO-101, KIO-201 or KIO-301 products, or any other products that we successfully develop;
- establish a sales and marketing infrastructure to commercialize our KIO-101, KIO-201, or KIO-301 products in the U.S., if approved; and
- add operational, financial, and management information systems and personnel, including personnel to support our product development and future commercialization efforts.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and licensing

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, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates, including our KIO-301, KIO-101, and KIO-201 products, 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 KIO-101, KIO-201, and KIO-301 products, or any other products that we would otherwise prefer to develop and market ourselves.

Based on our cash on hand at December 31, 2022, we believe we will have sufficient cash to fund planned operations into July 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 its products. To continue development, we will need to raise additional capital through debt and/or equity financing, or access additional funding through grants. Although we successfully completed our IPO and several subsequent registered offerings and private placements of our securities, additional capital may not be available on terms favorable to us, if at all. We do not know if our future offerings will succeed. Accordingly, no assurances can be given that management will be successful in these endeavors. Our recurring losses from operations have caused management to determine there is substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities or any other adjustments that might be necessary should we be unable to continue as a going concern.

Off-Balance Sheet Arrangements

We had no material off-balance sheet arrangements at December 31, 2022.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item is contained in the consolidated financial statements filed as part of this Annual Report on Form 10-K are listed under Item 15 of Part IV below. Our auditors are EisnerAmper LLP, Iselin, New Jersey, with a PCAOB ID Number 274.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such

information is accumulated and communicated to our management, including our Chief Executive Officer and Executive Vice President of Finance, to allow for timely decisions regarding required disclosure.

In connection with this annual report, as required by Rules 13a-15I and 15d-15(e) under the Securities Exchange Act of 1934, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2022, our Chief Executive Officer, who is our Principal Executive Officer, and our Executive Vice President of Finance, who is our Principal Financial and Accounting Officer. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. This assessment included review of the documentation of controls, evaluation of the design effectiveness of controls, testing of the operating effectiveness of controls, and a conclusion on this evaluation. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. This assessment included review of the documentation of controls, evaluation of the design of effectiveness of controls, testing of the operating effectiveness of controls and a conclusion on this evaluation.

Based upon the evaluation described above, our Chief Executive Officer and Executive Vice President of Finance have concluded that our disclosure controls and procedures that support financial reporting were not effective as of the period ending December 31, 2022 due to material weaknesses described below.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company in accordance with as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Management of the Company has assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2022. In making its assessment of internal control over financial reporting, management used the criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). As a result of that evaluation, management concluded our internal control over financial reporting was not effective as of December 31, 2022.

In making this assessment, we identified material weaknesses in our internal control over financial reporting. 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 annual or interim consolidated financial statements will not be prevented or detected on a timely basis. Material weaknesses in the Company's internal control over financial reporting have been identified. Specifically, the Company did not maintain effective controls regarding:

a) information technology general controls ("ITGC") which could result in misstatements potentially impacting all financial statement accounts and disclosures. Specifically, user access controls were not

appropriately designed and maintained to adequately restrict network user and privileged access to the appropriate personnel. In addition, there was a lack of sufficient segregation of duties.

b) the design and maintenance of formal accounting policies and processes to analyze, account for and disclose significant and unusual transactions in accordance with U.S. generally accepted accounting principles.

c) the execution of controls with a sufficient level of precision over the completeness and accuracy of financial information used in the preparation of the Company's financial statements.

Remediation Efforts

Subsequent to year-end the Company has implemented a new accounting system and through that process has designed role-specific permissions ensuring that there are appropriate access controls by function. Additionally, the Company has designed automated system workflows for journal entry approval, new vendor creation and modification, and procurement related approvals for PO's and related invoices to ensure proper segregation of duties and appropriate evidence of approval.

Throughout the year we established and maintained accounting policies, procedures and controls to account for and disclose significant unusual transactions. Additionally, we engaged technical resources for technical advisory services and will continue to consult with technical resources to ensure that proper expertise is consulted as needed on complex accounting applications. This will be an ongoing area of remediation to ensure that significant transactions are appropriately analyzed and the accounting treatment is documented.

Subsequent to year-end, management is working toward a greater level of precision over the completeness and accuracy of information through the implementation of a new accounting system, as discussed above, which provides for greater automation related to previously manual tasks. Specifically, the new accounting system is being used to generate purchase orders for all material contracts and purchase commitments. The finance team is in the process of building reporting on all open contract commitments, which will be shared with management to verify the completeness and ensure accuracy of financial reporting.

The process of implementing an effective financial reporting system is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a financial reporting system that is adequate to satisfy our reporting obligations. As we continue to evaluate and take actions to improve our internal control over financial reporting, we may take additional actions to address control deficiencies or modify certain of the remediation measures described above.

We plan to enhance our processes to identify and appropriately apply applicable accounting requirements to better evaluate and understand 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.

While progress has been made to enhance our internal control over financial reporting, we are still in the process of implementing, documenting and testing these processes, procedures and controls. Additional time is required to complete implementation and to assess and ensure the sustainability of these procedures. We will continue to devote significant time and attention to these remedial efforts. However, the material weaknesses cannot be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

The scope of our management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2022, includes all of our subsidiaries. As a smaller reporting company under under Rule 405 of the Securities Act of 1933, as amended and a non-accelerated filer, we are exempt from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002. As a result, EisnerAmper LLP, our independent

registered public accounting firm, has not audited or issued an attestation report with respect to the effectiveness of our internal control over financial reporting as of December 31, 2022.

Changes in Internal Control over Financial Accounting and Reporting

Except for the above noted material weaknesses and the remediation activities that have since been undertaken, there were no other changes in the Company's internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rule 13a-15 that occurred during the quarter ended December 31, 2022 that have materially affected or are reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Incorporated by reference to our definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act in connection with our 2023 Annual Meeting of Stockholders.

ITEM 11. EXECUTIVE COMPENSATION

Incorporated by reference to our definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act in connection with our 2023 Annual Meeting of Stockholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Incorporated by reference to our definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act in connection with our 2023 Annual Meeting of Stockholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Incorporated by reference to our definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act in connection with our 2023 Annual Meeting of Stockholders.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Incorporated by reference to our definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act in connection with our 2023 Annual Meeting of Stockholders.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Consolidated Financial Statements

The consolidated financial statements filed as part of this report are listed on the Index to Financial Statements on page F-1.

Financial Statement Schedules

None. Financial statement schedules have been omitted since the required information is included in our Consolidated Financial Statements contained elsewhere in this Annual Report on Form 10-K.

Exhibits

The exhibits listed in the Exhibit Index are filed as a part of this Annual Report on Form 10-K.

EXHIBIT INDEX

The following exhibits are filed as part of this Annual Report on Form 10-K. Where such filing is made by incorporation by reference to a previously filed document, such document is identified.

Exhibit Number	Description of Exhibit
2.1†††	Stock Purchase Agreement, dated as of March 7, 2016, by and among the Registrant and the Sellers named therein (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on March 7, 2016 and incorporated by reference thereto).
2.2†††	Share Purchase Agreement, dated as of December 18, 2020, by and among the Registrant and the Sellers named therein (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on December 21, 2020 and incorporated by reference thereto).
2.3†††	Stock Purchase Agreement, dated as of October 21, 2021, by and among the Registrant and the Sellers named therein (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on October 26, 2021 and incorporated by reference thereto).
3.1	Restated Certificate of Incorporation of the Registrant (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on February 20, 2015 and incorporated by reference thereto).
3.2	Certificate of Amendment to the Restated Certificate of Incorporation of the Registrant, filed July 10, 2018 (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on July 11, 2018 and incorporated by reference thereto).
3.3	Certificate of Amendment to the Restated Certificate of Incorporation of the Registrant, filed August 28, 2019 (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on August 29, 2019 and incorporated by reference thereto).
3.4	Certificate of Amendment to the Restated Certificate of Incorporation of the Registrant, filed June 25, 2020 (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on November 8, 2021 and incorporated by reference thereto).
3.5	Certificate of Amendment to the Restated Certificate of Incorporation of the Registrant, filed September 23, 2022 (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on September 26, 2022 and incorporated by reference thereto).
3.6	Certificate of Ownership and Merger of the Registrant, filed November 5, 2021 (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on June 26, 2020 and incorporated by reference thereto).
3.7	Third Amended and Restated By-laws of the Registrant (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on August 4, 2022 and incorporated by reference thereto).
3.8	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on June 27, 2016 and incorporated by reference thereto).
3.9	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on June 14, 2017 and incorporated by reference thereto).
3.10	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on April 17, 2018 and incorporated by reference thereto).
3.11	Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on December 21, 2020 and incorporated by reference thereto).
3.12	Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on July 26, 2022 and incorporated by reference thereto).
4.1	Description of Securities (previously filed as an exhibit to the Registrant's Annual Report on Form 10-K filed on March 24, 2020 and incorporated by reference thereto).
4.2	Specimen Stock Certificate evidencing the shares of common stock (previously filed as an exhibit to the Registrant's Registration Statement on Form S-1 filed on July 30, 2014 and incorporated by reference thereto).
4.4	Form of Common Stock Purchase Warrant, dated June 14, 2017 (previously filed as an exhibit to the Registrant's Registration Statement on Form S-1 filed on June 5, 2017 and incorporated by reference thereto).
4.5	Form of Common Stock Purchase Warrant, dated April 17, 2018 (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on April 13, 2018 and incorporated by reference thereto).
4.6	Form of Common Stock Purchase Warrant, dated October 2, 2019 (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on September 30, 2019 and incorporated by reference thereto).
4.7	Form of Common Stock Purchase Warrant, dated January 3, 2020 (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on December 31, 2019 and incorporated by reference thereto).
4.8	Form of Common Stock Purchase Warrant, dated January 6, 2021 (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on January 6, 2021 and incorporated by reference thereto).
4.9	Form of Common Stock Purchase Warrant, dated August 11, 2021 (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on August 10, 2021 and incorporated by reference thereto).
4.10	Form of Placement Agent Warrant, dated August 11, 2021 (previously filed as an exhibit to the Registrant's Current Report on Form 8-

	K filed on August 10, 2021 and incorporated by reference thereto).
4.11	Form of Class A Warrant (previously filed as an exhibit to the Registrant's Amendment No. 3 to Registration Statement on Form S-1 filed on July 21, 2022 and incorporated by reference thereto)
4.12	Form of Class B Warrant (previously filed as an exhibit to the Registrant's Amendment No. 3 to Registration Statement on Form S-1 filed on July 21, 2022 and incorporated by reference thereto)
4.13	Warrant Agency Agreement, dated July 22, 2022, by and between the Registrant and VStock Transfer, LLC (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on July 26, 2022 and incorporated by reference thereto).
4.14	Form of Common Stock Purchase Warrant, dated November 22, 2022 (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on November 21, 2022 and incorporated by reference thereto).
4.15	Form of Common Stock Purchase Warrant, dated February 3, 2023 (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on February 3, 2023 and incorporated by reference thereto).
10.1#	2005 Equity Incentive Plan, as amended (previously filed as an exhibit to the Registrant's Registration Statement on Form S-1 filed on July 30, 2014 and incorporated by reference thereto).
10.2#	2014 Equity Incentive Plan, as amended (previously filed as an exhibit to the Registrant's definitive proxy statement on Schedule 14A filed on August 15, 2022 and incorporated by reference thereto).
10.3#	Employee Stock Purchase Plan (previously filed as an exhibit to Amendment No. 3 to the Registrant's Registration Statement on Form S-1 filed on September 12, 2014 and incorporated by reference thereto).
10.4	Form of Indemnification Agreement (previously filed as an exhibit to the Registrant's Registration Statement on Form S-1 filed on July 30, 2014 and incorporated by reference thereto).
10.5#	Form of Notice of Stock Option Grant pertaining to the 2014 Equity Incentive Plan (previously filed as an exhibit to the Registrant's Registration Statement on Form S-1 filed on July 30, 2014 and incorporated by reference thereto).
10.6#	Form of Notice of Stock Unit Award pertaining to the 2014 Equity Incentive Plan (previously filed as an exhibit to the Registrant's Registration Statement on Form S-1 filed on July 30, 2014 and incorporated by reference thereto).
10.7†	Intellectual Property License Agreement, dated as of September 26, 2018, by and between the Registrant and SentrX Animal Care, Inc. (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on October 2, 2018 and incorporated by reference thereto).
10.8	Kiora Pharmaceuticals, Inc. Amended and Restated Change in Control Severance Plan (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on December 3, 2019 and incorporated by reference thereto).
10.9††	Exclusive Sub-License Agreement, dated as of September 12, 2013, by and between Jade Therapeutics, Inc. and Biotime, Inc. (previously filed as an exhibit to the Registrant's Annual Report on Form 10-K filed on March 4, 2020 and incorporated by reference thereto).
10.10††	Amendment No. 1 to Sub-License Agreement, dated as of September 18, 2015, by and between Jade Therapeutics, Inc. and Biotime, Inc. (previously filed as an exhibit to the Registrant's Annual Report on Form 10-K filed on March 4, 2020 and incorporated by reference thereto).
10.11††	Amendment No. 2 to Sub-License Agreement, dated as of February 17, 2016, by and between Jade Therapeutics, Inc. and Biotime, Inc. (previously filed as an exhibit to the Registrant's Annual Report on Form 10-K filed on March 4, 2020 and incorporated by reference thereto).
10.12	Registration Rights Agreement, dated as of December 18, 2020, by and among the Registrant and the Sellers listed therein (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on December 21, 2020 and incorporated by reference thereto).
10.13	Registration Rights Agreement, dated as of January 5, 2021, by and among the Registrant and the Purchasers listed therein (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on January 6, 2021 and incorporated by reference herein).
10.14#	Separation Agreement, dated as of January 31, 2022, by and between the Registrant and Stephen From. (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on February 1, 2022 and incorporated by reference thereto)
10.15††	Patent and Know How Assignment Agreement, dated as of July 2, 2013, by and between Panoptes Pharma Ges.m.b.H and 4SC Discovery GmbH (previously filed as an exhibit to the Registrant's Annual Report on Form 10-K filed on March 25, 2021 and incorporated by reference thereto).
10.16††	Patent License Agreement, dated as of July 2, 2013, by and between Panoptes Pharma Ges.m.b.H. and 4SC Discovery GmbH (previously filed as an exhibit to the Registrant's Annual Report on Form 10-K filed on March 25, 2021 and incorporated by reference thereto).
10.17#	Employment Agreement, dated as of July 22, 2021, by and between the Registrant and Brian M. Strem (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on July 26, 2021 and incorporated by reference thereto).
10.18#	Employment Agreement, dated as of October 21, 2021, by and between the Registrant and Eric J. Daniels (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on October 26, 2021 and incorporated by reference thereto).
10.19	Consulting Agreement, dated as of March 9, 2022, by and between the Registrant and Danforth Advisors, LLC (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on April 26, 2022 and incorporated by reference thereto).
10.20#	Offer Letter, dated as of August 17, 2022, by and between the Registrant and Melissa Tosca (previously filed as an exhibit to the

	Registrant's Current Report on Form 8-K filed on September 16, 2022 and incorporated by reference thereto).
10.21	Form of Inducement Letter, dated as of November 17, 2022, by and between the Registrant and the Holders named therein (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on November 21, 2022 and incorporated by reference thereto).
10.22	Securities Purchase Agreement, dated as of February 2, 2023, by and between the Registrant and Lincoln Park Capital Fund, LLC (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on February 3, 2023 and incorporated by reference thereto).
10.23	Registration Rights Agreement, dated as of February 2, 2023, by and between the Registrant and Lincoln Park Capital Fund, LLC (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on February 3, 2023 and incorporated by reference thereto).
10.24†††	Purchase Agreement, dated as of February 3, 2023, by and between the Registrant and Lincoln Park Capital Fund, LLC (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on February 3, 2023 and incorporated by reference thereto).
10.25†††	Registration Rights Agreement, dated as of February 3, 2023, by and between the Registrant and Lincoln Park Capital Fund, LLC (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on February 3, 2023 and incorporated by reference thereto).
21.1	Subsidiaries of the Registrant (previously filed as an exhibit to the Registrant's Annual Report on Form 10-K filed on April 15, 2022 and incorporated by reference thereto).
23.1*	Consent of Independent Registered Public Accounting Firm.
31.1*	Certification of principal executive officer pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of principal financial and accounting officer pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of principal executive officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of principal financial and accounting officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.

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

†† Certain confidential portions of this exhibit were omitted because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

††† Schedules and exhibits have been omitted from this exhibit pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish copies of any of the omitted schedules and exhibits upon request by the U.S. Securities and Exchange Commission.

Management contract or compensatory plan or arrangement.

ITEM 16. Form 10-K Summary

None.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
KIORA PHARMACEUTICALS, INC.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Kiora Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Kiora Pharmaceuticals, Inc. (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred losses from operations and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matters does not alter in

any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

In-Process Research and Development Impairment Analysis

As of December 31, 2022, the Company had in-process research and development assets of approximately $10.6 million. As described in Note 2 to the financial statements, the Company performs its impairment test of these items annually, or whenever events or changes in circumstances indicate that the carrying value of the in-process research and development assets exceeds its fair value. The Company performed its annual impairment test of these assets in the third quarter of 2022. The Company's impairment test involves comparing the carrying value of the in-process research and development assets to their estimated fair value. There was no impairment loss determined as a result of the Company's annual testing. The Company's fair value estimates require management to make significant estimates and assumptions including the timing and amounts of projected cash flows, probability of success in reaching market and discount rates.

We identified the impairment test of in-process research and development as a critical audit matter due to the significant judgments made by management in the estimates and assumptions used in developing the fair value estimates. This in turn led to a high degree of auditor judgment, subjectivity, and effort in performing procedures to evaluate the reasonableness of management's significant estimates and assumptions. Additionally, the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. We obtained an understanding and evaluated the design of controls over the Company's impairment test of in-process research and development assets, including developing the estimate of fair value. We evaluated the current status of the Company's active research and development programs. In addition, we utilized our valuation specialists with specialized skills and knowledge, in evaluating the reasonableness of the Company's methodology for estimating fair value using the income approach; evaluating the discount rates used by management by comparing it to a range of discount rates developed using the modified capital asset pricing model; and evaluating the mathematical accuracy of certain calculations included in the income approach.

Valuation of Warrant Liability

For the year ended December 31, 2022, the Company recorded a change in fair value of warrant liability of $1.4 million. As described in Note 2 to the financial statements, the Company recorded a liability for warrants issued in July 2022 and recorded the change in fair value of the warrants to the statement of operations from issuance through the date the warrants were reclassified to equity in September 2022. The Company's fair value estimates require management to make significant estimates and assumptions including the appropriateness of the model used, the term of the warrants, the volatility of the Company's stock, and the probability of securing shareholder approval to approve the issuance of warrants and a reverse stock split to make available sufficient authorized shares, subject to an adjustment based on evidence of market data.

We identified the valuation of the liability warrants as a critical audit matter due to the significant judgements made by management in the estimates and assumptions used in developing the fair value estimates. This in turn led to a high degree of auditor judgement, subjectivity, and effort in performing procedures to evaluate the reasonableness of management's significant estimates and assumptions. Additionally, the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. We obtained an understanding and evaluated the design of controls over the Company's recording of the warrant instruments. In addition, we utilized our valuation specialists with specialized skills and knowledge, in evaluating the reasonableness of the Company's

methodology for estimating fair value; evaluating the assumptions used by Company and performing a sensitivity analysis of a range of inputs.

/s/ EisnerAmper LLP
We have served as the Company's auditor since 2014.

EISNERAMPER LLP
Iselin, New Jersey
March 23, 2023

KIORA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2022	December 31, 2021
ASSETS		
Current Assets:		
Cash and Cash Equivalents	$ 5,964,556	$ 7,854,690
Prepaid Expenses and Other Current Assets	343,069	606,520
Tax Receivables	1,373,041	529,560
Total Current Assets	7,680,666	8,990,770
Property and Equipment, Net	55,177	73,999
Restricted Cash	49,260	45,000
Intangible Assets and In-Process R&D, Net	10,743,164	10,768,164
Operating Lease Assets with Right-of-Use	116,992	209,411
Other Assets	33,000	42,964
Total Assets	$ 18,678,259	$ 20,130,308
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	$ 1,008,262	$ 160,621
Accrued Expenses	1,835,934	1,330,141
Operating Lease Liabilities	105,782	118,846
Contingent Consideration, short-term	322,385	—
Total Current Liabilities	3,272,363	1,609,608
Non-Current Liabilities:		
Contingent Consideration	3,309,175	3,048,955
Deferred Tax Liability	689,121	802,131
Non-Current Operating Lease Liabilities	—	90,566
Total Non-Current Liabilities	3,998,296	3,941,652
Total Liabilities	7,270,659	5,551,260
Commitments and Contingencies (Note 12)		
Stockholders' Equity:		
Preferred Stock, $0.01 Par Value: 10,000,000 shares authorized at December 31, 2022 and 2021;3,750 designated Series A, 0 shares issued and outstanding at December 31, 2022 and 2021, 10,000 designated Series B, 0 shares issued and outstanding at December 31, 2022 and 2021; 10,000 shares designated Series C, 0 shares issued and outstanding at December 31, 2022 and 2021, 20,000 shares designated Series D, 7 shares issued and outstanding at December 31, 2022 and 2021;1,280 shares designated as Series E, 0 shares issued and outstanding at December 31, 2022 and 2021	—	—
Common Stock, $0.01 Par Value: 50,000,000 shares authorized at December 31, 2022 and 2021;1,796,472 and 316,599 shares issued and outstanding at December 31, 2022 and 2021, respectively	17,986	3,166
Additional Paid-In Capital	146,035,314	135,541,662
Accumulated Deficit	(134,462,959)	(120,879,349)
Accumulated Other Comprehensive Loss	(182,741)	(86,431)
Total Stockholders' Equity	11,407,600	14,579,048
Total Liabilities and Stockholders' Equity	$ 18,678,259	$ 20,130,308

See Accompanying Notes to the Consolidated Financial Statements.

KIORA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended December 31,	
	2022	2021
Operating Expenses:		
Research and Development	3,448,925	5,350,264
General and Administrative	8,277,993	5,323,649
Goodwill Impairment	—	4,037,811
Change in Fair Value of Contingent Consideration	582,605	(475,956)
Total Operating Expenses	12,309,523	14,235,768
Operating Loss Before Other Income	(12,309,523)	(14,235,768)
Other (Expense) Income, Net:		
Change in Fair Value of Warrant Liability	(1,425,102)	—
Gain on Forgiveness of Loan	—	278,190
Gain on Disposal of Fixed Assets	4,211	—
Interest Income	56,891	1,141
Interest Expense	(8,599)	(6,851)
Foreign Currency Loss	(14,498)	—
Total Other (Expense) Income, Net	(1,387,097)	272,480
Loss Before Income Tax Benefit	(13,696,620)	(13,963,288)
Income Tax Benefit	113,010	192,603
Net Loss	$ (13,583,610)	$ (13,770,685)
Net Loss per Common Share - Basic and Diluted	$ (18.55)	$ (57.12)
Weighted Average Shares Outstanding - Basic and Diluted	732,303	241,099
Other Comprehensive Loss:		
Net Loss	$ (13,583,610)	$ (13,770,685)
Foreign Currency Translation Adjustments	(96,310)	(85,629)
Comprehensive Loss	$ (13,679,920)	$ (13,856,314)

See Accompanying Notes to the Consolidated Financial Statements.

KIORA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
Years Ended December 31, 2022 and 2021

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2021	**7**	**$ —**	**316,599**	**$ 3,166**	**$ 135,541,662**	**$ (86,431)**	**$ (120,879,349)**	**$ 14,579,048**
Stock-Based Compensation	—	—	—	—	462,450	—	—	462,450
Issuance of Panoptes Holdback Shares	—	—	10,087	100	(100)	—	—	—
Issuance of Common Stock from Public Offering, Net of Offering Costs of $505,020	—	—	592,392	5,924	2,456,914	—	—	2,462,838
Issuance of Series E Preferred Stock from Public Offering, Net of Offering Costs of $136,401	1,280	13	0	—	665,178	—	—	665,191
Conversion of Series E Preferred Stock into Common Stock	(1,280)	(13)	160,000	1,600	(1,587)	—	—	—
Reclassification of Warrant Liability	—	—	—	—	3,674,791	—	—	3,674,791
Cancellation of Reverse Stock Split Fractional Shares	—	—	(2,215)	—	(15,629)	—	—	(15,629)
Issuance of Shares of Common Stock from Warrant Exercises	—	—	65,000	650	519,350	—	—	520,000
Issuance of Common Stock from Warrant Inducement, Net of Issuance Costs of $381,360	—	—	654,609	6,546	2,732,285	—	—	2,738,831
Foreign Currency Translation Adjustment	—	—	—	—	—	(96,310)	—	(96,310)
Net Loss	—	—	—	—	—	—	**(13,583,610)**	(13,583,610)
Balance at December 31, 2022	**7**	**$ —**	**1,796,472**	**$ 17,986**	**$ 146,035,314**	**$ (182,741)**	**$ (134,462,959)**	**$ 11,407,600**

See Accompanying Notes to the Consolidated Financial Statements.

KIORA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
Years Ended December 31, 2021 and 2020

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2020	**4,138**	**$ 41**	**138,910**	**$ 1,389**	**$ 116,837,777**	**$ (802)**	**$ (107,108,664)**	**$ 9,729,741**
Stock-Based Compensation	—	—	—	—	842,475	—	—	842,475
Issuance of Common Stock from Private Placement, Net of Offering Costs of $11,142	—	—	38,278	383	7,988,478	—	—	7,988,861
Issuance of Common Stock from Registered Direct Offering, Net of Offering Costs of $993,666	—	—	116,721	1,167	9,755,181	—	—	9,756,348
Issuance of Shares of Common Stock from Warrant Exercises	—	—	260	3	49,998	—	—	50,001
Conversion of Series C Preferred Stock into Common Stock	(4,092)	(41)	21,312	213	(172)	—	—	—
Conversion of Series D Preferred Stock into Common Stock	(39)	—	273	3	(3)	—	—	—
Shares Issued to Bayon Shareholders at Acquisition	—	—	845	8	67,928	—	—	67,936
Foreign Currency Translation Adjustment	—	—	—	—	—	(85,629)	—	(85,629)
Net Loss	—	—	—	—	—		(13,770,685)	(13,770,685)
Balance December 31, 2021	**7**	**$ —**	**316,599**	**$ 3,166**	**$ 135,541,662**	**$ (86,431)**	**$ (120,879,349)**	**$ 14,579,048**

See Accompanying Notes to the Consolidated Financial Statements.

KIORA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2022	**2021**
Operating Activities		
Net Loss	$ (13,583,610)	$ (13,770,685)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation and Amortization of Intangible Assets	41,609	45,296
Reduction of Right-of-Use Assets	92,419	181,977
Stock-Based Compensation	462,450	842,475
Change in Fair Value of Contingent Consideration	582,605	(505,675)
Change in Fair Value of Warrant Liability	1,425,102	—
Deferred Taxes	(113,010)	(192,603)
Paycheck Protection Program Loan Forgiveness	—	(278,190)
Goodwill Impairment Loss	—	4,037,811
Gain on Disposal of Assets	(4,211)	—
Changes in Operating Assets and Liabilities, Net of Effects of Business Acquired:		
Prepaid Expenses and Other Current Assets	275,161	(156,951)
Tax Receivables	(872,736)	(441,196)
Other Assets	(22,465)	14,111
Accounts Payable	782,463	(310,665)
Operating Lease Liabilities	(103,629)	(181,977)
Accrued Expenses	609,719	40,882
Net Cash Used in Operating Activities	(10,428,133)	(10,675,390)
Investing Activities:		
Purchase of Property and Equipment	—	(63,865)
Acquisitions, Net of Cash Acquired	—	(93,155)
Proceeds on Sale of Equipment	6,375	—
Net Cash Provided by (Used in) Investing Activities	6,375	(157,020)
Financing Activities:		
Proceeds from Public Offerings, Net of Offering Costs	5,377,719	17,745,207
Proceeds from Warrant Inducement, Net of Issuance Costs	2,738,831	—
Exercise of Warrants	520,000	50,001
Payments Made for Fractional Shares Related to the Reverse Stock Split	(15,629)	—
Repayment of Loan Payable	—	(212,282)
Net Cash Provided by Financing Activities	8,620,921	17,582,926
Effect of Exchange Rate Changes on Cash	(85,037)	(81,503)
Net (Decrease) Increase in Cash	(1,885,874)	6,669,013
Cash, Including Restricted Cash, Beginning of Year	7,899,690	1,230,677
Cash, Including Restricted Cash, End of Year	$ 6,013,816	$ 7,899,690
Supplemental Disclosures of Noncash Operating and Financing Activities:		
Conversion of Series C Preferred Stock into Common Stock	$ —	$ 213
Conversion of Series D Preferred Stock into Common Stock	$ —	$ 3
Conversion of Series E Preferred Stock into Common Stock	$ 1,600	$ —
Creation of Right-of-Use Assets and Related Lease Liabilities	$ 55,415	$ 313,312
Grant of Restricted Stock Awards	$ 300	$ —

See Accompanying Notes to the Consolidated Financial Statements.

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2022

1. Business, Presentation and Recent Accounting Pronouncements

Business Overview

Kiora is a clinical-stage specialty pharmaceutical company developing and commercializing therapies for the treatment of ophthalmic diseases. On November 5, 2021, Kiora Pharmaceuticals, Inc. (formerly known as EyeGate Pharmaceuticals, Inc.) ("Kiora" or the "Company") filed with the Secretary of State of the State of Delaware, a Certificate of Ownership and Merger, merging its wholly-owned Delaware subsidiary, Kiora Pharmaceuticals, Inc., (incorporated in October 2021) into the Company and amending the Company's certificate of incorporation to change its name to "Kiora Pharmaceuticals, Inc." effective November 8, 2021 (the "Name Change").

The Company's 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. The Company initiated a Phase 1b clinical trial in the third quarter of 2022. On March 17, 2022, the Company was granted Orphan Drug Designation from the U.S. FDA for the Active Pharmaceutical Ingredient ("API") in KIO-301. 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, immune-modulatory and small-molecule inhibitor of Dihydroorotate Dehydrogenase ("DHODH") with what the Company believes 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 the fourth quarter of 2021, the Company reported top-line safety and tolerability from a phase 1b proof-of-concept ("POC") study evaluating KIO-101 in patients with ocular surface inflammation. The Company expects to initiate a Phase 2 clinical trial in the first quarter of 2023. 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, the Company is developing KIO-201, for patients with Persistent Corneal Epithelial Defects ("PCED"), which is an orphan disease and as such, the Company is currently seeing orphan drug designation. The Company is also evaluating KIO-201 in patients recovering from surgical wounds, such as those undergoing photorefractive keratectomy ("PRK") surgery for corneal wound repair after refractive 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. The Company is currently evaluating KIO-201 in a Phase 2 clinical trial in patients with PCEDs and released top-line data in Q1 2023. We expect to release full data in Q2 2023. The Company is in planning stages of a Phase 3b trial for patients recovering from the laser vision correction procedure PRK and plans to initiate the study before the end of 2023.

Since its inception, Kiora has devoted substantially all of its efforts to business planning, research and development, and raising capital.

Going Concern

The accompanying Consolidated Financial Statements have been prepared assuming that Kiora will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal

course of business. At December 31, 2022, Kiora had unrestricted Cash and Cash Equivalents of $ 6.0 million, and an Accumulated Deficit of $ 134.5 million. Kiora has incurred losses and negative cash flows since inception, and future losses are anticipated. Based on its cash on hand at December 31, 2022, the Company anticipates having sufficient cash to fund planned operations into July 2023, however, the acceleration or reduction of cash outflows by Company management can significantly impact the timing for the need to raise additional capital to complete development of its products. To continue development, Kiora will need to raise additional capital through equity financing, license agreements, and/or additional U.S. government grants. Although historically the Company has been successful at raising capital, most recently raising net proceeds of approximately $2.7 million in a warrant inducement transaction that closed on November 22, 2022, net of placement agent fees of $0.3 million and expense of $ 0.1 million, additional capital may not be available on terms favorable to Kiora, if at all. The Company does not know if any future offerings will succeed. Accordingly, no assurances can be given that Company management will succeed in these endeavors. The Company's recurring losses from operations have caused management to determine there is substantial doubt about the Company's ability to continue as a going concern. The Consolidated Financial Statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities or any other adjustments that might be necessary should the Company be unable to continue as a going concern.

Reverse Stock Split

On September 23, 2022, the Company filed a Certificate of Amendment to its Restated Certificate of Incorporation (the "Amendment") with the Secretary of State of the State of Delaware to effect a one-for-forty (1-for-40) reverse stock split of its outstanding common stock. The Amendment was approved by the Company's stockholders at the Company's 2022 Annual Meeting of Stockholders held on September 23, 2022, and by the Company's board of directors. The Amendment became effective on September 27, 2022.

The reverse stock split affected all shares of the Company's common stock outstanding immediately prior to the effective time of the Amendment. As a result of the reverse stock split, proportionate adjustments were made to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all stock options, and restricted stock awards issued by the Company and outstanding immediately prior to the effective time of the Amendment, which resulted in a proportionate decrease in the number of shares of the Company's common stock reserved for issuance upon exercise or vesting of such stock options, and restricted stock awards, and, in the case of stock options, a proportionate increase in the exercise price of all such stock options. In addition, the number of shares reserved for issuance under the Company's equity compensation plans immediately prior to the effective time of the Amendment was reduced proportionately. The reverse stock split did not affect the number of shares or par value of common stock authorized for issuance under the Company's Amended and Restated Certificate of Incorporation, which remained at 50,000,000 shares.

No fractional shares were issued as a result of the reverse stock split. Stockholders of record who would otherwise have been entitled to receive a fractional share received a cash payment in lieu thereof. The reverse stock split affected all stockholders proportionately and did not affect any stockholder's percentage ownership of the Company's common stock (except to the extent that the reverse stock split results in any stockholder owning only a fractional share). As a result of the reverse stock split, the number of the Company's outstanding shares of common stock as of September 27, 2022 decreased from 43,163,123 (pre-split) shares to 1,079,045 (post-split) shares.

All share and per share amounts in the accompanying financial statements and related footnotes have been adjusted retroactively to reflect the reverse stock split as if it had occurred at the beginning of the earliest period presented. While the number of warrants outstanding did not change, the underlying shares did and are presented reflecting the split. The Company's common stock began trading on The Nasdaq Capital Market on a split-adjusted basis when the market opened on September 27, 2022.

Adoption of Accounting Standards

In August 2020, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. This guidance removes the liability and equity separation models for convertible instruments with a cash conversion feature or beneficial conversion feature. As a result, companies will more likely account for a convertible debt instrument wholly as debt, and for convertible preferred stock wholly as preferred stock (i.e., as a single unit of account). In addition, the guidance simplifies the settlement assessment that issuers perform to determine whether a contract in their own equity qualifies for equity classification. Finally, the guidance requires entities to use the if-converted method to calculate earnings per share for all convertible instruments. ASU 2020-06 is effective for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years. The Company adopted ASU 2020-06 on January 1, 2022. The adoption of ASU 2020-06 did not have a material effect for the Company.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40) to clarify an issuer's accounting for certain modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. Specifically, the ASU provides a principles-based framework to determine whether an issuer should recognize the modification or exchange as an adjustment to equity or an expense. The guidance is effective for annual reporting periods beginning after December 15, 2021, and interim periods within those fiscal years. The Company adopted ASU 2021-04 on January 1, 2022. The adoption of ASU 2021-04 did not have a material effect for the Company.

In November 2021, the FASB issued ASU 2021-10, which requires business entities to disclose information about certain government assistance they receive. Such disclosure requirements include the nature of the transactions and the related accounting policy used, the line items on the balance sheet and income statement that are affected and the amounts applicable to each financial statement line item and significant terms and conditions of the transactions. ASU 2021-10 was effective for the Company January 1, 2022. The adoption of ASU 2021-10 did not have a material effect for the Company.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying Consolidated Financial Statements include the accounts of the Company and its subsidiaries, Jade Therapeutics, Inc. ("Jade"), Kiora Pharmaceuticals GmbH ("Kiora GmbH") (formerly known as Panoptes Pharma Ges.m.b.H or "Panoptes") (effective December 18, 2020 when the Company acquired all of the capital stock of Panoptes), Bayon Therapeutics, Inc. ("Bayon") (effective October 21, 2021 when the Company acquired all of the capital stock of Bayon), and Kiora Pharmaceuticals Pty Ltd ("Kiora Pty") (formerly known as Bayon Therapeutics Pty Ltd), collectively referred to as "the Company". All inter-company balances and transactions have been eliminated in consolidation. These Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP").

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make significant estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities, at the date of the financial statements, and the reported amounts of expenses during the reporting periods. The Company makes significant estimates and assumptions in recording the accruals for the Company's clinical trial and research activities, establishing the useful lives of intangible assets and property and equipment, conducting impairment reviews of goodwill, in-process research and development (IPR&D), stock-based compensation, assumptions used to value warrants including warrant modifications and

inducements, and contingent considerations payable. The Company bases its estimates on historical experience and various other assumptions that it believes to be reasonable under the circumstances. Although the Company monitors and regularly assesses these estimates, actual results could differ significantly from these estimates. The Company records changes in estimates in the period that it becomes aware of the change.

Foreign Currency Translation

Operations of Kiora GmbH are conducted in euros which represent its functional currency. Operations of Kiora Pty are conducted in Australian dollars, which represent its functional currency. Balance sheet accounts of such subsidiaries were translated into U.S. dollars at the exchange rate in effect at the balance sheet date and income statement accounts were translated to the average rate of exchange prevailing during the period. Translation adjustments resulting from this process, are included in accumulated other comprehensive loss on the Consolidated Balance Sheets and a component of other comprehensive income (loss) on the Consolidated Statements of Operations and Comprehensive Loss.

Cash and Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments purchased with a maturity of 90 days or less when acquired that are not restricted as to withdrawal, to be the equivalent of cash for the purpose of balance sheet and statement of cash flows presentation. The Company invests its cash in either U.S. government or treasury money market funds with maturities of 90 days or less. At December 31, 2022 and 2021, the Company has classified $ 49.3 thousand and $45.0 thousand as restricted cash, respectively.

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation. Depreciation is provided for on a straight-line basis over the estimated useful life of 2 to 5 years for all assets. Maintenance and repair costs are expensed as incurred. The Company reviews its property and equipment whenever events or changes in circumstances indicate that the carrying value of certain assets might not be recoverable and recognizes an impairment loss when it is probable that the estimated cash flows are less than the carrying value of the asset.

Impairment of Long-Lived Assets

The Company evaluates potential impairment of long-lived assets and long-lived assets to be disposed of and considers whether long-lived assets held for use have been impaired whenever events or changes in circumstances indicate that the related carrying amount may not be recoverable, or that the period of their recovery may have changed. Management makes significant estimates and assumptions regarding future sales, cost trends, productivity and market maturity in order to test for impairment. Management reports those long-lived assets to be disposed of and assets held for sale at the lower of carrying amount or fair value less cost to sell. Based on current facts, estimates and assumptions, management believes that no assets are impaired at December 31, 2022. There is no assurance that management's estimates and assumptions will not change in future periods.

Research and Development Expenses

The Company expenses research and development ("R&D") expenditures as incurred. R&D expenses are comprised of costs incurred in performing R&D activities, including salaries, benefits, facilities, research-related overhead, sponsored research costs, contracted services, license fees, expenses related to generating, filing, and maintaining intellectual property and other external costs. Because the Company believes that, under its current process for developing its products, the viability of the products is essentially concurrent with the establishment of technological feasibility, no costs have been capitalized to date.

Goodwill

Goodwill is the excess of the acquisition cost of a business over the fair value of the identifiable net assets acquired. In 2022, the Company had no goodwill. In 2021, this consisted of the goodwill of the Company's subsidiaries Jade and Kiora GmbH and Bayon. Goodwill is not amortized and is tested for impairment on an annual basis in the fourth quarter of each fiscal year and whenever events or circumstances change that would more likely than not reduce the fair value of a reporting unit below its carrying amount. The Company had no goodwill as of December 31, 2022, and accordingly did not need to perform an impairment analysis. As of December 31, 2021, the Company performed qualitative and quantitative impairment evaluations on its goodwill. As a result, goodwill as of December 31, 2021 was reduced to zero after taking an impairment loss of $4.0 million. The fair value is determined using the income approach with a reconciliation to the Company's market capitalization. The impairment is reported on the Consolidated Statements of Operations and Comprehensive Loss.

In-Process Research and Development

The Company records in-process R&D projects acquired in asset acquisitions that have not reached technological feasibility and which have no alternative future use. For in-process R&D projects acquired in business combinations, the Company capitalizes the in-process R&D project as an indefinite-lived intangible asset and evaluates this asset annually for impairment until the R&D process has been completed. Once the R&D process is complete, the Company amortizes the R&D asset over its remaining useful life. The Company performed an annual evaluation of it's indefinite-lived intangible assets for impairment as of August 31, 2022 with a quantitative analysis. As of December 31, 2022 the Company also performed a qualitative update analysis for impairment and based on this analysis, the fair value of these products was greater than their carrying value. The Company considered the development timelines for its program and noted no qualitative factors that would indicate potential impairment of its indefinite-lived intangible assets. At December 31, 2022 and 2021, there is $10.6 million respectively of in-process R&D as part of intangible assets and in-process R&D, net on the Consolidated Balance Sheets.

Accrued Clinical Expenses

As part of the Company's process of preparing the Consolidated Financial Statements, the Company is required to estimate its accrued expenses. This process includes reviewing open contracts and purchase orders, communicating with its applicable personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated costs incurred for the service when the Company has not yet been invoiced or otherwise notified of actual costs. The majority of the Company's service providers invoice monthly in arrears for services performed. The Company makes estimates of its accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known at the time. The Company periodically confirms the accuracy of these estimates with the service providers and makes adjustments if necessary.

Business Segment and Geographical Information

The Company identifies operating segments as components of the enterprise for which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company views its operations and manages its business as fully integrated and operating in one business segment (research and development), and the Company operates in three geographic areas.

Income Taxes

The Company will record a deferred income tax asset and liability for the expected future income tax consequences of events that have been recognized in the Company's consolidated financial statements and income tax returns. The Company will record a deferred income tax asset and liability based on differences

between the financial statement carrying, or "book", amounts of assets and liabilities, and the tax bases of the assets and liabilities using the enacted income tax regulations in effect in the years in which the differences are expected to reverse. A valuation allowance against deferred income tax asset will be recorded if, based on the weight of available evidence, it is more likely than not that some or all of the deferred income tax assets will not be realized. As of December 31, 2022 and 2021, all of the Company's net deferred income tax assets were subject to a full valuation allowance. As of December 31, 2022 and 2021, the Company has a net deferred tax liability of $0.7 million and $0.8 million, respectively.

The Company recognizes the impact of an uncertain income tax position in the financial statements if it believes that the position is more likely than not to be sustained by the relevant taxing authority. As of December 31, 2022, the Company had no unrecognized uncertain income tax positions.

Warrant Liability

The Company classifies warrants to purchase shares of its common stock as a liability on its Consolidated Balance Sheets when the warrant is a free-standing financial instrument that may require the Company to transfer cash consideration upon exercise and that cash transfer event would be out of the Company's control. Such a "warrant liability" is initially recorded at fair value on date of grant using the Black-Scholes model, and it is subsequently re-measured to fair value at each subsequent balance sheet date. Changes in the fair value of the warrant are recognized as a component of other income (expense), net in the Consolidated Statements of Operations and Comprehensive Loss. The Company will adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrant or meeting the requirements to be reclassified to equity.

For warrants that do not meet the criteria of a liability warrant and are classified on the Company's Consolidated Balance Sheets as equity instruments, the Company uses the Black-Scholes model to measure the value of the warrants at issuance and then applies the relative fair-value of the equity transaction between common stock, preferred stock and warrants. Common stock, and equity-classified warrants each are considered permanent equity.

Refunds for Research and Development

Kiora, through its Kiora GmbH and Kiora Pty Ltd. subsidiaries, is eligible to receive certain refundable tax incentives associated with its research and development expenses in Austria and Australia. These refunds are realized in the form of a cash payment when received, following the incurred research & development expenses. The Company records the refundable payment as a tax receivable and a reduction in expense in the period in which the research and development expenses are incurred. As of December 31, 2022 and 2021, the Company has a research & development tax receivable of $1.3 million and $0.5 million, respectively.

Concentration of Credit Risk and Off-Balance-Sheet Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist principally of cash and cash equivalents. The Company invests cash in accredited financial institutions and cash equivalents in widely held money market funds. Consequently, such funds are subject to minimal credit risk.

The Company has no significant off-balance-sheet risk such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

Comprehensive Loss

Comprehensive loss is defined as the change in stockholders' equity during a period from transactions and other events and circumstances from non-owner sources. The foreign currency translation adjustments are the Company's only component of other comprehensive loss.

Stock-Based Compensation

Stock-based compensation represents the cost related to stock-based awards granted to employees and others. The Company measures stock-based compensation cost to employees and non-employees at grant date, based on the estimated fair value of the award. Compensation cost for employee awards is recognized as expense on a straight-line basis over the employee requisite service period. The Company estimates the fair value of stock options using the Black-Scholes valuation model. The Company recorded compensation expense for non-employee awards with graded vesting using the accelerated expense attribution method. The Company's policy is to record forfeitures as they occur.

Net Loss per Share – Basic and Diluted

Basic and diluted net loss per share is computed by dividing net loss available to common shareholders by the weighted-average number of common shares outstanding for the period, which, for basic net loss per share, does not include the weighted-average unvested restricted common stock that has been issued but is subject to forfeiture of 30,000 shares for year ended December 31, 2022 and 375 shares for the year ended December 31, 2021.

Dilutive common equivalent shares consist of stock options, warrants, and preferred stock and are calculated using the treasury stock method, which assumes the repurchase of common shares at the average market price during the period. Under the treasury stock method, options and warrants will have a dilutive effect when the average price of common stock during the period exceeds the exercise price of options or warrants. Common equivalent shares do not qualify as participating securities. In periods where the Company records a net loss including the years ended December 31, 2022 and 2021, unvested restricted common stock and potential common stock equivalents are not included in the calculation of diluted net loss per share as their effect would be anti-dilutive. All shares of Common Stock that may potentially be issued in the future are as follows:

	Year Ended December 31,	
	2022	2021
Common Stock Warrants	1,597,606	168,932
Employee Stock Options	84,751	12,954
Restricted Stock	30,000	375
Preferred Stock	52	52
Total Shares of Common Stock Issuable	1,712,409	182,313

Related-Party Transactions

During the year ended December 31, 2022, the Company entered into certain related-party transactions, making payments for services to one vendor and six consultants, all of whom also are stockholders of the Company. These transactions generally are ones that involve a stockholder or option holder of the Company to whom the Company also makes payments during the year, typically as a consultant or a service provider. The Company incurred expenses of approximately $0.1 million for services to the related party vendor Ora, Inc. who is providing the Company with clinical study services for KIO-301. One of the Company's directors is an executive at Ora, Inc. $0.1 million of this amount was included in accounts payable at December 31, 2022 and was subsequently paid.

During the year ended December 31, 2021, the Company entered into certain related-party transactions, making payments for services to one vendors, six consultants and two public universities, all of whom also are stockholders of the Company. Additionally, on January 6, 2021, the Company completed a private placement of 38,278 shares of Common Stock and warrants to purchase up to 38,278 shares of Common Stock to an affiliate of Armistice Capital, LLC, with a combined purchase price per share and warrant of $209.00. Steven J. Boyd and Keith Maher, each of whom were members of the Company's board of directors through August 3, 2021,

are affiliates of Armistice Capital, LLC, and Mr. Boyd held voting and investment power over such entity. The total net proceeds from the private placement were approximately $8.0 million. Lastly, on October 21, 2021, the Company acquired Bayon of which the Company's CEO, Brian M. Strem, was a Co-Founder and Managing Director. Except for the private placement and Bayon acquisition as described previous, the transactions with related parties during the year ended December 31, 2021 are not material to the accompanying Consolidated Financial Statements.

Fair Value of Financial Instruments

Each period the Company revalues its contingent consideration obligations associated with business acquisitions to their fair value. The estimate of the fair value of contingent consideration is determined by applying probability of success, discount rate, and updated timing of the payment. The outstanding payments relate to obligation from acquisitions made by the Company. Below is the list of obligations for each relevant transaction are as of December 31, 2022 as follows:

Acquisition	Milestone Achievement Condition	Contingent Consideration Payable	
Bayon			
	Successful completion of Phase 1b	$ 0.5	million
	Successful completion of Phase 2	$ 1.0	million
	Successful completion of Phase 3	$ 4.0	million
	FDA approval	$ 1.7	million
Panoptes			
	Beginning of Phase 3	$ 4.8	million
	FDA approval	$ 4.8	million
Jade			
	FDA approval	$ 2.2	million

Changes in the fair value of contingent consideration are included within "Operating Expenses" in the Company's Consolidated Statements of Operations and Comprehensive Loss. Below are the status of each transaction's contingent consideration:

Bayon: As of December 31, 2021, the Company recorded contingent consideration at fair value of $ 0.9 million as a result of the Bayon acquisition which closed on October 21, 2021. During the year ended December 31, 2022, the Company recorded an increase in estimated fair value of $0.3 million. As of December 31, 2022, the Company had contingent consideration at fair value of $1.1 million.

Panoptes: The Panoptes transaction closed December 18, 2020. As of December 31, 2021, the Company recorded contingent consideration of $ 1.6 million. During the year ended December 31, 2022, the Company recorded an increase in estimated fair value of $0.1 million. The estimated fair value of contingent consideration as of December 31, 2022 was $1.7 million.

Jade: As of December 31, 2021, the Company had a fair value of contingent consideration of $ 0.6 million. During the year ended December 31, 2022, the contingent consideration was increased by $0.2 million for a change in fair value. As of December 31, 2022, the Company had fair value of contingent consideration of $0.7 million.

At December 31, 2022 and 2021, the Company had no other assets or liabilities that are subject to fair value methodology and estimation in accordance with U.S. GAAP.

3. Fair Value

There were no assets measured at fair value on a recurring basis and there were no liabilities valued at fair value using Level 1 or 2 inputs. The following table provides information for liabilities measured at fair value on a recurring basis using Level 3 inputs:

	December 31, 2022	December 31, 2021
Contingent Consideration:		
Current	322,385	—
Noncurrent	3,309,175	3,048,955
Total Contingent Consideration	$ 3,631,560	$ 3,048,955

The Company initially values contingent consideration related to business combinations using a probability-weighted calculation of potential payment scenarios discounted at rates reflective of the risks associated with the expected future cash flows for certain milestones. Key assumptions used to estimate the fair value of contingent consideration include projected financial information, market data and the probability and timing of achieving the specific targets as discussed in Note 14. Acquisitions. After the initial valuation, the Company generally uses its best estimate to measure contingent consideration at each subsequent reporting period using the following unobservable Level 3 inputs:

	Valuation Technique	Unobservable Inputs	December 31, 2022	December 31, 2021
	Discounted cash flow	Payment discount rate	14.7%	13.1%
Bayon		Payment period	2023 - 2028	2023 - 2028
Panoptes		Payment period	2024 - 2028	2024 - 2028
Jade		Payment period	2026	2026
Bayon		Probability of Success for payment	17% - 67%	12% - 72%
Panoptes		Probability of Success for payment	17% - 36%	17% - 36%
Jade		Probability of Success for payment	56%	47%

Significant changes in these assumptions could result in a significantly higher or lower fair value. The contingent consideration reported in the above table resulted is adjusted quarterly based upon the passage of time or the anticipated success or failure of achieving certain milestones. The changes in contingent consideration of $0.6 million as of December 31, 2022, was primarily driven by higher estimated probabilities of success and an increased discount factor and was recorded as a change in fair value of contingent consideration within the Consolidated Statements of Operations and Comprehensive Loss.

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4. Property and Equipment

Property and equipment at December 31, 2022 and 2021 consists of the following:

	Estimated Useful Life (Years)	2022	2021
Laboratory Equipment	3	$ 88,399	$ 88,399
Office Equipment	3	3,409	3,614
Office Furniture	5	58,119	72,549
Leasehold Improvements	2	22,569	22,569
Total Property and Equipment, Gross		172,496	187,131
Less Accumulated Depreciation		117,319	113,132
Total Property and Equipment, Net		$ 55,177	$ 73,999

Depreciation expense was $16,596 and $20,296 for the years ended December 31, 2022 and 2021, respectively.

5. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2022	2021
Payroll and Benefits	$ 1,312,443	$ 937,970
Professional Fees	282,721	194,425
Clinical Trials	57,020	168,785
Other	183,750	28,961
Total Accrued Expenses	$ 1,835,934	$ 1,330,141

6. Debt

In May 2020, the Company received loan funds (the “Loan”) from the Paycheck Protection Program (“PPP”) of $ 0.3 million. In April 2021, the Company was notified by the Small Business Administration (“SBA”) that this Loan was forgiven in full.

The Company has no additional indebtedness at December 31, 2022 and 2021.

7. Intangible Assets and In-Process R&D

Intangible assets at December 31, 2022 consist of the rights to trade-secrets and know-how related to the manufacturing of KIO-201. During the third quarter of 2018, the Company entered into an intellectual property license agreement with SentrX Animal Care, Inc. (“SentrX”) with respect to certain rights relating to the manufacturing of KIO-201. The intangible assets were recorded at $0.3 million, representing the upfront payment paid to SentrX. Additionally, SentrX is eligible to receive milestone payments totaling up to $4.8 million, upon and subject to the achievement of certain specified development and commercial milestones. These future milestone payments to SentrX will increase the carrying value of the intangible assets. The Company’s intangible assets are amortized on a straight-line basis over the estimated useful lives. Additionally, in-process R&D as of December 31, 2022 and 2021 consists of projects acquired from the acquisitions of Jade, Bayon and Panoptes that have not reached technological feasibility and which have no alternative future use. Once the

R&D process is complete, the Company will amortize the R&D asset over its remaining useful life. The Company periodically evaluates these assets for impairment.

Intangible assets and in-process R&D at December 31, 2022 and 2021 consists of the following:

	Estimated Useful Life (Years)	2022	2021
Trade Secrets	10	$ 250,000	$ 250,000
Less: Accumulated Amortization		(106,250)	(81,250)
Intangible Assets, Net		143,750	168,750
In-Process R&D		10,599,414	10,599,414
Total Intangible Assets and In-Process R&D, Net		$ 10,743,164	$ 10,768,164

Amortization expense on intangible assets was $ 25 thousand for each of the years ended December 31, 2022 and 2021.

Expected future amortization expense is as follows for the years ending December 31,:

	Intangible Assets
2023	$ 25,000
2024	25,000
2025	25,000
2026	25,000
2027	25,000
Thereafter	18,750
Total	$ 143,750

8. Capital Stock

On January 6, 2021, the Company completed a private placement of 38,278 shares of Common Stock and warrants to purchase up to 38,278 shares of Common Stock to an affiliate of Armistice Capital, LLC, with a combined purchase price per share and warrant of $209.00. The total net proceeds from the private placement were approximately $8.0 million. The warrants have an exercise price of $ 209.00 per share, subject to adjustments as provided under the terms of the warrants and will be exercisable on the six-month anniversary of their issuance date. The warrants are exercisable for five years from the issuance date.

On July 27, 2021, a holder elected to convert 4,092 shares of Series C Preferred stock that were issued in a public offering on April 17, 2018 into 21,313 shares of Common Stock.

On August 11, 2021, the Company completed a registered direct offering priced at-the-market under Nasdaq Rules for 116,721 shares of Common Stock with a purchase price of $92.10 per share. The Company also completed a concurrent private placement of unregistered warrants to purchase up to an aggregate of 58,361 shares of Common Stock at an exercise price of $ 89.60 per share that are exercisable immediately upon issuance and will expire five and one-half years following the date of issuance. In addition, the Company issued to the placement agent warrants to purchase up to 5,836 shares of Common Stock at an exercise price of $115.124 per share, which expire five years following the date of issuance. The total net proceeds to the Company from the offering were approximately $9.8 million.

On September 17, 2021, holders elected to convert 39 shares of Series D Preferred stock that were issued in connection with the Panoptes acquisition into 273 shares of Common Stock.

On June 18, 2022, in connection with the Company's acquisition of Panoptes Pharma Ges.m.b.H in December 2020 ("Panoptes Acquisition"), the Company issued an aggregate of 10,087 shares of common stock to former shareholders of Panoptes, which had been held back for a period of eighteen months following the closing of the Panoptes acquisition to satisfy post-closing adjustment and indemnification obligations pursuant to the terms of the Share Purchase Agreement between the Company and the former shareholders of Panoptes.

On July 22, 2022, the Company entered into an underwriting agreement to issue and sell stock and warrants in a public offering (the "Public Offering"). On July 25, 2022, the underwriter fully exercised the over-allotment option granted by the Company to purchase stock and warrants (the "Option"). On July 26, 2022, the Public Offering closed, and the Company issued and sold (i) 592,392 shares of common stock (the "Common Shares") (including 98,138 Common Shares sold pursuant to the exercise of the Option), (ii) 1,280 shares of Series E Convertible Preferred Stock (the "Preferred Shares") convertible into up to 160,000 shares of common stock, (iii) 30,095,697 Class A Warrants (including 3,925,525 Class A Warrants sold pursuant to the exercise of the Option), and (iv) 30,095,697 Class B Warrants (including 3,925,525 Class B Warrants sold pursuant to the exercise of the Option) (the "Class B Warrants" and together with the Class A Warrants, the "Warrants"). Upon exercise, the warrants will convert on a 40 for 1 basis into a total of 1,504,785 common shares. The public offering price of $8.00 per Common Share, Class A Warrant and Class B Warrant or $ 1,000 per Preferred Share, 5,000 Class A Warrants and 5,000 Class B Warrants resulted in net proceeds to the Company, of approximately $5.3 million net of underwriting discount and commissions of $ 0.4 million and expense of $0.3 million.

Each Warrant is exercisable at a price per share of common stock of $ 8.00. The Class A Warrants will expire on September 23, 2023 and the Class B Warrants will expire on September 23, 2027. The exercise prices of the Warrants are subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting the Company's common stock.

During August 2022, all holders of the Series E Preferred Shares issued in the Public Offering, elected to convert their Series E Preferred Shares into 160,000 shares of Common Stock.

On November 17, 2022, the Company entered into warrant exercise inducement offer letters with some of the Class A Warrant holders who agreed to exercise for cash all of their Class A Warrants to purchase 654,609 shares of common stock originally issued in the Public Offering in exchange for the Company's agreement to issue new warrants (the "Inducement Warrants") on substantially the same terms as the Class A Warrants to purchase up to 654,609 shares of Common Stock. 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 eighteen month anniversary of their initial exercise date. The Company received aggregate gross proceeds of approximately $3.1 million from the exercise of the Class A Warrants by the selling stockholders and the sale of the Inducement Warrants. The Company paid its placement agent in connection with the inducement transactions a fee equal to 8% of gross proceeds from the exercise of the Class A Warrants.

9. Warrants

At December 31, 2022 and 2021, the following warrants were outstanding:

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	Number of Awards	Weighted Average Exercise Price	Weighted Average Remaining Term in Years
Outstanding at December 31, 2020	68,168	$ 336.40	2.45
Issued	102,476	135.65	4.68
Exercised	(260)	192.00	
Expired	(1,452)	2,100.00	
Outstanding at December 31, 2021	168,932	$ 199.65	3.42
Issued	2,159,395	7.38	2.55
Exercised	(719,609)	5.06	
Expired	(11,112)	900.00	
Outstanding at December 31, 2022	1,597,606	$ 21.22	3.07

All of the warrant agreements provide for a cashless exercise in the event a registration statement covering the issuance of the shares of common stock underlying the warrants is not effective, whereby the number of shares to be issued upon exercise of such warrants will be reduced based on the exercise price and the market value of the shares at the time of exercise. The outstanding warrants expire from 2023 through 2027.

10. Equity Incentive Plan

In 2005, the Company approved the 2005 Equity Incentive Plan (the “2005 Plan”). The 2005 Plan provides for the granting of options, restricted stock or other stock-based awards to employees, officers, directors, consultants, and advisors. During 2010, the maximum number of shares of Common Stock that may be issued pursuant to the 2005 Plan was increased to 59,414 shares. The Board of Directors (the “Board”) is responsible for administration of the 2005 Plan. The Company’s Board determines the term of each option, the option exercise price, the number of shares for which each option is granted and the rate at which each option is exercisable. Incentive stock options may be granted to any officer or employee at an exercise price per share of not less than the fair value per common share on the date of the grant (not less than 110% of fair value in the case of holders of more than 10% of the Company’s voting stock) and with a term not to exceed ten years from the date of the grant (five years for incentive stock options granted to holders of more than 10% of the Company’s voting stock). Nonqualified stock options may be granted to any officer, employee, consultant, or director at an exercise price per share of not less than the par value per share. Following adoption of the 2014 Equity Incentive Plan (the “2014 Plan”), no further grants were made under the 2005 Plan. General terms of the 2014 Plan remain the same as that of the 2005 plan.

The Company’s Board adopted the 2014 Plan and the Employee Stock Purchase Plan (the “ESPP”), and the Company’s Stockholders approved the 2014 Plan and the ESPP Plan in February 2015. As of December 31, 2022, the maximum number of shares of Common Stock that may be issued pursuant to the 2014 Plan and the ESPP was 220,733 and 284 shares, respectively.

In January 2022, the number of shares of common stock issuable under the 2014 Plan automatically increased by 583 shares pursuant to the terms of the 2014 Plan. Additionally, in September 2022, the number of shares of common stock issuable under the 2014 Plan was increased by 200,000 shares, as approved by the Company’s Stockholders. These additional shares are included in the total of 220,733 shares issuable under the 2014 Plan.

The following is a summary of stock option activity for the years ended December 31, 2022 and 2021:

KIORA PHARMACEUTICALS, INC.
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	Number of Options	Weighted Average Exercise Price	Weighted Average Contractual Life (In Years)
Outstanding at December 31, 2020	6,249	$ 840.88	2.30
Granted	8,654	164.30	
Expired	(825)	1,046.00	
Forfeited	(1,124)	259.70	
Outstanding at December 31, 2021	12,954	$ 426.25	5.56
Exercisable at December 31, 2021	5,087	$ 847.31	3.09
Vested and Expected to Vest at December 31, 2021	12,954	$ 426.25	5.56
Granted	78,641	8.49	
Expired	(14)	842.57	
Forfeited	(6,830)	446.34	
Outstanding at December 31, 2022	84,751	$ 36.92	9.59
Exercisable at December 31, 2022	4,939	$ 442.52	7.27
Vested and Expected to Vest at December 31, 2022	84,751	$ 36.92	9.59

During the years ended December 31, 2022 and 2021, the Board approved the grant of options to purchase 78,641 and 8,654 shares of its Common Stock, respectively. All option grants were pursuant to the 2014 Plan. In general, options granted under the 2014 Plan vest with respect to one-third of the underlying shares on the one-year anniversary of the grant date and the remainder ratably over a 24-month period. For the years ended December 31, 2022 and 2021, the fair value of each option grant has been estimated on the date of grant using the Black-Scholes Option Pricing Model with the following weighted-average assumptions:

	2022	2021
Risk-Free Interest Rate	2.42%	1.82%
Expected Life	5.0 years	10.0 years
Expected Average Volatility	140%	140%
Expected Dividend Yield	0%	0%

Using the Black-Scholes Option Pricing Model, the estimated weighted average fair value of an option to purchase one share of common stock granted during the years ended December 31, 2022 and 2021 was $27.08 and $145.63 respectively.

KIORA PHARMACEUTICALS, INC.
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The following is a summary of restricted stock activity for the years ended December 31, 2022 and 2021:

	Number of Shares	Weighted-Average Grant Date Fair Value	Weighted-Average Remaining Recognition Period
Non-vested Outstanding at December 31, 2020	1,697	$ 283.23	1.66
Released	(1,173)	292.62	
Forfeited	(149)	264.04	
Non-vested Outstanding at December 31, 2021	375	$ 261.47	1.09
Awarded	30,000	6.78	
Released	(248)	261.45	
Forfeited	(127)	261.51	
Non-vested Outstanding at December 31, 2022	30,000	$ 6.78	2.79

During the years ended December 31, 2022 and 2021, 127 and 149 shares of restricted stock, which had not vested, were forfeited and returned to the Company, respectively. During the years ended December 31, 2022 and 2021, the Board approved the grant of 30,000 and 0 restricted shares of Common Stock, respectively. All grants of restricted shares were pursuant to the 2014 Plan. These vest with respect to one-third of the underlying shares on the one-year anniversary of the grant date and the remainder ratably over a 24-month period.

The total stock-based compensation expense for employees and non-employees is included in the accompanying Consolidated Statements of Operations and as follows:

	Year Ended December 31,	
	2022	2021
Research and Development	$ 343,475	$ 246,386
General and Administrative	118,975	596,089
Total Stock-Based Compensation Expense	$ 462,450	$ 842,475

The fair value of options granted for the years ended December 31, 2022 and 2021 was approximately $ 0.6 million and $1.2 million, respectively. As of December 31, 2022 and 2021, there was approximately $0.9 million and $1.0 million of total unrecognized compensation expense related to unvested stock-based compensation arrangements granted, which cost is expected to be recognized over a weighted average period of 2.5 and 2.3 years, respectively. The aggregate intrinsic value of stock options outstanding at December 31, 2022 and 2021 was $0.

As of December 31, 2022, there were 101,850 shares of Common Stock available for grant under the 2014 Plan and 191 shares available under the Company's ESPP.

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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11. Income Taxes

The components of loss before income taxes are as follows:

	Year Ended December 31,	
	2022	2021
Domestic	$ (10,563,302)	$ (10,639,818)
Foreign	(3,133,318)	(3,323,470)
Total Loss Before Income Taxes	$ (13,696,620)	$ (13,963,288)

The components of income tax (benefit) expense are as follows:

	Year Ended December 31,	
	2022	2021
Deferred Taxes:		
Federal	$ 4,954	$ (24,086)
State	(117,964)	(168,517)
Total Deferred Taxes	$ (113,010)	$ (192,603)
Income Tax Benefit	$ (113,010)	$ (192,603)

The difference between the effective rate reflected in the provision for income taxes on loss before taxes and the amounts determined by applying the applicable statutory U.S. tax rate are analyzed below:

	Year Ended December 31,	
	2022	2021
United States Federal Income Tax Rate	21.00 %	21.00 %
State Taxes, Net of Federal Benefit	(2.59)	3.35
Permanent Differences	(9.24)	0.72
Goodwill Impairment	—	(6.07)
Change in Valuation Allowance	(9.53)	(21.33)
Research and Development Credits	0.58	1.09
Tax Rate Differential	2.89	1.00
State Non-Income Based Tax	—	0.01
Other	(0.26)	1.61
Effective Tax Rate Expense	2.84 %	1.38 %

KIORA PHARMACEUTICALS, INC.
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The Company's deferred tax assets and liabilities consist of the following:

	Year Ended December 31,	
	2022	2021
Net Deferred Tax Liability:		
Net Operating Loss Carryforwards	$ 22,809,667	$ 20,689,134
Research and Development Credit Carryforwards	2,925,890	2,853,598
Capitalized Research and Development	4,606,902	5,640,428
Stock-Based Compensation	782,355	835,432
Cash Versus Accrual Adjustments	336,360	128,188
Total Deferred Tax Assets	31,461,174	30,146,780
Valuation Allowance	(29,593,286)	(28,298,339)
Net Deferred Tax Asset	1,867,888	1,848,441
Depreciation and Amortization	(477)	(956)
In-Process Research and Development	(2,556,532)	(2,649,616)
Net Deferred Tax Liability	$ (689,121)	$ (802,131)

As of December 31, 2022, the Company has federal and state net operating loss carryforwards of approximately $ 80.5 million and $52.6 million, respectively, to offset future federal and state taxable income. Federal NOL carryforwards as of December 31, 2017 totaling $46.1 million, and state NOL carryforwards as of December 31, 2022 totaling $52.6 million will expire at various dates through 2042. Federal NOL carryforwards generated during the years ended December 31, 2018 and forward totaling $34.4 million will carry forward indefinitely, but their utilization will be limited to 80% of taxable income. The Company has foreign net operating loss carryforwards of $10.7 million as of December 31, 2022, which can be carried forward indefinitely. As of December 31, 2022, the Company also has federal and state research and development tax credit carryforwards of approximately $2.5 million and $0.5 million, respectively, to offset future income taxes, which expire at various times through 2042. The federal and state net operating loss and research tax credit carryforwards may be subject to the limitations provided in the Internal Revenue Code ("IRC") Sections 382 and 383. Approximately $0.6 million of the federal net operating loss attributable to Jade is subject to a Section 382 limitation. Jade's carryover of its research and development credits will be subject to the Section 383 limitation.

The Company files United States federal income tax returns and income tax returns in the Commonwealth of Massachusetts, California, North Carolina and Utah, as well as foreign tax returns for its subsidiaries in Austria and Australia. The Company filed all foreign tax returns for its former French subsidiary EyeGate Pharma S.A.S., which was dissolved December 31, 2021. The Company is not under examination by any jurisdiction for any tax year.

The Company has recorded a valuation allowance against its United States and foreign deferred tax assets in each of the years ended December 31, 2022, and 2021 because the Company's management believes that it is more likely than not that these assets will not be realized. The valuation allowance increased by approximately $1.3 million and $3.0 million during the years ended December 31, 2022 and 2021, respectively, primarily as a result of the increase in net operating losses and credits, adjustments for accrual to cash basis items, and capitalized research and development expenses.

As of December 31, 2022 and 2021, the Company had no unrecognized tax benefits or related interest and penalties accrued. The Company will recognize interest and penalties related to income taxes in income tax expense. The Company has not, as yet, conducted a study of R&D credit carryforwards, which are fully reserved for. This study may result in an adjustment to the Company's R&D credit carryforwards and related

valuation allowance, however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position.

The net operating loss and tax credit carryforwards are subject to review by the Internal Revenue Service in accordance with the provisions of Section 382 of the Internal Revenue Code. Under this Internal Revenue Code section, substantial changes in the Company's ownership may limit the amount of net operating loss carryforwards that could be utilized annually in the future to offset the Company's taxable income. Specifically, this limitation may arise in the event of a cumulative change in ownership of the Company of more than 50% within a three-year period. Any such annual limitation may significantly reduce the utilization of the Company's net operating loss carryforwards before they expire. The closing of the Company's initial public offering, alone or together with transactions that have occurred or that may occur in the future, may trigger an ownership change pursuant to Section 382, which could limit the amount of research and development tax credit and net operating loss carryforwards that could be utilized annually in the future to offset the Company's taxable income, if any. Any such limitation as the result of the Company's additional sales of common stock by the Company could have a material adverse effect on the Company's results of operations in future years.

12. Commitments and Contingencies

Leases

The Company is a party to three real property operating leases for the rental of office or lab space. In February 2022, the Company entered into a lease for an office facility in Encinitas, California with a term through October 31, 2023, which is now used for its corporate headquarters. The Company recorded a right-of-use (ROU) asset and lease liability upon lease commencement in May 2022. The Company also has office and laboratory space of approximately 3,540 square feet in Salt Lake City, Utah with a term through November 30, 2023. The Company has office space in Vienna, Austria of approximately 1,555 square feet with a term through October 31, 2023 as a result of the Panoptes acquisition effective December 18, 2020.

Additional ROU assets and lease liabilities were recorded upon the new lease agreements or extensions that were effective as of December 31, 2021.

Operating lease assets and liabilities are recognized at the lease commencement date at the present value of lease payments to be paid. Operating lease assets represent the Company's right to use an underlying asset and are based upon the operating lease liabilities adjusted for prepayments or accrued lease payments. To determine the present value of lease payments to be paid, the Company estimated incremental secured borrowing rates corresponding to the maturities of the leases. The Company estimated a rate of 10% based on prevailing financial market conditions, comparable company and credit analysis, and management judgment. The Company recognizes expense for its leases on a straight-line basis over the lease term. Operating lease expense, consisting of the reduction of the right-of-use asset and the imputed interest on the lease liability, totaled $0.1 million and $0.2 million for the years ended December 31, 2022 and 2021, respectively.

Future annual minimum lease payments were as follows as of December 31, 2022:

	Operating Leases
2023	105,523
Less: Amounts Representing Interest	(1,830)
Lease Liabilities	$ 103,693

KIORA PHARMACEUTICALS, INC.
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License Agreements

The Company is a party to seven license agreements as described below. These license agreements require the Company 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, the Company (through its subsidiary, Kiora Pharmaceuticals GmbH) entered into a patent and know-how assignment agreement with 4SC Discovery GmbH ("4SC") transferring to it all patent rights and know-how to the compound KIO-101. The Company is responsible for paying royalties of 3.25% on net sales of KIO-101.

On July 2, 2013, the Company (through its 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. The Company is eligible to receive milestone payments totaling up to €155 million, upon and subject to the achievement of certain specified developmental and commercial milestones. We have not received any milestones from 4SC. In addition, the Company is eligible to receive royalties of 3.25% on net sales of KIO-101.

On September 12, 2013, the Company (through its subsidiary, Jade Therapeutics, Inc.) entered into an agreement with Lineage Cell Therapeutics, Inc. ("Lineage"), formerly known as BioTime, Inc. granting to the Company the exclusive worldwide right to commercialize cross-linked thiolated carboxymethyl hyaluronic acid ("modified HA") for ophthalmic treatments in humans. The agreement requires the Company 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, the Company (through its 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 in specific territories. Under the Mediolanum agreement, the Company 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 in development and commercial milestones and a 7% royalty on net sales of KIO-101 in the territories through the longer of the expiration 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, the Company 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, the Company in-licensed the rights to trade secrets and know-how related to the manufacturing of KIO-201. The SentrX Agreement enables the Company 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, the Company (through its subsidiary, Kiora Pharmaceuticals Pty Ltd) entered into an agreement with the University of California ("UC") granting to the Company the exclusive rights to its pipeline of photoswitch molecules. The agreement requires the Company 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 KIO-301 revenue. 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, the Company (through its subsidiary, Kiora Pharmaceuticals Pty Ltd) entered into an agreement with Photoswitch Therapeutics, Inc. ("Photoswitch") granting to the Company 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 and upon first commercial sale of the product.

COVID-19

The continued spread of the COVID-19 pandemic could adversely impact the Company's clinical studies. In addition, COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions, and business shutdowns. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which could negatively affect the Company's ability to raise additional capital on attractive terms or at all. The extent to which COVID-19 may impact the Company's business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the emergence of new variants, and the effectiveness of actions to contain and treat COVID-19. The Company cannot presently predict the scope and severity of any potential disruptions to its business, including to ongoing and planned clinical studies. Any such shutdowns or other business interruptions could result in material and negative effects to the Company's ability to conduct its business in the manner and on the timelines presently planned, which could have a material adverse impact on its business, results of operation, and financial condition. As of the date of this report, there have been no material adverse effects to the Company's ongoing business operations from COVID-19.

13. Employee Benefit Plans

The Company has an employee benefit plan for its United States-based employees under Section 401(k) of the Internal Revenue Code. The Plan allows all eligible employees to make contributions up to a specified percentage of their compensation. Under the Plan, the Company may, but is not obligated to, match a portion of the employee contribution up to a defined maximum. The Company made no matching contribution for the year ended December 31, 2022.

As a result of the 401(k) plan compliance review for the year ended December 31, 2021, the Company contributed approximately $ 29.2 thousand to eligible participants during the third quarter of 2022. As of December 31, 2022, the Company has accrued an additional estimate of $8.5 thousand for contributions likely due as a result of the 401(k) plan compliance review to be performed for the year ended December 31, 2022.

14. Acquisitions

Bayon Therapeutics, Inc. Acquisition

Effective October 21, 2021, the Company acquired all of the capital stock of Bayon, a privately held ophthalmic specialty pharmaceutical company focused on developing light sensitive small molecules. With the Bayon acquisition, Bayon became a wholly-owned subsidiary of Kiora. The assets acquired and liabilities assumed have been recorded at fair value on the date of the acquisition. The excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill, which is not expected to be deductible for tax purposes.

Under the terms of the Bayon acquisition agreement, in consideration for 100% of the outstanding equity interests in Bayon, the Company paid cash in the amount of $0.1 million to certain sellers and creditors and issued 845 shares of Kiora common stock. The former stockholders of Bayon are also eligible to receive up to $7.1 million in additional cash or stock payments based on clinical trial and FDA approval milestones for Bayon's product candidates, as set forth in the Purchase Agreement. If milestone payments are exercised for shares, shares will be issued at a price of $80.40 per share for the Phase 1b milestones. The remaining

milestones will be calculated at a $132.00 per share. The cash or stock earn-out payments were recorded as contingent consideration and fair valued at $ 1.0 million at the acquisition date.

The fair value of the shares issued in the Bayon acquisition was approximately $ 0.1 million based on the average closing price of the Company's Common Stock for five trading days immediately preceding the closing date, or $ 80.40 per share.

The following table summarizes the preliminary purchase price allocation and the estimated fair value of the net assets acquired and liabilities assumed in the Bayon acquisition at the date of acquisition.

	Bayon
Current Assets[1]	$ 5,290
In-Process R&D	1,063,000
Goodwill	406,599
Accounts Payable	(36,525)
Deferred Tax Liability	(265,808)
Total Consideration	$ 1,172,556

[1] Current Assets include cash and receivables of $ 3.9 thousand and $ 1.4 thousand, respectively.

	Common Shares	Price per Share[a]	Amount
Contingent consideration at fair value	—	—	$ 1,007,556
Cash Consideration	—	—	97,066
Kiora Common Stock	845	$ 80.40	67,934
Total Fair Value of Consideration			$ 1,172,556

Net loss in the Consolidated Statement of Operations for the twelve months ended December 31, 2021 includes net losses of Bayon of $ 0.1 million from the date of acquisition. The acquired intangible assets, which consist solely of in-process research and development, will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval, the intangible assets are then accounted for as finite-lived intangible assets and amortized on a straight-line basis over its estimated useful life.

The Company recognized approximately $ 0.1 million of acquisition-related costs for the Bayon acquisition that were expensed in the year ended December 31, 2021 as a component of general and administrative expense.

15. Subsequent Events

On February 3, 2023, the Company completed a private placement with Lincoln Park for 52,798 shares of common stock and warrants to purchase up to 105,596 shares of common stock. The total net proceeds from the private placement were approximately $ 0.2 million. The warrants have an exercise price of $3.538 per share, subject to adjustments as provided under the terms of the warrants, and will be exercisable on the six-month anniversary of the closing date. The warrants are exercisable for five years from the issuance date.

On February 3, 2023, the Company entered into a purchase agreement with Lincoln Park, pursuant to which Lincoln Park has agreed to purchase from the Company up to an aggregate of $10.0 million of common stock (subject to certain limitations), from time to time and at the Company's sole discretion over the term of the

purchase agreement. On February 22, 2023, the Company completed its first issuance under this agreement for a total of 20,000 shares sold to Lincoln Park for proceeds of $0.1 million.

On February 10, 2023, a holder exercised Inducement Warrants resulting in the issuance of 50,000 shares of common stock and proceeds of $ 0.3 million.

SIGNATURES

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 23, 2023 By: /s/ Brian M. Strem
President and Chief Executive Officer

Date: March 23, 2023 By: /s/ Melissa Tosca
Executive Vice President of Finance

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

Signature	Title	Date
/s/ Brian M. Strem Brian M. Strem	President and Chief Executive Officer (Principal Executive Officer)	March 23, 2023
/s/ Melissa Tosca Melissa Tosca	Executive Vice President of Finance (Principal Financial and Accounting Officer)	March 23, 2023
/s/ Paul Chaney Paul Chaney	Director	March 23, 2023
/s/ Kenneth Gayron Kenneth Gayron	Director	March 23, 2023
/s/ Praveen Tyle Praveen Tyle	Director	March 23, 2023
/s/ David Hollander David Hollander	Director	March 23, 2023
/s/ Aron Shapiro Aron Shapiro	Director	March 23, 2023
/s/ Erin Parsons Erin Parsons	Director	March 23, 2023

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Kiora Pharmaceuticals, Inc. (formerly Eyegate Pharmaceuticals, Inc.) on Form S-1 (Nos. 333-269570 and 333-268940), Form S-3 (Nos. 333-255311 and 333-234255) and on Form S-8 (Nos. 333-267754, 333-264640, 333-241657, 333-202207, 333-209441, 333-216227, 333-223431 and 333-231207) of our report dated March 23, 2023, on our audit of the financial statements as of December 31, 2022 and 2021, and for each of the years then ended, which report is included in this Annual Report on Form 10-K to be filed on or about March 23, 2023. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Iselin, New Jersey
March 23, 2023

Exhibit 31.1

Certification

I, Brian M. Strem, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Kiora Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 23, 2023

/s/ Brian M. Strem, Ph.D.

Brian M. Strem, Ph.D.
President and Chief Executive Officer
(Principal executive officer)

Exhibit 31.2

Certification

I, Melissa Tosca, certify that:

1. I have reviewed this Annual Report on Form 10-K of Kiora Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 23, 2023

/s/ Melissa Tosca

Melissa Tosca

Executive Vice President of Finance

(Principal financial and accounting officer)

Exhibit 32.1

CERTIFICATION OF PERIODIC FINANCIAL REPORT
PURSUANT TO 18 U.S.C. SECTION 1350

The undersigned officer of Kiora Pharmaceuticals, Inc. (the "Company") hereby certifies to his knowledge that the Company's Annual Report on Form 10-K for the year ended December 31, 2022 (the "Report") to which this certification is being furnished as an exhibit, as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company. This certification is provided solely pursuant to 18 U.S.C. Section 1350 and Item 601(b)(32) of Regulation S-K ("Item 601(b)(32)") promulgated under the Securities Act of 1933, as amended (the "Securities Act"), and the Exchange Act. In accordance with clause (ii) of Item 601(b)(32), this certification (A) shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and (B) shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

Date: March 23, 2023

/s/ Brian M. Strem, Ph.D.
Brian M. Strem, Ph.D.
President and Chief Executive Officer
(Principal executive officer)

Exhibit 32.2

CERTIFICATION OF PERIODIC FINANCIAL REPORT
PURSUANT TO 18 U.S.C. SECTION 1350

The undersigned officer of Kiora Pharmaceuticals, Inc. (the "Company") hereby certifies to his knowledge that the Company's Annual Report on Form 10-K for the year ended December 31, 2022 (the "Report") to which this certification is being furnished as an exhibit, as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company. This certification is provided solely pursuant to 18 U.S.C. Section 1350 and Item 601(b)(32) of Regulation S-K ("Item 601(b)(32)") promulgated under the Securities Act of 1933, as amended (the "Securities Act"), and the Exchange Act. In accordance with clause (ii) of Item 601(b)(32), this certification (A) shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and (B) shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

Date: March 23, 2023

/s/ Melissa Tosca
Melissa Tosca
Executive Vice President of Finance
(Principal financial and accounting officer)