

**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, 2024
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

(State or other jurisdiction of incorporation or organization)

98-0443284

(I.R.S. Employer Identification No.)

**332 Encinitas Blvd.
Suite 102**

Encinitas, CA 92024

(Address of Principal Executive Offices, including zip code)

(858) 224-9600

(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 x 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 x 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. x 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 (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). x 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	x	Smaller reporting company	x
		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 "

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. "

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). "

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of the shares of common stock on The Nasdaq Stock Market on June 30, 2024, was approximately \$12,242,441. 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 21, 2025, there were 3,000,788 shares of the registrant's common stock outstanding.

Documents Incorporated by Reference

Portions of the registrant's definitive Proxy Statement to be delivered to stockholders in connection with the 2025 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after December 31, 2024, are incorporated by reference into Part III of this Annual Report on Form 10-K.

KIORA PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
For the Year Ended December 31, 2024

TABLE OF CONTENTS

	Page
Forward-Looking Statements	2
 PART I	
Item 1. Business	3
Item 1A. Risk Factors	17
Item 1B. Unresolved Staff Comments	44
Item 1C. Cybersecurity	44
Item 2. Properties	46
Item 3. Legal Proceedings	47
Item 4. Mine Safety Disclosures	47
 PART II	
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	48
Item 6. Reserved	48
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	48
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	60
Item 8. Consolidated Financial Statements and Supplementary Data	60
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	60
Item 9A. Controls and Procedures	60
Item 9B. Other Information	61
Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	61
 PART III	
Item 10. Directors, Executive Officers and Corporate Governance	62
Item 11. Executive Compensation	62
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	62
Item 13. Certain Relationships and Related Transactions, and Director Independence	62
Item 14. Principal Accounting Fees and Services	62
 PART IV	
Item 15. Exhibits, Consolidated Financial Statement Schedules	63
Index to Consolidated Financial Statements	F-1
Item 16. Form 10-K Summary	68
Signatures	92

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this “Annual Report on Form 10-K”, this “Annual Report” or this “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 preclinical studies and clinical trials conducted by us and our development partners;
- the ability to obtain and maintain regulatory approval of our product candidates, and the labeling for any approved products;
- the scope, progress, expansion, and costs of developing and commercializing our product candidates;
- the size and growth of the potential markets for our product candidates and the ability to serve those markets;
- our expectations regarding our expenses and revenue, the sufficiency of our cash resources and needs for additional financing;
- the anticipated benefits of our strategic co-development and commercialization agreement with Théa Open Innovation (TOI);
- 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; and
- the anticipated trends and challenges in our business and the market in which we operate.

We discuss many of these risks in detail under the heading “Item 1A. Risk Factors” beginning on page of [17](#) 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 retinal diseases. We were originally incorporated in 1998 under the name of Optis France S.A. in Paris, France. We were formed as a Delaware corporation on December 28, 2004, under the name of EyeGate Pharmaceuticals, Inc., and changed our name to Kiora Pharmaceuticals, Inc. effective November 8, 2021 in connection with a merger of one of our wholly owned subsidiaries.

We are developing KIO-301, with an initial focus on patients with later stages of vision loss due to retinitis pigmentosa (collectively including any and all sub-forms, "RP"). KIO-301 is a potential vision-restoring small molecule that acts as a "photoswitch" specifically created 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 ("RGCs") (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. 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. We initiated a Phase 1b clinical trial in the third quarter of 2022 and dosed the first patient in November 2022 with the last patient completing the study in September 2023. Data from this trial were presented in November 2023 at the American Academy of Ophthalmology Annual Meeting. The full data package triggered multiple discussions with various potential pharmaceutical partners. After assessing all available options, in January 2024, we chose to partner with Théa Open Innovation ("TOI"), a sister company of Laboratories Théa. In addition to the financial terms of this partnership, we have formed a joint steering committee with TOI for the continued development and potential commercialization of KIO-301. In July 2024, we were granted Orphan Medicinal Product Designation by the European Medicines Agency for KIO-301 for the treatment of non-syndromic, rod-dominant retinal dystrophies, which includes diseases like retinitis pigmentosa, choroideremia, Stargardt disease and others. In September 2024, the European Medicines Agency expanded our Orphan Medicinal Product Designation to also include syndromic, rod-dominant retinal dystrophies that include diseases like Usher's syndrome, which has non-ocular aspects of diseases in addition to retinal involvement. In October 2024, we, in collaboration with our partner TOI, announced that we received regulatory approval to initiate a Phase 2 clinical trial to investigate KIO-301 for vision restoration in patients with retinitis pigmentosa. The ABACUS-2 trial is expected to be a 36 patient, multi-center, double-masked, randomized, controlled, multiple dose study enrolling patients with ultra-low vision or no light perception regardless of their underlying gene mutation associated with retinitis pigmentosa. Enrollment of the first patient is expected to begin in the first half of 2025 following validation of novel functional vision endpoints. These functional assessments may serve as approvable primary endpoints in subsequent registration studies in the United States, Europe and other major regions. KIO-301 (formerly known as B-203) was acquired through the Bayon Therapeutics, Inc. ("Bayon") transaction which closed October 21, 2021.

We are also developing KIO-104 for the treatment of retinal inflammatory diseases, including Diabetic Macular Edema (DME) and Posterior Non-Infectious Uveitis, a rare T cell-mediated, intraocular inflammatory disease. KIO-104 is a novel and potent, non-steroidal small-molecule inhibitor of dihydroorotate dehydrogenase ("DHODH") formulated for intravitreal delivery, and is ideally suited to suppress overactive T-cell activity to treat the underlying inflammation. We believe KIO-104 to be best-in-class with picomolar potency and a validated immune modulating mechanism of action designed to overcome the off-target side effects and safety issues associated with commercially available DHODH inhibitors. Data from a Phase 1b/2a study, reported in October 2022, showed that a single injection of KIO-104 decreased intraocular inflammation and improved visual acuity for the duration of the study. Further, there was evidence of reduced Cystoid Macular Edema from baseline. KIO-104 (formerly known as PP-001) was acquired through the acquisition of Panoptes Pharma GmbH (Panoptes) in the fourth quarter of 2020.

We are considering strategic partnering for our KIO-101 asset, which 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 uses the

same active compound in KIO-104, but is formulated as an ophthalmic topical eye drop. 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 findings observed in both healthy patients and those with ocular surface inflammation.

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 341.5 million in the U.S. as of March 2025, about 97,571 people in the U.S. would be expected to have RP. With a worldwide population presently estimated at over 8.1 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 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 an ODD 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 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 an ODD in the treatment of RP, conferring increased regulatory collaboration with the FDA, and market exclusivity if clinical trials demonstrate safety and efficacy. On March 17, 2022, we were granted an ODD by the FDA for the active ingredient in KIO-301. In July 2024, we were granted Orphan Medicinal Product Designation by the European Medicines Agency for KIO-301 for the treatment of non-syndromic, rod-dominant retinal dystrophies, which includes diseases like retinitis pigmentosa, choroideremia, Stargardt disease and others. In September 2024, the European Medicines Agency expanded our Orphan Medicinal Product Designation to also include syndromic, rod-dominant retinal dystrophies that includes diseases like Usher's syndrome, which has non-ocular aspects of diseases in addition to retinal involvement. Currently, no therapeutics are approved to treat patients with RP.

A possible market expansion beyond RP would be to evaluate KIO-301 in patients with geographic atrophy (GA), an advanced stage of age-related dry macular degeneration. Like RP, GA results in photoreceptor

degeneration while maintaining RGC viability. Thus, KIO-301 could benefit these patients who have lost vision. There are about 1 million patients in the U.S. with GA and to date, no therapeutics are approved to treat this disease.

Diabetic Macular Edema and Posterior Non-Infectious Uveitis Market Overview

Diabetic macular edema (DME) is a late stage complication of patients with diabetic retinopathy. This disease is partially caused by overactive inflammation in the retina causing a build up of extracellular fluid which can cause layers of the retina to separate and thus impair vision either temporarily or permanently. It is estimated that 34.2 million Americans have diabetes¹ and that approximately 750,000 Americans have DME². Current treatments involve chronic steroid use or anti-VEGF treatments.

Non-infectious uveitis involving the posterior segment is an important and leading cause of vision loss. While oral corticosteroid therapy is the first-line approach, depending on its underlying cause, uveitis often cannot be controlled after tapering of the steroid to a dose that is safe for chronic treatment. Thus, steroid-sparing immunosuppressive therapy can play an important role for treating this disease.

There are approximately 0.2 million cases of posterior non-infectious uveitis annually in the U.S., UK and EU.³

Our Solution: KIO-104

KIO-104 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 (adenosine triphosphate and guanosine triphosphate). They also play a role in the formation of glycogen, signal-transduction pathways, and as components of co-enzymes (nicotinamide adenine dinucleotide and flavin adenine dinucleotide). 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 S.A. 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.

¹ Based on data from the American Diabetes Association. Statistics. Available at: <https://www.diabetes.org/resources/statistics/statistics-about-diabetes>. Accessed September 13, 2021.

² Varma R, Bressler NM, Doan QV, et al. Prevalence of and risk factors for diabetic macular edema in the United States. *JAMA Ophthalmol.* 2014;132(11):1334-1340. doi: 10.1001/jamaophthalmol.2014.2854.

³ Based on prevalence data from the International EyeCOPE Study published in *Ophthalmology and Therapy* (June 2021) Volume 10, pages 565–580.

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. 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 has been established that leflunomide is 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 Presentation of Rheumatoid Arthritis Market (OPRA+) 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, 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 estimated to be approximately 1.8 million⁴ 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.

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

As noted above, KIO-101 is a member of a family of DHODH inhibitors, known to be disease modifying agents in autoimmune diseases. KIO-101 is a topical ophthalmic formulation of the same API as KIO-104. As a significant portion of the ocular surface inflammation due to underlying autoimmune diseases is caused by over-active T-cells, it is believed that a DHODH inhibitor has the potential to positively impact this disease.

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 for which a Phase 2 clinical study is approved to initiate enrollment of patients with mid to late-stage retinitis pigmentosa in collaboration with TOI.
 - Continue clinical development of KIO-104 for which a Phase 2 clinical study is approved to initiate enrollment of patients with retinal inflammation due to diseases like diabetic macular edema and posterior non-infectious uveitis.
- Increase Equity Value through Collaborations
 - Seek partnership for our KIO-101 product candidate to continue its development activities.
 - Pursue strategic collaborations to further our existing assets with respect to new indication potential and more detailed mechanism of action, which can result in new intellectual property.

⁴ Based on prevalence data from the Epidemiology of RMD study published in Rheumatology International (April 2017) 37:1551–1557.

Collaborations

On January 25, 2024, we entered into an agreement with TOI, a sister company of Laboratories Théa, with respect to KIO-301. The agreement grants TOI the global rights (except for certain countries in Asia) to co-develop and commercialize KIO-301 in ophthalmology. We and TOI will operate under a Joint Steering Committee for the strategic and operational components of KIO-301's continued development. In exchange, we received an upfront payment of \$16 million and will be eligible to receive aggregate clinical development, regulatory and commercial milestone payments of up to \$285 million and tiered commercial royalties up to the low 20% on net sales. Further, TOI is responsible for all research and development costs of KIO-301.

On July 21, 2023, we entered into a Memorandum of Understanding with the Choroideremia Research Foundation ("CRF") to support strategic development of KIO-301 in Choroideremia ("CHM"). CHM is a rare, inherited retinal disease that causes blindness. This collaboration could accelerate our development of KIO-301 for this indication, which also is included in the TOI partnership. Under the collaboration, CRF will assist us with access to clinical and scientific thought leaders to assist in further development of KIO-301 for CHM. CRF will also provide aid in enrollment of patients for any future trials of KIO-301 for CHM.

Our Development

Product	Indication	Preclinical	Phase One	Phase Two	Phase Three	Commercial Rights
Retinal Disease Programs						
KIO-301 (Intravitreal)	Retinitis Pigmentosa (Mutation Agnostic)	██████████	██████████	██████████		Théa Open Innovation (global less Asia)
	Choroideremia	██████████	██████████	██████████		
	Stargardt Disease	██████████	██████████	██████████		
KIO-104 (Intravitreal)	Retinal Inflammation	██████████	██████████	██████████		Kiora
	Proliferative Vitreoretinopathy	██████████				

* KIO-301 has been granted Orphan Disease Designation in the USA and EU

Clinical Development

KIO-301: Retinitis Pigmentosa

Phase 1b Study:

In the fourth quarter of 2022, we initiated a first-in-human clinical trial of KIO-301, referred to as the ABACUS study. The study was designed to evaluate the safety and efficacy of KIO-301 in patients with late-stage Retinitis Pigmentosa.

Design

This was a Phase 1b open-label, single ascending dose clinical trial for people living with retinitis pigmentosa. The study enrolled six patients and evaluated 12 eyes. The first cohort of three patients included individuals with no or bare light perception due to the progression of RP. The second cohort included patients able to perceive light but with ultra-low vision, clinically diagnosed as being able to detect hand motion or count fingers, but incapable of reading even the largest letter on an eye chart. Dose escalations were performed in each patient's contralateral eye. The primary endpoints were 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 was being conducted at The Royal Adelaide Hospital in Adelaide, South Australia as well as at a private ophthalmology clinic in Adelaide, South Australia.

Study Results

We completed the last patient dosing of the initial trial in September 2023 with topline results announced on November 4, 2023 at the American Academy of Ophthalmology retina sub-specialty day. KIO-301 achieved its primary endpoint of safety and tolerability at all doses tested with no ocular nor non-ocular serious adverse events. Regarding key secondary efficacy endpoints, KIO-301 consistently demonstrated improvements in vision from baseline, including expansion of visual fields, improved visual acuity and light perception, higher success rates in multiple functional vision tests, increased neural activity within the primary visual cortex and improvements in quality of life.

KIO-104: Non-Infectious Posterior Uveitis

Phase 1b/2a Study:

A first-in-human clinical study to evaluate the safety of an intravitreal injection of KIO-104 in patients with chronic, non-infectious uveitis was conducted and the final study report was completed in 2021.

Design

KIO-104 was delivered as a single, intravitreal injection of 300, 600, and 1,200 ng per eye. The primary objective of the study assessed the safety, tolerability and pharmacokinetics ("PK") of ascending doses of KIO-104 in 12 patients. The secondary objectives assessed intraocular inflammation and visual acuity.

Study Results

KIO-104 showed an excellent safety profile and promising efficacy signals in improvement of inflammatory parameters and visual acuity in uveitis patients with an apparent dose dependent treatment effect in improvement of visual acuity at Day 14 post dosing. Upon analyzing only the highest dose group (1,200 ng), a fundamental mean improvement of visual acuity was seen in the patients, which started within the first week post injection (Day 7) and lasted beyond the last study visit (Day 28). Apart from improved visual acuity, improvements in vitreous haze and reduction in macular edema were observed in the patients treated with KIO-104.

Intellectual Property and Proprietary Rights

Overview

We are building an intellectual property portfolio for our active platforms, KIO-104 and KIO-301, 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 and KIO-104 including composition-of-matter, formulations thereof and its therapeutic uses in the treatment of ocular disorders and diseases and more. Our

KIO-301 portfolio of patents covers composition-of-matter, methods of use, and formulations thereof. 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 34 active and valid patents that will expire between 2025 and 2035. We have applied for an additional 52 patents, which if approved will expire between 2035 and 2044.

License Agreements

We are a party to six 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 January 25, 2024, we entered into an agreement with TOI to co-develop and commercialize KIO-301 globally (except for certain countries in Asia) in the field of ophthalmology. This agreement carries a collaborative approach to the continued development of KIO-301 (of which TOI is 100% responsible for direct costs of all research and development activities) and upon the achievement of certain clinical development, regulatory and commercial milestones, we will become eligible to receive up to \$285 million in aggregate. We also received an up-front payment from TOI of \$16 million and have a tiered commercial royalty structure up to the low 20% of net sales.

On May 1, 2020, we, through our subsidiary Bayon, entered into an agreement with Photoswitch Therapeutics, Inc. (“Photoswitch”) granting to us access to certain patent applications and intellectual property 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.

On May 1, 2020, we, through our subsidiary Bayon, entered into an agreement with 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. We are 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. In addition, the agreement requires us to pay sublicense fees for the grant of rights under a sublicense agreement at 8% of sublicense revenue prior to enrolling the first patient in any Phase 1 or Phase II (if Phase I is not performed) clinical trial of a licensed product, 6% of sublicense revenue prior to enrolling the first patient in any Phase III clinical trial of a licensed product, or 4% of sublicense revenue prior to any arms-length first commercial sale of a licensed product. On October 30, 2023, we, through our subsidiary Bayon, entered into an agreement with UC to amend the UC licensing agreement effective November 5, 2023, granting us exclusive rights to a patent application covering specific formulations of KIO-301, which was previously jointly owned by UC and Bayon. Further, Bayon has the ability to assign or transfer the agreement providing written notice is given within at least 15 days prior to any such assignment, providing written assignment agreement by successor within 30 days, and by paying an assignment fee of \$30,000 within thirty days of the assignment. Per the terms of the agreement, upon execution of the amendment, we were required to pay UC \$15,000. Per these terms, we made a payment to UC for \$0.7 million related to the up-front payment received from TOI upon execution of the strategic development and commercialization agreement. The agreement expires on the date of the last-to-expire patent included in the licensed patent portfolio which is currently January 2030, however if patents that are currently pending approval are issued, the license expiration would extend into 2041.

On September 26, 2018, we entered into an intellectual property licensing agreement (the “SentrX Agreement”) with SentrX Animal Care, Inc. (“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. On June 7, 2023, we entered into an amendment agreement (the "SentrX First Amendment") whereby SentrX removed our obligation to make any further payments, milestone or otherwise. The term of the agreement is until the product is no longer in the commercial marketplace. In addition, on June 7, 2023, we entered into a new exclusive license agreement (the "New SentrX Agreement") with SentrX, whereby we out-licensed certain KIO-201 patents for use in animal health and veterinary medicine. Under the New SentrX Agreement, SentrX is obligated to pay us a flat low single-digit royalty on net sales, and is effective until the last licensed patent terminates. On August 16, 2023, SentrX was acquired by Dômes Pharma Group. In July 2024, we decided to cease continued development of KIO-201 in combination with an antibiotic, and provided notice to Dômes Pharma of its intention to cease continued maintenance of all related licensed IP and its willingness to transfer control of the prosecution and maintenance of the licensed patents at their request.

On July 2, 2013, we (through our subsidiary, Kiara Pharmaceuticals, GmbH) entered into an out-license agreement with 4SC granting 4SC the exclusive worldwide right to commercialize the compound KIO-101 for RA 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 any product commercialized by 4SC using the compound in KIO-101 and KIO-104.

On July 2, 2013, we (through our subsidiary, Kiara 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, KIO-104, or any other therapeutic product that uses the compound.

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-104 or KIO-301 are approved by the FDA or regulatory bodies in other countries, for commercial sale, we may enter into additional agreements with third parties to sell KIO-104 or KIO-301 in countries not already partnered, 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-104 or KIO-301 (where TOI does not have commercialization rights) 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-104 or KIO-301.

Manufacturing

We 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 source raw materials, 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-104, 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 preclinical laboratory and animal testing and formulation studies in compliance with the FDA's 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 preclinical and clinical testing and approval process requires substantial time, effort, and financial resources. Preclinical 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 preclinical 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 preclinical 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, preclinical 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.

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 Current Good Manufacturing Practice or 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 the 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-104 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-104, 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 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, 2024, 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.

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 28, 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.” In connection with the name change, we changed our symbol on the Nasdaq Capital Market to “KPRX”. 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 (858) 224-9600.

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 website 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.

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. 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 investors 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.
- We depend heavily on the future success of KIO-104 and KIO-301. If we are unable to successfully obtain marketing approval for KIO-104, or KIO-301, or experience significant delays in doing so, or if after obtaining marketing approvals, we fail to commercialize KIO-104 or KIO-301, our business will be materially harmed.
- If clinical trials of KIO-104, KIO-301, or any other product candidate that we may 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-104, KIO-301, or any other product candidate.
- Even if KIO-104, KIO-301, or any other product candidate that we may 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-104, 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-104, 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-104, KIO-301, or any other product candidate that we may develop; and our ability to generate revenue will be materially impaired.
- We incur increasing 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.
- If we identify a material weakness in our internal control over financial reporting in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely meet 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. 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 income was approximately \$3.6 million for the year ended December 31, 2024. Our net loss was \$12.5 million for the year ended December 31, 2023 and \$143.4 million from the period of inception (December 28, 2004) through December 31, 2024. To date, we have financed our operations primarily through private placements and public offerings of our securities, and payments from our license agreements. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and, beginning in 2008, clinical trials. We are still in the development stage of our product candidates, and we have not completed development of any drugs. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year.

We anticipate that our expenses will continue to be significant with the clinical trials for the ongoing development of our KIO-104 and KIO-301 products.

Our expenses will also increase if and as we:

- seek marketing approval for KIO-104 and KIO-301, whether alone or in collaboration with third parties;
- continue the research and development of KIO-104 and KIO-301;
- 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-104 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 patient enrollment or in completing the clinical trials of KIO-104, 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-104, 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-104 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-104 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-104 and KIO-301 product candidates. In the future, we expect to raise additional financial resources for the continued clinical development of KIO-104, 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, 2024, we had cash and cash equivalents of \$3.8 million and short-term investments of \$23.0 million for a total of \$26.8 million.

With the current cash and short-term investments on hand, we believe we will have sufficient cash to fund planned operations into 2027, 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. 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 preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. Our commercial revenues, if any, will be derived from sales of KIO-104, KIO-301, or any other product candidates 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 grants 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 investors 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-104 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.

Taxing authorities could reallocate our taxable income among our subsidiaries, which could increase our overall tax liability.

We are organized in the United States, and have wholly-owned subsidiaries in United States, Austria and Australia. If we succeed in growing our business, we may conduct increased operations through subsidiaries in various tax jurisdictions pursuant to transfer pricing arrangements between us and our subsidiaries. If two or more affiliated companies are located in different countries, the tax laws or regulations of each country generally will require that such arrangements be priced the same as those between unrelated companies dealing at arm's length and that appropriate documentation is maintained to support the value of such arrangements. Our transfer pricing policies were formulated with the assistance of third-party experts; however, tax authorities in any country may disagree with our transfer pricing policies and procedures and we are subject to more tax audits as a result of having subsidiaries in foreign countries. If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arm's length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could

result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties it would increase our tax liability, which could adversely affect our financial condition, results of operations and cash flows.

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-104 and KIO-301. If we are unable to successfully obtain marketing approval for KIO-104 and KIO-301, or experience significant delays in doing so, or if after obtaining marketing approvals, we fail to commercialize KIO-104 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-104 and KIO-301, and we expect to invest a significant portion of our efforts and financial resources in the development of KIO-104 in the future. There remains a significant risk that we may fail to successfully develop either product candidate.

We cannot accurately predict when or if KIO-104 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 obtaining marketing approval to commercialize KIO-104 and KIO-301.

The success of KIO-104 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-104 and KIO-301;
- making arrangements with third-party manufacturers for commercial quantities of KIO-104 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-104 and KIO-301, if and when approved, whether alone or in collaboration with others;
- acceptance of KIO-104 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-104 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-104 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-104 and KIO-301, which would materially harm our business.

If clinical trials of KIO-104, KIO-301, or any other product candidate that we may 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-104, KIO-301, or any other product candidate.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

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

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize KIO-104, 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 preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates.

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

We may not be able to initiate or continue clinical trials for KIO-104 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-104 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-104, 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-104, KIO-301, or any other product candidate that we may 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-104, 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-104 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-104 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-104, 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-104, KIO-301, and possibly other product candidates that we may 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-104, 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-104, 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-104, 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-104, KIO-301, or any other product candidate that we may develop achieves marketing approval, we expect that it will be priced at a premium over competitive products.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we are able to commercialize KIO-104, 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-104, 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 sales 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-104 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. On January 25, 2024, we entered into an agreement with TOI relating to KIO-301, which grants TOI global rights (except for certain countries in Asia) to co-develop and co-commercialize KIO-301 in ophthalmology. 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.

We are dependent on TOI for the successful co-development and commercialization of KIO-301. If TOI does not devote sufficient resources to the co-development and commercialization of KIO-301, are unsuccessful in their efforts, or chooses to terminate their agreement with us, the potential revenue may not materialize.

In January 2024, we entered into a strategic co-development and commercialization agreement with TOI. Under the agreement, we granted TOI exclusive worldwide co-development and commercialization rights, excluding certain countries in Asia, to KIO-301 for the treatment of degenerative retinal diseases. In exchange, we received an upfront payment of \$16 million, and will be eligible to receive up to \$285 million upon achievement of pre-specified clinical development, regulatory and commercial milestones, tiered royalties of up to low 20% on net sales; and reimbursement of certain KIO-301 research and development expenses.

Under the agreement, TOI is solely and exclusively responsible for all costs and activities related to Phase III clinical trials for KIO-301. TOI may determine, however, that it is commercially reasonable to de-prioritize or discontinue the development of the KIO-301. These decisions may occur for many reasons, including internal business reasons, results from clinical trials or because of unfavorable regulatory feedback.

Further, on review of the safety and efficacy data, the FDA may impose requirements on the programs that render them commercially nonviable. In addition, under the agreement, TOI has certain decision-making rights in determining the development and commercialization plans and activities for the programs. We may disagree with TOI about the development strategy they employ, but we will have limited rights to impose our development strategy on TOI. Similarly, TOI may decide to seek marketing approval for, and limit commercialization of KIO-301 to narrower indications than we would pursue. More broadly, if TOI elects to discontinue the development of KIO-301, we may be unable to advance the product candidate ourselves.

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-104 and KIO-301 for clinical trials and expect to continue to do so in connection with the commercialization of KIO-104, 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-104, 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-104 and KIO-301, preclinical and clinical supplies of our other product candidates that we may develop, and commercial supplies of products if and when any of our product candidates receive marketing approval. Our current and anticipated future dependence upon others for the manufacture of KIO-104, 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-104 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-104, 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-104 and KIO-301, or for fill-finish

services. The prices at which we are able to obtain supplies of KIO-104, KIO-301, and fill-finish services may vary substantially over time and adversely affect our financial results.

If our third-party manufacturers for KIO-104 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-104, 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-104, 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 39 pending patents. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. In particular, during prosecution of any patent application, the issuance of any patents based on the application may depend upon our ability to generate additional preclinical or clinical data that support the patentability of our proposed claims. We may not be able to generate sufficient additional data on a timely basis, or at all. Moreover, changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection.

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

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

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

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

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we 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-104, 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-104, 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-104, KIO-301, or any other product candidate.

The activities associated with the development and commercialization of our product candidates, including KIO-104 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-104, 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-104, 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-104, 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 that we have now or may have in the future, obtain marketing approvals for KIO-104, 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 that we have now or 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-104, 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 current and 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-104 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-104 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, Eric Daniels, our Chief Development Officer, Melissa Tosca, our Chief Financial 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 employment agreements with Dr. Strem, Dr. Daniels and Ms. Tosca, they may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, 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.

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 common stock is thinly traded and hence the 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;
- the results of clinical trials of KIO-104, KIO-301, or any other product candidate that we may develop;
- the 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-104 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.

General Risk Factors

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.

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

As of December 31, 2024, we had federal net operating loss carryforwards of approximately \$31.7 million, no state net operating loss carryforwards, and no federal and state research and development tax credit carryforwards available to reduce future taxable income. These federal net operating loss carryforwards are from net operating losses generated during the year ended December 31, 2018 and later, and as such 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. In 2024, we 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. The analysis determined that ownership changes (under the definition of Section 382) occurred in multiple years. The base limitation calculated for these changes ranged from \$170,643 to \$494,650. In addition to the annual NOL limitation, we had a Net Unrealized Built-In Loss (NUBIL) on the date of the ownership changes in multiple years. The total NUBIL was \$17,519,701. As a result of the NUBIL, we adjusted our Federal NOL carryforwards for the 2018 through 2022 tax years down by a total of \$9,126,676 in total with the filing of our 2023 tax return. Additionally, \$3,146,111 of the NUBIL was recognized as an unfavorable book to tax adjustment during the 2023 tax year. The remaining NUBIL will be recognized in tax years 2024 and 2025. 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) in the event we have more than \$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 \$250 million or (b) in the event we have less than \$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 increasing 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, 2024, intangible assets, net, represented approximately \$6.7 million, or 18% of our total assets. 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 1C. CYBERSECURITY

Overview

Our IT and related systems are critical to the efficient operation of our business and essential to our ability to perform day to day processes. We face persistent security threats, including threats to our IT infrastructure and unlawful attempts to gain access to our confidential or otherwise proprietary information, or that of our employees, via phishing/malware campaigns and other cyberattack methods.

Our security policies and processes are based on industry best practices and are revisited regularly to ensure their appropriateness based on risk, threats and current technological capabilities. We regularly assess our threat landscape and monitor our systems and other technical security controls, maintain information security policies and procedures, including a breach response plan, ensure maintenance of backup and protective systems, and engage with a Managed Service Provider who has a team of security personnel managing our efforts and initiatives. We review System and Organization Controls 1 (SOC 1 Type II) certifications where relevant from key third party partners and other service providers with access to information assets at least annually.

We maintain Information Systems Incident Management Standards that are intended to ensure information security events and weaknesses associated with information systems are communicated and acted on in a timely manner. Our internal controls and procedures address cybersecurity and include processes intended to ensure that security breaches are reported to appropriate personnel and, if warranted, analyzed for potential disclosure. While we have experienced cybersecurity attacks, such attacks to date have not materially affected the Company or our business strategy, results of operations, or financial condition.

From an operational perspective, we use vulnerability scanning tools to assess potential data security risks. We correlate the results and prioritize any key actions based on threat modeling analysis and monitor any such actions in-progress with the system owners based on assigned timelines for remediation. However, patch and vulnerability management, including for products and information assets, remains a complex and key risk that can lead to exploits, security breaches and service disruption. In addition, our online employees are required to participate in cyber, information security, and privacy training at least annually.

We also maintain insurance coverage that is intended to address certain aspects of cybersecurity risks.

To date, there have not been any known cybersecurity threats that have materially affected the Company.

Governance

Board Oversight of Cybersecurity Matters

Assessing and managing information security matters is the responsibility of our Board of Directors. The Board of Directors' Audit Committee is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats. The Board meets with the senior executives, specifically the Chief Executive Officer, and Chief Financial Officer on at least an annual basis to discuss cybersecurity posture. The Board also periodically receives targeted briefings related to cybersecurity and reviews our incident response capabilities. The Audit Committee receives regular reports from management concerning our significant cybersecurity threats and risk and the processes we have implemented to address them. The Audit Committee also receives various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Management of Cybersecurity Risks

The senior executives work to protect our information systems from cybersecurity threats and to promptly assist in coordinating a response to any cybersecurity incidents in accordance with our cybersecurity incident response and recovery plans. Our Chief Executive Officer is responsible for helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports. Our Chief Financial Officer is responsible for preparing budgets, helping to integrate cybersecurity risk considerations into our overall risk management strategy, and communicating key priorities to relevant personnel. Both executives have experience overseeing the information technology function and implementing and overseeing internal controls frameworks in our industry. We have engaged an IT Managed Service Provider

who assists in the oversight of our corporate-wide data security, including developing, implementing and enforcing security policies to manage our overall cybersecurity risks. The senior executives regularly meet with our IT Managed Service Provider during the course of the year to review and discuss cybersecurity issues.

Strategy

Our Security Culture

We protect our information assets and manage risk by promoting a culture that communicates security risks, designs secure IT systems and operates according to approved processes to reduce the likelihood and impact of security incidents. We achieve this objective by:

- Designing, implementing and maintaining solutions with appropriate security controls;
- Sustaining solutions with required patching and vulnerability remediation;
- Creating and executing controls in support of policy as well as regulatory compliance;
- Ensuring that our policies, processes, practices and technologies proactively protect, shield, defend and remediate cyber threats; and
- Delivering quality communications and annual training to stakeholders on cyber awareness and computing hygiene.

We believe that the conduct of our employees is critical to the success of our information security. We keep our employees apprised of threats, risks and the part that they play in protecting both themselves and the company. We conduct periodic compliance training for our employees regarding the protection of sensitive information, which includes training intended to prevent the success of cyberattacks. We also conduct regular phishing simulations to increase employee awareness on how to spot phishing attempts, and what to do if they suspect an email to be a phishing attack.

We execute penetration testing against our technical environment and processes, and continuously monitor our network and systems for signs of intrusion. We also retain consultants to enhance our penetration testing program with current trends and methodologies utilized against other companies, ensuring we are proactively reducing risk from emerging threats.

We assess our service providers prior to allowing our information to be processed, stored or transmitted by third parties, and we include standardized contractual requirements in each contract where appropriate. We validate our service providers' security via questionnaires, open-source intelligence and, where appropriate, SOC 1 Type II reports on financially significant third-party service providers. Our process also includes regular monitoring of risk related to third parties on a periodic basis or when services or product purchases expand beyond their original scope or intended use.

ITEM 2. PROPERTIES

We currently have three facilities, including our principal executive office located at 332 Encinitas Blvd., Suite 102, Encinitas, CA, 92024 under a lease that expires in April 2025; our office located at 11 North Terrace, Adelaide, Australia, 5000 under a month-month lease term; and our office located at Herrengasse 5, 1010 Vienna, Austria under a lease that expires in October 2028. 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

We are not currently a party to any legal proceedings, however, 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".

Holdings

There were 30 holders of record of our common stock as of March 21, 2025. 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

There were no sales of unregistered securities during the fiscal year ended December 31, 2024 that were not previously reported on a Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

Purchase of Equity Securities

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

ITEM 6. RESERVED

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 17 of this Annual Report on Form 10-K. You should carefully review all of these factors, 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 product candidates for the treatment of ophthalmic diseases. We were formed as a Delaware corporation on December 28, 2004, under the name of EyeGate Pharmaceuticals, Inc., and changed our name to Kiara Pharmaceuticals, Inc. effective November 8, 2021.

Our first product candidate 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. On March 17, 2022, we were granted orphan drug designation by the FDA for the API in KIO-301. We initiated a Phase 1b clinical trial in third quarter of 2022, known as the ABACUS study, and dosed the first patient in November 2022. We completed the last patient dosing of the initial trial in September 2023 with topline results announced on November 4, 2023 at the American Academy of Ophthalmology retina sub-specialty day. In October 2024, we, in collaboration with our partner TOI, announced that we received regulatory approval to initiate a Phase 2 clinical trial to investigate KIO-301 for vision restoration in patients with retinitis pigmentosa. The ABACUS-2 trial is expected to be a 36 patient, multi-center, double-masked, randomized, controlled, multiple dose study enrolling patients with ultra-low vision or no light perception regardless of their underlying gene mutation associated with retinitis pigmentosa. Dosing of the first patient with KIO-301 is expected to begin in the first half of 2025 following validation of novel functional vision endpoints. These functional assessments may serve as approvable primary endpoints in subsequent registration studies in the United States, Europe and other major regions. KIO-301 (formerly known as B-203) was acquired through the Bayon transaction which closed October 21, 2021.

Our second product candidate is KIO-104, which focuses on patients with retinal inflammation due to diseases including Diabetic Macular Edema, Posterior Non-Infectious Uveitis and more. KIO-104 is a next-generation, non-steroidal, immuno-modulatory and small-molecule inhibitor of DHODH. We believe KIO-104 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). Clinical proof-of-concept of the potential for the active pharmaceutical ingredient in KIO-104 has been demonstrated in multiple non-clinical and clinical studies. This includes a first-in-human, open-label, phase 1 clinical trial, which investigated the use of KIO-104 for treating Posterior Non-Infectious Uveitis. Results, which were reported in October 2022, showed that a single intravitreal injection of KIO-104 decreased intraocular inflammation in a dose-dependent fashion, and improved visual acuity significantly during the duration of the study. Further, KIO-104 reduced macular edema (swelling) which if unchecked, can lead to permanent vision loss. The drug was well tolerated, with no serious side effects on intraocular tissues or other serious adverse events observed. We are currently approved to start enrolling patients in a Phase 2 trial for KIO-104 in retinal inflammation and expect enrollment to commence in the first half of 2025.

In August 2023, we decided to halt development work on our anterior segment assets, specifically KIO-101 and KIO-201. In July 2024, we made a strategic decision to cease future development or partnership leading to commercialization of KIO-201 and impaired the remaining asset balance. We are actively pursuing partnership opportunities for the KIO-101 program.

In January 2024, we entered into a strategic development and commercialization agreement with Théa Open Innovation (TOI), a sister company of the global ophthalmic specialty company Laboratoires Théa (Théa). Under the agreement, we granted TOI exclusive worldwide development and commercialization rights, excluding certain countries in Asia, to KIO-301 for the treatment of degenerative retinal diseases. In exchange, we will receive an up-front, payment of \$16 million; will become eligible to receive up to \$285 million upon

achievement of pre-specified clinical development, regulatory and commercial milestones; tiered royalties of up to low 20% on net sales; and reimbursement of certain KIO-301 research and development expenses.

From inception through December 31, 2024, our losses from operations have aggregated \$143.4 million. As a result of the collaboration with TOI in 2024, our net income was \$3.6 million for the twelve months ended December 31, 2024. Our net loss was \$12.5 million for the twelve months ended December 31, 2023. 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-104 product candidate, and any other product candidates we advance to clinical development. If we obtain regulatory approval for KIO-104, we expect to incur significant expenses to create an infrastructure to support the commercialization of KIO-104 including sales, marketing, and distribution functions.

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. 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 and research collaboration agreements as performance obligations toward milestones that were met. In the future, we anticipate our revenue to include additional milestone payments under our current and/or future collaboration agreements. We do not expect to generate any revenue from the sale of products unless and until such time that our product candidates have advanced through clinical development and regulatory approval, if ever. We expect that any revenue we generate, if at all, will fluctuate from quarter-to-quarter as a result of the timing and amount of payments relating to such services and milestones and the extent to which any of our products are approved and successfully commercialized. We expect to continue to incur significant operating losses as we fund research and clinical trial activities relating to our therapeutic assets, consisting of KIO-301 and KIO-104, 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, preclinical research, and clinical trial and regulatory-related costs;
- expenses incurred under agreements with sites and consultants that conduct our clinical trials; 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-104, KIO-301 (to the extent there are any unreimbursed expenses), 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-104, 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 for our full time employees, including stock-based compensation. Other general and administrative expenses include professional fees for investor relations and external communications, auditing, tax, patent costs, and legal services.

We expect that general and administrative expenses will remain consistent for the near future.

Other Income, Net

Other income, net consists primarily of 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.

Revenue Recognition

To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, Revenue from Contracts with Customers, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

We apply the five-step model to contracts when we determines that it is probable we will collect the consideration we are entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assesses whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

In a contract with multiple performance obligations, we must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each distinct performance obligation which determines how the transaction price is allocated among the performance obligation. The estimation of the stand-alone selling price(s) may include estimates regarding forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. We evaluate each performance obligation to determine if it can be satisfied at a point in time or over time. Any change made to estimated progress towards completion of a performance obligation and, therefore, revenue recognized will be recorded as a change in estimate. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

Amounts received prior to satisfying the revenue recognition criteria are recognized as deferred revenue. Amounts expected to be recognized as revenue within the twelve months following the balance sheet date are classified as the current portion of deferred revenue. Amounts not expected to be recognized as revenue within the twelve months following the balance sheet date are classified as deferred revenue, net of current portion.

Collaboration Revenue

If a license to our intellectual property is determined to be distinct from the other performance obligations identified in a contract, we recognize revenues from the transaction price allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from the allocated transaction price. We evaluate the measure of progress at each reporting period and, if necessary, adjust the measure of performance and related revenue or expense recognition as a change in estimate.

At the inception of each arrangement that includes milestone payments, we evaluate whether the milestones are considered probable of being reached. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or a collaboration partner's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of milestones that are within our or a collaboration partner's control, such as operational development milestones and any related constraint, and, if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which will affect collaboration revenues and earnings in the period of adjustment. Revisions to our estimate of the transaction price may also result in negative collaboration revenues and earnings in the period of adjustment.

For arrangements that include sales-based royalties, including commercial milestone payments based on the level of sales, and a license is deemed to be the predominant item to which the royalties relate, we will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied, or partially satisfied.

Collaboration Agreements

We entered into a research agreement that falls under the scope of ASC 808, Collaborative Arrangements. Reimbursements from a collaboration partner are recorded as a reduction to research and development expense. Similarly, amounts that are owed to a collaboration partner are recognized as research and development expense.

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.

Intangible Assets

Intangible assets acquired in a business combination are recognized separately from goodwill and are initially recognized at fair value at the acquisition date. We test intangible assets for impairment as of August 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 its indefinite-lived intangible assets for impairment as of August 31, 2024 with a quantitative analysis. The estimated fair value of the KIO-201 assets was less than their carrying value due to the strategic decision to cease all future development or partnership leading to commercialization. Accordingly, we recognized an impairment loss of \$2.0 million. As of December 31, 2024, we 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 resulting in no additional impairment. We considered the development progress and timelines for its programs 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, preclinical 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, preclinical 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.

Income Taxes

During the fourth quarter of 2024, we recorded an adjustment to its income tax provision based on new information obtained from the completion of complex tax analyses, specifically a Section 382 study to assess the availability of historical net operating losses (NOLs) and a transfer pricing analysis. These analyses provided additional insight into our tax position and were necessary to accurately determine the tax liability.

Under Accounting Standards Codification (ASC) 250, Accounting Changes and Error Corrections, changes in accounting estimates are accounted for prospectively. As the adjustment resulted from new information that was not reasonably knowable at prior reporting dates and required specialized technical expertise, we have determined that the change constitutes a change in estimate rather than a correction of an error.

As a result, we recognized an increase in our tax liability of \$2.3 million in the fourth quarter of 2024. This change in estimate is reflected in our consolidated financial statements for the year ended December 31, 2024.

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 Annual Report on Form 10-K for detailed information regarding the status of recently issued accounting pronouncements.

Other Information

Net Operating Loss Carryforwards

As of December 31, 2024, we had federal net operating loss carryforwards of approximately \$31.7 million and no state operating loss carryforwards, to offset future federal and state taxable income. Federal NOL carryforwards generated during the years ended December 31, 2018 and forward totaling \$31.7 million will carry forward indefinitely, but their utilization will be limited to 80% of taxable income. We had foreign net operating loss carryforwards of \$12.8 million as of December 31, 2024, which can be carried forward indefinitely.

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 our ownership may limit the amount of net operating loss carryforwards that could be utilized annually in the future to offset our taxable income. Specifically, this limitation may arise in the event of a cumulative change in ownership of more than 50% within a three-year period.

In 2024, we had a formal section 382 analysis performed. The analysis determined that ownership changes (under the definition of Section 382) occurred in multiple years. The base limitation calculated for these changes ranged from \$170,643 to \$494,650. In addition to the annual NOL limitation, we had a Net Unrealized Built-In Loss (NUBIL) on the date of the ownership changes in multiple years. The total NUBIL was \$17,519,701. As a result of the NUBIL, we adjusted our Federal NOL carryforwards for the 2018 through 2022 tax years down by a total of \$9,126,676 in total with the filing of our 2023 tax return. Additionally, \$3,146,111 of the NUBIL was recognized as an unfavorable book to tax adjustment during the 2023 tax year. The remaining NUBIL will be recognized in tax years 2024 and 2025.

The NUBIL results in additional future tax deductions (“recognized built in losses” or “RBIL”), which would be treated as pre-change losses and subject to the 382 limitation if recognized during the 5-year statutory recognition period. The total amount of RBILs limited by Section 382 is \$17,519,701 and the annual allowance is \$170,643 (relating to the 2018 change for RBILs incurred through the 2022 change) and \$178,445 (for RBILs incurred after 2022) per year, therefore the availability of the RBILs will take many years, at which point we will be able to start using the NOLs that have not yet expired.

Due to the annual limitations calculated during the analysis, it has been determined that all federal and state net operating losses that do not have an unlimited carryforward period will expire unused. Additionally, all federal and state R&D credits will also expire unused. As a result, we are writing down our federal and state NOLs by

\$46,054,630 and \$54,655,301, respectively and our federal and state R&D credit carryforwards by \$2,549,084 and \$447,490, respectively. This is reflected in the 2024 tax provision.

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, 2024 and 2023

The following table summarizes the results of our operations for the years ended December 31, 2024 and 2023:

	Year Ended December 31,		
	2024	2023	Change
Revenue:			
Collaboration Revenue	\$ 16,000,000	\$ —	\$ 16,000,000
Grant Revenue	20,000	—	20,000
Total Revenue	16,020,000	—	16,020,000
Operating Expenses:			
General and Administrative	\$ 5,542,324	\$ 4,663,146	\$ 879,178
Research and Development	7,842,207	4,027,037	3,815,170
Collaboration Credit	(2,945,350)	—	(2,945,350)
In-Process R&D Impairment	2,008,000	1,904,314	103,686
Change in Fair Value of Contingent Consideration	(937,469)	1,992,399	(2,929,868)
Total Operating Expenses	11,509,712	12,586,896	(1,077,184)
Operating Income (Loss) Before Other Income	4,510,288	(12,586,896)	17,097,184
Total Other Income, Net	1,149,450	163,319	986,131
Income (Loss) Before Income Tax Expense	5,659,738	(12,423,577)	18,083,315
Income Tax Expense	(2,065,005)	(90,319)	(1,974,686)
Net Income (Loss)	\$ 3,594,733	\$ (12,513,896)	\$ 16,108,629

Revenue

The increase of \$16.0 million was attributable to the revenue recognized from the up-front payment pursuant the strategic development and commercialization agreement with TOI and from a grant from the Choroideremia Research Foundation.

General and Administrative Expenses

The increase of \$0.9 million was driven by an increase in personnel related costs of \$0.5 million related to market adjustments and higher bonus expenses. Additionally, professional fees increased by \$0.4 million due to expanded social media and investor relations services. Franchise taxes increased by \$0.2 million, offset by a reduction in D&O insurance premiums of \$0.2 million and reduced rent expense costs of \$50 thousand related to closure of the Salt Lake City location.

Research and Development Expenses

The increase of \$3.8 million was primarily due to increased spending on preclinical, CMC and clinical trial related activities for KIO-301 of \$1.8 million, preclinical and CMC activities related to KIO-104 of \$0.7 million, travel and research consulting costs of \$0.2 million, and increased personnel costs related to compensation and other benefits of \$0.2 million. These costs were partially offset by a net reduction in expenses of \$1.2 million resulting from a decrease in research tax credits expected from Australian and Austrian government programs of \$1.8 million and an increase in expense reimbursement related to the strategic development and commercialization agreement with TOI of \$2.9 million, reduced preclinical development and CMC costs for KIO-101 of \$0.8 million and KIO-201 of \$38 thousand.

In-Process R&D Impairment

In-Process R&D impairment increased by \$0.1 million due to the full impairment of KIO-201. This resulted from a strategic Board-approved decision to stop pursuing partnership opportunities for this program which we had been pursuing since August 2023.

Change in Fair Value of Contingent Consideration

The change in fair value of contingent consideration decreased \$(0.9) million. The change in fair value of contingent consideration is primarily due to the full impairment of KIO-201 resulting in a reduction of future potential Jade milestone payments.

Other Income (Expense), Net

Other income (expense) increased by \$1.0 million primarily due to increased net interest income and accrued interest amortization of approximately \$1.2 million resulting from funds raised in the first quarter of 2024 offset by the write off of an intangible asset related to the SentrX Agreement of \$0.1 million and unrealized losses related to foreign currency activity of \$0.1 million.

Income Tax Expense

Income tax expense increased by \$2.0 million as a result of foreign and domestic pre-tax income during 2024 resulting primarily from the up-front payment pursuant the strategic development and commercialization agreement with TOI.

Research and Development Expenses by Program

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

	Year Ended December 31,		
	2024	2023	Change
Research and Development Expenses by Program			
KIO-101	\$ 25,456	\$ 797,876	\$ (772,420)
KIO-104	671,739	—	671,739
KIO-201	30,875	68,840	(37,965)
KIO-301	3,836,105	1,990,202	1,845,903
Unallocated Research and Development Expenses			
Personnel	2,562,417	2,372,040	190,377
R&D Tax Expense (Credit)	17,894	(1,736,398)	1,754,292
Other Research	697,721	534,477	163,244
Total Research and Development Expenses	\$ 7,842,207	\$ 4,027,037	\$ 3,815,170

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, 2024, we have raised a total of approximately \$148.7 million from such sales of our equity and debt securities, both as a public company and prior to our initial public offering, as well as approximately \$31.1 million in payments received under our license agreements and government grants, \$0.3 million received pursuant to the loan under the Paycheck Protection Plan, which was fully forgiven in April 2021, and \$3.4 million received in R&D tax credits.

In January 2024, we entered into a License Agreement with TOI, whereby we received an up-front payment of \$16 million and will become eligible to receive up to \$285 million upon achievement of pre-specified clinical development, regulatory and commercial milestones and tiered royalties of up to low 20% on net sales; and reimbursement of all KIO-301 research and development expenses moving forward from the date of the execution of the License Agreement.

At December 31, 2024, we had unrestricted Cash and cash equivalents of approximately \$3.8 million, short-term investments of \$23.0 million and an accumulated deficit of \$143.4 million. Prior to the License Agreement with TOI in 2024, we had incurred losses and negative cash flows since inception, and future losses are anticipated. However, based on the cash and short-term investments on hand at December 31, 2024, we anticipate having sufficient cash to fund planned operations into 2027 and do not currently anticipate an immediate need to raise additional capital to fund operations.

Comparison of Years Ended December 31, 2024 and 2023

The following table sets forth the primary sources and uses of cash for the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
Net Cash Provided by/(Used in) Operating Activities	\$ 8,559,115	(9,556,951)
Net Cash Used in Investing Activities	(22,662,611)	—
Net Cash Provided by Financing Activities	15,498,155	5,966,066

Operating Activities

During the year ended December 31, 2024, we recorded net income of \$3.6 million and adjusted primarily for non-cash expense for stock-based compensation in the amount of \$0.7 million, a decrease in the change in fair value of contingent consideration of \$0.9 million, an increase of \$2.0 million due to an impairment of in-process R&D, an increase in prepaid expenses and other assets of \$1.8 million, decreases in accounts payable of \$0.2 million and accrued expenses of \$3.3 million, which was partially offset by a decrease in tax credits receivable of \$1.6 million. During the year ended December 31, 2023, we recorded a net loss of \$12.5 million and adjusted primarily for non-cash expense for stock-based compensation in the amount of \$0.8 million, an increase in the change in fair value of contingent consideration of \$2.0 million, an increase of \$1.9 million due to an impairment of in-process R&D, decreases in accounts payable of \$0.8 million and accrued expenses of \$0.5 million, which was partially offset by an increase in tax credits receivable of \$0.5 million.

Investing Activities

During the year ended December 31, 2024, there was \$22.7 million net cash used in investing activities related to the purchase and maturity of short-term investments. During the year ended December 31, 2023, there was no net cash provided by investing activities.

Financing Activities

During the year ended December 31, 2024, we received net proceeds of \$1.7 million from the exercise of warrants, and \$15.0 million from the completion of a private placement. During the year ended December 31, 2023, we received net proceeds of \$5.6 million from the completion of a public offering, net proceeds of \$0.4 million from equity line of credit purchases, \$0.3 million from the exercise of warrants, and \$0.1 million from the completion of a private placement.

Funding Requirements and Other Liquidity Matters

Our KIO-104 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-301 product outside of the territory already partnered with TOI;
- seek marketing approval for our KIO-104 product or any other products that we successfully develop;
- establish a sales and marketing infrastructure to commercialize our KIO-301 product outside of the territory already partnered with TOI;
- establish a sales and marketing infrastructure to commercialize our KIO-104 product, if approved; and
- seek partnerships for our KIO-101 product to continue our development activities;
- 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 (outside of the territory already partnered with TOI), KIO-101, and KIO-104 products, on terms that may not be favorable to us. We have currently paused development work on KIO-101 and are seeking partnership for any further development of those programs. For our active programs, 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-301 outside of the territory already partnered with TOI and KIO-104 products, or any other products that we would otherwise prefer to develop and market ourselves.

Based on our cash on hand and short-term investments at December 31, 2024, we believe that we will have sufficient cash to fund planned operations into 2027. 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, grants and other arrangements. Although historically we have been successful at raising capital, 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 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, 2024.

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 independent registered public accounting firm is Haskell & White LLP, who are headquartered in Irvine, California, with a PCAOB ID Number 200.

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 Chief Financial Officer, to allow for timely decisions regarding required disclosure.

In connection with this Annual Report, as required by Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, the Company's management, under the supervision of our Chief Executive Officer, who is our principal executive officer, and our Chief Financial Officer, who is our principal financial and accounting officer, carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2024. 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. 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. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Based upon the evaluation described above, with reasonable assurance, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures that support financial reporting were effective as of the period ended December 31, 2024.

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. Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2024. 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 effective as of December 31, 2024.

The scope of our management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2024, includes all of our subsidiaries. As a smaller reporting company 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, Haskell & White 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, 2024.

Changes in Internal Control over Financial Accounting and Reporting

As of December 31, 2024 and as of the date of this report, there were no changes in our internal control over financial reporting identified in connection with management's evaluation required by Rules 13a-15(d) and 15d-15(d) under the Exchange Act that occurred during the quarter ended December 31, 2024 that have materially affected or are reasonably likely to materially affect, our 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 2025 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 2025 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 2025 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 2025 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 2025 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 Amendment to the Restated Certificate of Incorporation of the Registrant, filed May 1, 2024 (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on May 1, 2024 and incorporated by reference thereto).
3.7	Certificate of Amendment to the Restated Certificate of Incorporation of the Registrant, filed June 6, 2024 (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on June 7, 2024).
3.8	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).
3.9	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).
3.10	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).
3.11	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).
3.12	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).
3.13	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).
3.14	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).
3.15	Certificate of Designation of Preferences, Rights and Limitations of Series F Convertible Preferred Stock (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on June 6, 2023 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).
4.3	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\).](#)
- 4.4 [Form of Common Stock Purchase Warrant, dated January 6, 2021 \(previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on January 6, 2021 and incorporated by reference thereto\).](#)
- 4.5 [Form of Common Stock Purchase Warrant, dated August 11, 2021 \(previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on August 10, 2021 and incorporated by reference thereto\).](#)
- 4.6 [Form of Placement Agent Warrant, dated August 11, 2021 \(previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on August 10, 2021 and incorporated by reference thereto\).](#)
- 4.7 [Form of Class B Warrant \(previously filed as an exhibit to the Registrant's Amendment No. 3 to Registration Statement on Form S-1 filed on July 21, 2022 and incorporated by reference thereto\).](#)
- 4.8 [Warrant Agency Agreement, dated July 22, 2022, by and between the Registrant and VStock Transfer, LLC \(previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on July 26, 2022 and incorporated by reference thereto\).](#)
- 4.9 [Form of Common Stock Purchase Warrant, dated February 3, 2023 \(previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on February 3, 2023 and incorporated by reference thereto\).](#)
- 4.10 [Form of Class C Common Stock Purchase Warrant \(previously filed as an exhibit to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 filed on June 1, 2023 and incorporated by reference thereto\).](#)
- 4.11 [Warrant Agency Agreement, dated June 6, 2023, between the Registrant and VStock Transfer, LLC \(previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on June 6, 2023 and incorporated by reference thereto\).](#)
- 4.12 [Form of Tranche A Warrant \(previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on February 1, 2024 and incorporated by reference thereto\).](#)
- 4.13 [Form of Tranche B Warrant \(previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on February 1, 2024 and incorporated by reference thereto\).](#)
- 4.14 [Form of Pre-Funded Warrant \(previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on February 1, 2024 and incorporated by reference thereto\).](#)
- 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 \(previously filed as an exhibit to the Registrant's definitive proxy statement on Schedule 14A filed on July 21, 2023 and incorporated by reference thereto\).](#)
- 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 [Kiara 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 ^{††}	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).
10.13 ^{††}	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).
10.14 [#]	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).
10.15 ^{††}	First Amendment to Intellectual Property License Agreement, dated as of June 12, 2023, between Kiora Pharmaceuticals, Inc. and Sentrx Animal Care, Inc. (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on June 15, 2023 and incorporated by reference thereto).
10.16 ^{††}	Exclusive License Agreement, dated as of June 12, 2023, between Kiora Pharmaceuticals, Inc. and Sentrx Animal Care, Inc. (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on June 15, 2023 and incorporated by reference thereto).
10.17 ^{††}	License Agreement, dated as of May 1, 2020, between Bayon Therapeutics, Inc. and the Regents of the University of California (previously filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q filed on November 9, 2023 and incorporated by reference thereto).
10.18 ^{††}	First Amendment to License Agreement, dated as of November 5, 2023, between Bayon Therapeutics, Inc. and the Regents of the University of California (previously filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q filed on November 9, 2023 and incorporated by reference thereto).
10.19 ^{††}	Exclusive License and Development Agreement, dated as of January 25, 2024, by and between the Registrant and Théa Open Innovation SAS (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on January 31, 2024 and incorporated by reference thereto).
10.20 ^{†††}	Form of Securities Purchase Agreement, dated as of January 31, 2024, by and between the Registrant and the purchasers named therein (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on February 1, 2024 and incorporated by reference thereto).
10.21	Employment Agreement by and between Kiora Pharmaceuticals, Inc. and Eric J. Daniels, dated as of January 10, 2025 (previously filed as exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on January 15, 2025 and incorporated by reference thereto).
10.22	Employment Agreement by and between Kiora Pharmaceuticals, Inc. and Melissa Tosca, dated as of January 10, 2025 (previously filed as exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on January 15, 2025 and incorporated by reference thereto).
14.1	Code of Ethics and Business Conduct.
16.1	Letter from EisnerAmper LLP regarding change in certifying accountant (previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on March 30, 2023 and incorporated by reference thereto).
19.1*	Insider Trading Policy
21.1	Subsidiaries of the Registrant
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.
97.1*	Kiora Pharmaceuticals, Inc. Clawback Policy
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, Haskell & White LLP	F-2
Consolidated Balance Sheets as of December 31, 2024 and 2023	F-4
Consolidated Statements of Operations and Comprehensive Income (Loss) for the Years Ended December 31, 2024 and 2023	F-5
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2024 and 2023	F-6
Consolidated Statements of Cash Flows for the Years Ended December 31, 2024 and 2023	F-8
Notes to Consolidated Financial Statements	F-9

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
Kiora Pharmaceuticals, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Kiora Pharmaceuticals, Inc. (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2024 and 2023, and the consolidated results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the consolidated 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 consolidated 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, audits 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matters communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which they relate.

In-Process Research and Development - Impairment Analysis

Description of the Critical Audit Matter

As of December 31, 2024 and 2023, the Company had in-process research and development assets of approximately \$6.7 million and \$8.7 million, respectively. As described in Note 2 to the consolidated financial statements, the Company performs an impairment test of these items annually and whenever events or changes in circumstances indicate that the carrying value of the in-process research and development assets exceeds their respective fair values. The Company performed its most recent annual impairment test of these assets in the third quarter of 2024. The Company's impairment test involves comparing the carrying value of the in-process research and development assets to their estimated fair values. The Company recognized an impairment of \$2.0 million during the year ended December 31, 2024 as a result of the annual impairment test.

The Company's fair value estimates require management to make significant estimates and judgments, including the timing and amounts of projected cash flows (both revenues and expenses), probabilities of success in product development and regulatory approvals, and appropriate discount and royalty rates.

We identified the evaluation of the Company's impairment test of in-process research and development assets as a critical audit matter due to significant management estimates and judgments inherently required in determining 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, several of which extend many years into the future. Additionally, the audit effort involved the use of professionals with specialized skill and knowledge.

How the Critical Audit Matter Was Addressed in the Audit

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. We obtained an understanding of the development status and development plan for each asset. We also obtained an understanding of management's impairment testing process, which includes management's engagement of a third-party valuation expert and the identification of key inputs and assumptions to the fair value model. We assessed the knowledge, skill and ability of the third-party expert and evaluated the sufficiency and appropriateness of the audit evidence supporting key inputs and assumptions to the fair value model. We also utilized a valuation specialist with specialized skills and knowledge in evaluating the reasonableness of the Company's methodology for estimating fair value and evaluating the appropriateness of discount rates used by management in the fair value model. We performed independent mathematical accuracy tests of the Company's fair value model.

/s/ Haskell & White LLP
HASKELL & WHITE LLP

We have served as the Company's auditor since 2023.

Irvine, California
March 25, 2025

KIORA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2024	2023
ASSETS		
Current Assets:		
Cash and Cash Equivalents	\$ 3,792,322	\$ 2,454,684
Short-Term Investments	22,999,760	—
Prepaid Expenses and Other Current Assets	2,042,487	233,382
Collaboration Receivables	601,197	—
Tax Receivables	270,246	2,049,965
Total Current Assets	29,706,012	4,738,031
Non-Current Assets:		
Property and Equipment, Net	5,232	8,065
Restricted Cash	4,057	4,267
Intangible Assets and In-Process R&D, Net	6,687,100	8,813,850
Operating Lease Assets with Right-of-Use	57,170	106,890
Other Assets	24,913	40,767
Total Assets	\$ 36,484,484	\$ 13,711,870
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	\$ 415,590	\$ 206,260
Accrued Expenses	4,588,657	1,380,666
Accrued Collaboration Credit	981,111	—
Operating Lease Liabilities	23,355	47,069
Total Current Liabilities	6,008,713	1,633,995
Non-Current Liabilities:		
Contingent Consideration	4,191,490	5,128,959
Deferred Tax Liability	490,690	779,440
Non-Current Operating Lease Liabilities	33,815	59,822
Total Non-Current Liabilities	4,715,995	5,968,221
Total Liabilities	10,724,708	7,602,216
Commitments and Contingencies (Note 12)		
Stockholders' Equity:		
Preferred Stock, \$0.01 Par Value: 10,000,000 shares authorized at December 31, 2024 and 2023; 3,750 designated Series A, 0 shares issued and outstanding at December 31, 2024 and 2023; 10,000 designated Series B, 0 shares issued and outstanding at December 31, 2024 and 2023; 10,000 shares designated Series C, 0 shares issued and outstanding at December 31, 2024 and 2023; 20,000 shares designated Series D, 7 shares issued and outstanding at December 31, 2024 and 2023; 1,280 shares designated Series E, 0 shares issued and outstanding at December 31, 2024 and 2023; 3,908 shares designated Series F, 420 shares issued and outstanding at December 31, 2024 and 2023	4	4
Common Stock, \$0.01 Par Value: 150,000,000 and 50,000,000 shares authorized at December 31, 2024 and 2023, respectively; 3,000,788 and 856,182 shares issued and outstanding at December 31, 2024 and 2023, respectively	267,679	77,078
Additional Paid-In Capital	169,156,374	153,192,228
Accumulated Deficit	(143,382,122)	(146,976,855)
Accumulated Other Comprehensive Loss	(282,159)	(182,801)
Total Stockholders' Equity	25,759,776	6,109,654
Total Liabilities and Stockholders' Equity	\$ 36,484,484	\$ 13,711,870

See Accompanying Notes to the Consolidated Financial Statements.

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

	Year Ended December 31,	
	2024	2023
Revenue:		
Collaboration Revenue	\$ 16,000,000	\$ —
Grant Revenue	20,000	—
Total Revenue	16,020,000	—
Operating Expenses:		
General and Administrative	\$ 5,542,324	\$ 4,663,146
Research and Development	7,842,207	4,027,037
Collaboration Credit	(2,945,350)	—
In-Process R&D Impairment	2,008,000	1,904,314
Change in Fair Value of Contingent Consideration	(937,469)	1,992,399
Total Operating Expenses	11,509,712	12,586,896
Operating Income (Loss) Before Other Income	4,510,288	(12,586,896)
Other Income (Expense), Net:		
Impairment of Intangible Assets	(104,167)	—
Loss on Disposal of Fixed Assets	(3,859)	(28,379)
Interest Income	1,252,849	173,989
Interest Expense	(21,446)	(11,132)
Other Income, Net	26,073	28,841
Total Other Income, Net	1,149,450	163,319
Income (Loss) Before Income Tax Expense	5,659,738	(12,423,577)
Income Tax Expense	(2,065,005)	(90,319)
Net Income (Loss)	3,594,733	(12,513,896)
Deemed Dividends from Warrant Reset Provision	—	(530,985)
Net Income (Loss) Attributable to Common Shareholders	\$ 3,594,733	\$ (13,044,881)
Net Income (Loss) per Common Share - Basic	\$ 0.93	\$ (24.25)
Weighted Average Shares Outstanding - Basic	3,872,644	538,007
Net Income (Loss) per Common Share - Diluted	\$ 0.87	\$ (24.25)
Weighted Average Shares Outstanding - Diluted	4,125,075	538,007
Other Comprehensive Income (Loss):		
Net Income (Loss)	\$ 3,594,733	\$ (12,513,896)
Unrealized Gain on Marketable Securities	29,719	—
Foreign Currency Translation Adjustments	(129,077)	(60)
Comprehensive Income (Loss)	\$ 3,495,375	\$ (12,513,956)

See Accompanying Notes to the Consolidated Financial Statements.

KIORA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
Year Ended December 31, 2024

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2023	427	\$ 4	856,182	\$ 77,078	\$ 153,192,228	\$ (146,976,855)	\$ (182,801)	\$ 6,109,654
Stock-Based Compensation	—	—	—	—	656,593	—	—	656,593
Issuance of Common Stock and Warrants from Private Placement, Net of Offering Costs of \$1.2 million	—	—	1,755,556	158,000	13,650,816	—	—	13,808,816
Issuance of Common Stock from Warrant Exercises	—	—	358,831	32,295	1,657,043	—	—	1,689,338
Adjustments Due to the Rounding Impact from the Reverse Stock Split for Fractional Shares	—	—	(385)	—	—	—	—	—
Issuance of Common Stock from Restricted Stock Awards	—	—	30,604	306	(306)	—	—	—
Unrealized Gain on Marketable Securities	—	—	—	—	—	—	29,719	29,719
Foreign Currency Translation Adjustment	—	—	—	—	—	—	(129,077)	(129,077)
Net Income	—	—	—	—	—	3,594,733	—	3,594,733
Balance at December 31, 2024	427	\$ 4	3,000,788	\$ 267,679	\$ 169,156,374	\$ (143,382,122)	\$ (282,159)	\$ 25,759,776

See Accompanying Notes to the Consolidated Financial Statements.

KIORA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
Year Ended December 31, 2023

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2022	7	\$ —	199,608	\$ 17,986	\$ 146,035,314	\$ (134,462,959)	\$ (182,741)	11,407,600
Stock-Based Compensation	—	—	—	—	754,944	—	—	754,944
Issuance of Common Stock from Public Offering, Net of Offering Costs of \$729,038	3,908	39	244,181	21,976	5,573,947	—	—	5,595,962
Issuance of Common Stock from Private Placement, Net of Offering Costs of \$84,285	0	—	5,866	528	115,187	—	—	115,715
Issuance of Common Stock from ELOC Purchases	—	—	13,889	1,250	441,060	—	—	442,310
Issuance of Shares of Common Stock from Warrant Exercises	—	—	7,378	664	306,415	—	—	307,079
Conversion of Series F Preferred Stock into Common Stock	(3,488)	(35)	352,288	31,706	(31,671)	—	—	—
Issuance of Common Stock from Restricted Stock Awards	—	—	32,972	2,968	(2,968)	—	—	—
Foreign Currency Translation Adjustment	—	—	—	—	—	—	(60)	(60)
Net Loss	—	—	—	—	—	(12,513,896)	—	(12,513,896)
Balance December 31, 2023	427	\$ 4	856,182	\$ 77,078	\$ 153,192,228	\$ (146,976,855)	\$ (182,801)	\$ 6,109,654

See Accompanying Notes to the Consolidated Financial Statements.

KIORA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2024	2023
Operating Activities		
Net Income (Loss)	\$ 3,594,733	\$ (12,513,896)
Adjustments to Reconcile Net Income (Loss) to Net Cash Provided by (Used in) Operating Activities:		
Closure of EyeGate Pharma S.A.S. Subsidiary	—	(53,882)
Depreciation and Amortization of Intangible Assets	19,205	51,798
Impairment of Intangible Assets	104,167	—
Reduction of Right-of-Use Assets	46,500	10,626
Stock-Based Compensation	656,593	754,944
Impairment of In-Process R&D	2,008,000	1,904,314
Change in Fair Value of Contingent Consideration	(937,469)	1,992,399
Accretion of Discount on Marketable Securities	(283,474)	—
Change in Accrued Interest on Marketable Securities	(25,811)	—
Net Realized Gain on Marketable Securities	(4,519)	—
Change in Unrealized Gain on Cash Equivalents	119	—
Deferred Taxes	(288,750)	90,319
Loss on Disposal of Assets	3,760	28,379
Changes in Operating Assets and Liabilities:		
Prepaid Expenses and Other Current Assets	(1,823,897)	885
Collaboration Receivable	(601,197)	—
Tax and Other Receivables	1,634,464	(548,109)
Other Assets	15,231	(7,583)
Accounts Payable	226,119	(808,016)
Accrued Expenses	3,280,730	(459,713)
Accrued Collaboration Credit	981,111	—
Operating Lease Liabilities	(46,500)	584
Net Cash Provided by (Used in) Operating Activities	8,559,115	(9,556,951)
Investing Activities:		
Purchases of Property and Equipment	(6,256)	—
Purchases of Marketable Securities	(35,632,375)	—
Sales of Marketable Securities	1,338,256	—
Maturities of Marketable Securities	11,637,764	—
Net Cash Used in Investing Activities	(22,662,611)	—
Financing Activities:		
Gross Proceeds from Public Offering	—	6,325,000
Issuance Costs for Public Offering	—	(729,038)
Gross Proceeds from Private Placement	14,998,865	200,000
Issuance Costs for Private Placement	(1,190,049)	(84,285)
Proceeds from the Issuance of ELOC Purchases	—	442,310
Exercise of Warrants	1,689,339	307,079
Payment of Contingent Consideration	—	(495,000)
Net Cash Provided by Financing Activities	15,498,155	5,966,066
Effect of Exchange Rate Changes on Cash	(57,231)	36,020
Net Increase (Decrease) in Cash and Cash Equivalents	1,337,428	(3,554,865)
Cash and Cash Equivalents, Including Restricted Cash, Beginning of Year	2,458,951	6,013,816
Cash and Cash Equivalents, Including Restricted Cash, End of Year	\$ 3,796,379	\$ 2,458,951
Supplemental Disclosures of Noncash Operating and Financing Activities:		
Conversion of Series F Preferred Stock into Common Stock	\$ —	\$ 31,706
Creation of Right-of-Use Assets and Related Lease Liabilities	\$ —	\$ 114,747
Grant of Restricted Stock Awards	\$ 306	\$ 2,701

See Accompanying Notes to the Consolidated Financial Statements.

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

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.

KIO-301 is a product candidate 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. 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. The Company initiated a Phase 1b clinical trial in the third quarter of 2022 and completed the last patient dosing of the initial trial in September 2023 with topline results announced in November 2023. In January 2024, the Company entered into a strategic development and commercialization agreement (“License Agreement”) with Théa Open Innovation (“TOI”), a sister company of the global ophthalmic specialty company Laboratoires Théa (“Théa”). Under the agreement, Kiora granted TOI exclusive worldwide development and commercialization rights, excluding Asia, to KIO-301 for the treatment of degenerative retinal diseases. In exchange, Kiora received an up-front payment of \$16 million; will be eligible to receive up to \$285 million upon achievement of pre-specified clinical development, regulatory and commercial milestones; tiered royalties of up to low 20% on net sales; and reimbursement of all KIO-301 research and development expenses moving forward from the date of the execution of the License Agreement. In July 2024, the Company was granted Orphan Medicinal Product Designation by the European Medicines Agency for KIO-301 for the treatment of non-syndromic, rod-dominant retinal dystrophies, which includes diseases like retinitis pigmentosa, choroideremia, Stargardt disease and others. In September 2024, the European Medicines Agency expanded the Orphan Medicinal Product Designation to also include syndromic, rod-dominant retinal dystrophies that includes diseases like Usher’s syndrome, which has non-ocular aspects of diseases in addition to retinal involvement. In October 2024, the Company, in collaboration with its partner TOI, announced that it received regulatory approval to initiate a Phase 2 clinical trial to investigate KIO-301 for vision restoration in patients with retinitis pigmentosa. The ABACUS-2 trial is expected to be a 36 patient, multi-center, double-masked, randomized, controlled, multiple dose study enrolling patients with ultra-low vision or no light perception regardless of their underlying gene mutation associated with retinitis pigmentosa. Dosing of the first patient with KIO-301 is expected to begin in the first half of 2025 following validation of novel functional vision endpoints. These functional assessments may serve as approvable primary endpoints in subsequent registration studies in the United States, Europe and other major regions. KIO-301 (formerly known as B-203) was acquired through the Bayon Therapeutics, Inc. (“Bayon”) transaction which closed October 21, 2021.

KIO-104 is a product candidate focused on patients with retinal inflammation due to diseases including Diabetic Macular Edema, Posterior Non-Infectious Uveitis and others. KIO-104 is a next-generation, non-steroidal, immunomodulatory 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. Clinical proof-of-concept of the potential for the active pharmaceutical ingredient in KIO-104 has been demonstrated in multiple non-clinical and clinical studies. This includes a first-in-human, open-label, Phase 1 clinical trial, which investigated the use of KIO-104 for treating Posterior Non-Infectious Uveitis.

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

Results, which were reported in October 2022, showed that a single intravitreal injection of KIO-104 decreased intraocular inflammation in a dose-dependent fashion, and improved visual acuity significantly during the duration of the study. Further, KIO-104 reduced macular edema (swelling) which if unchecked, can lead to permanent vision loss. The drug was well tolerated, with no serious side effects on intraocular tissues or other serious adverse events observed. The Company received approval to initiate a Phase 2 clinical trial of KIO-104 in patients with retinal inflammation and expects to initiate enrollment in the first half of 2025. KIO-104 (formerly known as PP-001 and containing the same Active Pharmaceutical Ingredient as KIO-101) was acquired through the acquisition of Panoptes Pharma Ges.m.b.H (“Panoptes”) in the fourth quarter of 2020.

In addition, the Company has one anterior segment asset, KIO-101 for patients with Ocular Presentation of Rheumatoid Arthritis. KIO-101 is an eye drop formulation containing the same Active Pharmaceutical Ingredient as KIO-104. The Company reported data from a Phase 1b proof-of-concept (“POC”) study evaluating KIO-101 in patients with ocular surface inflammation in Q4 2021. The Company is seeking a partner to complete the development and potential commercialization of this program.

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

Liquidity and Capital Resources

At December 31, 2024, the Company had unrestricted Cash and Cash Equivalents of \$3.8 million, Short-Term Investments of \$23.0 million and an Accumulated Deficit of \$143.4 million. Kiora has incurred losses and negative cash flows since inception, and future losses are anticipated. However, Management believes that the Company's capital resources as of December 31, 2024 will be sufficient to fund the Company's planned operations into 2027.

Reverse Stock Split

On June 6, 2024, 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-nine (“1-for-9”) reverse stock split of its outstanding common stock. The Amendment was approved by the Company's stockholders at the Company's 2024 Annual Meeting of Stockholders held on May 1, 2024, and by the Company's board of directors. The amendment became effective on June 11, 2024, the effective date of the reverse stock split.

The reverse stock split proportionally adjusted all shares of the Company's common stock outstanding and shares of common stock underlying outstanding options and warrants immediately prior to the effective date 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 warrants, stock options, and restricted stock awards issued by the Company and outstanding immediately prior to the effective date 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 warrants, stock options, and restricted stock awards, and, in the case of warrants and stock options, a proportionate increase in the exercise price of all such warrants and stock options. In addition, the number of shares reserved for issuance under the Company's equity compensation plans immediately prior to the effective date 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 Restated Certificate of Incorporation, which remained at 150,000,000 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 stockholders owning fractional shares). As a result of the reverse stock split, the number of the Company's outstanding shares of

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

common stock as of June 11, 2024 decreased from 26,735,116 (pre-split) shares to 2,970,545 (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 June 11, 2024.

Adoption of Accounting Standards

In December 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2023-07, Segment Reporting (Topic 280) - Improvements to Reportable Segment Disclosures. The new standard requires a company to disclose incremental segment information on an annual and interim basis, including significant segment expenses and measures of profit or loss that are regularly provided to the chief operating decision maker (CODM). The standard is effective for us beginning in fiscal year 2024 and interim periods within fiscal year 2025, with early adoption permitted. The Company adopted ASU 2023-07 on January 1, 2024. The adoption of ASU 2023-07 did not have a material effect on the Company (see Note 14).

Accounting Standards Pending Adoption

In November 2024, the FASB issued ASU 2024-03, Disaggregation of Income Statement Expenses ("ASU 2024-03"). The guidance in ASU 2024-03 requires new financial statement disclosures in tabular format, disaggregating information about prescribed categories underlying any relevant income statement expense captions. The standard is effective for fiscal years beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. Upon adoption, ASU 2024-03 may be applied prospectively or retrospectively. The Company is currently evaluating the impact that the adoption of ASU 2024-03 may have on its disclosures in its consolidated financial statements.

In December 2023, the FASB also issued ASU 2023-09, Income Taxes (Topic 740) - Improvements to Income Tax Disclosures. The new standard requires a company to expand its existing income tax disclosures, specifically related to the rate reconciliation and income taxes paid. The standard is effective for us beginning in fiscal year 2025, with early adoption permitted. We do not expect to early adopt the new standard. The new standard is expected to be applied prospectively, but retrospective application is permitted. We are currently evaluating the impact of ASU 2023-09 on the consolidated financial statements and related disclosures.

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

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

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 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 Income (Loss).

Cash and Cash Equivalents

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.

Restricted Cash

At December 31, 2024 and 2023, the Company has classified \$4.1 thousand and \$4.3 thousand as restricted cash, respectively. Non-current restricted cash consists of deposits with financial institutions for corporate credit cards.

Short-Term Investments

Short-term investments primarily consist of treasuries, corporate debt securities, and government and agency securities. The Company has classified these investments as available-for-sale securities, as the sale of such investments may be required prior to maturity to implement management strategies, and therefore has classified all investments with maturity dates beyond three months at the date of purchase as current assets in the accompanying audited consolidated balance sheets. Any premium or discount arising at purchase is amortized and/or accreted to interest income as an adjustment to yield using the straight-line method over the life of the instrument. Investments are reported at their estimated fair value. Unrealized gains and losses are included in accumulated other comprehensive income (loss) as a component of stockholders' equity until realized.

Allowance for Credit Losses

For available-for-sale securities in an unrealized loss position, the Company first assesses whether it intends to sell, or if it is more likely than not that it will be required to sell, the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through earnings. For available-for-sale securities that do not meet the aforementioned criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the severity of the impairment, any changes in interest rates, market conditions, changes to the underlying credit ratings and forecasted recovery,

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in interest income through an allowance account. Any impairment that has not been recorded through an allowance for credit losses is included in other comprehensive income (loss) on the consolidated balance sheets.

The Company excludes the applicable accrued interest from both the fair value and amortized cost basis of available-for-sale securities for purposes of identifying and measuring an impairment. Accrued interest receivable on investment securities is recorded within prepaid expenses and other current assets on the consolidated balance sheets. The Company's accounting policy is to not measure an allowance for credit loss for accrued interest receivable and to write-off any uncollectible accrued interest receivable as a reversal of interest income in a timely manner, which is considered to be in the period in which it is determined the accrued interest will not be collected.

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, 2024. There is no assurance that management's estimates and assumptions will not change in future periods.

Revenue Recognition

In accordance with FASB's Accounting Standards Codification (ASC) 606, Revenue from Contracts with Customers, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, it performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company applies the five-step model to contracts when it determines that it is probable it will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

In a contract with multiple performance obligations, we must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each distinct performance obligation which determines how the transaction price is allocated among the performance obligations. The estimation of the stand-alone selling price(s) may include estimates regarding forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. The Company evaluates each performance obligation to determine if it can be satisfied at a point in time or over time. Any change made to estimated progress towards completion of a performance obligation and, therefore, revenue recognized will be recorded as a change in estimate. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

Amounts received prior to satisfying the revenue recognition criteria are recognized as deferred revenue in the Company's balance sheet. Amounts expected to be recognized as revenue within the twelve months following the balance sheet date are classified as the current portion of deferred revenue. Amounts not expected to be recognized as revenue within the twelve months following the balance sheet date are classified as deferred revenue, net of current portion. As of December 31, 2024 and 2023, the Company did not have a deferred revenue balance.

Collaboration Revenue

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in a contract, the Company recognizes revenues from the transaction price allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from the allocated transaction price. The Company evaluates the measure of progress at each reporting period and, if necessary, adjusts the measure of performance and related revenue or expense recognition as a change in estimate.

At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being reached. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or a collaboration partner's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of milestones that are within the Company's or a collaboration partner's control, such as operational development milestones and any related constraint, and, if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which will affect collaboration revenues and earnings in the period of adjustment. Revisions to the Company's estimate of the transaction price may also result in negative collaboration revenues and earnings in the period of adjustment.

For arrangements that include sales-based royalties, including commercial milestone payments based on the level of sales, and a license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied, or partially satisfied.

In January 2024, the Company entered into a strategic development and commercialization agreement ("License Agreement") with Théa Open Innovation ("TOI"), a sister company of the global ophthalmic specialty company Laboratoires Théa ("Théa"). Under the agreement, the Company granted TOI exclusive worldwide development and commercialization rights, excluding certain countries in Asia, to KIO-301 for the treatment of degenerative retinal diseases (the "License"). The Company concluded that the Licensing Agreement contains one material performance obligation, the License. The transaction price includes the up-front, non-refundable payment of \$16.0 million (the "License Access Fee"). The Company did not include any development or

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

regulatory milestones in the transaction price because it is probable that changes in the estimate of receiving those milestones would result in significant reversals of cumulative revenue in future periods, due to the inherent risks and uncertainties in the drug development process. The sales-based milestones and royalties are not included in the transaction price per ASC 606-10-32-11 and ASC 606-10-55-65. There is no financing component in the License Agreement.

The initial transaction price will be allocated to the one performance obligation identified (i.e., the License), which was transferred to TOI at the execution of the License Agreement and the entire \$16.0 million transaction price was recognized in the first quarter of 2024 upon the satisfaction of the license performance obligation. Variable components of consideration related to development and regulatory milestones, commercial milestones, and royalties will be allocated to the transaction price if and when they occur. When it is probable that including milestones in the transaction price will not result in significant reversals of cumulative revenue in future periods, the Company will recognize the revenue for the milestones immediately since the license performance obligation to which the milestones relate has already been fully satisfied when the change in estimate of the variable consideration occurs. Since the reimbursement for the development activities clearly relates to those activities and are accounted for under ASC 808, the Company will recognize those amounts that are due from TOI as contra-R&D expense.

The License Access Fee was earned at a point in time (first quarter of 2024) and, as a result, the associated contract costs specifically, sublicense fees, were expensed at the same point in time (first quarter of 2024). All further revenue sources that may lead to sublicense fee payments will not be recognized until earned. As such, sublicense fees will be expensed in the same period as the revenue of the respective milestone or royalties are earned.

See Note 12 to the Consolidated Financial Statements for additional information.

Collaboration Agreements

The Company has entered into a research agreement that falls under the scope of ASC 808, Collaborative Arrangements. Reimbursements from a collaboration partner are recorded as a reduction to research and development expense in the consolidated statements of operations and comprehensive income (loss). Similarly, amounts that are owed to a collaboration partner are recognized as research and development expense in the consolidated statements of operations and comprehensive income (loss).

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, 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.

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 its indefinite-lived intangible assets for impairment as of August 31, 2024 and 2023 with a quantitative analysis. In connection with its analysis, the Company recognized an impairment of \$2.0 million and \$1.9 million as of August 31, 2024 and 2023, respectively. As of December 31, 2024 and 2023 the Company also performed a qualitative update analysis for impairment and based on this analysis, the fair

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

value of these products was greater than their carrying value. The Company considered the progress and development timelines for its programs and noted no qualitative factors that would indicate potential impairment of its indefinite-lived intangible assets. At December 31, 2024 and 2023, there is \$6.7 million and \$8.7 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 and three geographic areas. The Company's singular focus is developing innovative ophthalmic pharmaceutical products.

Income Taxes

During the fourth quarter of 2024, the Company recorded an adjustment to its income tax provision based on new information obtained from the completion of complex tax analyses, specifically a Section 382 study to assess the availability of historical net operating losses (NOLs) and a transfer pricing analysis. These analyses provided additional insight into the Company's tax position and were necessary to accurately determine the tax liability.

Under Accounting Standards Codification (ASC) 250, Accounting Changes and Error Corrections, changes in accounting estimates are accounted for prospectively. As the adjustment resulted from new information that was not reasonably knowable at prior reporting dates and required specialized technical expertise, the Company has determined that the change constitutes a change in estimate rather than a correction of an error.

As a result, the Company recognized an increase in its tax liability of \$2.3 million in the fourth quarter of 2024. This change in estimate is reflected in the Company's consolidated financial statements for the year ended December 31, 2024.

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, 2024 and 2023, all of the Company's net deferred income tax assets were subject to a full valuation allowance. For the years ended December 31, 2024 and 2023, the Company has income tax expense of \$2.1 million and \$0.1 million, respectively.

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

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, 2024, the Company had no unrecognized uncertain income tax positions.

Warrants

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 Income (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 and 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, 2024 and 2023, the Company has a research and development tax receivable of \$0.2 million and \$1.9 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 Income (Loss)

Comprehensive income (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 and the unrealized gain (loss) on marketable securities are the Company's only components of other comprehensive income (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

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

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 Income (Loss) per Share – Basic and Diluted

Basic and diluted net income (loss) per share is computed by dividing net income (loss) available to common stockholders by the weighted-average number of common shares outstanding for the period, which, for basic net income (loss) per share, does not include the weighted-average unvested restricted common stock that has been issued but is subject to forfeiture of 46,697 shares for year ended December 31, 2024 and 25,493 shares for the year ended December 31, 2023.

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, unvested restricted common stock and potential common stock equivalents are not included in the calculation of diluted net income (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,	
	2024	2023
Common Stock Warrants, Excluding Pre-funded Warrants	7,389,523	1,451,589
Employee Stock Options	161,303	90,327
Unvested Restricted Common Stock	46,697	25,486
Preferred Stock, as Converted into Common Stock	42,426	42,426
Common Stock Reserved for Future Issuance	450,815	20,400
Total Shares of Common Stock Issuable	<u>8,090,764</u>	<u>1,630,228</u>

Related-Party Transactions

During the year ended December 31, 2024, the Company did not enter into any significant related-party transactions. During the year ended December 31, 2023, in connection with the acquisition of Bayon Therapeutics, Inc., the Company issued \$0.5 million in milestone payments to former shareholders of Bayon Therapeutics, Inc., including the Company's President and CEO and Chief Development Officer.

Fair Value Measurements

Fair value accounting is applied to all financial assets and liabilities that are recognized or disclosed at fair value in the consolidated financial statements on a recurring basis (at least annually). As of December 31, 2024 and 2023, the carrying amounts of cash equivalents, short-term investments, receivables, accounts payable, and accrued liabilities approximated their fair values due to their relatively short maturities.

Assets and liabilities recorded at fair value on a recurring basis on the consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

Level 1 - Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2 - Inputs (other than quoted prices in active markets included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following table summarizes the Company's financial instruments measured at fair value on a recurring basis as of December 31, 2024. There were no financial instruments measured at fair value as of December 31, 2023.

	Total	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of December 31, 2024				
Cash Equivalents:				
Money Market Funds	\$ 562,604	\$ 562,604	\$ —	\$ —
US Treasury Securities	691,917	—	691,917	—
Total Cash Equivalents Measured at Fair Value	\$ 1,254,521	\$ 562,604	\$ 691,917	\$ —
Short-term Investments:				
US Treasury Securities	\$ 92,314	\$ —	\$ 92,314	\$ —
Government Agency Securities	18,540,550	—	18,540,550	—
Corporate Debt Securities	4,062,673	—	4,062,673	—
Asset Backed Securities	304,223	—	304,223	—
Total Short-term Investments Measured at Fair Value	\$ 22,999,760	\$ —	\$ 22,999,760	\$ —
Total Assets Measured at Fair Value	\$ 24,254,281	\$ 562,604	\$ 23,691,677	\$ —

The Company's in-process R&D is measured at fair value on a nonrecurring basis using unobservable Level 3 inputs. As of December 31, 2024 and 2023, the in-process R&D balance was \$6.7 million and \$8.7 million, respectively.

In connection with historical acquisitions, additional consideration may be owed by the Company related to the achievement of certain milestones and such contingent consideration payments are required by U.S. GAAP to

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

be presented at fair value. The following table provides information for liabilities measured at fair value on a recurring basis using Level 3 inputs:

	December 31, 2024	December 31, 2023
Contingent Consideration:		
Non-current	\$ 4,191,490	\$ 5,128,959
Total Contingent Consideration	<u>\$ 4,191,490</u>	<u>\$ 5,128,959</u>

3. Fair Value

Short-term Investments

The following table summarizes short-term investments as of December 31, 2024. There were no short-term investments as of December 31, 2023.

	Amortized Cost	Unrealized		Estimated Fair Value
		Gains	Losses	
US Treasuries	\$ 92,273	\$ 40	\$ —	\$ 92,313
Government Agency Securities	18,517,164	28,008	(4,621)	18,540,551
Corporate Debt Securities	4,058,879	5,901	(2,107)	4,062,673
Asset Backed Securities	301,844	2,379	—	304,223
Total Short-term Investments	<u>\$ 22,970,160</u>	<u>\$ 36,328</u>	<u>\$ (6,728)</u>	<u>\$ 22,999,760</u>

The following table summarizes the maturities of the Company's short-term investments at December 31, 2024:

	Amortized Cost	Estimated Fair Value
Due in one year or less	\$ 21,659,580	\$ 21,688,074
Due in one to five years	1,310,580	1,311,686
Total Short-term Investments	<u>\$ 22,970,160</u>	<u>\$ 22,999,760</u>

The following table shows the Company's available-for-sale investments' gross unrealized losses and fair value aggregated by investment category and length of time that individual securities have been in a continuous loss position, at December 31, 2024:

	Less than 12 months		
	Count	Fair Value	Unrealized Losses
Government Agency Securities	4	\$ 3,369,962	\$ (4,621)
Corporate Debt Securities	9	801,149	(2,107)
Total	<u>13</u>	<u>\$ 4,171,111</u>	<u>\$ (6,728)</u>

The Company reviews its investments each quarter to identify and evaluate investments that have an indication of possible other-than-temporary impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, any changes to the underlying credit risk of the investment, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. The unrealized losses in the Company's investments were caused by changes in interest rates resulting from changing economic conditions, and not from a decline in credit of their underlying issuers. The Company may be required to sell these investments prior to maturity to implement management strategies, however, it is not likely that the

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

Company will sell these investments before recovery of their amortized cost basis. As such, the Company has classified these losses as temporary in nature.

Contingent Consideration

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 as of December 31, 2024 as follows:

Acquisition	Milestone Achievement Condition	Contingent Consideration Payable	
Bayon	KIO-301		
	Successful completion of Phase 2	\$	1.0 million
	Successful completion of Phase 3	\$	4.0 million
Panoptes	FDA approval	\$	1.7 million
	KIO-104		
	Beginning of Phase 3	\$	4.8 million
	FDA approval	\$	4.8 million

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

Bayon: The Bayon acquisition closed on October 21, 2021. As of December 31, 2023, the Company recorded contingent consideration of \$2.4 million. During the year ended December 31, 2024, the Company recorded a decrease in estimated fair value of \$0.2 million. The estimated fair value of contingent consideration as of December 31, 2024 was \$2.2 million.

Panoptes: The Panoptes transaction closed December 18, 2020. As of December 31, 2023, the Company recorded contingent consideration of \$2.0 million. During the year ended December 31, 2024, the Company recorded an increase in estimated fair value of \$3.3 thousand. The estimated fair value of contingent consideration as of December 31, 2024 was \$2.0 million.

Jade: As of December 31, 2023, the Company recorded contingent consideration of \$0.8 million. During the year ended December 31, 2024, the Company reduced the contingent consideration liability related to KIO-201 of approximately \$0.8 million as a result of the strategic decision to cease continued development or partnership leading to commercialization. As of December 31, 2024, the fair value of contingent consideration for this acquisition was zero.

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 above. 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:

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

	Valuation Technique	Unobservable Inputs	December 31, 2024	December 31, 2023
	Discounted cash flow	Payment discount rate	15.1%	13.1%
Bayon		Payment period	2027 - 2029	2025 - 2027
Panoptes		Payment period	2027 - 2028	2026 - 2028
Jade		Payment period	N/A	2027
Bayon		Probability of Success for milestone	48% - 77%	42% - 71%
Panoptes		Probability of Success for milestone	30% - 33%	30% - 33%
Jade		Probability of Success for milestone	—%	56%

Significant changes in these assumptions could result in a significantly higher or lower fair value. The contingent consideration reported in the above table is adjusted quarterly based upon the passage of time or the anticipated success or failure of achieving certain milestones. The decrease in contingent consideration of \$0.9 million as of December 31, 2024, was primarily driven by a reduction in the liability related to KIO-201 of approximately \$0.8 million resulting from the strategic decision to cease continued development or partnership leading to commercialization and was recorded as a change in fair value of contingent consideration of \$(0.9) million within the Consolidated Statements of Operations and Comprehensive Income (Loss).

At December 31, 2024 and 2023, the Company had no other assets or liabilities that are subject to fair value methodology and estimation in accordance with U.S. GAAP.

In-process R&D

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.

ASC 350 allows an entity to first assess qualitative factors to determine whether events and circumstances indicate that it is more likely than not (that is, a likelihood of more than 50 percent) that an indefinite-lived intangible asset is impaired. If it is more likely than not that the asset is impaired, the entity must calculate the fair value of the asset and record an impairment charge if the carrying amount exceeds fair value. If an entity concludes that it is not more likely than not that the asset is impaired, no further action is required. An indefinite-lived intangible asset should be tested for impairment if events or changes in circumstances indicate that it is more likely than not that the asset is impaired. If such events or changes have occurred, a quantitative assessment is required.

If an entity bypasses the qualitative assessment or determines from its qualitative assessment that an indefinite-lived intangible asset is more likely than not impaired, a quantitative impairment test should be performed. The quantitative impairment test compares the fair value of an indefinite-lived intangible asset with the asset's carrying amount. If the fair value of the indefinite-lived intangible asset is less than the carrying amount, an impairment loss should be recognized in an amount equal to the difference in accordance with ASC 350-30-35-19.

The Company values in-process R&D related to asset acquisitions using the Income Approach which measures the value of an asset by the present value of its future economic benefits. These benefits can include earnings, cost savings, tax deductions, or proceeds from its disposition. Value indications are developed by discounting expected cash flows at a rate of return that incorporates the risk-free rate for the use of funds, the expected rate of inflation, and risks associated with the particular investment. The selected discount rate is the Company's weighted average cost of capital ("WACC"), which provides an expected rate of return based on the Company's

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

capital structure, the required yield on the Company's equity, and the required yield on the interest-bearing debt of which there is currently none.

Management completed, with the assistance of a third party valuation firm, a quantitative assessment of in-process R&D as of August 31, 2024, the Company's annual impairment test date, which includes the following unobservable Level 3 inputs:

	Valuation Technique	Unobservable Inputs	Input	Discount Rate
KIO-104	Multi-Period Excess Earnings Method	Probability of success for next development phase	17% to 36%	43%
KIO-301	Multi-Period Excess Earnings Method	Probability of success for next development phase	23% to 43%	43%

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	December 31,	
	2024	2023
Prepaid Research and Development	\$ 1,181,699	\$ 23,066
Prepaid General and Administrative	118,371	73,109
Prepaid Insurance	96,141	123,807
Other	646,276	13,400
Total Prepaid Expenses and Other Current Assets	\$ 2,042,487	\$ 233,382

5. Property and Equipment

Property and equipment at December 31, 2024 and 2023 consists of the following:

	Estimated Useful Life (Years)	2024		2023	
		2024	2023	2024	2023
Laboratory Equipment	3	\$ —	\$ —	\$ 11,832	\$ 11,832
Office Equipment	3	—	—	2,521	2,521
Office Furniture	5	6,256	6,256	—	—
Total Property and Equipment, Gross		6,256	6,256	14,353	14,353
Less Accumulated Depreciation		1,024	1,024	6,289	6,289
Total Property and Equipment, Net		\$ 5,232	\$ 5,232	\$ 8,065	\$ 8,065

Depreciation expense was \$5 thousand and \$30 thousand for the years ended December 31, 2024 and 2023, respectively.

6. Accrued Expenses

Accrued expenses consist of the following:

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

	December 31,	
	2024	2023
Payroll and Benefits	\$ 1,169,618	\$ 875,254
Professional Fees	55,032	43,387
Clinical Trials	875,072	397,465
Income Tax	2,328,042	—
Other	160,893	64,560
Total Accrued Expenses	<u>\$ 4,588,657</u>	<u>\$ 1,380,666</u>

7. Intangible Assets and In-Process R&D

Intangible assets at December 31, 2023 consisted 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 was 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 would have increased the carrying value of the intangible assets, however, on June 7, 2023, the Company entered into an amendment agreement (the "SentrX First Amendment") whereby SentrX removed the Company's obligation to make any further payments, milestone or otherwise. The term of the agreement is until the product is no longer in the commercial marketplace. In addition, on June 7, 2023, we entered into a new exclusive license agreement (the "New SentrX Agreement") with SentrX, whereby we out-licensed certain KIO-201 patents (focused on the combination of KIO-201 with an antibiotic) for use in animal health and veterinary medicine. Under the New SentrX Agreement, SentrX is obligated to pay the Company a flat low single-digit royalty on net sales and is effective until the last licensed patent terminates. In August 2023, SentrX was acquired by Dômes Pharma. In July 2024, the Company decided to cease continued development of KIO-201 in combination with an antibiotic, and provided notice to Dômes Pharma of its intention to cease continued maintenance of all related licensed intellectual property and its willingness to transfer control of the prosecution and maintenance of the licensed patents at their request. The Company recognized an impairment of \$0.1 million to the write-off the carrying value of the intangible assets. The Company's intangible assets are amortized on a straight-line basis over the estimated useful lives. As of December 31, 2024 there were no intangible assets.

Additionally, in-process R&D as of December 31, 2024 and 2023 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, 2024 and 2023 consists of the following:

	Estimated Useful Life (Years)	2024	2023
Trade Secrets	10	\$ 250,000	\$ 250,000
Less: Accumulated Amortization		(145,833)	(131,250)
Less: Impairment		(104,167)	—
Intangible Assets, Net		—	118,750
In-Process R&D		6,687,100	8,695,100
Total Intangible Assets and In-Process R&D, Net		<u>\$ 6,687,100</u>	<u>\$ 8,813,850</u>

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

Amortization expense on intangible assets was \$15 thousand and \$25 thousand for the years ended December 31, 2024 and 2023, respectively. In July 2024, the Company decided to cease continued development of KIO-201 and wrote-off the intangible asset balance of approximately \$0.1 million.

8. Capital Stock

All amounts of shares of common stock in the transactions described below have been adjusted to reflect post Amendment adjusted shares of common stock of the Company.

On May 1, 2024, the Company held its 2024 Annual Meeting of Stockholders (the "Annual Meeting") where the Company's stockholders voted to approve various proposals including (i) adoption of a new Equity Incentive Plan, the "2024 Equity Incentive Plan", (ii) an amendment to the Company's Restated Certificate of Incorporation to increase the number of authorized shares of Common Stock to 150,000,000, which the Company filed with the Secretary of State for the State of Delaware on May 1, 2024 and (iii) the approval, as contemplated by Nasdaq Listing Rule 5635, of the issuance of up to 5,486,066 shares of Common Stock upon the exercise of Tranche A Warrants and Tranche B Warrants issued in the private placement that closed on February 5, 2024.

On January 31, 2024, the Company entered into a private placement agreement with Maxim Group LLC serving as placement agent for 1,755,556 shares of common stock, pre-funded warrants to purchase up to 1,261,582 shares of common stock, and accompanying Tranche A and Tranche B warrants to purchase up to an aggregate of 5,486,066 shares of common stock. The total net proceeds from the private placement were approximately \$13.8 million.

The Tranche A warrants are exercisable for up to 2,743,033 shares of common stock at an exercise price of \$5.4684 per share for an aggregate of up to \$15.0 million and will expire at the earlier of (i) 30 days following the announcement of full data (expected in 2026) from the Company's Phase 2 clinical trial (ABACUS-2) of KIO-301 in patients with retinitis pigmentosa and the daily VWAP of the Company's common stock equaling or exceeding \$9.9432 per share for 30 consecutive trading days following the announcement and (ii) five years from the date of stockholder approval of the warrants.

The Tranche B warrants are exercisable for up to 2,743,033 shares of common stock at an exercise price of \$5.4684 per share for an aggregate of up to \$15.0 million and will expire at the earlier of (i) 30 days following the announcement of topline data (expected in 2026) from the planned Phase 2 trial of KIO-104 in retinal inflammation and the daily VWAP of the Company's common stock equaling or exceeding \$12.4290 per share for 30 consecutive trading days following the announcement and (ii) five years from the date of stockholder approval of the warrants.

During June 2023, 329 shares of Series F Convertible Preferred Stock were converted into 298,758 shares of common stock. During July and August 2023, 59 shares of Series F Convertible Preferred Stock were converted into 53,530 shares of common stock.

On March 30, 2023, the Company entered into an underwriting agreement to issue and sell stock and warrants in a public offering. On June 6, 2023, the public offering closed, and the Company issued and sold (i) 244,181 shares of common stock (including 83,333 shares of common stock sold pursuant to the exercise of the over-allotment option), (ii) 434 shares of Series F Convertible Preferred Stock convertible into up to 3,552,372 shares of common stock, (iii) 638,889 Class C Warrants (including 83,333 Class C Warrants sold pursuant to the exercise of the over-allotment option), and (iv) 638,889 Class D Warrants (including 83,333 Class D Warrants sold pursuant to the exercise of the over-allotment option). The public offering price of \$9.90 per share of common stock, Class C Warrant and Class D Warrant, and \$8,999.10 per share of Series F Convertible Preferred Stock, 101 Class C Warrants and 101 Class D Warrants, resulted in net proceeds to the Company of approximately \$5.6 million net of underwriting discount and commissions of \$0.5 million and other expenses of

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

\$0.2 million. On June 6, 2023, the underwriter fully exercised the over-allotment option granted by the Company to purchase stock and warrants.

Each Class C Warrant is, and each Class D Warrant was, exercisable at a price per share of common stock of \$9.90. The Class C Warrants will expire on June 6, 2028 and the Class D Warrants expired on June 6, 2024. 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. In addition, on August 7, 2023, the first business day after the 60th calendar day immediately following the initial exercise day, the exercise price of the warrants was reduced to \$4.7079 per share pursuant to the reset provision which stated that the warrants would be reduced to the lesser of (i) the exercise price then in effect and (ii) 90% of the average of the volume weighted average price of the Company's common stock for the five (5) trading day period immediately prior to the reset date. In accordance with ASU 2021-04, the warrant reset of the exercise price was evaluated as a modification of equity-classified written call options. Modifications or exchanges that are not related to debt or equity financings, compensation for goods or services, or other exchange transactions within the scope of other guidance should be recognized as a dividend consistent with ASC 815-40-35-17(d). The dividend amount is measured as the excess, if any, of the fair value of the modified or exchanged instrument over the fair value of that instrument immediately before it is modified or exchanged in accordance with ASC 815-40-35-16. The Company considered the guidance in paragraphs 815-40-35-14 through 35-17 and determined that the circumstances of the warrant modification indicate that the modification is executed separate from a new equity offering, debt origination or debt modification. As such, on August 7, 2023, the date on which the modification became effective, the incremental change in the fair value of the 1,277,778 outstanding warrants was recognized as a deemed dividend totaling \$0.5 million that increases net loss attributable to common stockholders in accordance with paragraph 815-40-35-17(d) and ASC 260-10-45-15. During November 2023, 911 shares of common stock were issued upon the exercise of Class C Warrants and 911 shares of common stock were issued upon the exercise of Class D Warrants for \$8.6 thousand in aggregate exercise proceeds. In February 2024, 101,684 shares of common stock were issued upon exercise of Class C Warrants at \$4.7079 per share for aggregate proceeds of approximately \$0.4 million. Additionally, 203,934 shares of common stock were issued upon exercise of Class D Warrants at \$4.7079 per share for aggregate proceeds of approximately \$1.0 million. During June 2024, 53,213 shares of common stock were issued upon the exercise of Class D Warrants at \$4.7079 per share for aggregate proceeds of approximately \$0.3 million.

On February 3, 2023, the Company completed a private placement with Lincoln Park Capital, LLC ("Lincoln Park") for 5,866 shares of common stock and warrants to purchase up to 11,733 shares of common stock. The total net proceeds from the private placement were approximately \$0.1 million. The warrants have an exercise price of \$31.842 per share, subject to adjustments as provided under the terms of the warrants, and became 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 also 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 2,222 shares sold to Lincoln Park for proceeds of \$0.1 million. In April 2023, the Company completed additional issuances for a total of 11,667 shares sold to Lincoln Park for proceeds of \$0.3 million. On January 31, 2024, the Company terminated the purchase agreement with Lincoln Park.

On February 10, 2023, 5,556 shares were issued upon the exercise of inducement warrants issued in November 2022 for total proceeds of \$0.3 million.

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

9. Warrants

At December 31, 2024 and 2023, the following warrants were outstanding:

	Number of Awards	Weighted Average Exercise Price	Weighted Average Remaining Term in Years
Outstanding at December 31, 2022	177,512	\$ 190.98	3.07
Issued	1,289,511	4.95	3.02
Exercised	(7,378)	53.73	
Expired	(8,056)	979.20	
Outstanding at December 31, 2023	1,451,589	21.60	2.46
Issued	6,747,648	4.45	4.77
Exercised	(358,831)	4.71	
Expired	(450,883)	12.45	
Outstanding at December 31, 2024	7,389,523	\$ 7.06	5.06

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 2025 through 2029.

In October 2024, an investor notified the Company of their intention to abandon 1,206 warrants that were issued in August 2021 with an original expiration in February 2027. This decrease is included with the expired warrants in the table above.

10. Equity Incentive Plan

The Company's Board of Directors ("the Board") adopted the 2014 Equity Incentive Plan (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. Following the adoption of the 2014 Plan, no further grants were made under the 2005 Equity Incentive Plan which had been in place since 2005.

The Board subsequently adopted the 2024 Equity Incentive Plan (the "2024 Plan") and the Company's Stockholders approved the Plan in May 2024. Following adoption of the 2024 Plan, no further grants were made under the 2014 Plan.

Consistent with the 2005 and 2014 Plans, the 2024 Plan provides for the granting of stock options (incentive and nonqualified), restricted stock or other stock-based awards to employees, officers, directors, consultants, and advisors. The Board is responsible for administration of the 2024 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.

As of December 31, 2024, the maximum number of shares of Common Stock that may be issued pursuant to the 2024 Plan and the ESPP was 555,556 and 32 shares, respectively.

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

As of December 31, 2024, there were 450,815 shares of Common Stock available for grant under the 2024 Plan and 23 shares available under the Company's ESPP.

The following is a summary of stock option activity for the years ended December 31, 2024 and 2023:

	Number of Options	Weighted Average Exercise Price	Weighted Average Contractual Life (In Years)
Outstanding at December 31, 2022	9,457	\$ 367.00	8.48
Granted	84,956	10.00	
Expired	(102)	3,851.03	
Forfeited	(3,929)	46.64	
Outstanding at December 31, 2023	90,382	41.43	9.25
Exercisable at December 31, 2023	173,394	138.29	9.24
Vested and Expected to Vest at December 31, 2023	90,382	41.43	9.25
Granted	74,137	4.35	
Expired	(1,443)	446.13	
Forfeited	(1,773)	7.04	
Outstanding at December 31, 2024	161,303	\$ 21.15	9.00
Exercisable at December 31, 2024	53,047	\$ 51.29	8.53
Vested and Expected to Vest at December 31, 2024	161,303	\$ 21.15	9.00

During the years ended December 31, 2024 and 2023, the Board approved the grant of options to purchase 74,137 and 84,956 shares of Common Stock, respectively. All option grants were pursuant to the 2024 Plan. The Company grants time-based stock options which generally vest 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 Company has also issued grants with a four-year vesting term, of which one-fourth of the underlying shares vested immediately, one-fourth on the one-year anniversary of the grant date and the remainder vest ratably over a 24-month period. The fair value of time-based stock options is determined using the Black-Scholes Option Pricing Model, with such value recognized as expense over the service period, which is typically three years, net of actual forfeitures. For the years ended December 31, 2024 and 2023, 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:

	2024	2023
Risk-Free Interest Rate	4.17% - 4.45%	3.95% - 4.61%
Expected Life	6.0 years	5.0 - 5.6 years
Expected Average Volatility	139.8% - 139.9%	141.0% - 145.2%
Expected Dividend Yield	—%	—%

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, 2024 and 2023 was \$4.35 and \$10.00 respectively. The expected term of the options granted is calculated in accordance with the simplified method, whereby for service-based awards the expected life is calculated as a midpoint between the vest and expiry period. The Company uses the simplified method as there is not a sufficient history of share option exercises. Expected volatility is based on the historical volatility of the Company's common stock. The risk-free interest rate is determined based upon a constant U.S. Treasury security rate with a contractual life that approximates the expected term of the option.

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

The following is a summary of restricted stock activity for the years ended December 31, 2024 and 2023:

	Number of Shares	Weighted-Average Grant Date Fair Value	Weighted-Average Remaining Recognition Period
Non-vested Outstanding at December 31, 2022	3,336	\$ 60.97	2.77
Awarded	30,013	9.52	
Released	(7,489)	13.40	
Forfeited	(367)	34.44	
Non-vested Outstanding at December 31, 2023	25,493	14.75	2.57
Awarded	30,604	4.35	
Released	(8,621)	16.69	
Forfeited	(779)	15.59	
Non-vested Outstanding at December 31, 2024	46,697	\$ 7.56	2.19

During the years ended December 31, 2024 and 2023, 779 and 367 shares of restricted stock, which had not vested, were forfeited and returned to the Company, respectively. During the years ended December 31, 2024 and 2023, the Board approved the grant of 30,604 and 30,013 restricted shares of Common Stock, respectively. All grants of restricted shares during 2024 were pursuant to the 2024 Plan. All grants of restricted shares during 2023 were pursuant to the 2014 Plan. The restricted shares of Common Stock 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 Comprehensive Income (Loss) and as follows:

	Year Ended December 31,	
	2024	2023
General and Administrative	\$ 277,085	\$ 345,488
Research and Development	379,508	409,456
Total Stock-Based Compensation Expense	\$ 656,593	\$ 754,944

The fair value of options granted for the years ended December 31, 2024 and 2023 was approximately \$0.3 million and \$0.8 million, respectively. As of December 31, 2024 and 2023, there was approximately \$0.5 million and \$0.8 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 3.8 and 2.1 years, respectively. The stock options outstanding and exercisable as of December 31, 2024 and 2023 had an aggregate intrinsic value of \$0. The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for options that had exercise prices lower than \$3.30 and \$4.70, the closing price of the Company's stock on December 31, 2024 and 2023, respectively.

Unamortized compensation expense related to the restricted stock awards amounted to \$0.3 million and \$0.3 million as of December 31, 2024 and 2023, respectively, and is expected to be recognized over a weighted average period of approximately 3.9 and 2.3 years, respectively.

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

11. Income Taxes

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

	Year Ended December 31,	
	2024	2023
Domestic	\$ 1,994,760	\$ (9,384,178)
Foreign	3,664,978	(3,039,399)
Total Income (Loss) Before Income Taxes	<u>\$ 5,659,738</u>	<u>\$ (12,423,577)</u>

The components of income tax expense are as follows:

	Year Ended December 31,	
	2024	2023
Current Taxes:		
Federal	\$ 1,034,971	\$ —
State	312,323	—
Foreign	1,006,461	—
Total Current Taxes	<u>\$ 2,353,755</u>	<u>\$ —</u>
Deferred Taxes:		
Federal	\$ (262,917)	\$ (280,954)
State	(25,833)	371,273
Total Deferred Taxes	<u>\$ (288,750)</u>	<u>\$ 90,319</u>
Income Tax Expense	<u>\$ 2,065,005</u>	<u>\$ 90,319</u>

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

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

	Year Ended December 31,	
	2024	2023
United States Federal Income Tax Rate	21.00 %	21.00 %
State Taxes, Net of Federal Benefit	83.60	13.26
Non-deductible R&D Expenses	—	(3.49)
Contingent Consideration	(3.46)	(3.36)
GILTI Inclusion	21.39	(1.12)
382 Limited Amortization - RBIL	11.60	—
ASC 718 - ISOs	0.60	—
Other Permanent Differences	0.55	(0.65)
Section 250 Deduction	(10.69)	—
Change in Valuation Allowance	(349.18)	(27.61)
Research and Development Credits	(0.47)	0.24
Tax Rate Differential	2.69	0.32
Foreign Stock Compensation	0.98	—
Foreign Credits to Expire Unused	44.76	—
True-up Other	9.39	—
True-up Federal Credits	—	(0.08)
382 Limited NOLs - RBIL	33.65	—
NOLs to Expire Unused	169.82	—
Other	0.03	0.76
Effective Tax Rate Expense	<u>36.26 %</u>	<u>(0.73)%</u>

The Company's deferred tax assets and liabilities consist of the following:

	Year Ended December 31,	
	2024	2023
Net Deferred Tax Liability:		
Net Operating Loss Carryforwards	\$ 9,240,807	\$ 25,982,646
Research and Development Credit Carryforwards	—	2,955,627
Capitalized Research and Development	4,169,983	4,743,068
Stock-Based Compensation	871,698	784,366
Cash Versus Accrual Adjustments	61,681	77,729
Total Deferred Tax Assets	<u>14,344,169</u>	<u>34,543,436</u>
Valuation Allowance	(13,139,483)	(33,025,829)
Net Deferred Tax Asset	<u>1,204,686</u>	<u>1,517,607</u>
In-Process Research and Development	(1,695,376)	(2,297,047)
Net Deferred Tax Liability	<u>\$ (490,690)</u>	<u>\$ (779,440)</u>

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

As of December 31, 2024, the Company has federal net operating loss carryforwards of approximately \$31.7 million and no state net operating loss carryforwards, to offset future federal and state taxable income. Federal NOL carryforwards generated during the years ended December 31, 2018 and forward totaling \$31.7 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 \$12.8 million as of December 31, 2024, which can be carried forward indefinitely. As of December 31, 2024, the Company had no federal and state research and development tax credit carryforwards to offset future income taxes.

The Company files United States federal income tax returns and income tax returns in the Commonwealth of Massachusetts, California, New Jersey and Utah, as well as foreign tax returns for its subsidiaries in Austria and Australia. 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, 2024, and 2023 because the Company's management believes that it is more likely than not that these assets will not be realized. The valuation allowance changed by approximately \$(19.9) million and \$3.4 million during the years ended December 31, 2024 and 2023, respectively, primarily as a result of the decrease in net operating losses and credits, adjustments for accrual to cash basis items, and capitalized research and development expenses.

As of December 31, 2024 and 2023, 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.

In 2024, the Company had a formal Section 382 analysis performed. The analysis determined that multiple ownership changes (under the definition of Section 382) occurred. The base limitation calculated for these changes ranged from \$170,643 to \$494,650. In addition to the annual NOL limitation, the Company had a Net Unrealized Built-In Loss (NUBIL) on the date of the ownership changes in multiple years totaling \$17,519,701. As a result of the NUBIL, the Company adjusted their Federal NOL carryforwards for the 2018 through 2022 tax years down by a total of \$9,126,676 in total with the filing of its 2023 tax return. Additionally, \$3,146,111 of the NUBIL was recognized as an unfavorable book to tax adjustment during the 2023 tax year. The remaining NUBIL will be recognized in tax years 2024 and 2025.

The NUBIL results in additional future tax deductions ("recognized built in losses" or "RBIL"), which would be treated as pre-change losses and subject to the 382 limitation if recognized during the 5-year statutory recognition period. The total amount of RBILs limited by Section 382 is \$17,519,701 and the annual allowance is \$170,643 (relating to the 2018 change for RBILs incurred through the 2022 change) and \$178,445 (for RBILs incurred after 2022) per year, therefore the availability of the RBILs will take several years, at which point we will be able to start using the NOLs that have not yet expired.

Due to the annual limitations calculated during the analysis, it has been determined that all federal and state net operating losses that do not have an unlimited carryforward period will expire unused. Additionally, all federal and state R&D credits will also expire unused. As a result, the Company reduced its federal and state NOLs by

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

\$46,054,630 and \$54,655,301, respectively and its federal and state R&D credit carryforwards by \$2,549,084 and \$447,490, respectively.

12. Commitments and Contingencies

Leases

The Company is a party to three real property operating leases for the rental of office space. In February 2022, the Company entered into an 18-month lease in Encinitas, California (the "Encinitas Lease"), which is now used for its corporate headquarters. The Encinitas Lease commenced in May 2022 and was amended to extend its term through April 30, 2025. Subsequent to year-end, the Company executed a new lease in Encinitas, California (see Note 15). The Company recorded a right-of-use (ROU) asset and lease liability upon lease commencement and lease amendment in May 2022 and November 2023, respectively. In May 2022, the Company entered into a 12-month lease for office space in Adelaide, Australia (the "Adelaide Lease") which expired in May 2023. Following expiration, the landlord agreed to extend the Adelaide Lease on a month-month basis, whereby the Company must provide 90-day notice of termination. The Adelaide Lease is a short-term lease which is exempt for ROU asset and lease liability reporting. The Company also entered into a lease for 910 square feet of office space in Vienna, Austria ("the Vienna Lease"). The Vienna Lease commenced on October 15, 2023 with a term of 5 years through October 14, 2028. The Company recorded a ROU asset and lease liability upon lease commencement in October 2023.

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 8.50% 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, 2024 and 2023, respectively.

Future annual minimum lease payments were as follows as of December 31, 2024:

	Operating Leases
2025	26,752
2026	13,552
2027	13,558
2028	10,728
Less: Amounts Representing Interest	(7,420)
Lease Liabilities	<u>\$ 57,170</u>

License and Exclusive Rights Agreements

The Company is a party to six 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 January 25, 2024, the Company entered into a license agreement with TOI, a sister company of the global ophthalmic specialty company Théa. Under the agreement, Kiora granted TOI exclusive worldwide development and commercialization rights, excluding certain countries in Asia, to KIO-301 for the treatment of degenerative retinal diseases. In exchange, Kiora received an up-front payment of \$16 million; will be eligible to receive up to

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

\$285 million upon achievement of pre-specified clinical development, regulatory and commercial milestones; tiered royalties of up to low 20% on net sales; and reimbursement of certain KIO-301 research and development expenses. For the year ended December 31, 2024, the Company recorded offsetting expense credits of \$2.9 million related to reimbursable KIO-301 expenses.

On May 1, 2020, the Company (through its subsidiary, Bayon Therapeutics, Inc.) 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. On October 30, 2023, the Company, through its subsidiary, Bayon Therapeutics, Inc., entered into an agreement with the University of California (“UC”) to amend its licensing agreement dated May 1, 2020 effective November 5, 2023, granting the Company exclusive rights to a patent application covering specific formulations of KIO-301, which was previously jointly owned by UC and Bayon. Further, Bayon has the ability to assign or transfer the agreement providing written notice is given within at least 15 days prior to any such assignment, providing written assignment agreement by successor within 30 days, and by paying an assignment fee of \$30,000 within 30 days of the assignment. Per the terms of the agreement, upon execution of the amendment the Company was required to pay UC \$15,000.

On May 1, 2020, the Company (through its subsidiary, Bayon Therapeutics, Inc.) 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. In addition, the agreement requires the Company to pay sublicense fees for the grant of rights under a sublicense agreement at 8% of sublicense revenue prior to enrolling the first patient in any Phase 1 or Phase II (if Phase I is not performed) clinical trial of a licensed product, 6% of sublicense revenue prior to enrolling the first patient in any Phase III clinical trial of a licensed product, or 4% of sublicense revenue prior to any arms-length first commercial sale of a licensed product. On October 30, 2023, the Company, through its subsidiary, Bayon Therapeutics, Inc., entered into an agreement with UC to amend its licensing agreement dated May 1, 2020 effective November 5, 2023, granting the Company exclusive rights to a patent application covering specific formulations of KIO-301, which was previously jointly owned by UC and Bayon. Further, Bayon has the ability to assign or transfer the agreement providing written notice is given within at least 15 days prior to any such assignment, providing written assignment agreement by successor within 30 days, and by paying an assignment fee of \$30,000 within 30 days of the assignment. Per the terms of the agreement, upon execution of the amendment the Company was required to pay UC \$15,000. Per these terms, the Company made a payment to UC for \$0.7 million related to the upfront payment received from TOI upon execution of the strategic development and commercialization agreement. The agreement expires on the date of the last-to-expire patent included in the licensed patent portfolio which is currently January 2030, however if patents that are currently pending approval are issued, the license expiration would extend into 204.

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

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. On June 7, 2023, the Company entered into an amendment agreement (the "SentrX First Amendment") whereby SentrX removed the Company's obligation to make any further payments, milestone or otherwise. The term of the amendment agreement remains unchanged, which is until the product is no longer in the commercial marketplace. In addition, on June 7, 2023, the Company entered into a new exclusive license agreement (the "New SentrX Agreement") with SentrX, whereby the Company out-licensed certain KIO-201 patents (focused on the combination of KIO-201 with an afor use in animal health and veterinary medicine. Under the New SentrX Agreement, SentrX is obligated to pay the Company a flat low single-digit royalty on net sales, and is effective until the last licensed patent terminates. In August 2023, SentrX was acquired by Dômes Pharma. In July 2024, the Company decided to cease continued development of KIO-201 in combination with an antibiotic, and provided notice to Dômes Pharma of its intention to cease continued maintenance of all related licensed IP and its willingness to transfer control of the prosecution and maintenance of the licensed patents at their request.

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 used in KIO-101 and KIO-104 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 any product commercialized by 4SC using the compound in KIO-101 and KIO-104.

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 used in KIO-101 and KIO-104. The Company is responsible for paying royalties of 3.25% on net sales of KIO-101, KIO-104 or any other therapeutic product that uses the compound.

Agreements Terminated or Settled Within the Year

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 7, 2023, the Company (through its subsidiary Kiora Pharmaceuticals GmbH) agreed to a settlement agreement with Mediolanum to terminate the existing out-licensing rights by Mediolanum to commercialize KIO-101 for uveitis, dry eye and viral conjunctivitis in Italy, France, Belgium and Netherlands including all related commercial milestone payments and royalty obligations. The Company agreed to pay a termination fee of \$0.1 million, of which \$50,000 was paid upon execution of the agreement, and \$50,000 was paid on the one year anniversary of the termination which occurred in September 2024.

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

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, however in September 2024, the Company terminated this agreement.

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, 2024.

14. Segment Information

The Company operates in and reports as a single reportable segment, focused on the development of innovative ophthalmic pharmaceutical products.

Our CODM is our President and Chief Executive Officer, Brian M. Strem. The CODM does not evaluate profitability nor evaluate performance or allocate resources below the level of the consolidated Company. The accounting policies of the segment are the same as those described in the summary of significant accounting policies. The CODM reviews operating expenses and net income (loss) presented on a consolidated basis for purposes of allocating resources and evaluating financial performance. These metrics serve as benchmarks to evaluate the business, measure performance, identify trends, prepare financial projections, and make strategic decisions. The CODM does not evaluate performance or allocate resources based on segment assets data; therefore, total segment assets are not presented. As part of the adoption of ASU 2023-07, the prior years' segment information has been disclosed herein to align with the current year's presentation.

The following table presents the revenue, significant expenses, and net income (loss) for the Company's single reportable segment:

KIORA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2024

	Year Ended December 31,	
	2024	2023
Total Revenue	\$ 16,020,000	\$ —
Less: Significant and Other Segment Expenses		
General and Administrative	5,542,324	4,663,146
Research and Development		
KIO-101	25,456	797,876
KIO-104	671,739	—
KIO-201	30,875	68,840
KIO-301	3,836,105	1,990,202
KIO-301 Collaboration Credit	(2,945,350)	—
Unallocated Research and Development Expenses ⁵	3,278,032	1,170,119
In-Process R&D Impairment	2,008,000	1,904,314
Change in Fair Value of Contingent Consideration	(937,469)	1,992,399
Interest Income	(1,252,849)	(173,989)
Other Segment Expenses ⁶	(768)	10,670
Income Tax Expense	2,065,005	90,319
Net Income (Loss)	\$ 3,594,733	\$ (12,513,896)

15. Subsequent Events

Leases

In January 2025, the Company entered into a lease in Perth, Australia (the "Perth Lease") and another in Brisbane, Australia (the "Brisbane Lease"). Both leases commenced in February 2025 with a term of 2 years through January 2027.

In March 2025, the Company entered into a new lease in Encinitas, California (the "New Encinitas Lease"). The lease will commence in June 2025 with a term of 3 years and 3 months through August 31, 2028.

Credit Line Agreement

In March 2025, the Company entered into a credit line with UBS (the "Credit Line") providing for a \$10.0 million revolving line of credit. The Credit Line bears interest at the 30-day Secured Overnight Financing Rate ("SOFR") average, plus 1.5%. The SOFR rate is variable. The Credit Line is secured by a first priority lien and security interest in the Company's marketable securities held in its managed investment accounts with UBS.

⁵ Unallocated research and development expenses primarily include personnel costs, research consulting and scientific advisory expenses.

⁶ Other segment expenses primarily include interest expense, other income, net, and loss on disposal of fixed assets.

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 25, 2025

By: /s/ Brian M. Strem
President and Chief Executive Officer

Date: March 25, 2025

By: /s/ Melissa Tosca
Chief Financial Officer

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:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Brian M. Strem</u> Brian M. Strem	President and Chief Executive Officer (Principal Executive Officer)	March 25, 2025
<u>/s/ Melissa Tosca</u> Melissa Tosca	Chief Financial Officer (Principal Financial and Accounting Officer)	March 25, 2025
<u>/s/ Praveen Tyle</u> Praveen Tyle	Director	March 25, 2025
<u>/s/ Lisa Walters-Hoffert</u> Lisa Walters-Hoffert	Director	March 25, 2025
<u>/s/ David Hollander</u> David Hollander	Director	March 25, 2025
<u>/s/ Aron Shapiro</u> Aron Shapiro	Director	March 25, 2025
<u>/s/ Erin Parsons</u> Erin Parsons	Director	March 25, 2025
<u>/s/ Carmine Stengone</u> Carmine Stengone	Director	March 25, 2025

Insider Trading Policy

This Insider Trading Policy (the "Policy") provides guidelines to employees, officers and directors of Kiora Pharmaceuticals, Inc. (the "Company") with respect to transactions in the Company's securities.

Applicability of the Policy

This Policy applies to all transactions in the securities of the Company or certain other publicly traded companies, including common stock, options for common stock, and any other securities the Company may issue from time to time. It applies to all officers of the Company, all members of the Company's Board of Directors ("directors"), and all employees of, and consultants and contractors to, the Company and its subsidiaries who receive, or have access to, Material Nonpublic Information (as defined below). This group of people, members of their immediate families, and members of their households are sometimes referred to in this Policy as "Covered Persons." This Policy also applies to any person who receives Material Nonpublic Information from any Covered Person.

General Policy

It is the policy of the Company to oppose the unauthorized disclosure of any nonpublic information acquired in the workplace and the misuse of Material Nonpublic Information in securities trading.

Specific Policies

Trading on Material Nonpublic Information:

1. No Covered Person shall engage in any transaction involving a purchase or sale of any securities of the Company or any other public company to the extent such person obtained Material Nonpublic Information regarding such other public company while providing services to the Company (each, an "Other Company"), including any offer to purchase or offer to sell securities and including a gift of securities, during any period commencing with the date that he or she possesses Material Nonpublic Information concerning the Company or, if applicable, any Other Company, and ending at the close of business on the second trading day following the date of public disclosure of that information or (if earlier) at such time as the Material Nonpublic Information is no longer material. For purposes of this Policy, information will be considered to have been disclosed to the "public" once it has been disclosed by means of a press release or a filing with the Securities and Exchange Commission (the "SEC").

Tipping:

1. Covered Persons should never disclose ("tip") Material Nonpublic Information to any other person (including family members) where such information may be used by such person to his or her benefit by trading in the securities of companies to which such information relates, nor shall such Covered Person make recommendations or express opinions on the basis of Material Nonpublic Information as to trading in the securities of the Company or any Other Company to which such Material Nonpublic Information relates. Even if you are not in the possession of Material Nonpublic Information, do not recommend to any other person that they buy or sell securities of the Company or any Other Company. (Remember that "tipping" Material Nonpublic Information is always prohibited, and that your recommendation could be imputed to the Company and may be misleading if you do not have all relevant information.)
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2. If a Covered Person receives inquiries about the Company from securities analysts, reporters, or others, decline comment and direct them to the Compliance Officer. Do not discuss Material Nonpublic Information where it may be overheard, such as in restaurants, elevators, restrooms and other public places. Remember that cellular phone conversations are often overheard and that voicemail and e-mail messages may be retrieved by persons other than their intended recipients.

Confidentiality:

1. Nonpublic information relating to the Company is the property of the Company and the unauthorized disclosure of such information is forbidden.

10b5-1 Programs:

1. Pursuant to SEC Rule 10b5-1, directors, officers, and employees of the Company may establish written programs which permit (i) automatic trading of the Company's stock through a third-party broker or (ii) trading of the Company's stock by an independent person (e.g. an investment broker) who is not aware of Material Nonpublic Information at the time of the trade. Once a program is implemented in accordance with SEC Rule 10b5-1, including any applicable cooling-off period, trades pursuant to such program shall not be subject to the limitations and restrictions set forth in other sections of this Policy. Trading pursuant to a program may occur at a time outside of the Company's trading window or when the person on whose behalf such trade is made is aware of Material Nonpublic Information. Each program (or the form of program established by an investment bank or other third party) must be reviewed and approved within ten (10) trading days by the Compliance Officer, or appropriate designee, to help confirm compliance with this policy and the applicable securities laws. Rule 10b5-1 plans may only be adopted during an open trading window. You should consult your own legal and tax advisors before entering into, modifying, or terminating a Rule 10b5-1 plan.

Liability for Tipping:

Covered Persons may also be liable for improper transactions by any person to whom they have disclosed Material Nonpublic Information regarding the Company or any Other Company or to whom they have made recommendations or expressed opinions on the basis of such information as to trading in the securities of the Company or any Other Company (such person is commonly referred to as a "tippee"). The SEC has imposed large penalties even when the disclosing person did not profit from the trading. The SEC, the stock exchanges, and FINRA use sophisticated electronic surveillance techniques to uncover insider trading. Penalties for trading on or communicating Material Nonpublic Information can be severe, both for individuals involved in such unlawful conduct and their employers and supervisors, and may include jail terms, criminal fines, civil penalties and civil enforcement injunctions. Given the severity of the potential penalties, compliance with this Policy is absolutely mandatory.

- Possible Disciplinary Actions:
1. Employees of the Company who violate this Policy shall also be subject to disciplinary action by the Company, which may include ineligibility for future participation in the Company's equity incentive plans or termination of employment.

Trading Window:

1. The period beginning approximately fourteen days before the end of each fiscal quarter and ending two trading days following the date of public disclosure of the financial results for that fiscal quarter is a particularly sensitive period of time for transactions in the Company's securities
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from the perspective of compliance with applicable securities laws. This sensitivity is due to the fact that directors, officers, and certain employees, consultants and contractors will, during that period, often possess Material Nonpublic Information about the expected financial results for the fiscal quarter.

2. Accordingly, to ensure compliance with this Policy and applicable federal and state securities laws, all Covered Persons must refrain from conducting transactions involving the purchase or sale of the Company's securities other than during the period (the "trading window") commencing at the close of business on the second trading day following the date of public disclosure of the financial results for a particular fiscal quarter or year and continuing until fourteen days prior to the end of the next fiscal quarter.
3. It should be noted however, that even during the trading window any person possessing Material Nonpublic Information concerning the Company should not engage in any transactions in the Company's securities until such information has been known publicly for at least two trading days. Trading in the Company's securities during the trading window should not be considered a "safe harbor," and all Insiders should use good judgment at all times.
4. From time to time, other types of Material Nonpublic Information may be pending and not publicly disclosed. While such Material Nonpublic Information is pending, the Company may impose special blackout periods during which Covered Persons are prohibited from trading in the Company's securities. If the Company imposes a special blackout period, it will notify the Covered Persons affected.

Preclearance of Trades:

1. Except as permitted in Section 4 above, the Company has determined that all directors, officers, and employees of the Company should refrain from trading in the Company's securities, even during the open trading window, without first complying with the Company's "preclearance" process. Each director, officer, and employee should contact the Compliance Officer prior to commencing any trade in the Company's securities. The Compliance Officer will have the authority to prohibit trades during the trading window if he or she determines that directors, officers, and employees may possess Material Nonpublic Information.
2. The Company may also find it necessary, from time to time, to require compliance with the preclearance process from certain consultants, and contractors other than and in addition to directors, officers and employees.

Prohibition Against Short-Swing Profits:

1. Directors and executive officers of the Company must also comply with the reporting obligations and limitations on short-swing transactions set forth in Section 16 of the Securities Exchange Act of 1934, as amended. The practical effect of these provisions is that executive officers and directors who purchase and sell the Company's securities within a six-month period must disgorge all profits to the Company whether or not they had knowledge of any Material Nonpublic Information. Under these provisions, and so long as certain other criteria are met, the receipt and exercise of an option under the Company's equity incentive plans is not deemed a purchase under Section 16. However, the sale of any such shares is a sale under Section 16.

Prohibited Transactions:

1. Covered Persons are prohibited from engaging in the following transactions in the Company's securities unless advance approval is obtained from the Compliance Officer:
 - a. With respect to any director or executive officer of the Company, selling any Company securities of the same class within six (6) months after purchase;
 - b. Effecting a short sale of Company securities;
 - c. Buying or selling put options, call options or other derivative securities relating to the Company's securities;
 - d. Holding Company securities in a margin account or pledging Company security as collateral for a loan; and
 - e. Entering into any hedging or monetization transactions or similar arrangements with respect to Company securities.

Compliance Officer:

1. The Company has appointed the Chief Financial Officer, or any individual that the Company's Chief Executive Officer may designate from time to time, as the Compliance Officer for this Policy. The duties of the Compliance Officer include, but are not limited to, the following:
 - a. assisting with implementation and enforcement of this Policy;
 - b. circulating this Policy to all employees and ensuring that this Policy is amended as necessary to remain up to date with insider trading laws;
 - c. pre-clearing all trading in securities of the Company by Covered Persons; and
 - d. providing approval of any Rule 10b5-1 plans.

Individual Responsibility:

1. Every officer, director, and employee has the individual responsibility to comply with this Policy against insider trading. Appropriate judgment should be exercised in connection with any trade in the securities of the Company or any Other Company.
2. A Covered Person may, from time to time, have to forego a proposed transaction in the securities of the Company or an Other Company even if he or she planned to make the transaction before learning of the Material Nonpublic Information and even though the Covered Person believes he or she may suffer an economic loss or forego anticipated profits by waiting.

Definition of Material Nonpublic Information

Material

It is not possible to define all categories of material information. Materiality, however, involves a relatively low threshold. Information is generally regarded as "material" if it has market significance, that is, if its public dissemination is likely to affect the market price of securities, or if it otherwise is information that a reasonable investor would want to know before making an investment decision.

While it may be difficult under this standard to determine whether particular information is material, there are various categories of information that are particularly sensitive and, as a general rule, should always be considered material. Examples of such information may include:

1. Financial results
 2. Projections of future earnings or losses
 3. News of a pending or proposed merger
 4. News of the disposition of a subsidiary
 5. Impending bankruptcy or financial liquidity problems
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6. Acquisition or loss of substantial rights or relationships
7. Changes in dividend policy
8. New product candidate or project announcements of a significant nature
9. Significant pricing changes
10. Stock splits
11. New equity or debt offerings
12. Acquisitions
13. Significant litigation exposure due to actual or threatened litigation
14. Major changes in senior management

Either positive or negative information may be material. Material information is not limited to historical facts but may also include projections and forecasts. With respect to a future event, such as a merger, acquisition or introduction of a new product, the point at which negotiations or product development are determined to be material is determined by balancing the probability that the event will occur against the magnitude of the effect the event would have on a company's operations or stock price should it occur. Thus, information concerning an event that would have a large effect on stock price, such as a merger, may be material even if the possibility that the event will occur is relatively small. **When in doubt about whether particular nonpublic information is material, you should presume it is material. If you are unsure whether information is material, you should either consult the Compliance Officer before making any decision to disclose such information (other than to persons who need to know it) or to trade in or recommend securities to which that information relates or assume that the information is material.**

Nonpublic

Insider trading prohibitions come into play only when you possess information that is material and "nonpublic." The fact that information has been disclosed to a few members of the public does not make it public for insider trading purposes. To be "public" the information must have been disseminated in a manner designed to reach investors generally, and the investors must be given the opportunity to absorb the information. **Even after public disclosure of information about the Company, you must wait until the close of business on the second trading day after the information was publicly disclosed before you can treat the information as public.**

Nonpublic information may include:

- (i) information available to a select group of analysts or brokers or institutional investors;
- (ii) undisclosed facts that are the subject of rumors, even if the rumors are widely circulated; and
- (iii) information that has been entrusted to the Company on a confidential basis until a public announcement of the information has been made and enough time has elapsed for the market to respond to a public announcement of the information (normally two trading days).

As with questions of materiality, if you are not sure whether information is considered public, you should either consult with the Compliance Officer or assume that the information is nonpublic and treat it as confidential.

Certain Exception

The exercise of stock options for cash under the Company's stock option plans or the purchase of shares under any Company employee stock purchase plan (but not the sale of any such shares) is exempt from

this Policy, because the other party to the transaction is the Company itself and the price is fixed by the terms of the option agreement or the plan.

ACKNOWLEDGMENT AND CERTIFICATION

The undersigned does hereby acknowledge receipt of the Company's Insider Trading Policy. The undersigned has read and understands (or has had explained) such Policy and agrees to be governed by such Policy at all times in connection with the purchase and sale of securities and the confidentiality of nonpublic information.

(Signature)

(Please print name)

Date: _____



CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Forms S-1 (Nos. 333-271699, 333-269570, 333-268940 and 333-264641), Form S-3 (No. 333-277460) and Forms S-8 (Nos. 333-279296, 333-274974, 333-267754, 333-264640, 333-241657, 333-202207, 333-209441, 333-216227, 333-223431 and 333-231207) of Kiora Pharmaceuticals, Inc. (the “Company”) of our report dated March 25, 2025, relating to our audits of the Company’s consolidated financial statements as of December 31, 2024 and 2023, and for each of the years then ended, included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2024 filed with the U.S. Securities and Exchange Commission.

/s/ Haskell & White LLP
HASKELL & WHITE LLP

Irvine, California
March 25, 2025

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 25, 2025

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

Brian M. Strem, Ph.D.

President and Chief Executive Officer

(Principal executive officer)

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 25, 2025

/s/ Melissa Tosca

Melissa Tosca

Chief Financial Officer

(Principal financial and accounting officer)

**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, 2024 (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 25, 2025

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

Brian M. Strem, Ph.D.

President and Chief Executive Officer

(Principal executive officer)

**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, 2024 (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 25, 2025

/s/ Melissa Tosca

Melissa Tosca

Chief Financial Officer

(Principal financial and accounting officer)

KIORA PHARMACEUTICALS, INC.
CLAWBACK POLICY**1. Introduction**

The Board of Directors (the “**Board**”) of the Kiora Pharmaceuticals, Inc. (the “**Company**”) believes that it is in the best interests of the Company and its shareholders to create and maintain a culture that emphasizes integrity and accountability and that reinforces the Company’s pay-for-performance compensation philosophy. The Board has therefore adopted this policy which provides for the recoupment of certain executive compensation in the event of an Accounting Restatement resulting from material noncompliance with financial reporting requirements under the federal securities laws (the “**Policy**”). This Policy is designed to comply with Section 10D of the Securities Exchange Act of 1934 (the “**Exchange Act**”).

2. Administration

This Policy shall be administered by the Board or, if so designated by the Board, the Compensation Committee, in which case references herein to the Board shall be deemed references to the Compensation Committee. Any determinations made by the Board shall be final and binding on all affected individuals.

3. Covered Executives

This Policy applies to each individual who served or serves as a current or former Covered Executive, at any time during the applicable performance period for any performance-based compensation Received by such executive on or after the Effective Date.

4. Recoupment; Accounting Restatement

In the event the Company is required to prepare an Accounting Restatement of its financial statements due to the Company’s material noncompliance with any financial reporting requirement under the securities laws, the Board will:

- a. review, with respect to each Covered Executive, all performance-based compensation Received by such Covered Executive during the applicable period,
 - b. determine the amount of excess Incentive Compensation Received by such Covered Executive during the applicable period;
 - c. require reimbursement or forfeiture of any excess Incentive Compensation Received by any Covered Executive during the three completed fiscal years immediately preceding the date on which the Company is required to prepare an Accounting Restatement; and
 - d. reasonably promptly but in any event no later than 60 days after the date an Accounting Restatement is filed with the SEC, provide to each Covered Executive a written notice containing the amount of excess Incentive Compensation and a demand for repayment or return, as applicable.
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5. Incentive Compensation

For purposes of this Policy, Incentive Compensation means any of the following; provided that, such compensation is granted, earned, or vested based wholly or in part on the attainment of a financial reporting measure:

- Annual bonuses and other short- and long-term cash incentives.
- Stock options.
- Stock appreciation rights.
- Restricted stock.
- Restricted stock units.
- Performance shares.
- Performance units.

Financial reporting measures include:

- Company stock price.
- Total shareholder return.
- Revenues.
- Net income.
- Earnings before interest, taxes, depreciation, and amortization (EBITDA).
- Funds from operations.
- Liquidity measures such as working capital or operating cash flow.
- Return measures such as return on invested capital or return on assets.
- Earnings measures such as earnings per share.

6. Excess Incentive Compensation: Amount Subject to Recovery

The amount to be recovered will be the excess of the Incentive Compensation paid to the Covered Executive based on the erroneous data over the Incentive Compensation that would have been paid to the Covered Executive had it been based on the restated results, as determined by the Board.

If the Board cannot determine the amount of excess Incentive Compensation Received by the Covered Executive directly from the information in the Accounting Restatement, then it will make its determination based on a reasonable estimate of the effect of the Accounting Restatement.

7. Method of Recoupment

The Board will determine, in its sole discretion, the method for recouping Incentive Compensation hereunder based on all applicable facts and circumstances which may include, without limitation:

- a) requiring reimbursement of cash Incentive Compensation previously paid;
- b) seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards;
- c) offsetting the recouped amount from any compensation otherwise owed by the Company to the Covered Executive;
- d) cancelling outstanding vested or unvested equity awards; and/or
- e) taking any other remedial and recovery action permitted by law, as determined by the Board.

Notwithstanding anything herein to the contrary, the Company shall not be required to seek recoupment to the extent the Board determines that recoupment would be impracticable in a manner consistent with Rule 10D-1 of the Exchange Act and the listing standards of the national securities exchange on which the Company's securities are listed, because either the direct expenses paid to a third party to assist in enforcing this Policy against a Covered Executive would exceed the amount to be recovered from that Covered Executive, after the Company has made a reasonable attempt to recover the excess Incentive Compensation.

8. Reporting and Disclosure

The Company shall file all disclosures with respect to this Policy with the SEC in accordance with the requirements of all applicable securities laws and shall provide any documentation with respect thereto to Nasdaq in accordance with the listing rules.

9. No Indemnification

The Company shall not indemnify any Covered Executives or their beneficiaries against the loss of any incorrectly awarded Incentive Compensation pursuant to the terms of this Policy or otherwise indemnify or provide advancement of any costs related to the Company's enforcement of this Policy.

10. Interpretation

The Board is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. It is intended that this Policy be interpreted in a manner that is consistent with the requirements of Nasdaq Listing Rule 5608, any other applicable rules of Nasdaq and Section 10D of the Exchange Act and any applicable rules or standards adopted by the SEC.

11. Effective Date

This Policy shall be effective as of October 2, 2023 (the "**Effective Date**") and shall apply to Incentive Compensation that is Received by any Covered Executive on or after that date.

12. Amendment; Termination

The Board may amend or terminate this Policy from time to time in its discretion and shall amend this Policy as it deems necessary, including as and when it determines that it is legally required by any federal

securities laws, SEC rule or rules of any national securities exchange or national securities association on which the Company's securities are listed. Notwithstanding anything herein to the contrary, no amendment or termination of this Policy shall be effective if such amendment or termination would (after taking into account any actions taken by the Company contemporaneously with such amendment or termination) cause the Company to violate any federal securities laws, SEC rule or the rules of any national securities exchange or national securities association on which the Company's securities are listed.

13. Other Recoupment Rights

The Board intends that this Policy will be applied to the fullest extent of the law. The Board may require that any employment agreement, equity award agreement, or similar agreement entered into on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, require a Covered Executive to agree to abide by the terms of this Policy. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any similar policy in any employment agreement, equity award agreement, or similar agreement and any other legal remedies available to the Company.

14. Successors

This Policy shall be binding and enforceable against all Covered Executives and their beneficiaries, heirs, executors, administrators or other legal representatives.

15. Definitions

For purposes of this Policy, the following terms shall have the following meanings:

- a. "**Accounting Restatement**" means an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.
- b. "**Covered Executive**" means each executive officer, as determined by the Board in accordance with Section 10D of the Exchange Act and the listing standards of the national securities exchange on which the Company's securities are listed.
- c. "**Received**" means the date of actual or deemed receipt, and for purposes of the foregoing, Incentive Compensation shall be deemed received in the Company's fiscal period during which the applicable financial reporting measure is attained, even if payment or grant of the Incentive Compensation occurs after the end of that period.
- d. "**SEC**" means the U.S. Securities and Exchange Commission.