UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

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

Date of report (Date of earliest event reported): **January 9, 2023**

KIORA PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-36672	**98-0443284**
(Commission File Number)	(IRS Employer Identification No.)
332 Encinitas Boulevard **Suite 102** **Encinitas, California**	**92024**
(Address of principal executive offices)	(Zip Code)

(781) 788-9043
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 7.01. Regulation FD Disclosure.

Kiora Pharmaceuticals, Inc. (the "Company") hereby furnishes the updated investor presentation attached as Exhibit 99.1 to this Current Report on Form 8-K, which the Company may use in presentations to investors from time to time.

The information furnished pursuant to Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

The information furnished in this report, including Exhibit 99.1, shall not be deemed to constitute an admission that such information or exhibit is required to be furnished pursuant to Regulation FD or that such information or exhibit contains material information that is not otherwise publicly available. In addition, the Company does not assume any obligation to update such information or exhibit in the future.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The Company hereby furnishes the following exhibit:

99.1 Presentation of the Company

SIGNATURES

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

KIORA PHARMACEUTICALS, INC.

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

Date: January 9, 2023

Kiora Pharmaceuticals, Inc.

NASDAQ: KPRX

January 2023 | Corporate Outlook

KIORA PHARMACEUTICALS

Forward Looking Statements

Some of the statements in this presentation are "forward-looking" and are made pursuant to the safe harbor provision of the Private Securities Litigation Reform Act of 1995. These "forward-looking" statements include statements relating to, among other things, the development and commercialization efforts and other regulatory or marketing approval efforts pertaining to Kiora's products, including KIO-101, KIO-201 and KIO-301, as well as the success thereof, with such approvals or success may not be obtained or achieved on a timely basis or at all. These statements involve risks and uncertainties that may cause results to differ materially from the statements set forth in this presentation, including, among other things, market and other conditions and certain risk factors described under the heading "Risk Factors" contained in Kiora's Amended Annual Report on Form 10-K/A filed with the SEC on July 7, 2022, or described in Kiora's other public filings. Kiora's results may also be affected by factors of which Kiora is not currently aware. The forward-looking statements in this presentation speak only as of the date of this presentation. Kiora expressly disclaims any obligation or undertaking to release publicly any updates or revisions to such statements to reflect any change in its expectations with regard thereto or any changes in the events, conditions, or circumstances on which any such statement is based, except as required by law.

Corporate Highlights

Developing Therapeutics for Rare & Underserved Ophthalmic Diseases

Priority Asset – KIO-301: Vision Restoration in Retinitis Pigmentosa (RP)
- Small molecule "photoswitch" is gene mutation agnostic, easy to deliver
- Dosed 1st patient Q4 2022 in Phase 1b study
- Anticipate preliminary results 1H 2023

KIO-101: Ocular Surface Disease in Rheumatoid Arthritis & Other Autoimmune Diseases (OPRA+)
- Investigational New Drug Application for Phase 2 trial conditionally approved
- Disease modifying approach
- First patient, first visit planned for 1H 2023

KIO-201: A Novel, Modified Hyaluronic Acid (HA) Molecule for Ocular Wound Healing
- Phase 2 Persistent Corneal Epithelial Defects (PCED) trial (orphan indication) fully enrolled in Q4 2022
- Report results & initiate discussions with FDA for registration trial 1H 2023

Diverse Pipeline Offers Near Term Milestones

	Indication	Product Formulation	Development Stage: Pre-clinical	Phase 1	Phase 2	Phase 3
Posterior Segment	Retinitis Pigmentosa (Mutation Agnostic)	KIO-301 IVT	*Granted Orphan Drug Designation – March 2022*			
Anterior Segment	Ocular Presentation of Autoimmune Disease	KIO-101 Eye Drop				
	Persistent Corneal Epithelial Defects	KIO-201 Eye Drop				
	Corneal Surgical Wounds	KIO-201 Eye Drop				

2022 Recap: Strategic Focus

Pipeline

Sharpened Pipeline

- Targeting rare and/or differentiated ophthalmic indications
- Pursuing cost-effective paths to market

Milestones

Achieved Several Clinical and Regulatory Development Milestones

- Initiated ABACUS, a first-in-human Phase 1b trial for KIO-301 in RP
- Received Orphan Drug Designation (ODD) for KIO-301 in RP
- Initiated and completed enrollment of Phase 2 trial of KIO-201 for PCED
- Reported full results from KIO-101 Phase 1b trial in ocular surface inflammation
- Investigational New Drug Application conditionally approved for Phase 2 trial for KIO-101 in OPRA+

Finance

Implemented Operational and Financial Efficiencies & Strengthened Financial and Reporting Procedures

- Appointed Melissa Tosca as EVP Finance to oversee finance, reporting, and accounting
- Identified and updated gaps in legacy SEC reporting protocols
- Received ~$1.2M in refundable R&D tax credits
- Raised gross $20 million (past 18 months)

KIO-301

Vision Restoration in Retinitis Pigmentosa

Targeting RP
A Condition with No Available Treatments

Normal Vision

Vision Declines over Time

Prevalence
- 1 : 3,500 worldwide
- Approximate 100,000 in US

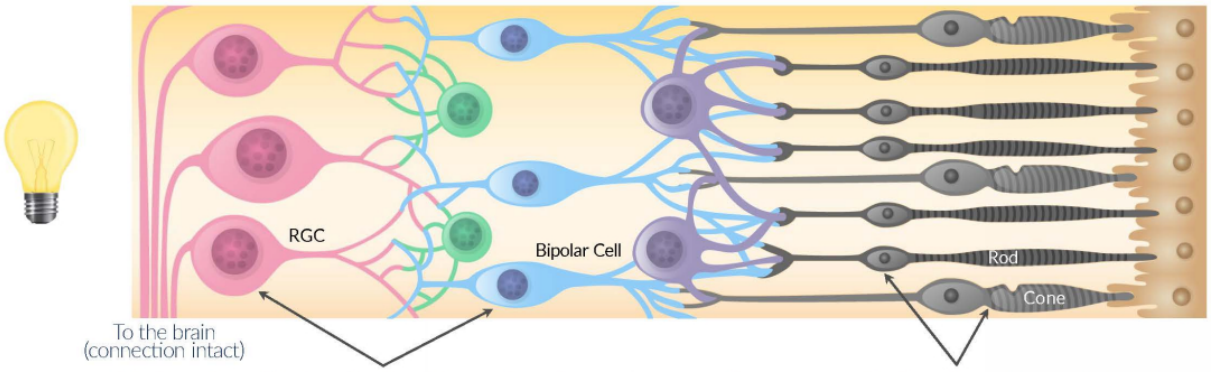
Etiology
- 50+ genetically distinct subtypes from 150+ mutations
- Inherited disease

Clinical Presentation
- Night blindness, reduced visual field range and eventual loss of central vision
- Visual acuity declines

Diagnosis
- Retinal exam (black bone-spicule pigmentation)
- ERG provides definitive diagnosis
- Genetic testing

American Academy of Ophthalmology

Downstream Neurons Remain Viable in RP



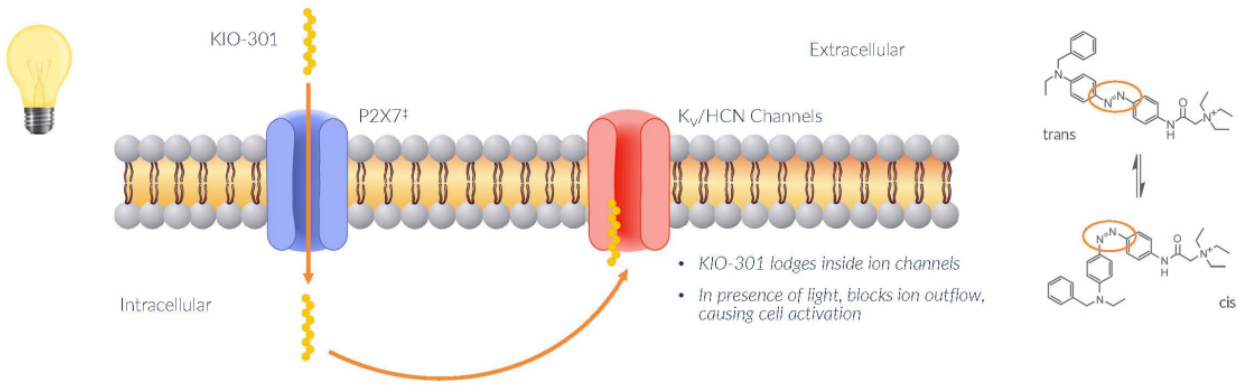
Bipolar cells and RGCs relay signal from rods and cones to the brain, where the image is "processed"

Photoreceptors (rods and cones) sense light and pass the signal to special transmitting cells

- RP results in death of photoreceptors
- Bipolar cells and Retinal Ganglion Cells (RGCs) remain intact and retain ability to send signals to the brain

KIO-301: Turns RGCs "ON" in the Presence of Light

- In RP, photoreceptors are no longer viable => companion "signal" cells (RGCs) are not capable of being activated
- KIO-301 preferentially enters these RGCs and turns them "ON" in the presence of light*

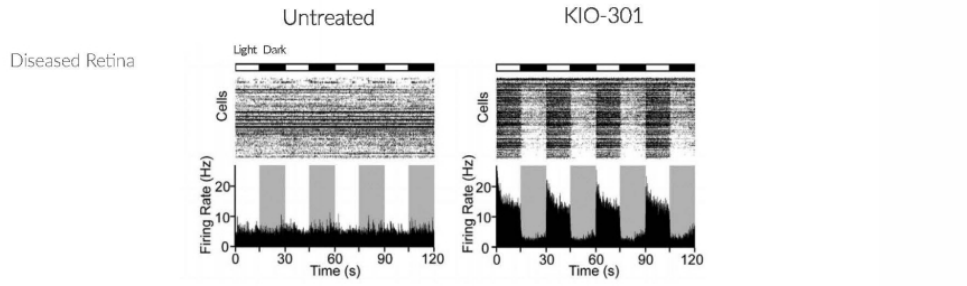


‡ P2X7 is solely expressed on RGCs and amacrine cells in the retina.

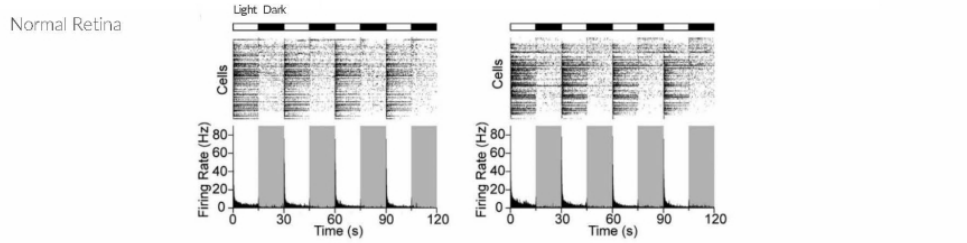
* Visual light causes shape change of KIO-301 (trans ⟶ cis), blocking the movement of positively charged ions out of the cell through the K_V/HCN channels. This build up of charged ions in the cell triggers activation (phototransduction signaling) to the brain.

Neuron. 92, 100-113 (2016)

KIO-301: Acts Selectivity in Diseased Retinas

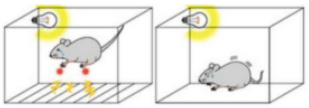


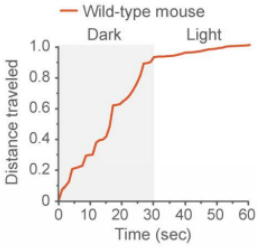
KIO-301 is selective for RGCs in Degenerating Retinas

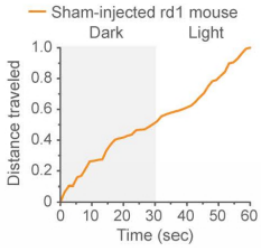


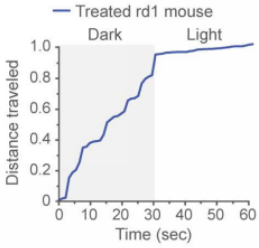
Sci. Rep. 7, 45487 (2017)

KIO-301: Behavioural Changes in Diseased Mice









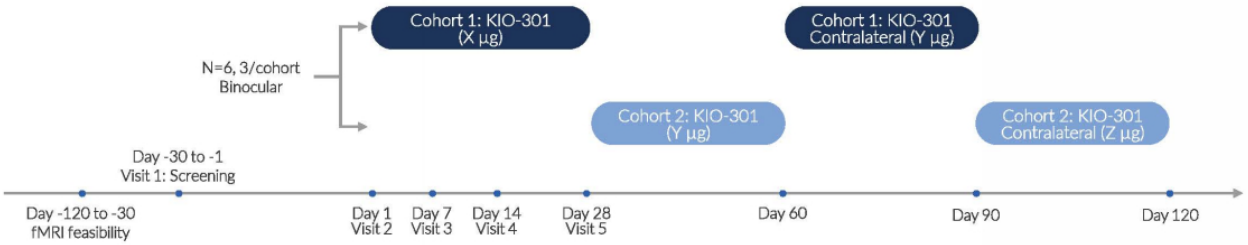
Distance traveled is a relative measure
N=10 mice/group
Mice evaluated 1d after IVT inj

rd1 mouse has similar retinal degeneration as observed in RP patients
Homologue molecule to KIO-301 API

Neuron. 81, 800-813 (2014)

KIO-301: Phase 1b Study Design (ABACUS)

Ongoing, Open Label, Single Ascending Dose Trial



Assessment days (shown only for Cohort 1 above) are repeated for each cohort per eye

Study Design	▪ Two cohorts, non-randomized, open-label, single IVT injection per eye ▪ Cohort 1 – NLP/LP patients; Cohort 2 – HM/CF patients ▪ 6 patients, 12 eyes
Outcome Measures	▪ Primary – safety (AEs), PK & labs ▪ Key secondary – object identification, intensity and contrast assessment, fMRI, perimetry
Review	▪ Safety review conducted by Investigators between any change in dose and between cohorts

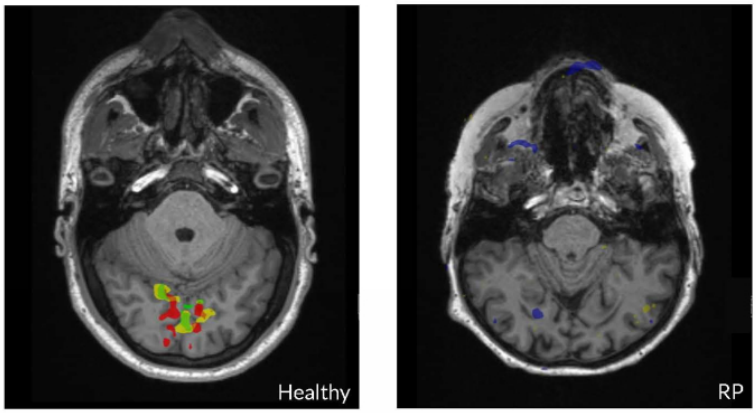
ClinicalTrials.gov Identifier: NCT05282953

Functional Assessments

How Do You Measure Success in Ultra-Low Vision Patients?

Objective
- Functional MRI
- Mobility/maze testing
- Object identification
- Perimetry

Subjective
- Patient reported feedback
- VFQ-25



Beyond RP for Photoswitch Platform

Indications
- Other inherited retinal diseases (rod-cone dystrophies)
- Age-related macular degenerative diseases
  > Geographic atrophy
  > Late-stage wAMD
- In combination with any and all gene-replacement therapies
- Screening for optogenetics

Expanding Exclusivity
- Protected through at least 2041 with combination of formulation, methods, and CoM patents
- Orphan Drug Designation regulatory protection

KIO-101

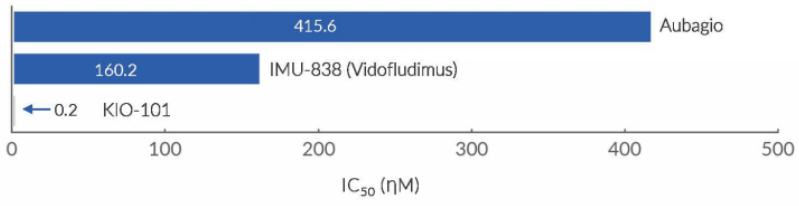
Ocular Presentation of Rheumatoid Arthritis & Other Autoimmune Diseases (OPRA+)

KIO-101: Selectively Targets T-Cell Mediated Inflammation in the Eye

KIO-101 is a DHODH* Inhibitor
- Validated target clinically and commercially
- $2B+ global sales in 2022

KIO-101 Locally Inhibits DHODH in Eye
- Decreases T_H cell function & proliferation locally
- Overcomes systemic delivery shortcomings

KIO-101 has Demonstrated Greater Specificity & Potency



*Dihydroorotate Dehydrogenase

Novel Approach to Address Major Need Among RA Patients & Beyond

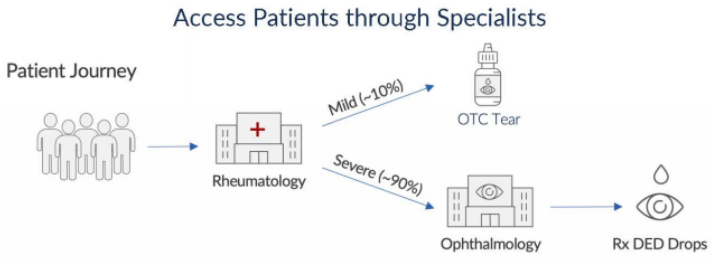
Ocular Surface Discomfort is the Most Common Non-Articular Complaint

DHODH Inhibition Ideally Suited for OPRA+

- Immune system attack of synovial joints manifests similarly on the ocular surface

Large Addressable Population

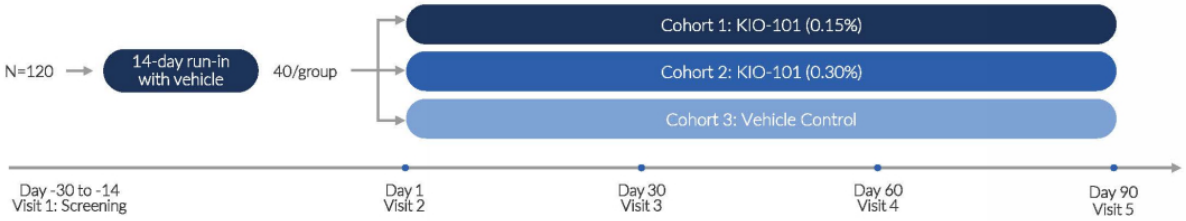
- US prevalence >500,000



Rheumatol. Int. 2017 Sep;37(9):1551-1557. Eyenet Magazine. 2016 Nov:37-9. IVOS. 2015 Jun;56(7):4437.

KIO-101: Initiating Phase 2 Study in 2023

Randomized, Multicenter, Double Masked, Multiple Ascending Dose Trial



Study Design

- Three-arm, randomized (1:1:1), controlled, double masked, 90-day BID topical dosing
- Dx of RA (or other AI disease), conjunctival hyperemia, ODS-VAS
- Up to 120 patients

Outcome Measures

- ODS-VAS, Schirmer's, conjunctival hyperemia, corneal staining, other
- AEs & safety labs

ClinicalTrials.gov Identifier: NCT05629364

KIO-201

Proprietary, Modified Form of Hyaluronic Acid (HA) to Heal Challenging Ocular Surface Wounds

Ocular Surface Wounds: Opportunity Set

Persistent Corneal Epithelial Defects (PCED)

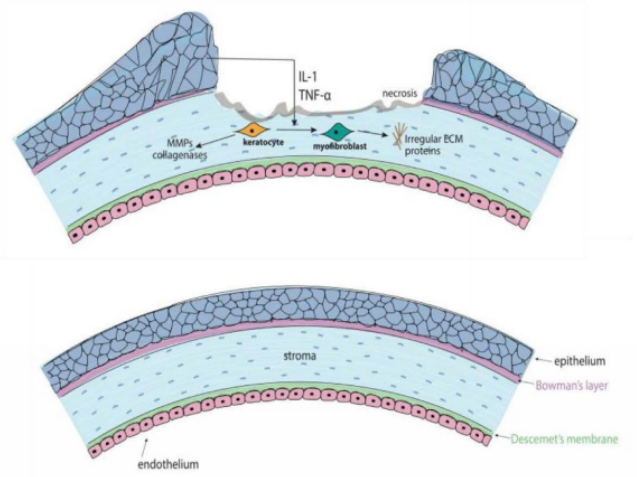
- Failure of normal closure of a corneal injury in 10–14 days, despite standard of care
- Orphan Drug Designation (ODD) opportunity

Ocular Surface Surgical Recovery

- PRK – Surgical correction of refractive errors for patients who are not candidates for LASIK
  > Standard of care is the use of bandage contact lens that can result in erosion of epithelium
- Keratoconus – Rare ocular disease where the cornea thins and bulges outward
  > Treatment option includes corneal cross-linking, a laser surgical procedure

Med. Hypothesis Discov. Innov. Ophthalmol. 8 (2019): 163-176.

KIO-201: Proprietary, Cross-Linked Form of HA



Ideally Suited to Promote Healing

- HAs known to promote epithelium healing
- Provides physical barrier to protect surface
- Enables greater epithelial cell migration
- "Normal" HAs limited by residence time & blurring

Clinical Experience Across Multiple Trials

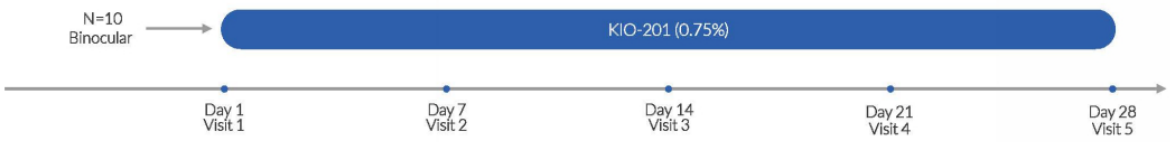
- 3 PRK surgical recovery (2 pilot, 1 pivotal*)
- 2 dry eye disease

* Regulated as a medical device until 2020

American Academy of Ophthalmology, Ocular Surgery News: April 10, 2019, Med. Hypothesis Discov. Innov. Ophthalmol. 8 (2019): 163-176.

KIO-201: Phase 2 PCED Study

Single-Arm, Open Label Trial (*Enrollment Completed*)



Study Design

- Single-arm, open label, 28 days 6x daily topical dosing
- Dx of Stage 1 or 2 PCED
- Up to 10 patients

Outcome Measures

- Safety & tolerability
- % of patients healed (<0.5 mm lesion size) at week 4, time to complete healing

ClinicalTrials.gov Identifier: NCT05436288

CORPORATE OVERVIEW

Management & Milestones

2023 Anticipated Milestones

Milestone	Timing
KIO-301 | Retinitis Pigmentosa	
Complete enrollment in Phase 1b RP study (ABACUS)	Q2 2023
Report initial results from ABACUS	1H 2023
Report complete results from ABACUS	2H 2023
KIO-201 | Ocular Wound Repair	
Receive Orphan Drug Designation PCED	Q1 2023
Report initial results from Phase 2 PCED study	1H 2023
FDA dialogue to initiate registration study	1H 2023
KIO-101 | OPRA+	
Initiate Enrollment in Phase 2 trial for KIO-101	1H 2023

Leadership Team

Brian M Strem, PhD
President & CEO

Melissa Tosca, CPA
EVP – Finance

Eric J Daniels, MD, MBA
Chief Development Officer

Stefan Sperl, PhD
EVP – CMC & Operations

Angela Dentiste, MBA
VP – Clinical Operations

Board of Directors

Paul Chaney
Chairman

Ken Gayron

David Hollander, MD, MBA

Erin Parsons

Aron Shapiro

Praveen Tyle

Brian M Strem, PhD
President & CEO

Scientific Advisory Board

Allen Ho, MD, PhD

Wills Eye Hospital

Christine Kay, MD, PhD

Vitreo Retinal Associates

Russel Van Gelder, MD, PhD

UW Medicine
UW School of Medicine

Charlie Wykoff, MD

Retina Consultants of Texas™

Daniel Durrie, MD

KU Medical Center
The University of Kansas

Paul Karpecki, OD, FAAO

Kentucky Eye Institute

Francis Mah, MD

Scripps

Victor Perez, MD

Duke University School of Medicine

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