

**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 10, 2022**

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

Delaware
(State or other jurisdiction of incorporation)

001-36672
(Commission File Number)

98-0443284
(IRS Employer Identification No.)

**1371 East 2100 South
Suite 200
Salt Lake City, Utah 84105**
(Address of principal executive offices)

84105
(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:

<u>Title of each class:</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered:</u>
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 10, 2022

CORPORATE OVERVIEW

January 2022



Forward Looking Statements

Some of the statements in this press release 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 press release, including, among other things, market and other conditions and certain risk factors described under the heading “Risk Factors” contained in Kiora’s Annual Report on Form 10-K filed with the SEC on March 25, 2021 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 press release speak only as of the date of this press release. 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.

Addressing Unmet Needs in Eye Care

Compelling Value Proposition

New Leadership – Renewed Focus

- Efficient investment to clinical inflection points

Large & Underserved Market Opportunities

- Transformative and reprioritized pipeline

Diversified Portfolio

Revolutionary small molecule with the potential to restore vision in patients with inherited or age-related retinal degeneration

- Unique small molecule MOA restores light perception
- *Entering Ph1b in Q3 2022*

Small molecule DHODH inhibitor to treat immunologic eye disease

- Validated disease modifying target in rheumatology
- *Ph1b trial reported safety, tolerability and significant reduction in clinical sign*

Eye drop to accelerate ocular wound healing and protect the ocular surface

- Next generation cross-linked hyaluronic acid (HA)
- *Ph3b ready*

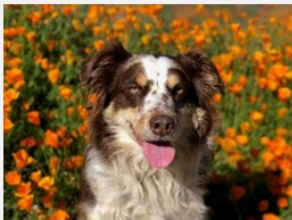
Pipeline

	Therapeutic Category	Product Delivery Route	Indication	Development Stage			
				Pre-clinical	Phase 1	Phase 2	Phase 3
Anterior Segment	Ocular Surface Disease	KIO-101 Eye Drop	Ocular Manifestations of Rheumatoid Arthritis				
	Ocular Wound Healing	KIO-201 Eye Drop	PRK Surgical Recovery				
Posterior Segment	Inherited Retinal Disease	KIO-301 IVT	Mutation Agnostic Retinitis Pigmentosa				
Systemic	Autoimmune	KIO-102 Oral	TBD				

KIO-301

Small Molecule Photoswitch for Retinal Reanimation

Retinitis Pigmentosa (RP) Disease Overview



Prevalence

- 1:3,000-1:5,000 (Orphan Disease)

Etiology

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

Clinical Presentation

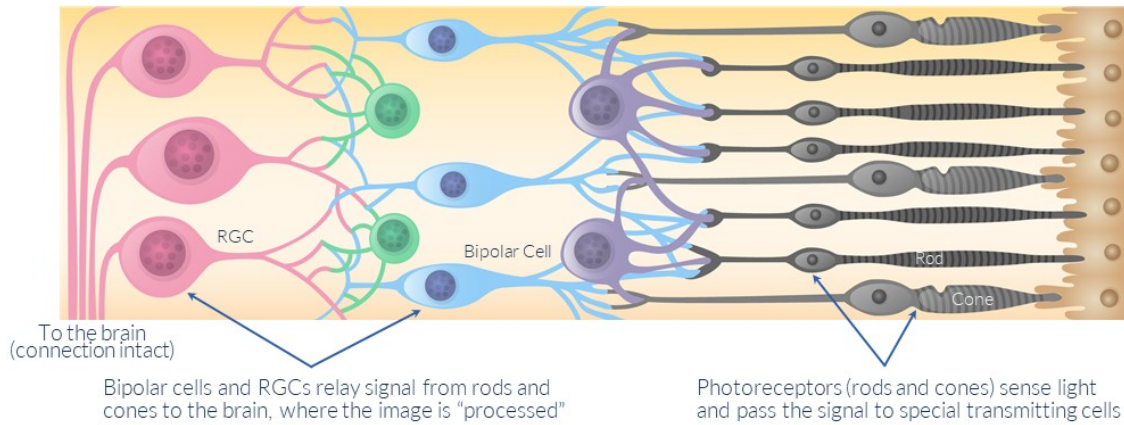
- Night blindness, reduced visual field range and eventual loss of central vision
- Visual acuity declines

Diagnosis

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

KIO-301 is mutation agnostic

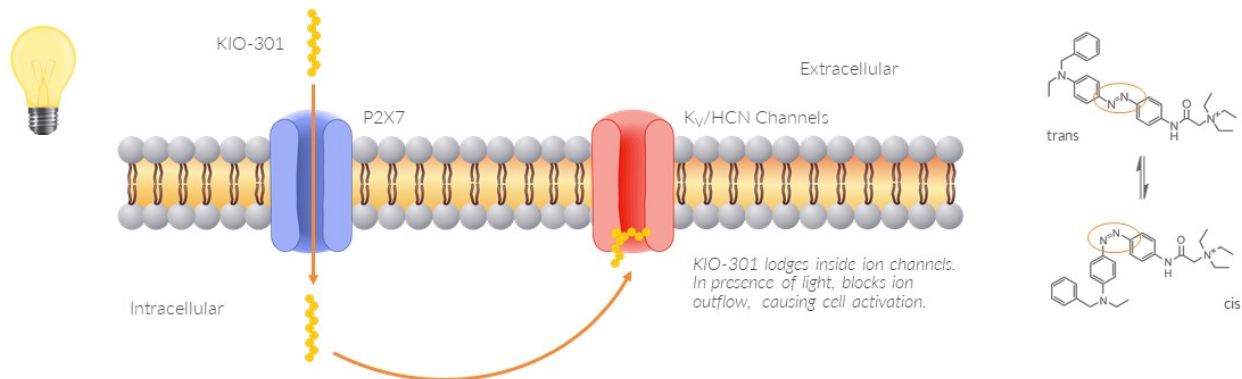
RP – How Retinal Degeneration Occurs



- Normal human retina has about 120 million rods (black & white, night vision, movement) and 6 million cones (color)
- Photoreceptors die (rods first, then cones), unable to activate Bipolar cells and Retinal Ganglion Cells (RGCs)
- Bipolar cells and RGCs remain intact and retain ability to send signals to the brain

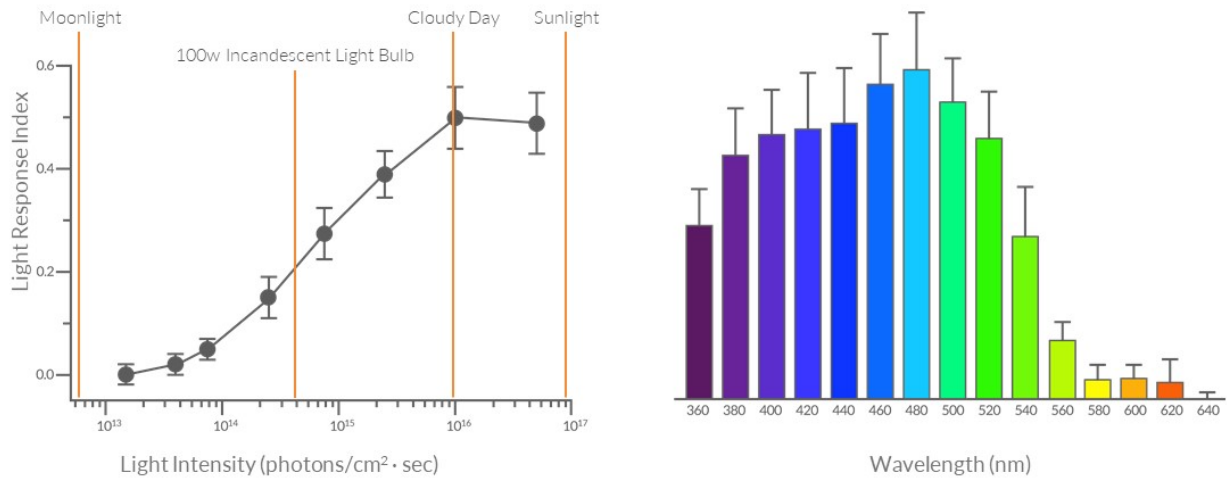
KIO-301 Turns RGCs "ON" in the Presence of Light

1. In RP, photoreceptors are no longer viable and therefore their companion "signal" cells (RGCs) are not capable of being activated or set to "OFF"
2. KIO-301 preferentially enters these "OFF" RGCs and turns them "ON" in the presence of light*



* 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.

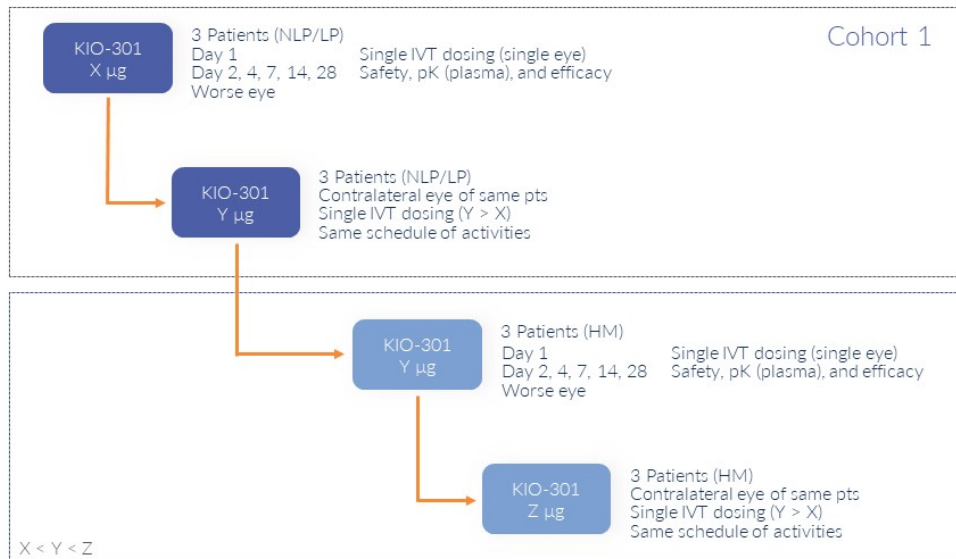
KIO-301: Light Intensity and Wavelength



Sci. Rep. 7, 45487 (2017); Banghart, Trauner et al (2008)

KIO-301: Phase 1b Study Design

Open Label, Single Ascending Dose Trial – Royal Adelaide Hospital, Australia



KIO-101

Potential 1st in Class Treatment for Ocular Manifestations of Rheumatoid Arthritis (RA)

Ocular Involvement of RA Overview



"The immune attack on the surface of the eye is a mirror image of what is destroying the joint synovium"
- Sandeep Jain, MD,
Univ of Illinois, College of Med

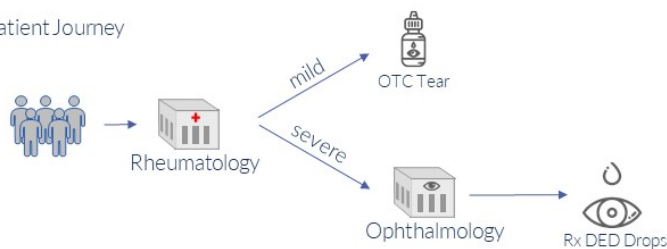
Rheumatoid Arthritis (RA) is a **chronic, systemic autoimmune disease** that primarily effects joint linings, causing swelling, bone erosion and deformity

- No cure exists but symptoms can be managed with disease modifying medications
 - DHODH inhibitors, IL-6, TNF- α antagonists and others

Large unmet need

- 3.3 million people in United States have RA
- >30% of these patients have ocular manifestations (~1.1m)
 - Ocular signs & symptoms are the most common, non-articular manifestations of RA

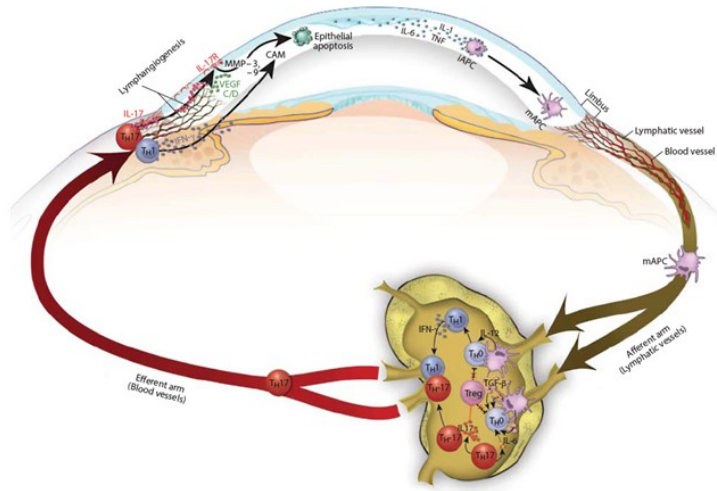
Patient Journey



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

RA Ocular Signs & Symptoms are Mediated by T Cells

KIO-101 acts upstream to inhibit proliferation of T helper cells (Th1 and Th17) in lymph node and on-site to suppress pro-inflammatory cytokine release



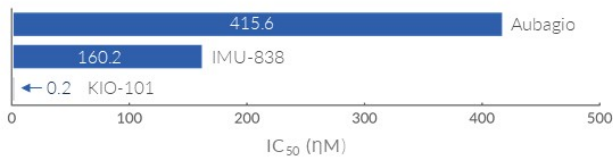
Arch Ophthalmol. 2012 Jan;130(1):90-100

DHODH Inhibitors

Validated Drug Class for Autoimmune Diseases

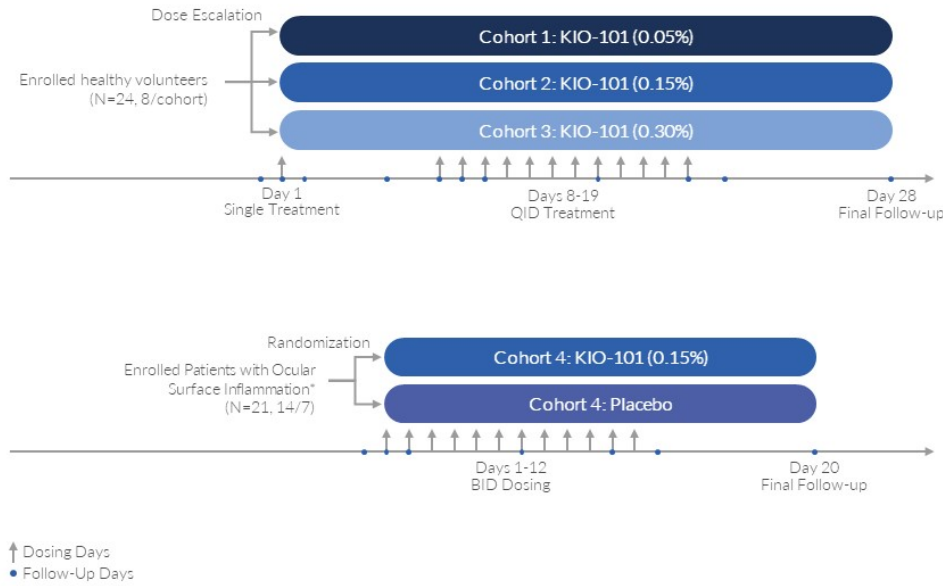
Company	Drug	Status*	Market / Revenue
Sanofi	Arava (leflunomide)	On market for RA	~\$2.5B annual revenue Low selectivity and potency results in off-target side effects <ul style="list-style-type: none"> Safety concerns of severe liver injury and other adverse events Black box added regarding the risk of severe liver injury
	Aubagio (teriflunomide)	On market for MS	
PTC Therapeutics	PTC299	Ph1b AML Ph2/3 COVID-19	
Immunic	IMU-838	Ph2/3 UC, MS, CD	
ASLAN	ASLAN003	Ph2 autoimmune	
Clear Creek Bio	Brequinar	Ph2 AML Ph2 COVID-19	
Kiora Pharmaceuticals	KIO-101	Ph2 Ocular RA Preclin autoimmune	

*As of April 2021



KIO-101 overcomes safety concerns with greater specificity and best in class potency

KIO-101: Exploratory Phase 1b Ocular Surface Inflammation Trial



Key Inclusion Criteria

- Ocular surface inflammation defined by OSDI of at least 22
- Conjunctival hyperemia ≤ Grade 2 on the Efron Scale

1° & 2° Outcomes

Safety ▪ pK ▪ Exploratory Efficacy Including OSDI, Conjunctival Hyperemia, Corneal Staining, and Tear Break-Up Time

Safety Analysis* – Summary Statistics Table (p values)

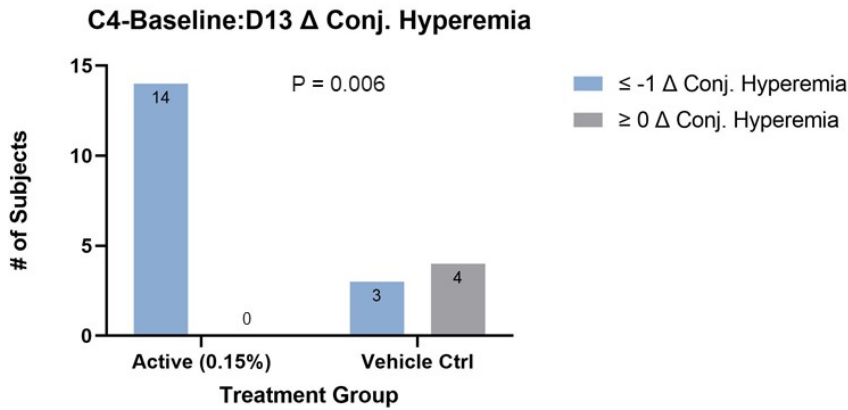
	All Actives (healthy only) vs Vehicle	Cohort 4 Only: Active vs Vehicle
AEs	0.6653	0.3615
SAEs**	NC	NC
Ocular AEs	0.2500	0.3371
Ocular SAEs***	NC	NC
Ocular Related AEs	0.2500	0.6244

Key Takeaways

Topical KIO-101 at low and mid doses tested is safe & well tolerated in both healthy subjects and those with ocular inflammation. High dose inconclusive.

* Safety Population; ** Zero SAEs reported; *** Zero Ocular SAEs reported

Conjunctival Hyperemia (sign)

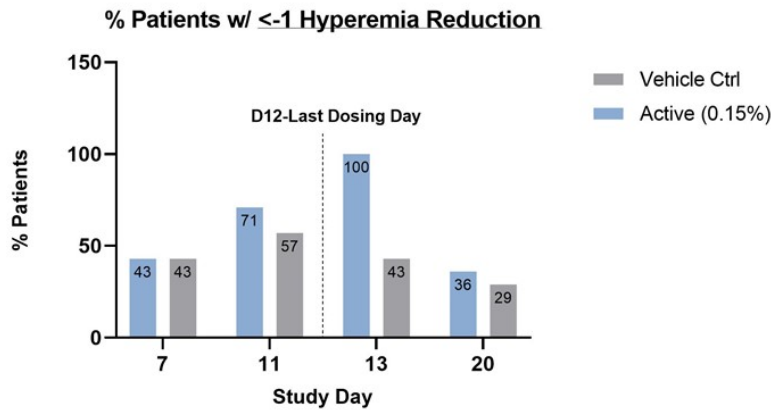


Key Finding

- Hyperemia was a key inclusion criteria
- 100% of subjects on active experienced improvement @ D13
- Hyperemia is an acceptable endpoint as a 'sign' for US FDA

p value calculated using Fisher's Exact Test

Change In Hyperemia By Day

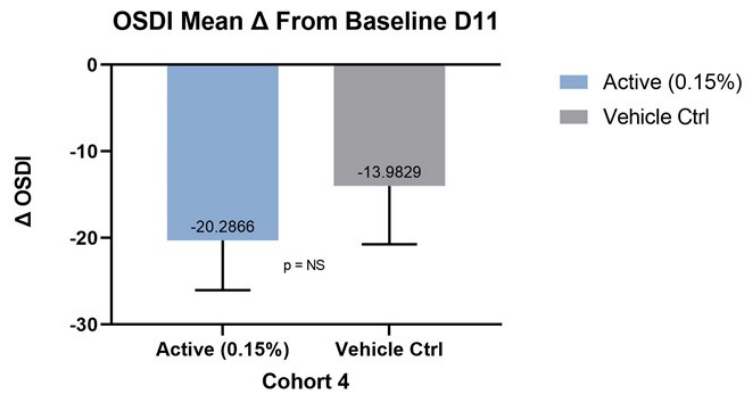


Drug Effect

Encouraging to see drug effect increase & decrease. Day 20 is 8 days following last dose.

Top-Line Data: OSDI

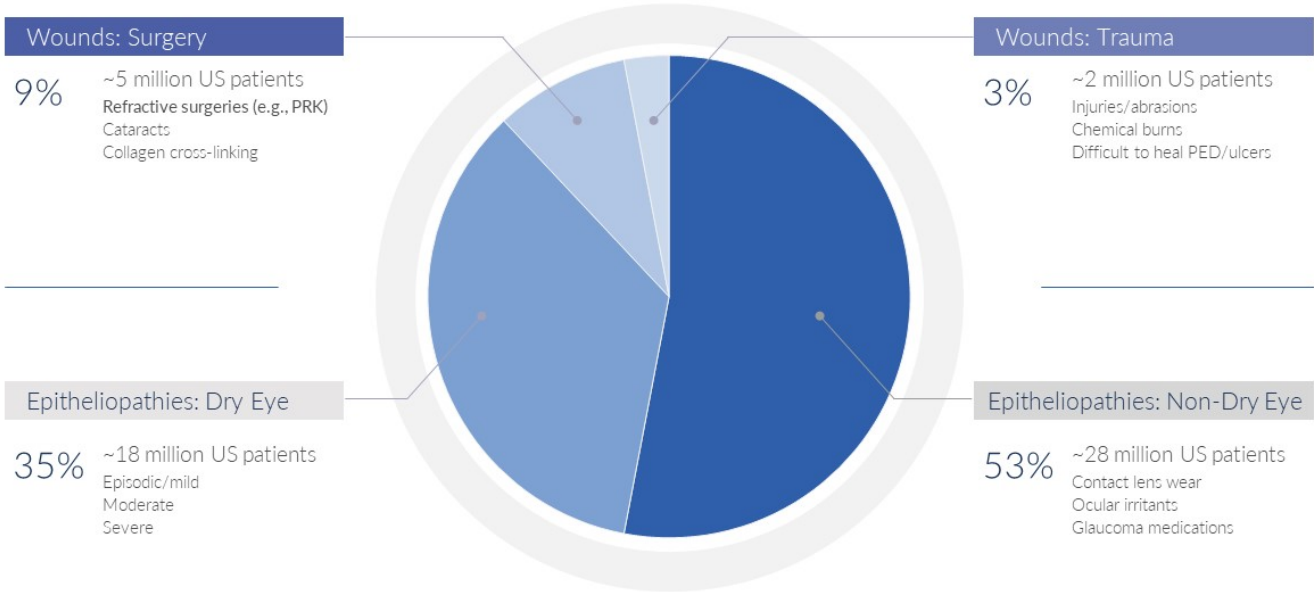
- Inclusion criteria was OSDI > 22
- OSDI measured @ screen & D11
- Active demonstrated small trend toward significance



KIO-201

Accelerating Ocular Surface Wound Healing

Ocular Surface Diseases



Refractive Surgery Overview

PRK

- PRK is a surgical correction of refractive errors for patients who are not suitable candidates for LASIK due to:
 - Inadequate corneal thickness
 - Larger pupil size
 - Dry eye
 - Anterior basement membrane disease
- PRK involves controlled mechanical removal of corneal epithelium with subsequent lasering of stroma

The Unmet Need

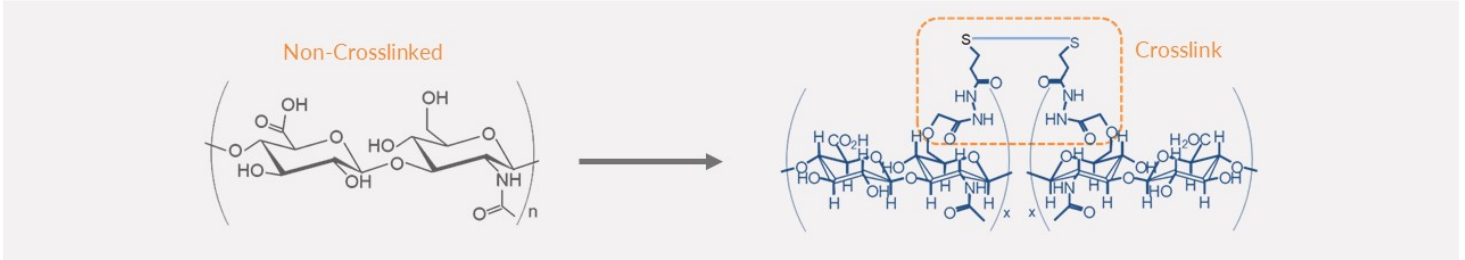
- While PRK yields superior visual results, complications include:
 - Post-operative pain
 - Risk of infection
 - Corneal haze
 - Decreased contrast sensitivity
 - Slower visual recovery
- Standard-of-care is a Bandage Contact Lens (BCL) which can result in subsequent erosion of epithelium

The Opportunity

- Enabling the epithelium to heal faster may mitigate peri-operative complications and improve long-term visual outcomes
- The PRK population is ideal:
 - Large population (~850,000 LASIK/PRK surgeries per year in the US)
 - Large wound (9mm), same size for all patients and known time zero
 - Time to healing well-established

KIO-201

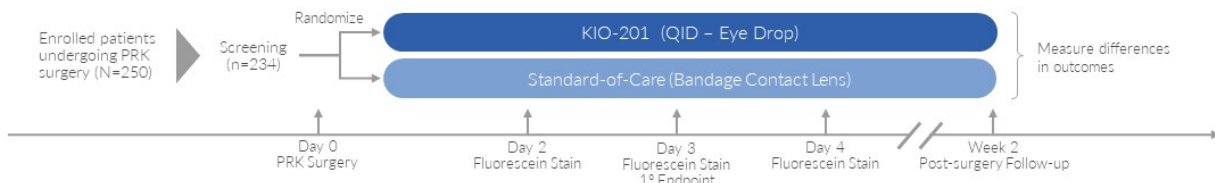
- KIO-201 is based on a modified form of the natural polymer hyaluronic acid (HA)
- HA is a material with a high viscosity that promotes wound healing by enabling enhanced cell migration
- 5 clinical trials completed (3 PRK surgical recovery and 2 dry eye)
 - > Approximately 400 eyes have been treated with KIO-201
 - > Strong safety and efficacy profile



Crosslinking Creates Unique Attributes Ideal for Ocular Surface

- Improved product stability
- Longer retention on the ocular surface over non-crosslinked HA (2 hours vs minutes)
- Able to achieve concentrations up to 7.5x current products
- Decreased viscosity during blinking = no blurred vision

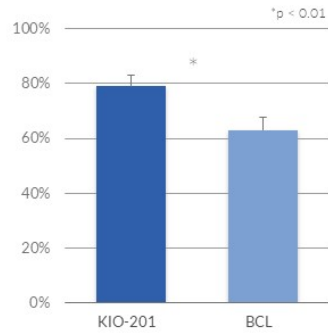
PRK Study Design



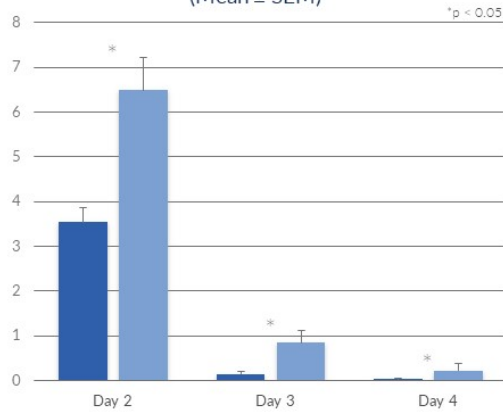
- Study Design**
 - Two-arm, randomized, positive-controlled, masked via reading center
- Outcome Measures**
 - Primary endpoint: Complete corneal re-epithelialization on Day 3 (% of eyes w/ fully closed wound and remain closed)
 - Key secondary endpoint: Mean wound size (days 2, 3, 4)
- Enrollment**
 - 250 patients enrolled (9 US sites)
 - 234 qualified patients randomized to KIO-201 or BCL group post-surgery (16 screen failures)

KIO-201 Demonstrated Superiority versus BCL

Percent of Patients with Complete Re-Epithelialization Day 3 (Mean ± SEM)



Mean Wound Size (mm²) (Mean ± SEM)



Recurrent Erosion

- Only 1 (0.9%) study eye in the KIO-201 group had recurrent erosion
- 4 (3.5%) study eyes in the Bandage Contact Lens (BCL) group had recurrent erosion

Corporate Overview

Executive Team



Brian M Strem, PhD
President & CEO



Sarah Romano, CPA
Chief Financial Officer



Eric J Daniels, MD, MBA
Chief Development Officer



Brenda Mann, PhD
VP - Research



Stefan Sperl, PhD
EVP - CMC & Operations



Angela Dentiste, MBA
VP - Clinical Operations

Board of Directors



Paul Chaney
Lead Independent Director



Stephen From
Executive Chairman



Ken Gayron



David Hollander, MD, MBA



Aron Shapiro



Praveen Tyle



Brian M Strem, PhD
President & CEO

Scientific Advisory Board

Allen Ho, MD, PhD



Christine Kay, MD, PhD



Russel Van Gelder, MD, PhD



Charlie Wykoff, MD



Retina Consultants of Texas™

Daniel Durrie, MD



Paul Karpecki, OD, FAAO



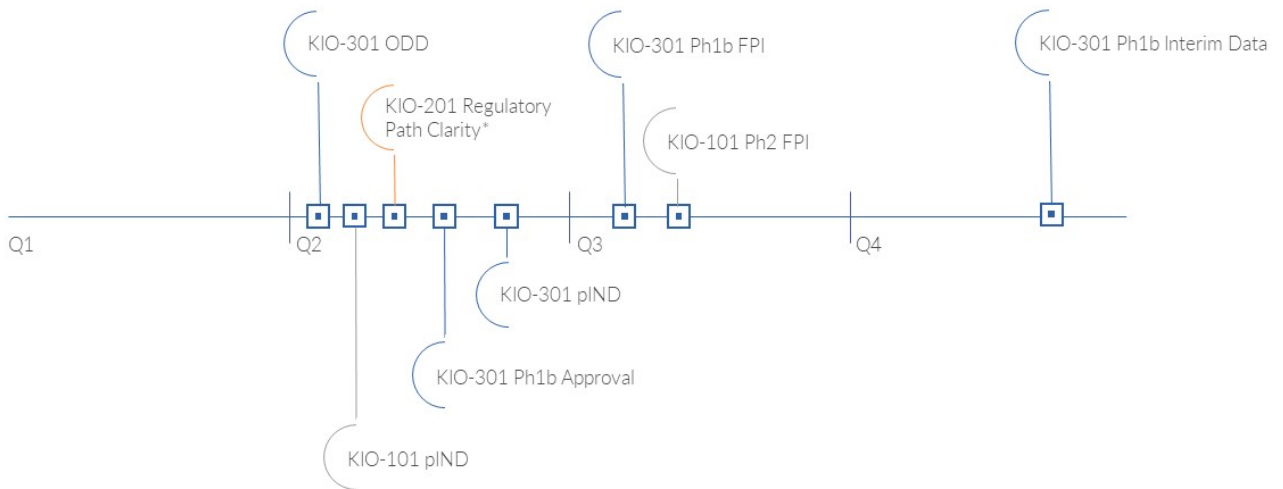
Francis Mah, MD



Victor Perez, MD



Key Expected 2022 Milestones



* - After regulatory clarity from FDA, will seek commercial partnership
 FPI - First Patient In, ODD - Orphan Drug Designation

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Contact:
info@kiorapharma.com

