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KALA BIO Clinical Readout Year End 2024 in High Value PCED Market



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- Experienced team: Developed & secured FDA approval for two ophthalmology products, EYSUVIS for dry eye disease and INVELTYS for post ocular surgery - Acquired by Alcon
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- Projected cash runway into Q2 2025 including anticipated remaining funding from CIRM grant
- Outstanding shares as of 9/30/23 include 2,693,116 common and preferred shares convertible into 5,124,600 common shares.



Leadership Team with Extensive Ophthalmology Innovation Experience



TODD BAZEMORE
President and
Chief Operating Officer









KIM BRAZZELL, PhD Head of R&D and Chief Medical Officer





CIBA OVISION.





MARK IWICKI Chair and Chief Executive Officer











DARIUS KHARABIChief Business Officer











MARY REUMUTH, CPA Chief Financial Officer









ERIC L.
TRACHTENBERG
Chief Legal Officer and Chief
Compliance Officer









KALA BIO is Advancing an Innovative Pipeline Based on Its Proprietary Mesenchymal Stem Cell Secretome (MSC-S) Platform for the Treatment of Rare Front and Back of the Eye Diseases

Product Candidate*	Indication	Route of Administration	Pre- Clinical	Phase 1	Phase 2	Phase 3
KPI-012 for Rare Ocular Surface Disease	Persistent Corneal Epithelial Defect (PCED)	Topical				
	Limbal Stem Cell Deficiency (LSCD)	Topical		·		
	Other rare corneal diseases	Topical				
KPI-014 Program for Rare Inherited Retinal Disease		Intravitreal Injection				



KALA BIO is a Leader in the Emerging Field of Mesenchymal Stem Cell Secretome (MSC-S) Therapy

Proprietary MSC-S Platform is a Cell-Free, Regenerative Approach to Disease Management

- Secretomes produced by collecting the biomolecules that are secreted by cells into the extracellular space to support their health and viability
- Offer many of the benefits of cell therapy without administering cells
- Avoids many of the safety and logistic concerns associated with current cell therapy approaches
- KALA MSC-S GMP manufactured from proprietary cell bank and well-defined CMC process, enabling consistent lot-to-lot safety, stability and biopotency

Secretomes Have Shown Benefits in Ocular Diseases, Including:

- Corneal injury
- Retinal degeneration
- Glaucoma
- Dry eye disease

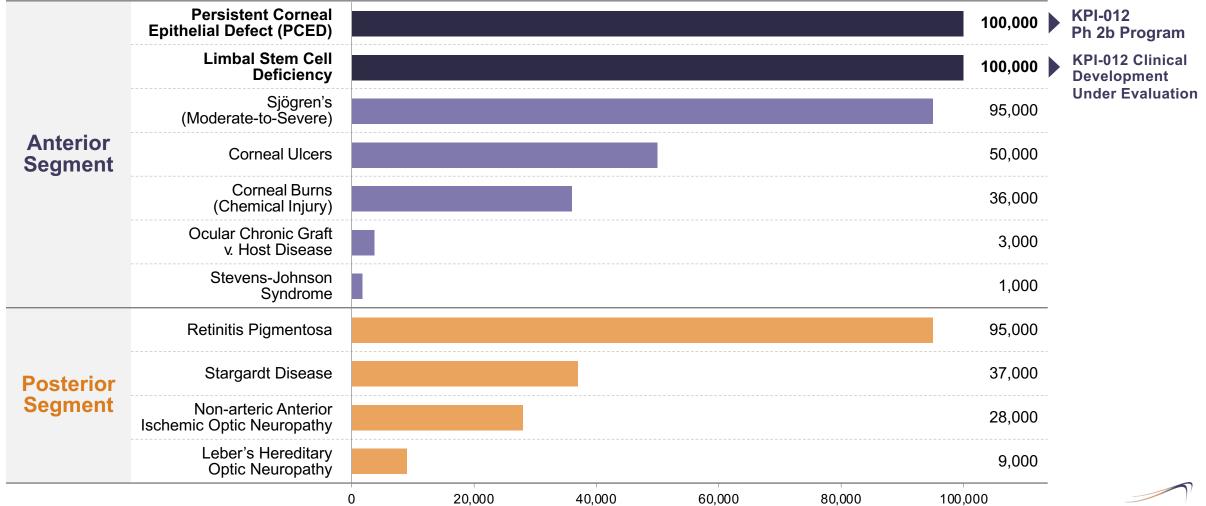
MSC-S Mechanisms of Action Include:

- Wound Healing/Tissue Repair
- Anti-inflammatory/Immunomodulatory
- Neurotrophic/Neuroprotective

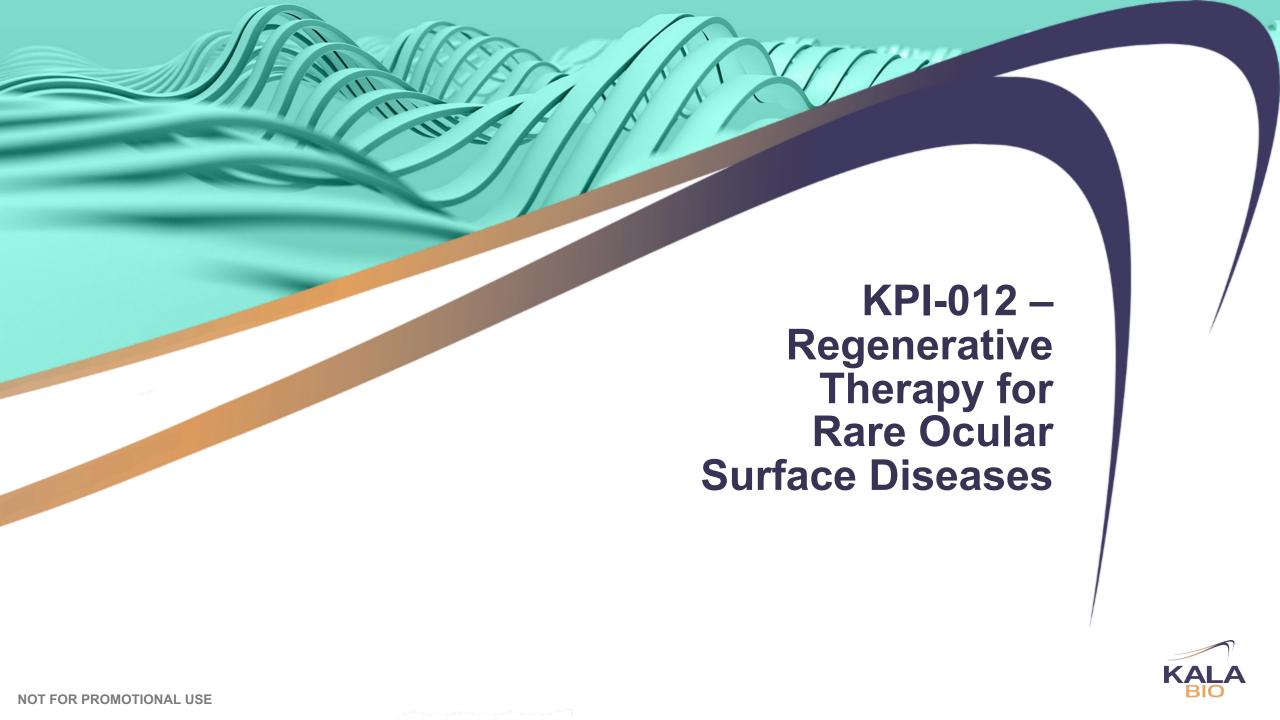


MSC-S Has Potential Applications in Multiple Rare Ocular Disease Segments

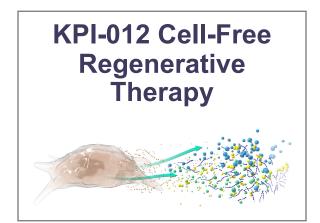
Approximate US Prevalence

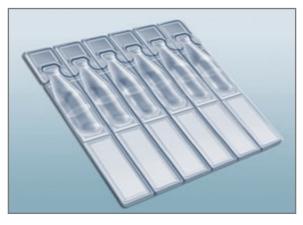






KPI-012 – Human Bone Marrow-Derived MSC-S Therapy in Development for Persistent Corneal Epithelial Defect (PCED)



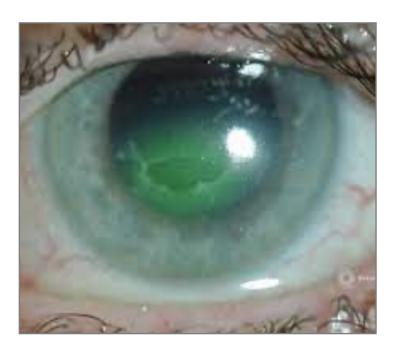


- Composed of biomolecules produced by human bone marrow-derived MSCs and formulated into topical ocular non-preserved single dose unit formulation
 - The simple convenient topical formulation should improve patient experience
- Contains key classes of biomolecules associated with corneal wound healing including growth factors, protease inhibitors and matrix proteins; provides multifactorial approach to addressing impaired corneal healing
- Currently in development for PCED with the goal of complete healing of the PCED
 - Multifactorial mechanism of action could address all underlying etiologies of PCED
- Orphan Drug and Fast Track Designations granted by FDA

KPI-012 Has the Potential to Treat Multiple Rare Corneal Diseases



KPI-012 in Phase 2b for PCED



- PCED persistent non-healing corneal defect that is refractory to conventional treatments
- Significant symptoms (e.g., pain, photophobia, visual impairment)
- If not healed, can lead to infection, stromal thinning/scarring, corneal perforation and vision loss
- Can be caused by a number of underlying etiologies including: trauma, neurotrophic keratitis, diabetic keratopathy, severe ocular surface disease, microbial/viral keratitis, corneal transplant/other ocular surgeries
 - Patients often have more than one underlying etiology
- Estimated incidence of approximately 100,000 patients in the US and 238,000 in the US, EU and Japan combined
- In Ph 1b clinical trial, KPI-012 produced clinical improvement in all 8 treated PCED patients with complete healing of the PCED in 6 of 8

PCED is an Underserved Market:

- There are currently no FDA-approved Rx products with a broad PCED indication for all underlying etiologies
- Oxervate® (nerve growth factor) has limited indication for Neurotrophic Keratitis (~1/3 PCED cases) and is complex and burdensome for patients to administer.

Other

PCED Etiologies

PCED is Clinically Burdensome with High Unmet Needs

Currently Approved Therapy Only Addresses ~1/3 of PCED Patients and is Complex and Burdensome for Patients to Administer

Unmet Needs in the Treatment of PCED:

- Single therapy that addresses multiple etiologies
 - PCED patients often have more than one underlying etiology, all needing to be addressed for effective wound healing
- Rapid and sustained wound healing
 - Patients at risk of developing permanent vision loss if defects are not healed quickly enough
 - Need for faster resolution of corneal defects
- Therapy that is well-tolerated and easily administered
 - Oxervate requires 6-times a day dosing and a 19-step preparation process
 - 16% of patients treated with Oxervate report eye pain as an Adverse Event, as per the Package Insert (PI); eye disorders eye irritation, blepharitis and corneal neovascularization also listed as adverse events in PI post-marketing section
 - There is a need for treatments with improved tolerability and that are simpler to administer

PCED is a Potential >\$1B Orphan Market Opportunity

- Currently no FDA-approved prescription therapies with broad PCED indication
 - Estimated PCED incidence of 100,000 patients in the US and 238,000 in the US, EU and Japan combined
 - Oxervate® (nerve growth factor) limited to Neurotrophic Keratitis (NK) indication only represents ~1/3 of PCED
 - Oxervate 2023 annual U.S. revenue estimated to be in excess of \$700M*
- KPI-012 could be first approved therapy with broad PCED indication and differentiated product profile
 - Potential for rapid and sustained healing, improved tolerability, convenient administration and an MOA to address all etiologies
 - ECP target list of ~1800 Cornea Specialists allows for a small rare disease sales force

^{*}Sources: primary and secondary research

Key Biomolecules in KPI-012 Can Address the Impaired Corneal Healing Processes in PCED with a Multifactorial Mechanism of Action

PCED: Impaired Corneal Healing Can be Driven by Disruption of One or More Key Biologic Pathways

- Impaired epithelial cell differentiation, proliferation and migration
- Enhanced proteolysis leading to basement membrane matrix degradation
- Impaired basement membrane matrix impacting epithelial cell attachment



KPI-012 Biomolecule Classes Can Address Impaired Healing with a Multifactorial Mechanism of Action

- Growth Factors (e.g., HGF, PEDF) Promote epithelial differentiation/proliferation/migration
- Protease Inhibitors (e.g., TIMP-1) Inhibit proteases that degrade basement membrane
- Matrix Proteins (e.g., Fibronectin) Repair matrix; promote adherence of epithelial cells to basement membrane; stimulate cell migration



The Key Biomolecules Present in KPI-012 Address Many of the Biologic Pathways Associated with Impaired Cornea Healing



Promising Results in PCED with Twice Daily (BID) Dosing in Phase 1b Clinical Trial

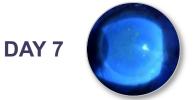
- Prospective single arm trial
- Initial safety cohort of 3 subjects without corneal disease dosed BID for 1 week showed no tolerability or safety issues
 - Efficacy cohort consisted of 8 PCED patients dosed BID for 1 to 8 weeks and followed for up to 19 weeks
 - Key efficacy endpoint healing of PCED based on corneal staining photographs
- Top line results in efficacy cohort
 - 8 of 8 patients showed improvement in PCED
 - 6 of 8 patients had complete healing of PCED
 - 4 of the 6 completely healed after 1 week
 - 1 of the 6 healed after 2 weeks; the other after 4 weeks
 - All healed patients remained healed through end of follow-up
 - KPI-012 well-tolerated with no safety issues observed

6/8 Completely Healed PCED Patients

	Mean	Median
PCED Size at Baseline (mm x mm)	5.1 x 3.5	5.6 x 2.9
PCED Duration at Baseline (Days)	58	32
PCED Healing Time (Days) KPI-012, 2x/day	12	7





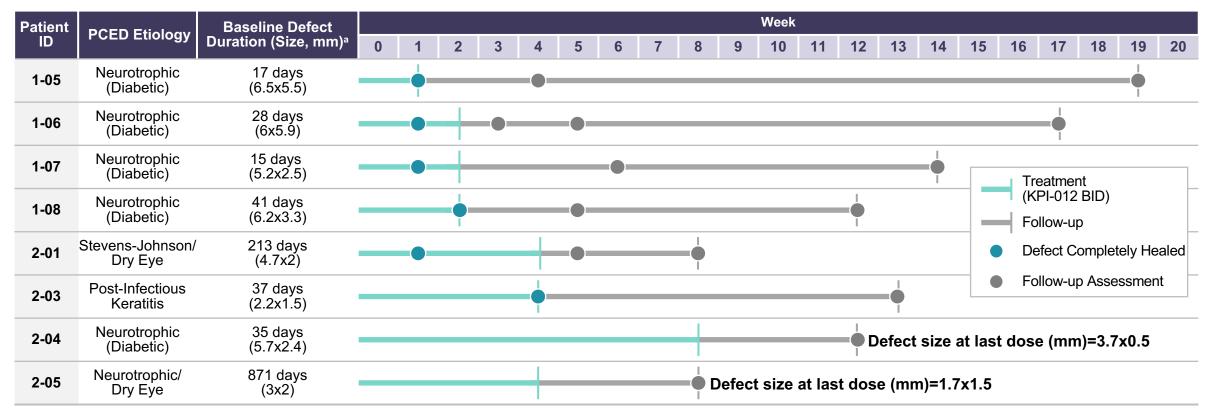




Representative images for a healed patient study eye



Complete Healing in 6 of 8 PCED Patients After 1–4 Weeks of BID Treatment with KPI-012 in Phase 1b Clinical Trial

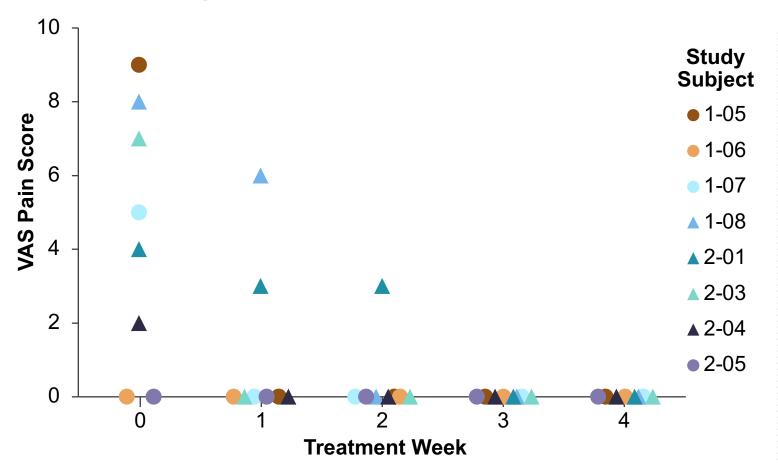


- 6 of 8 of participants completely healed by Week 4 of the trial and remained healed through end of follow-up
- Improvement in PCED lesion size was observed in participants who did not heal completely

Rapid and Sustained Healing in Patients with Varying Etiologies and Duration of Disease Suggests Potential for Broad Efficacy in PCED



Significant Pain Relief Within 1 Week of Treatment



Of Patients Reporting Pain at Baseline (6 of 8):

100% reported pain reduction at Week 1

67% reported 0 pain score at Week 1

100% reported 0 pain score at Week 3

Rapid Improvement in Pain in PCED Patients Treated with KPI-012



KPI-012 Development Progressing Towards Key Ph 2b Readout by Year End 2024

- Pre-IND meeting with FDA in 2020
 - FDA open to broad PCED indication
 - Provided guidance on CMC, clinical trial design and endpoints
- Orphan Drug and Fast Track designations granted by FDA for PCED
- US IND accepted Dec 2022; CHASE Phase 2b clinical trial cohort 2 (randomized, double-masked efficacy portion of trial) initiated in late Q2 2023
 - Phase 2b trial ongoing with results targeted by year end 2024
- Expect to leverage KPI-012 PCED CMC program and other IND-enabling activities to support anterior segment follow-on indications for KPI-012

If Phase CHASE 2b Results Positive Could Serve as First of Two Required Trials to Support BLA Submission



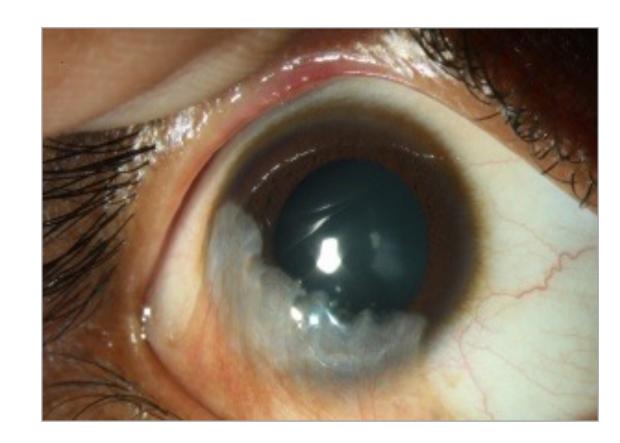
KPI-012 Clinical Update: CHASE Trial Design

- Initial 2-patient open label evaluation to establish safety of 3 U/ml QID dosing completed with no safety findings
 - 1 U/ml dose equivalent to what was tested in Ph 1b trial; 3 U/ml was not tested until ongoing trial
- 90 patient multicenter, randomized, double-masked efficacy trial with 1 U/ml QID, 3 U/ml QID and vehicle QID (30/treatment arm, 1:1:1 randomization) ongoing
- 8-week treatment period plus 2 week and 6-month follow-up
- ~35–40 investigative sites (mix of academic and independent sites)
- Primary endpoint
 - Proportion of subjects completely staining free at Week 8 in the KPI-012 treatment group vs. vehicle group with no staining at the site of the original lesion at Week 10 and no persistent staining elsewhere in the cornea at Week 10
 - Based on central-reader assessment of photographs of corneal fluorescein staining
- Top line data readout targeted by year end 2024



First KPI-012 Follow-on Indication Under Evaluation: Limbal Stem Cell Deficiency (LSCD)

- LSCD is a loss or deficiency of limbal epithelial stem cells, which play an essential role in maintaining the integrity of the ocular surface
- Sequalae include recurrent epithelial breakdown/keratopathy, conjunctival overgrowth, neovascularization, chronic inflammation and corneal scarring
- Can lead to loss of corneal clarity and vision impairment
- Also associated with significant symptomology
- There is a significant unmet need in LSCD
 - Currently, there are few treatment options and no pharmacological treatments
- ~100,000 patients in the US have LSCD





KPI-012 Validated Manufacturing Process

Thaw and Seed Working Cell Bank Vial

Bioreactor Production



Harvest Secretome



Processing



Drug Substance



Final Drug Product

- Formulation/Fill
- Blow-fill-seal unit dose



Process Control Analytics

KPI-012 manufacturing process is robust and scalable

- Drug Substance currently manufactured at scale to support pivotal clinical studies and early commercialization
- Final Drug Product currently manufactured using industry-standard unit dose blow-fillseal formulation and filling process

Final Drug Product released based on product potency, consistency and stability methods consistent with FDA Pre-IND meeting feedback, including protein Critical Quality Attributes (CQAs) and a cell-based potency assay

- Validated assays developed for protein CQAs
- Multiple engineering batches assaying CQAs and additional KPI-012 constituents support robust and consistent manufacturing process





KPI-014: Pre-Clinical MSC-S for Rare Inherited Retinal Disease

- There is a significant need for novel therapies for slowing of disease progression in inherited retinal diseases, including Retinitis Pigmentosa and Stargardt Disease
- Over 75% of clinical pipeline assets for Retinitis Pigmentosa are gene-specific therapies, which greatly limits trial eligibility
- Secretomes have demonstrated a neuroprotective effect in both in vitro and in vivo models of retinal degeneration
- KPI-014 contains neurotrophic factors, growth factors, anti-inflammatory/immune-modulatory factors and antioxidant inhibitors with the potential to protect and preserve retinal cell function

KPI-014 is a Promising Gene-agnostic Approach for the Treatment of Inherited Retinal Diseases





Patent and Regulatory Exclusivity

- Regulatory Exclusivity in the U.S.
 - If approved as a new biologic product under a BLA, KPI-012 should enjoy 12 years market exclusivity during which biosimilars cannot be launched
 - 7-year orphan exclusivity on the treatment of PCED
- Patent Exclusivity
 - A worldwide patent portfolio related to MSC-S and its use for the treatment of an ocular condition, such as PCED and other ocular surface diseases, has a 20-year patent term ending in 2040
 - If approval occurs after 2026, a patent term extension* may be available in the U.S., which can extend the term beyond 2040
- KPI-012 received Fast Track designation

Potential U.S. Regulatory Exclusivity and IP Protection Beyond 2040



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