



# Slowing the Progression of Macular Degeneration

Mission for Vision

Tom Lin, CEO  
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# Offering Summary

<b>Issuer</b>	<b>Belite Bio, Inc</b>
<b>Headquarters</b>	San Diego, California USA
<b>Transaction Type</b>	Initial Public Offering of American Depositary Shares (“ADS”)
<b>Exchange/Ticker</b>	Nasdaq Capital Market / BLTE
<b>ADSs Offered</b>	6,000,000 (100% Primary)
<b>Price Range</b>	\$5.50-\$6.50
<b>Offering Size</b>	\$36.0 million
<b>Overallotment Option</b>	900,000 (100% Primary)
<b>Insider Purchases</b>	Lin Bioscience International Ltd., our principal shareholder, has indicated an interest to purchase up to \$15.0 million of ADSs in this offering
<b>Post Offering Fully Diluted Shares Outstanding</b>	24,095,317 or 24,995,317 (with overallotment)
<b>Use of Proceeds</b>	68.2% dry AMD clinical trials, 29.3% general corporate purposes, and 2.5% STGD1 clinical trials
<b>Lead Book-Runner</b>	The Benchmark Company

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# Key Investment Highlights

- Targeting an unmet market for macular degeneration;
  - Significant support from our controlling shareholder Lin BioScience International Ltd.
    - Indicated an interest for up to US\$15.0 million of the offering;
    - Wholly-owned subsidiary of Lin BioScience, Inc., which is publicly traded on Taiwan exchange (stock code: 6696.TW) with an approximately US\$600 million market capitalization;
  - Potentially de-risked lead asset as a result of significant clinical development work
-

# Leadership

## Management



**Tom Lin, MMED, PhD, MBA**  
(Chairman, CEO)

- 10 years of executive management role in biotech, including 2 IPO
- Over 10 new drug developments in multiple therapeutic areas, including Ophthalmology, CNS, Cardiovascular, Oncology, Immuno-Oncology, Immunotherapies, Immunosuppressants
- University of Sydney, University of Melbourne, Harvard Medical School, Columbia University, London Business School, HK University



**Nathan Mata, PhD**  
(CSO)

- 15+ years of ophthalmic drug development experience across numerous indications including 2 NDAs for topical therapeutics (Durezol® and Zirgan®)
- Led the clinical development efforts for first RBP antagonist in advanced dry AMD and first visual cycle modulator in advanced dry AMD and STGD
- Introduced the industry's first Stargardt's ABCA4 knockout mice model
- University of Texas



**Jane Chiu, MS**  
(VP, Clinical Operations)

- 25 years clinical operations experience in multiple therapeutical area
- 15+ years as President/Managing Director of multinational CRO, conducting over 100 studies
- 10+ years of clinical operations experience in global pharma (Astellas, Bayer, Pfizer)
- Warwick University



**H.Y. Chuan**

- 11 years of capital raised, closed more than 10 transactions
- Wanda, Suning, etc.
- Columbia University, HK University

# Belite Bio Opportunity

Oral treatment for  
an unmet market

- **Belite Bio's lead asset LBS-008** is a novel, **orally administered, Retinol Binding Protein ("RBP4") antagonist** intended to slow or halt progression of vision loss in Stargardt disease (STGD1) and dry AMD. A Phase 3 trial has been initiated in adolescent STGD1 patients. Phase 2/3 trial in dry AMD is planned in 2022.
- **Granted Rare Pediatric Disease** in US / **Orphan Drug Disease** designation in US and I
- **Priority Review Voucher (PRV)** eligible, vouchers have sold for \$80M-\$125M.
- Currently **no approved treatments** for either STGD1 or dry AMD, significant market opportunity to become **Standard of Care**.

Potentially  
de-risked  
development

- Ongoing **2-year Phase 2 trial (6 months** of reported **interim** safety data and preliminary data) in STGD1. Goal is to halt or slow disease progression in early-onset patients.
  - **Established human proof-of-concept data** from a 2-year, Phase 2 trial of (a retinoid-based RBP4 antagonist) **in advanced dry AMD**.
  - Clinical development approach **endorsed by US NIH**, specifically **to treat dry AMD**.
  - **UK NIHR's** 2018 systematic review of >7,000 publications recommends RBP4 antagonist **priority for clinical development to treat both STGD1 and dry AMD**.
  - Highly **experienced senior management team** supported by **world-renowned advisors** and **influential key opinion leaders** with decades of clinical development experience.
-



# Board of Directors

## Board



**Tom Lin, MMED, PhD, MBA**  
(Chairman, CEO)



**John M. Longo, PhD**  
(Independent Director)

- Prof. of Rutgers Business School
- Chief Investment officer of Beacon Trust



**Gary C. Biddle, PhD, CPA**  
(Independent Director)

- Prof. of University of Melbourne
- INED of Kingdee Software, Shui On Land Limited, Real Pet Food Company.



**Ita Lu**  
(Independent Director)

- Managing partner of Taiwan Capital



**H.Y. Chuang, CFA, MBA, FRM**  
(CFO)



**Yvonne Chen**  
(Affiliated Director)

- COO of Lin Bio, our ultimate controlling shareholder



**Serena Chen**  
(Affiliated Director)

- Associate finance director of Lin Bio, our ultimate controlling shareholder

## Clinical Advisory Board



**Dr. Frank Holz**

- Chairman of Ophthalmology, University of Bonn



**Dr. Michel Michaelides**

- Ophthalmologist at Moorfields Eye Hospital
- Prof. of Ophthalmology, Univ. College London



**Dr. Hendrik P.N. Scholl**

- Prof. and Chairman of the Dept. of Ophthalmology, Univ. of Basel
- Co-Director of the Institute of Molecular and Clinical Ophthalmology in Basel

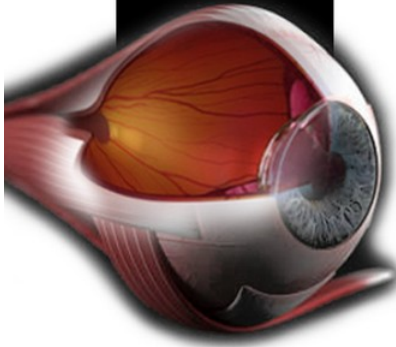


**Dr. Robyn Guymer**

- Prof. of Ophthalmology, University of Melbourne
- Deputy Director of the Centre for Eye Research Australia

LBS  
008

- DISCOVERY
- PRE-CLINICAL
- PHASE I
- PHASE II
- **PHASE III**
- MARKET



# BRING LIGHT TO INCURABLE BLINDNESS

For Dry Age-Related Macular Degeneration & Stargardt Disease

## KEY OPPORTUNITY

# Zero Approved Treatments

**FDA RPD, ODD**  
designations for Stargardt (US & EU)



## NIH Blueprint

“a promising first-in-class oral medication intended to slow or halt the progression of dry AMD”

Reference:  
<https://www.ninds.nih.gov/About-NINDS/Impact/Translational-Research-Success-Stories>

## Dry AMD MARKET

# 11M

dry AMD patients in the US (90% AMD are dry AMD)

# \$255B

estimated global direct healthcare cost of dry AMD

Reference: Globaldata, Lancet, Orphanet, STEM CELLS Translational

## STGD1 MARKET

# 1 in 10

inherited juvenile macular degeneration

# 30,000

STGD1 patients





# Clear Clinical Development Pathway

Reduction in Lesion Growth Rate as Measured by Retinal Imaging is an FDA Accepted Endpoint in STGD1 and dry AMD

### completed

Phase 1

- Completed, double-blind
- US SAD + AU SAD/MAD: 111 healthy adults
- Well tolerated and reduced mean RBP4 by ≥70% from baseline

### ongoing

Phase 1b/2 Adolescent STGD

- Open-label, Phase 1b completed, Phase 2 ongoing
- AU/TW Ph1b: 11 subjects completed
- AU/TW Ph2 (2-yr): 13 subjects
- Achieved a mean RBP4 reduction of > 70% without severe adverse events

Phase 3 Adolescent STGD

- Initiated, double-blind
- Global study (2-yr): 60 subjects
- Primary end point: change in lesion growth rate by retinal imaging

Phase 2/3 Dry AMD

- Expect to start in **2022**, randomized, double-blind
- Intermediate to advanced stage dry AMD
- Global study
- To evaluate the safety and efficacy

### planned

STGD NDA PRV

- PRV sale (in the last 3 years, price range \$80-125 million)

Phase 4

- In-lic pate
- Com patei expir withc exteri

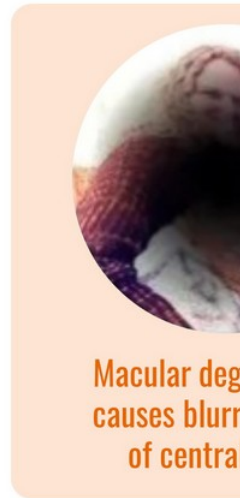
# Overview of Stargardt Disease & Dry AMD

## Stargardt Disease (STGD1)

- The **most common inherited retinal dystrophy** (blurring or loss of central vision) in both adults and children
- Caused by a **dysfunctional retina-specific gene (ABCA4)** which causes massive accumulation of toxic vitamin A byproducts ('bisretinoids') in the retina leading to retinal cell death and progressive loss of central vision
- Fluorescent properties of bisretinoids and the development of **retinal imaging** help ophthalmologists identify and monitor disease progression

## Dry AMD

- Shares a **similar pathophysiology with STGD1** and is a leading cause of central vision loss in people over 50



**A cytotoxic compound known as A2E is the most abundant bisretinoid identified in the retina of patients with STGD1 and Dry AMD; A2E has been shown to kill retinal tissue.**

Reference:

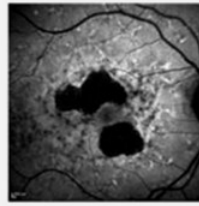
[www.rarediseases.info.nih.gov/diseases/181/stargardt-disease](http://www.rarediseases.info.nih.gov/diseases/181/stargardt-disease)

[www.ncbi.nlm.nih.gov/pmc/articles/PMC2848448/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2848448/)

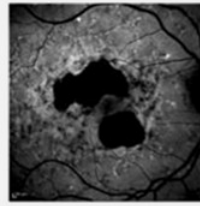
# Similar Pathophysiology in STGD1 & Dry AMD

- **STGD1 and dry AMD share a similar pathophysiology** characterized by excessive accumulation of cytotoxic bisretinoids, retinal cell death, and loss of vision
- **Vision loss occurs slowly**, despite peripheral expansion of 'dead retina', until the disease reaches the center of the eye (the macula)
- **Slowing the spread of 'dead retina'** is the intended **effect of LBS-008 treatment**

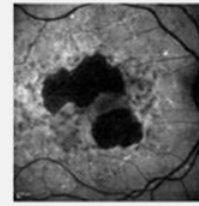
## STGD1: LATE-ONSET (61-YEAR OLD FEMALE)



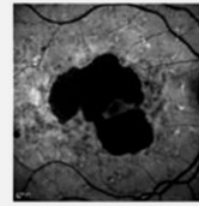
Baseline:  
0.1 LogMAR



+12 Months:  
0.1 LogMAR

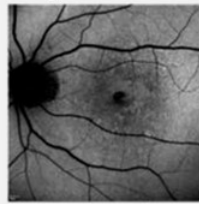


+24 Months:  
0.0 LogMAR

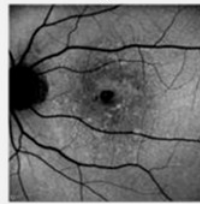


+36 Months:  
0.1 LogMAR

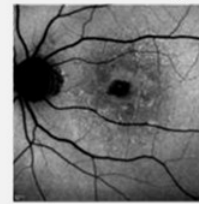
## Dry AMD: ADVANCED (73-YEAR OLD FEMALE)



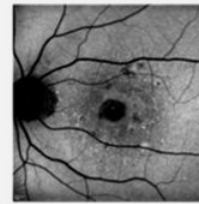
BL:  
0.2 LogMAR



+12 Mo:  
0.2 LogMAR



+ 24 Mo:  
0.3 LogMAR



+ 36 Mo:  
0.4 LogMAR

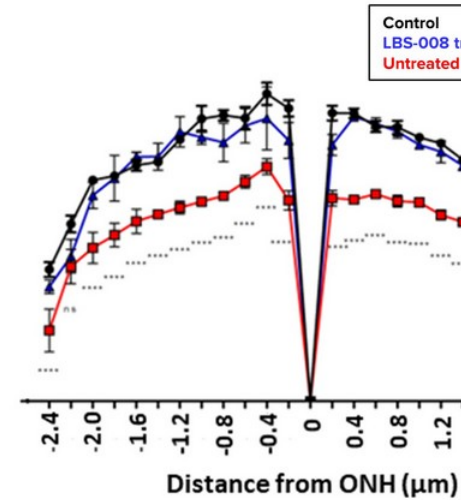
# Proof of Concept in a STGD1 Mouse Model: Preservation of the Retina

## Data Summary

- Like STGD1 patients, STGD1 mice harbor a mutated ABCA4 gene and protein and show pronounced accumulation of bisretinoids and retinal degeneration (reduced thickness of the retina, **red symbols**)
- Daily oral administration of LBS-008 prevents degeneration of the retina (**blue symbols**)
- Biochemical data show a statistically significant reduction in A2E levels (not shown)

## Beneficial Features of LBS-008

- Orally administered
- Non-retinoid
- Preserves retinal tissue in STGD1 model
- Reduces levels of toxic bisretinoids that have been implicated in progression of STGD1 and advanced dry AMD
- Effects reversible upon drug cessation



Abbreviations: ONH, optic nerve head (retina); ONL, outer nuclear layer (photoreceptor layer)

# De-risked Development Pathway: Proof-of-Concept from Phase 2 Fenretinide Study in Advanced Dry AMD

- **Fenretinide is a synthetic derivative of vitamin A (retinol). Fenretinide is able to compete with retinol for binding to RBP4 and reduce delivery of retinol to the retina.**
- Fenretinide was used in a **2-year, Phase 2, Proof-of-Concept trial** to determine whether reduction of circulating RBP4-retinol would be effective in the treatment of advanced dry AMD (Geographic Atrophy).
- **Results:** patients who achieved a **≥ 70% reduction of RBP4 from baseline**, showed statistically significant slowing of lesion growth.

**LBS-008 overcomes the limited bioavailability and lower potency of fenretinide.**

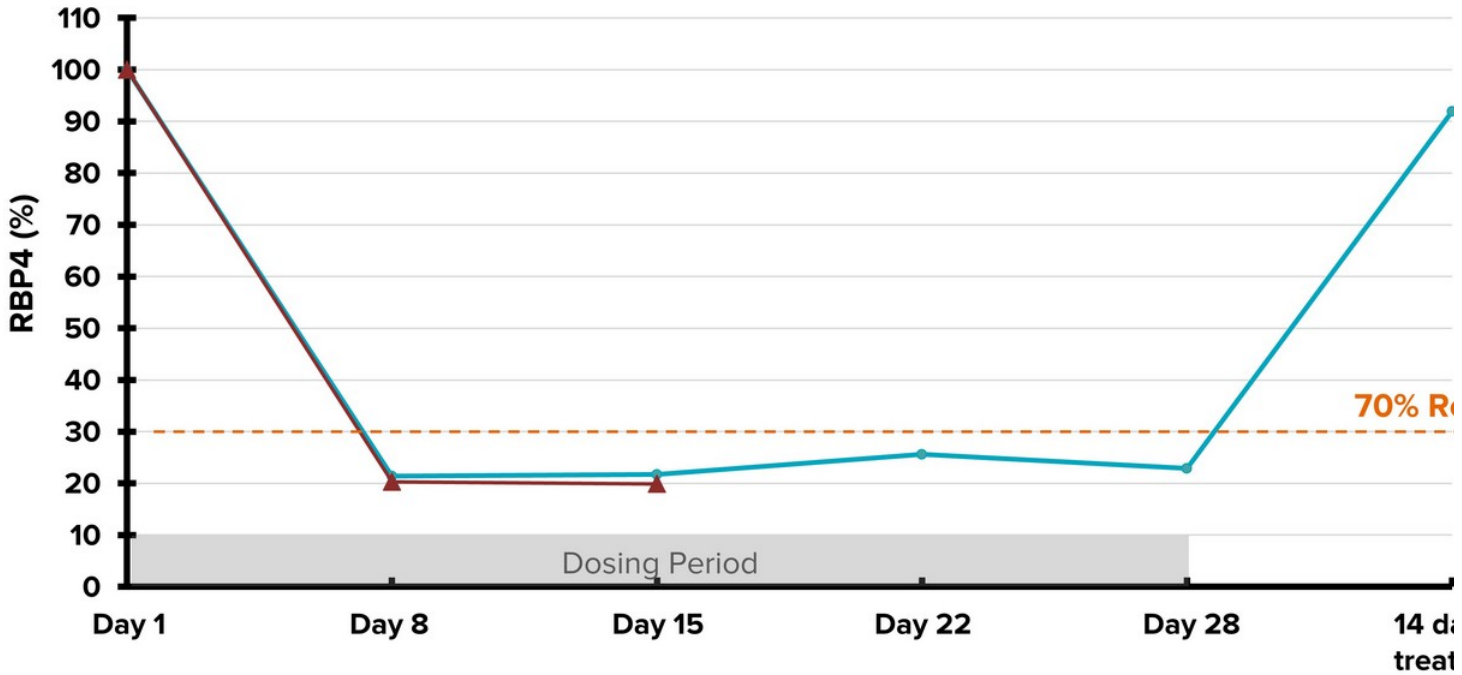




# Clinical Data



# Phase 1b Daily Dosing in Adolescent STGD1: Mean change of RBP4 (%)



Note: After Day 15, data were collected from 6 subjects in Australian sites only as data could not be collected due to COVID-19 restrictions at the NTUH site in Taiwan. Mean change of RBP4 (%) for 11 patients for the Day 1 to 15 is presented as the 11-Patients line, and data for the 6 patients in Australian sites for the whole Phase 1b portion is presented as the 6-Patients line.



# Phase 1b: Summary of Related Adverse Events

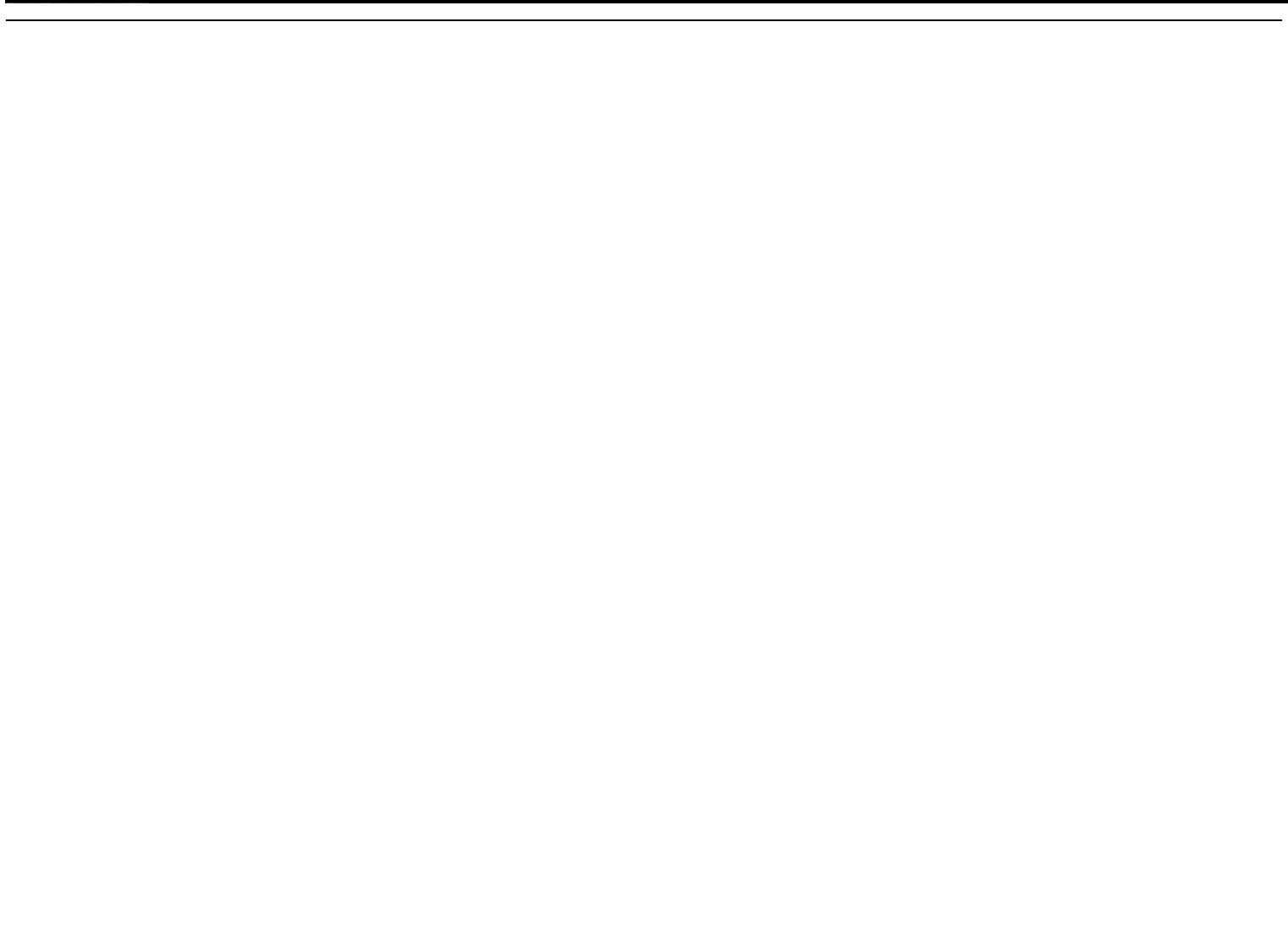
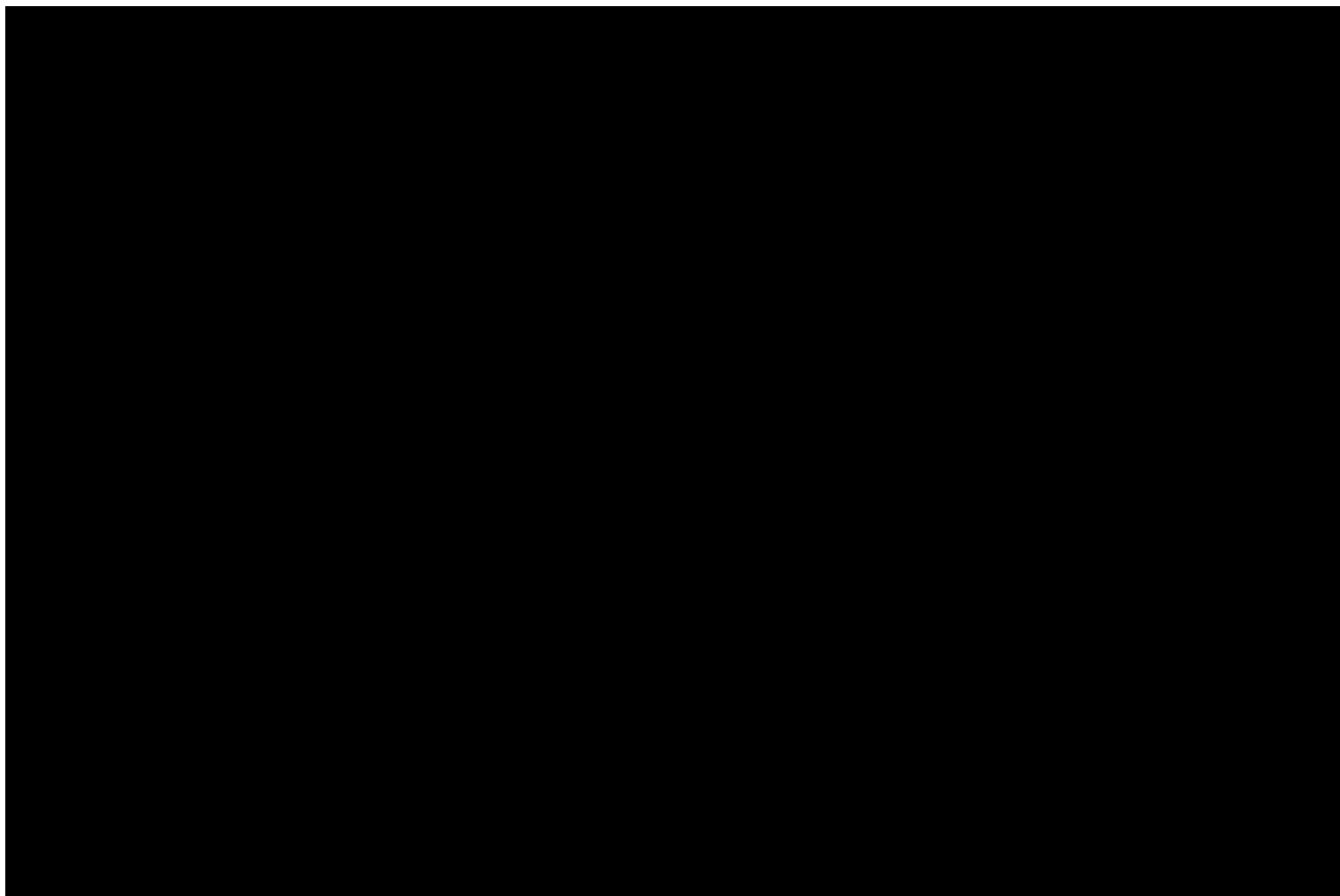
Adverse Events	Severity	Relationship to Drug	Frequency (#patients)	% Recovered
Xanthopsia	Mild	Definitely Related	7/11	7/7 (100%)
Delayed Dark Adaptation (DDA)	Mild	Definitely Related	7/11	7/7 (100%)
Night Vision Impairment	Mild	Definitely Related	1/11	7/7 (100%)

- All instances of DDA and Xanthopsia were **mild** and **transient**
  - These **AEs were anticipated** based on the mechanism of LBS-008 action
  - Subjects shown to have DDA based on laboratory measure were mostly **asymptomatic**
  - **No severe** AEs or SAEs reported and no AEs requiring discontinuation of treatment and all AEs were resolved
  - **No clinically significant** findings in relation to vital signs, physical exams or electrocardiograms
-

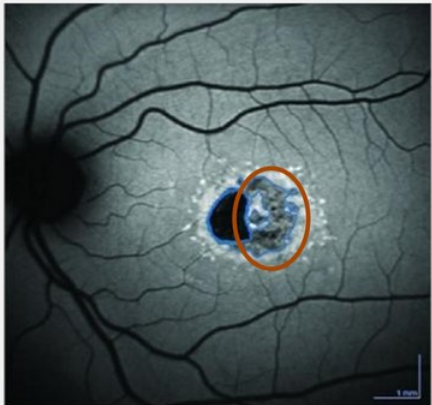
# Interim Phase 2 Results: Summary of Related Adverse Events

Adverse Events	Severity	Relationship to Drug	Frequency (#patients)	% Recovered
Xanthopsia	Mild	Definitely Related	6/13	3/6 (50%)
Delayed Dark Adaptation	Mild	Definitely Related	8/13	1/8 (12.5%)
Night Vision Impairment	Mild	Definitely Related	1/13	0/1
Increasing error score on FM100	Mild	Probably Related	1/13	0/1

- All instances of DDA and Xanthopsia were **mild** and **transient**
  - Subjects shown to have DDA based on laboratory measure were mostly **asymptomatic**
  - One subject recorded to have an increasing error score on FM100 test (tests color vision and color perception) showed only
  - **No severe AEs or SAEs** reported and no AEs requiring discontinuation of treatment
  - **No clinically significant** findings in relation to vital signs, physical exams or electrocardiograms
-



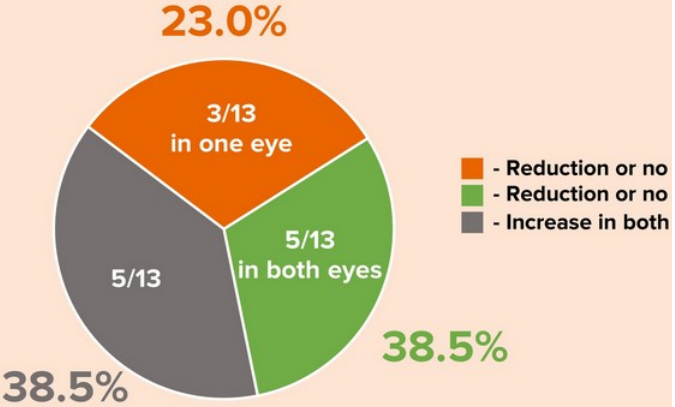
# Interim Phase 2 Data: Change in QDAF in Adolescent STGD1 Subjects



Areas of QDAF progressively evolve into 'dead retina'.

**8 of 13 STGD1 patients showed a reduction or no change in QDAF**

## Distribution of Change in QDAF

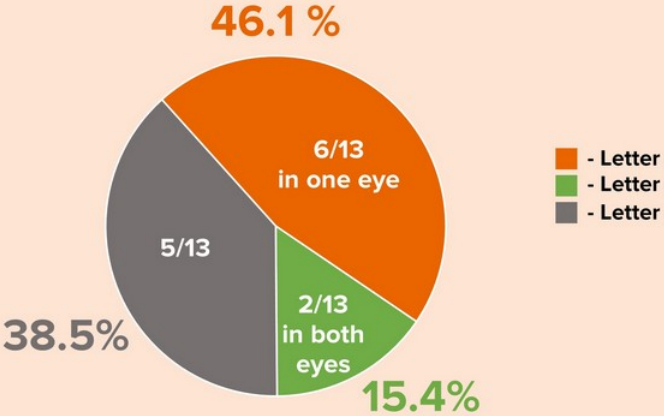


# Interim Phase 2 Results: Change of Vision in Adolescent STGD1 Subjects



Best-Corrected Visual Acuity (BCVA) Test Provides letter score for each eye

## Change in BCVA BCVA gain in 8 of 13 Subjects (61.5%)





# Capital Structure and Use of Proceeds

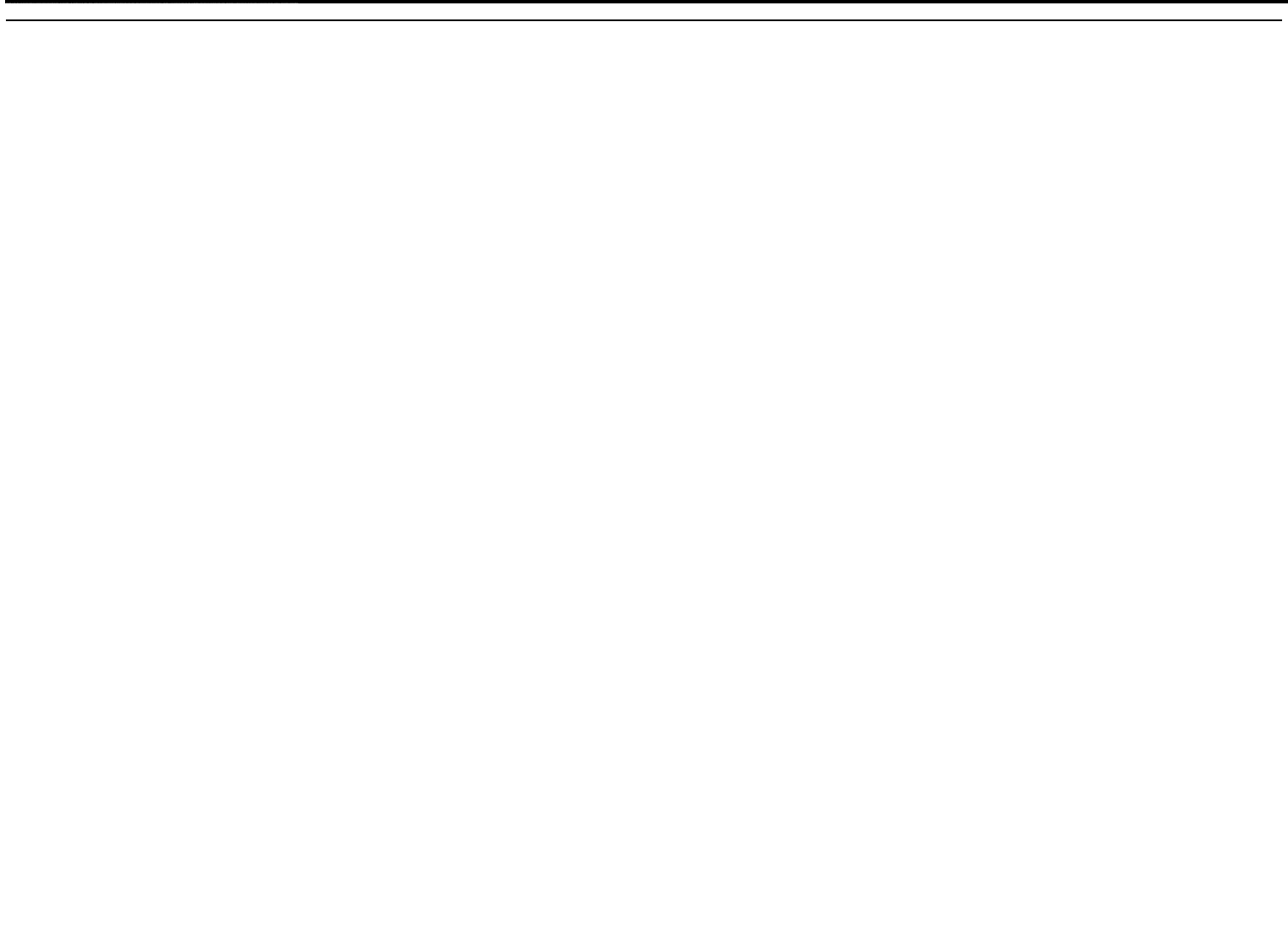
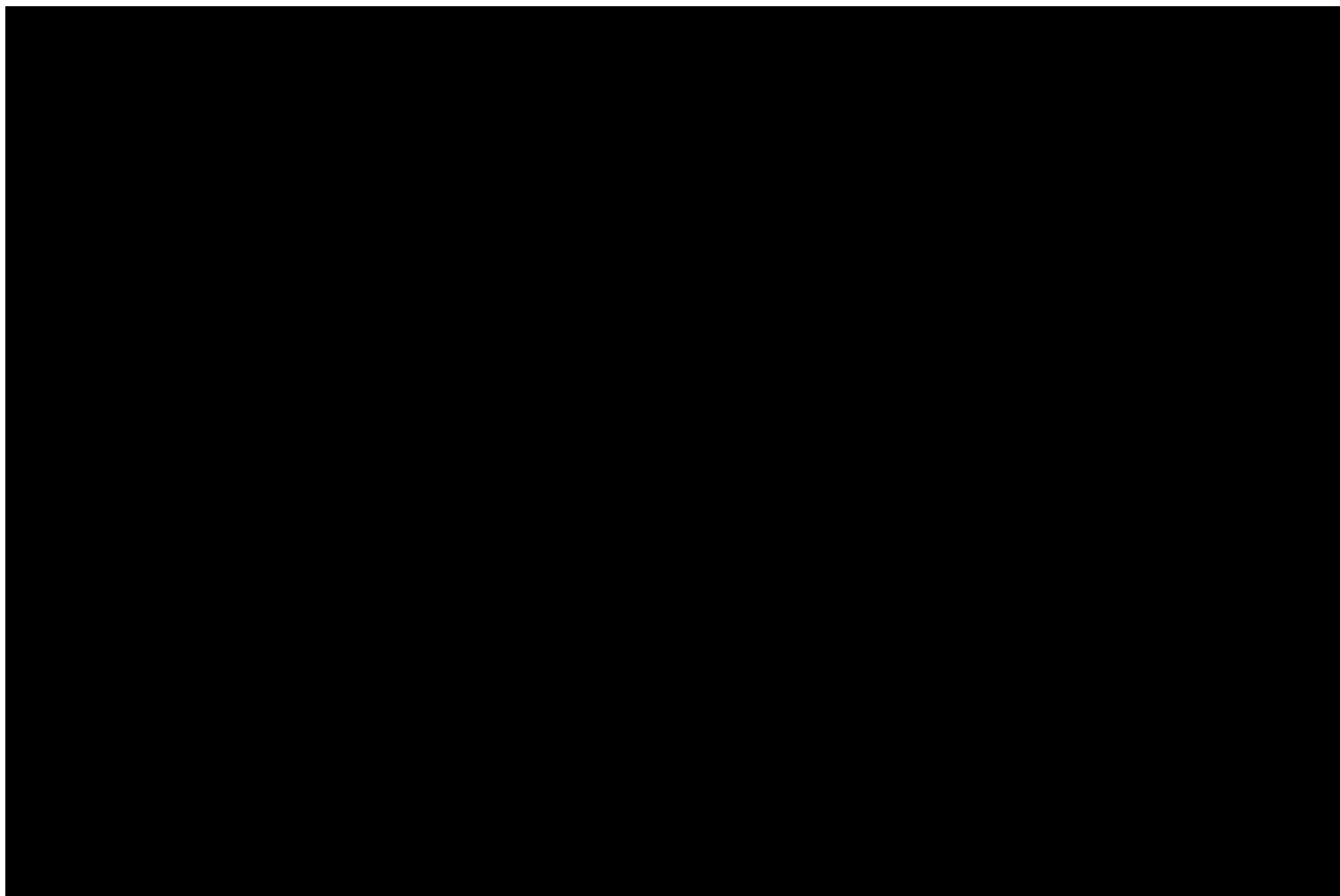
	Shares*	%
<b>Lin Bioscience International Ltd.**</b>	16,428,597	<b>59.0%</b>
<b>Management Team</b>	5,165,310	<b>18.6%</b>
<b>Pre-Offering Investors</b>	2,732,638	<b>9.8%</b>
<b>Other Investors in the Offering</b>	3,500,000	<b>12.6%</b>
<b>Totals***</b>	27,826,545	<b>100.00%</b>

Primary Purpose	Estimated Amount (in USD millions)
Dry AMD clinical trials	\$
General corporate purposes	:
STGD1 clinical trials	:
<b>Totals</b>	<b>\$</b>

\*Each ADS represents 1 Ordinary Share. Shares represents the sum of total number of ordinary shares owned by each group after the completion of this offering and the outstanding options granted under the Company's existing ESOP plans.

\*\*Including its \$15mn subscription in the IPO.

\*\*\*Represents the sum of 1) 18,095,317 ordinary shares outstanding immediately prior to the offering; 2) 6,000,000 ADSs outstanding immediately after this offering and 3) 3,731,228 shares to be issued upon exercise of outstanding options.





# Thank you

Tom Lin, CEO  
**Email** / [tomlin@belitebio.com](mailto:tomlin@belitebio.com)

For more info please visit



# Appendix

# Disease Progression in STGD1

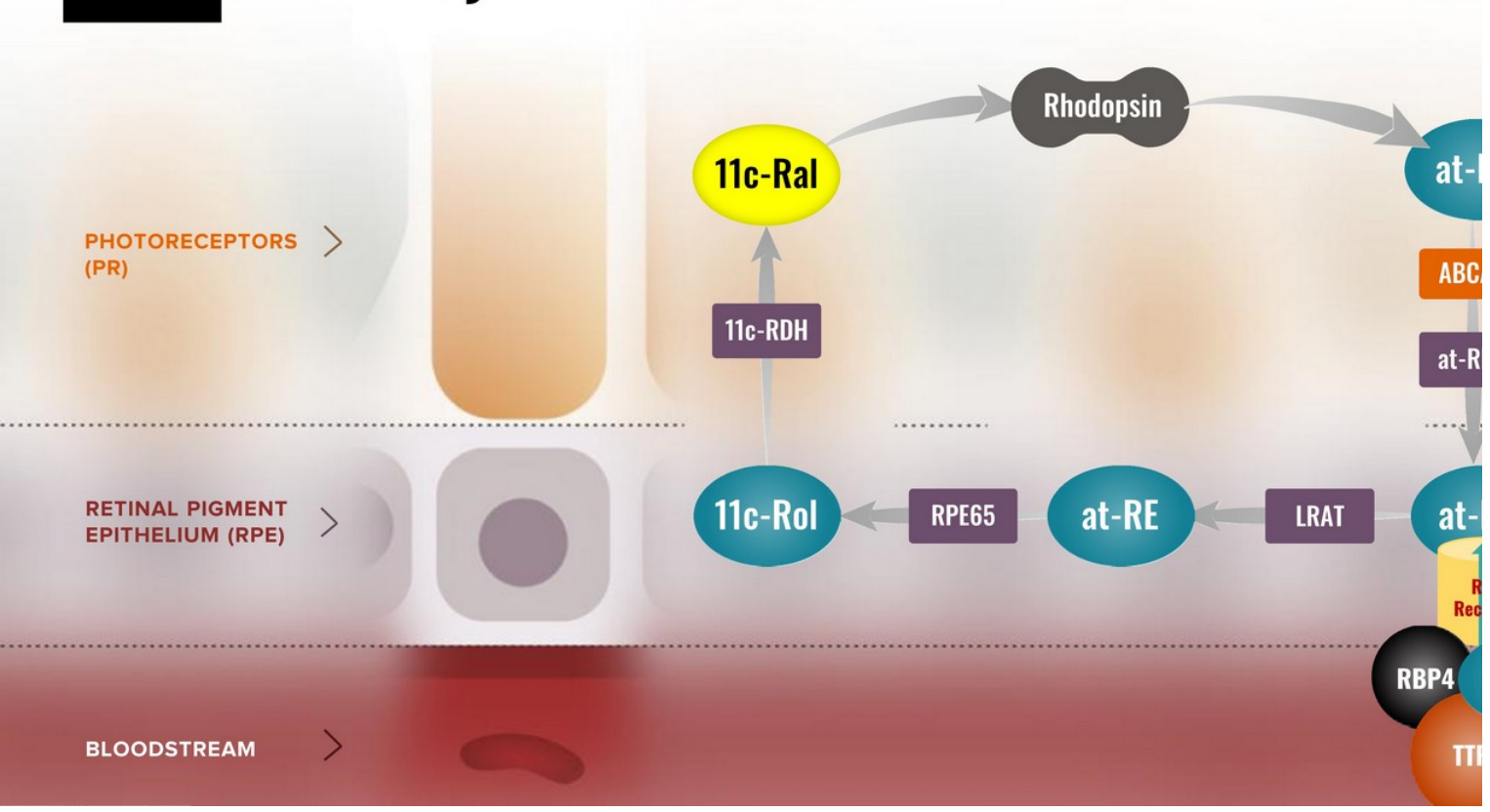
## ProgStar Case Study: Retinal Imaging at First Observation and 22 months later

- A2E and related bisretinoids exhibit a characteristic autofluorescence under retinal imaging allowing the disease to be detected and monitored.



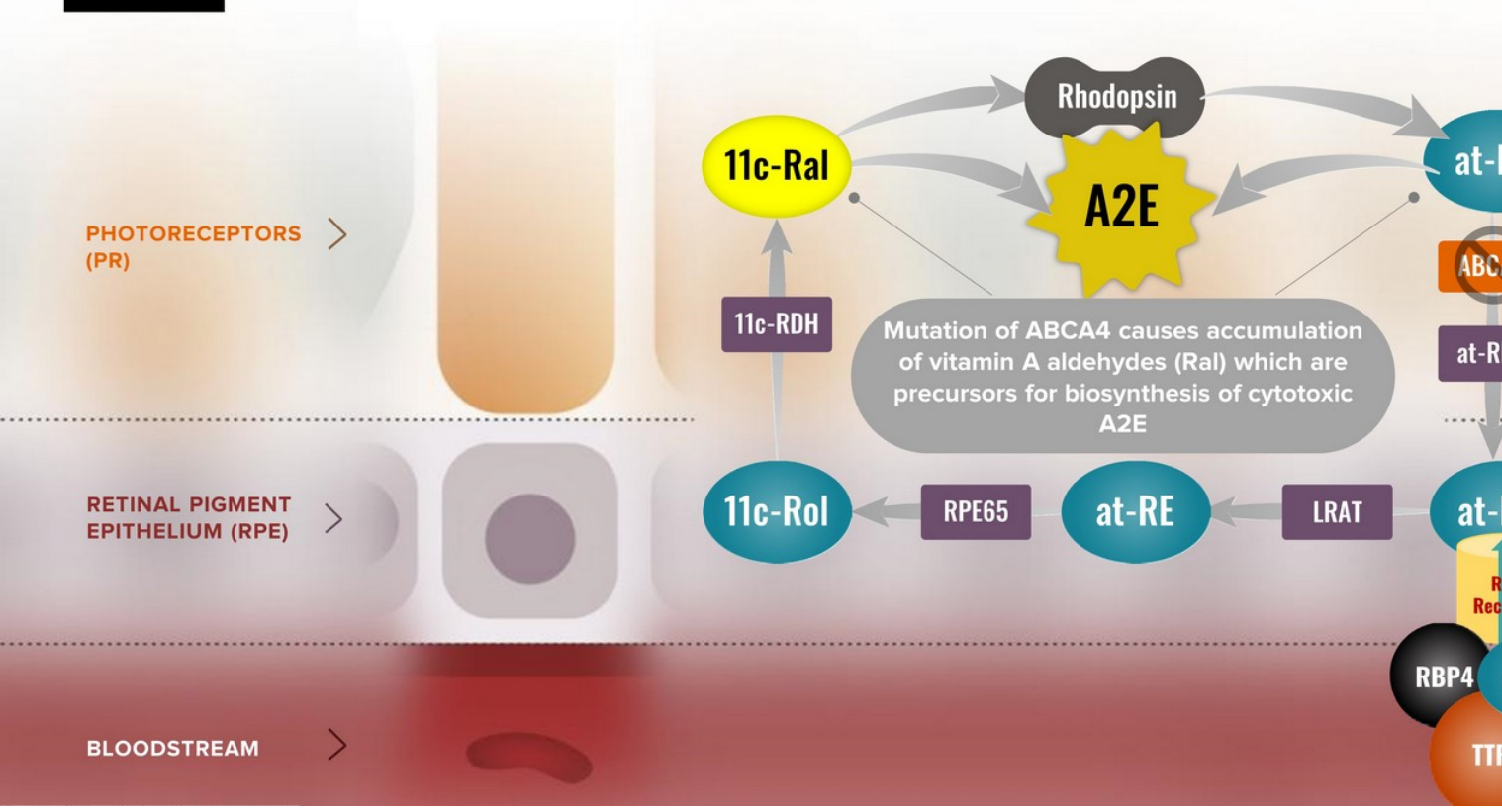
- **First Observation (left):** Black gray (QDAF) areas show dead retinal tissue due to increased accumulation of A2E and related bisretinoids.
- **Observation at 22 months (right):** Dead retinal tissue (DDAF) expands in areas which were previously healthy retinal tissue (QDAF).

# Normal Processing of Vitamin A in the Visual Cycle



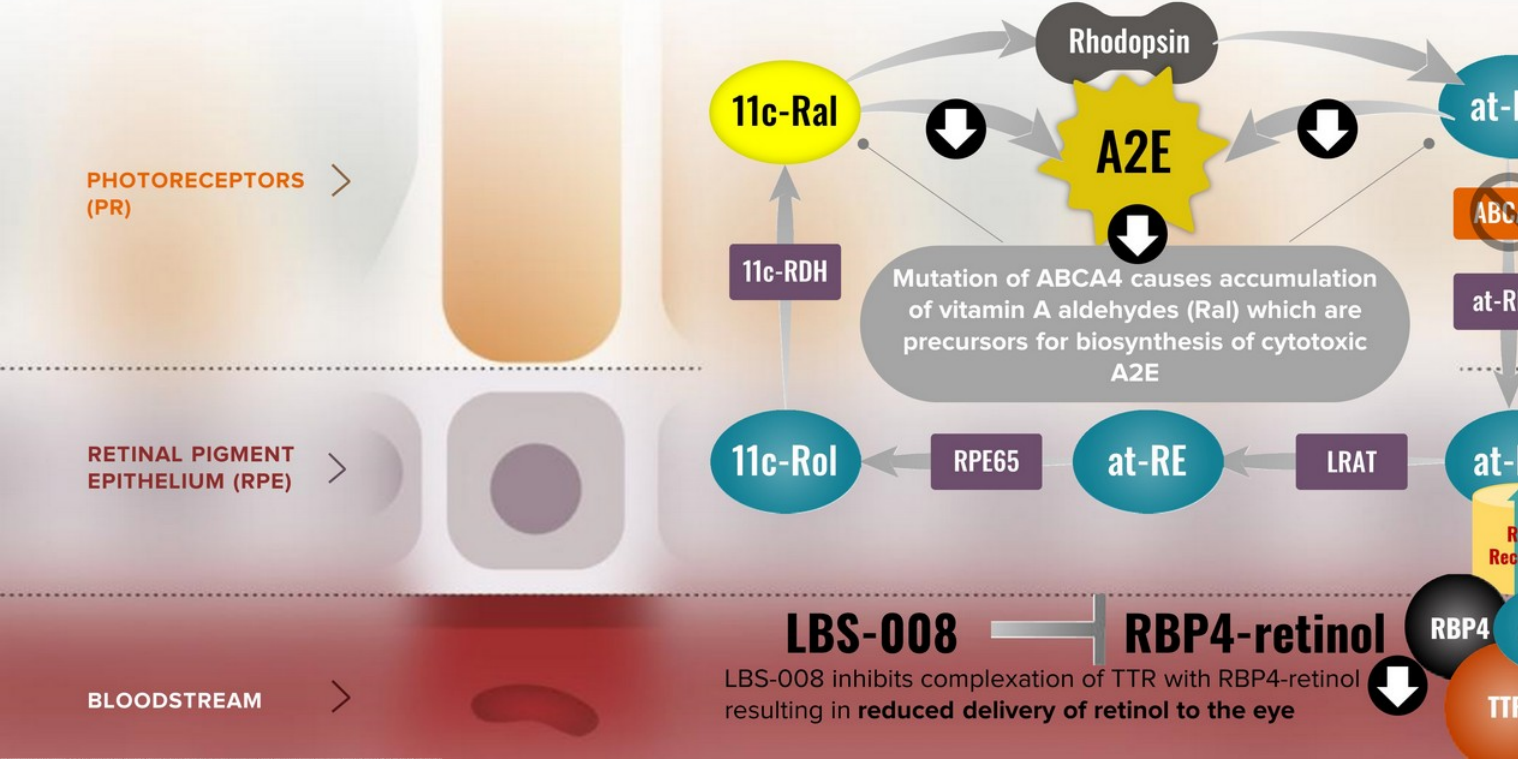


# Toxic Vitamin A Byproducts Accumulate in Patients with STGD1



# LBS-008 Mechanism of Action

Because bisretinoids are derived from vitamin A (retinol), reducing the delivery of retinol to the eye is expected to reduce bisretinoid levels in the eye leading to preservation of the retina.

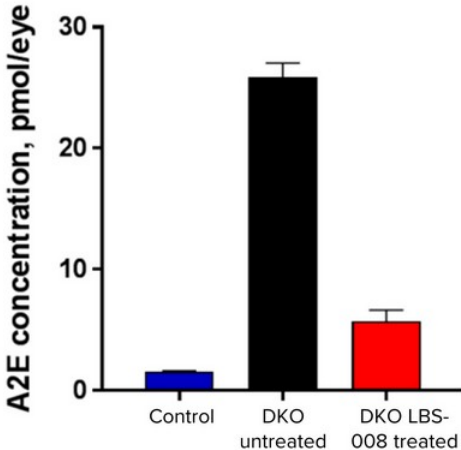
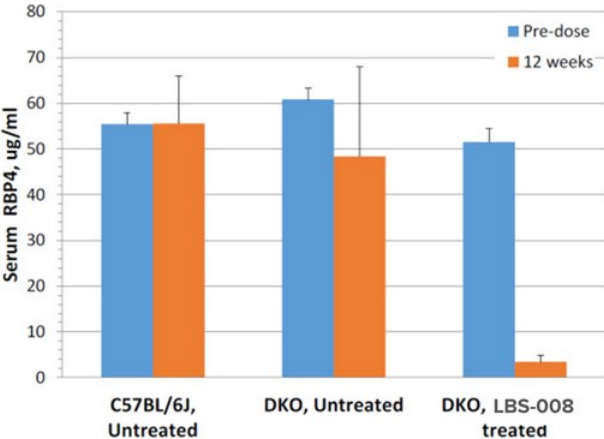




# RBP4 Reduction Reduces A2E Accumulation by 80%

## Effect of LBS-008 on biomarkers in a STGD1 mouse model (ABCA4<sup>-/-</sup>/RDH8<sup>-/-</sup>)

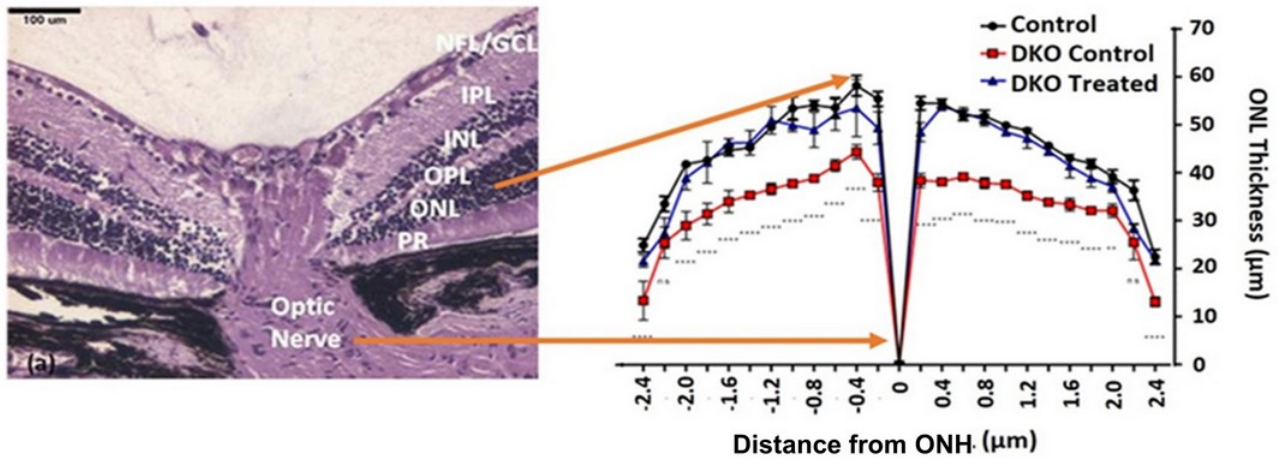
- Daily dosing at approx. 25mg/kg of LBS-008 for 12 weeks.
- A mean RBP4 reduction of ~90% in LBS-008 treated mice led to an ~80% reduction in A2E compared to untreated ABCA4<sup>-/-</sup> double knockout (DKO) mice.



# RBP4 Reduction Preserves Photoreceptor Cells

## Effect of LBS-008 on retinal pathology in a STGD1 mouse model ( $ABCA4^{-/-}/RDH8^{-/-}$ )

- **Outer Nuclear Layer (ONL)** thickness was significantly decreased in untreated  $ABCA4^{-/-}/RDH8^{-/-}$  mice, compared to mice treated with LBS-008
- Macular degeneration in dry AMD and STGD1 is associated with thinning of the ONL which indicates loss of photoreceptors



# Phase 1 Daily Dosing in Healthy Adults: Mean change of RBP4 (exclude PBO)

