Belite BIO

First Half 2022 Financial Results Conference Call

August 11, 2022
Nasdaq: BLTE

Forward-Looking Statements

This presentation contains forward-looking statements, including statements regarding the potential implications of clinical data for patients, and Belite Bio's advancement of, and anticipated preclinical activities, clinical development, regulatory milestones, and commercialization of its product candidates. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including but not limited to Belite Bio's ability to demonstrate the safety and efficacy of its drug candidates; the clinical results for its drug candidates, which may not support further development or regulatory approval; the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of Belite Bio's drug candidates; Belite Bio's ability to achieve commercial success for its drug candidates, if approved; Belite Bio's ability to obtain and maintain protection of intellectual property for its technology and drugs; Belite Bio's reliance on third parties to conduct drug development, manufacturing and other services; Belite Bio's limited operating history and Belite Bio's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; Belite Bio's ability to enter into additional collaboration agreements beyond its existing strategic partnerships or collaborations, and the impact of the COVID-19 pandemic on Belite Bio's clinical development, commercial and other operations, as well as those risks more fully discussed in the “Risk Factors” section in Belite Bio's filings with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Belite Bio, and Belite Bio undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

Belite Participants

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

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

- 11 years of capital market experience, closed more than US$32 billion transactions
- Wanda, Suning, CITIC Securities
- Columbia University, London Business School, HK University

Business Highlights

Oral treatment for an unmet market

- **Belite Bio's lead asset LBS-008** is a novel**, orally administered, Retinol Binding Protein 4 ("RBP4") antagonist** intended to slow or halt progression of vision loss in Stargardt disease (STGD1) and dry AMD.
- Currently **no approved treatments** for either STGD1 or dry AMD, significant market opportunity to become **Standard of Care**.
- Clinical development approach **endorsed by US NIH**, specifically **to treat dry AMD**.
- **UK NIHR's** 2018 systematic review of >7,000 publications recommends RBP4 antagonists as a **priority for clinical development to treat both STGD1 and dry AMD**.
- Dry AMD afflict **11 million patients** in the US and **196 million patients** worldwide.
- Without treatment, the continual increase in the size of the elderly population will worsen the impact of this disease.
- STGD1 is an orphan disease affecting approx. 1 in 10,000 children and adults.
- Granted **Fast Track Designation, Rare Pediatric Disease** in US / **Orphan Drug Disease** designation in US and EU for STGD1.
- **Priority Review Voucher (PRV)** eligible, vouchers have sold for $80M-$125M.

Clinical Development Milestones

Development Milestones

- **Phase 1 trial** in 111 healthy adults in US SAD and Australia SAD & MAD completed.
- A **2-year open label Phase 2 trial** (6 months of interim safety data and preliminary efficacy data available) in 13 adolescent STGD1 patients is ongoing. 12 months of treatment interim data expected in October, 2022.
- A **2-year double-blind Phase 3 (the "DRAGON") trial** has commenced in the US, UK, Germany, Belgium, Switzerland, Hong Kong, Taiwan, and Australia. Several patients have been enrolled. Expect to apply for enrollment in more jurisdictions and enroll at least 60 adolescent STGD1 patients globally.
- A **2-year Phase 2/3 trial in dry AMD** planned in Q4, 2022.

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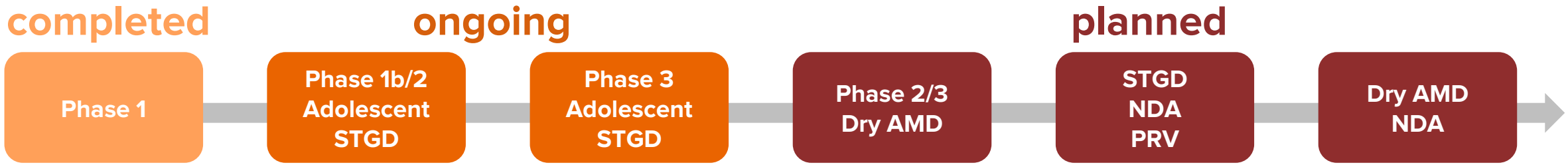
Clear Clinical Development Pathway

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



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

- 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**

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

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

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

- In-licensed **9 active patent families**
- Composition of matter patents expected to expire **2034-2035** without patent term extension

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Clinical Trial Design for STGD1

	STDG1 phase 2	STGD1 phase 3 ("Dragon")
Enrollment	13 participants	60 participants
Sites	Aus & TW	Global
Masking	Open Label	Double Blind
Placebo	N/A	2:1 ratio (LBS-008 : Placebo)
Duration	2 years	2 years
Primary measures	Safety & Tolerability, optimal dose	Safety & Tolerability, Efficacy (Lesion size growth, DDAF)
Other measures	Lesion size (DDAF), QDAF, BCVA, SD-OCT, microperimetry	QDAF, BCVA, SD-OCT, microperimetry

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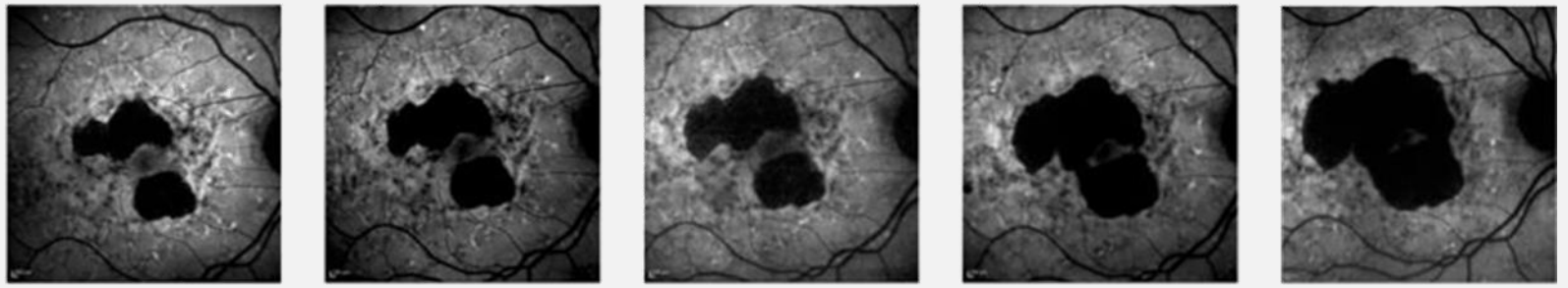
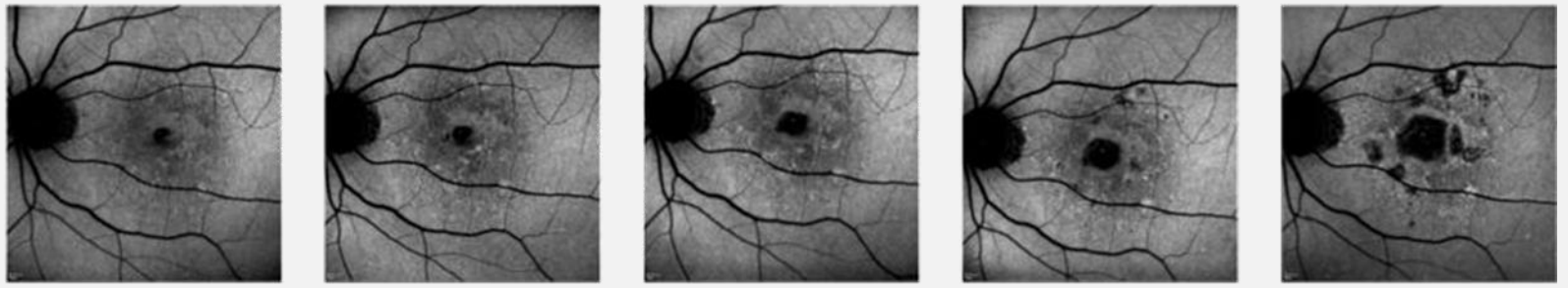
Similar Pathophysiology in STGD1 & Dry AMD

- **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)



Dry AMD: ADVANCED (73-YEAR OLD FEMALE)



Reference: Lindner et al. Differential Disease Progression in Atrophic Age-Related Macular Degeneration and Late-Onset Stargardt Disease. Invest Ophthalmol Vis Sci. 2017;58(2):1001-1007.

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Clinical Data

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Interim Phase 2 Results: Summary of Related Adverse Events

Adverse Events	Severity	Relationship to Drug	Frequency (#patients)	% Recovered	% On-going
Xanthopsia	Mild	Definitely Related	6/13	3/6 (50%)	3/6 (50%)
Delayed Dark Adaptation	Mild	Definitely Related	8/13	1/8 (12.5%)	7/8 (87.5%)
Night Vision Impairment	Mild	Definitely Related	1/13	0/1	1/1 (100%)
Increasing error score on FM100	Mild	Probably Related	1/13	0/1	1/1 (100%)

- 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 a **mild** impact
- **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

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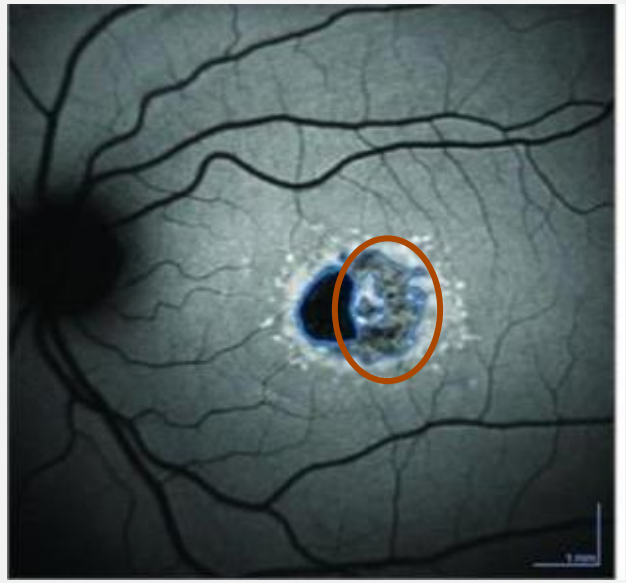
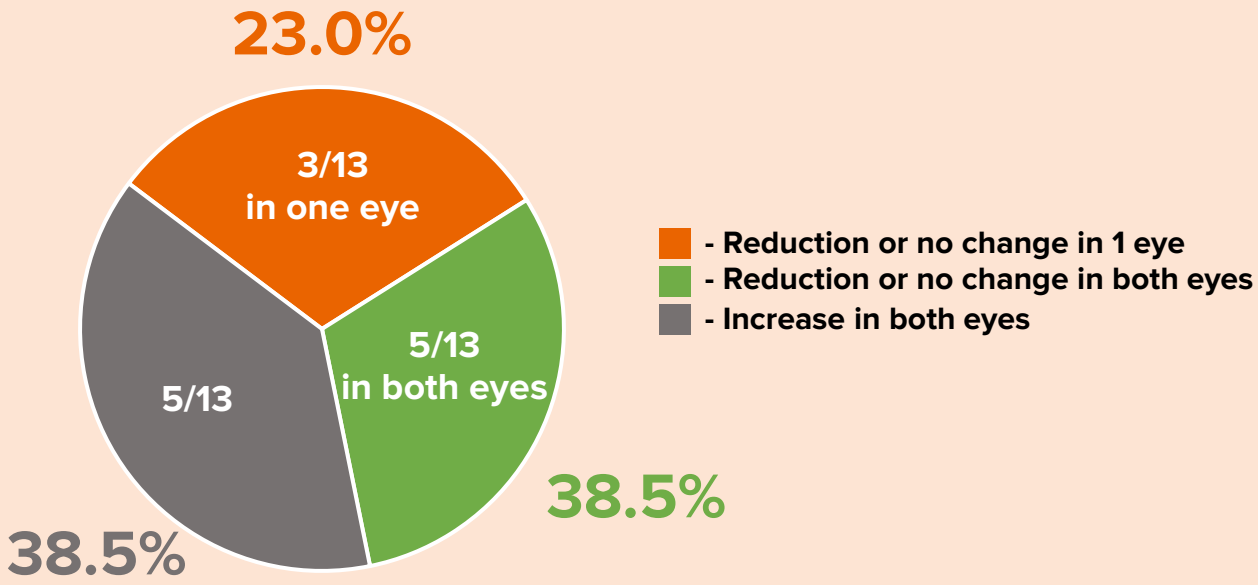
Interim Phase 2 Data: Change in QDAF in Adolescent STGD1 Subjects



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



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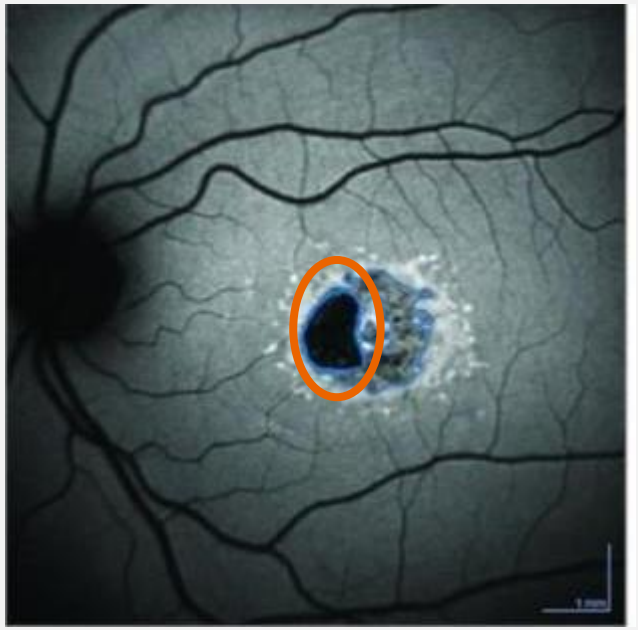
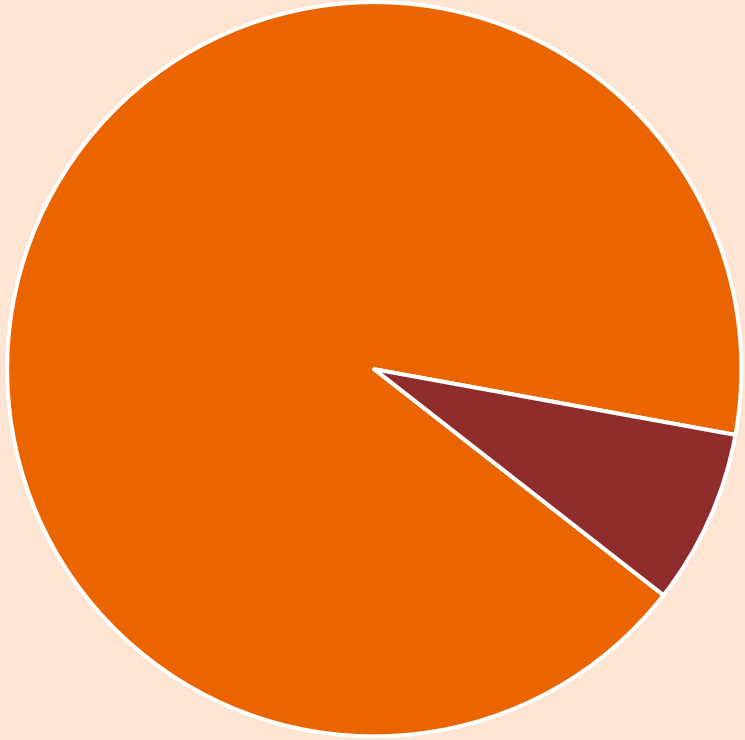
Interim Phase 2 Data: Change in DDAF in Adolescent STGD1 Subjects



DDAF, or lesion (“dead retina”) in STGD1 patient as measured by retinal imaging. This is the area where retinal cells and vision are lost.



92.3%

12 of 13 subjects showed no lesion growth

7.7%

1 of 13 subjects had lesion growth of 0.3 mm^2 in both eyes

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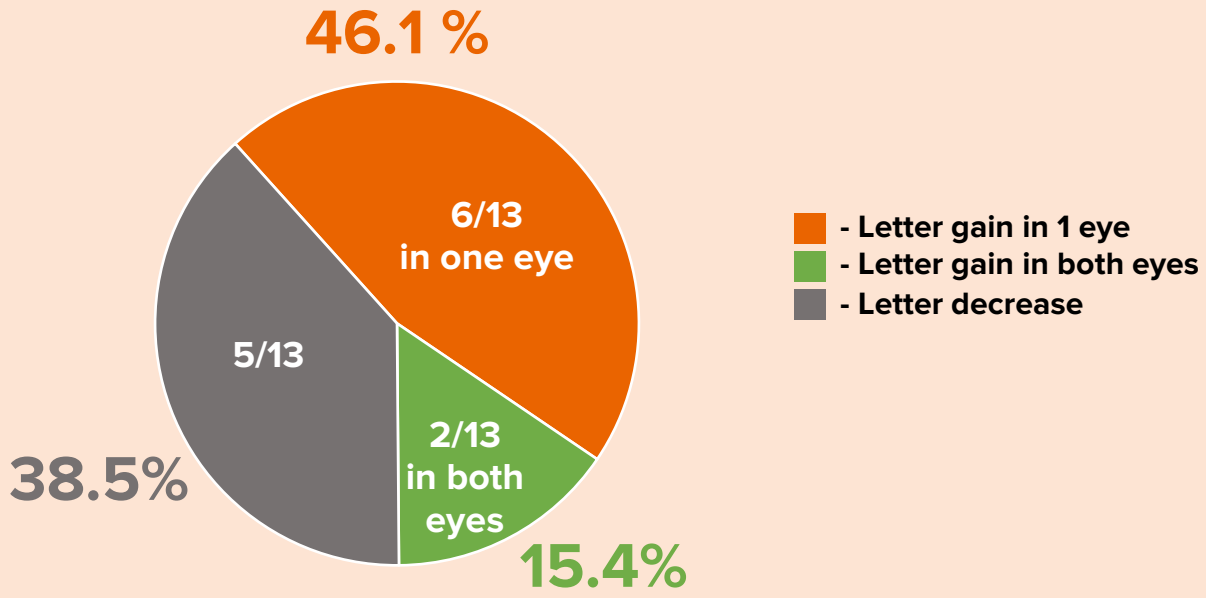
Interim Phase 2 Results: Change of Vision in Adolescent STGD1 Subjects

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

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



First Half 2022 Financial Results

For more info please visit: www.belitebio.com

First Half 2022 Financial Results

(In thousand USD)	For the six months ended June 30	
	2021	2022
Total operating expenses	4,798	3,559
- R&D	3,640	2,457
- G&A	1,158	1,102
Net loss	(4,721)	(3,461)

- IPO net proceeds: $36.1 million including the overallotment.
- Cash: $48.7 million.

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Appendix

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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

Macular degeneration causes blurred or loss of central vision

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

Reference:
www.rarediseases.info.nih.gov/diseases/181/stargardt-disease
www.ncbi.ie/supporting-you/everyday-living/eye-conditions/age-related-macular-degeneration-amd/

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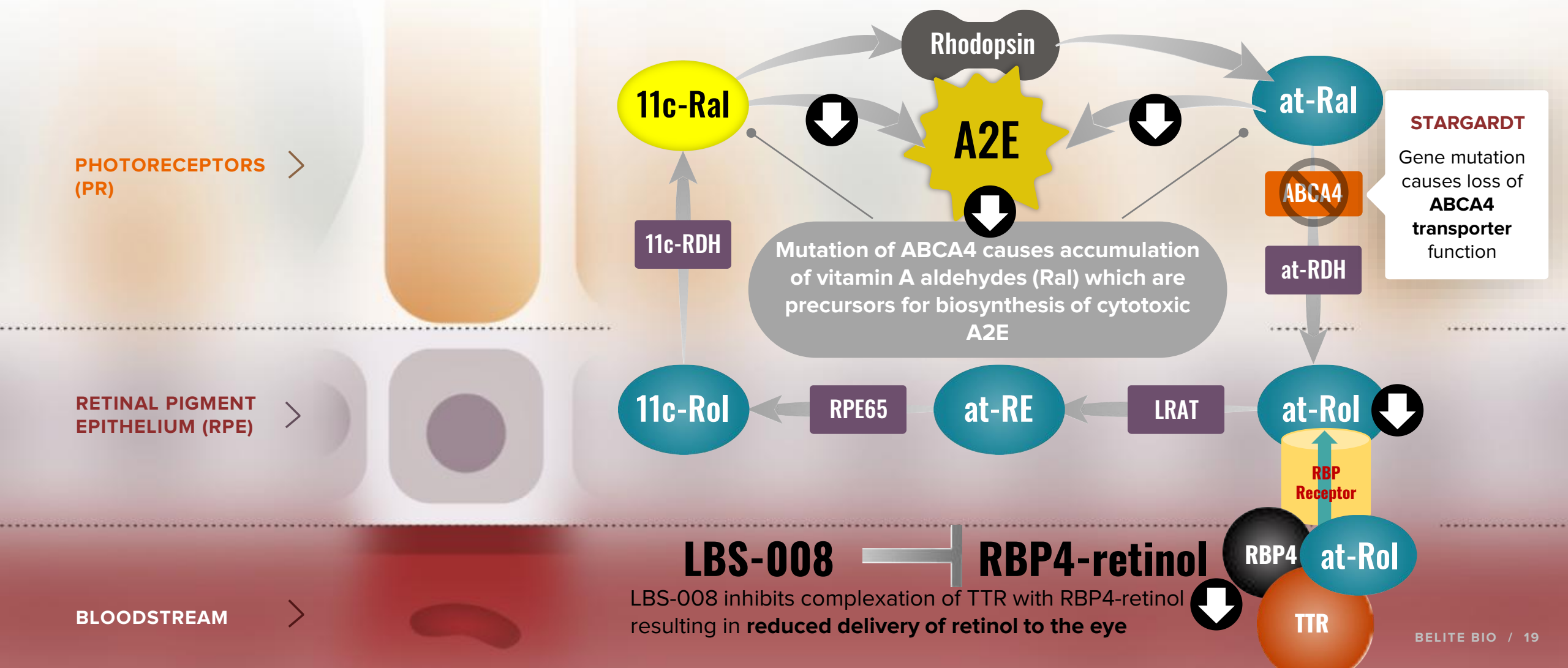
LBS-008 Mechanism of Action

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.



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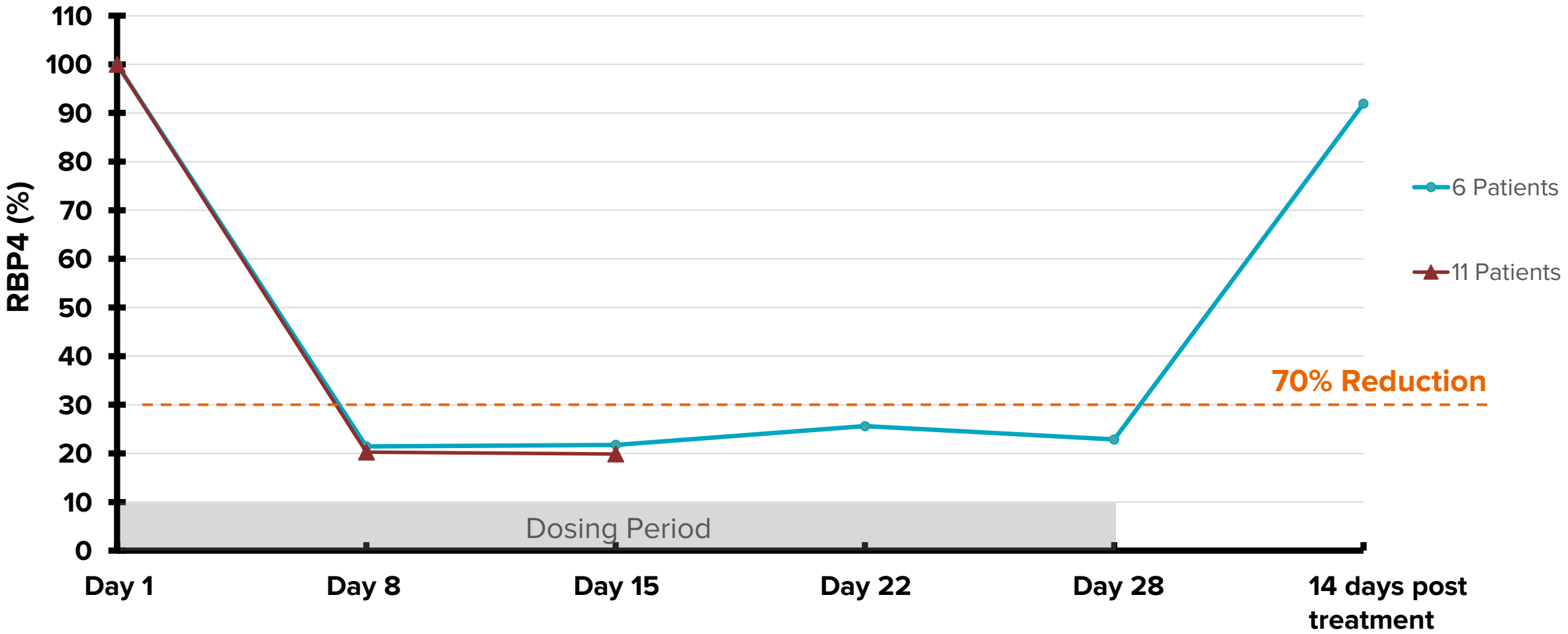
Phase 1b Daily Dosing in Adolescent STGD1: Mean change of RBP4 (%)



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 all 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.