Belite BIO

2022 Full-Year Financial Results Conference Call

April 3, 2023
Nasdaq: BLTE

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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

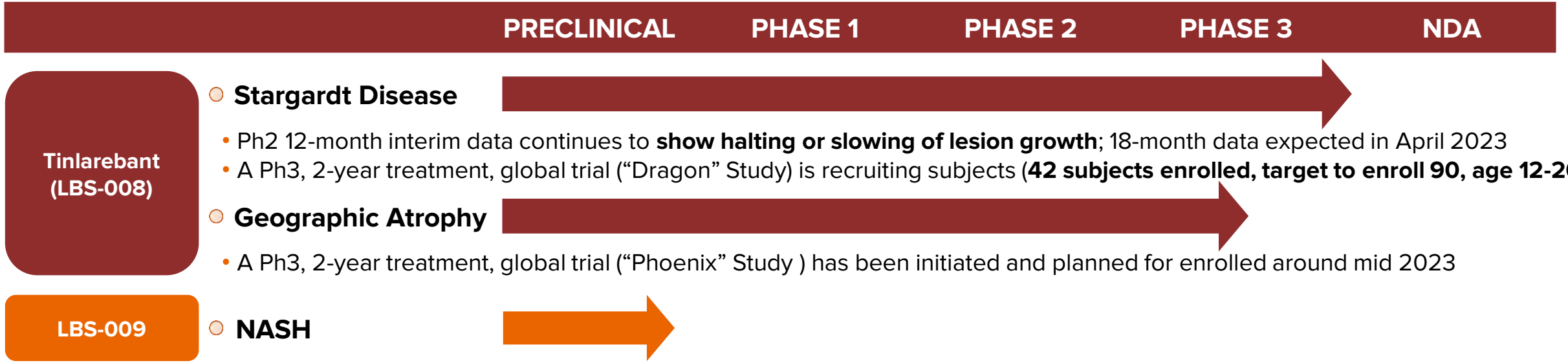
Nathan Mata, PhD
(CSO)

- 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)

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

Belite Bio Overview



- **Early intervention** with a **novel oral treatment** to potentially slow or halt disease progression in **STGD1 & GA in Dry AMD**
- **Unmet Market Opportunity:**
  - No approved treatments for STGD1 and no approved orally administered treatments for GA
- **Fast Track Designation & Rare Pediatric Disease** in US and **Orphan Drug Disease** designation in US / EU for STGD1
- In-licensed **9 active patent families**. Composition of matter patent until at least **2034/2035** without patent term extension

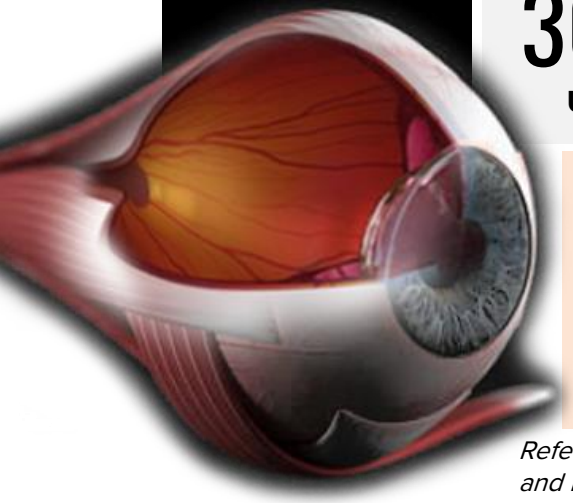
Belite BIO

Tinlarebant (LBS-008) Overview

Market Opportunity

Tinlarebant (LBS-008)

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



STARGARDT

1 in 10,000

The most common inherited retinal dystrophy

Patient population with Stargardt's Disease:

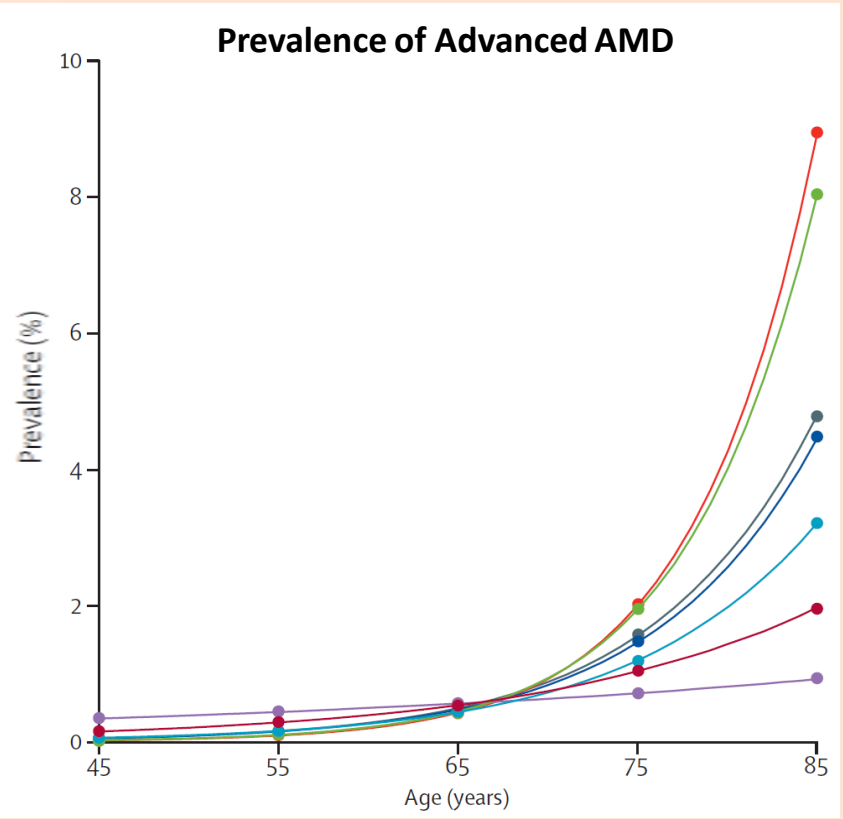
30k US

146k China

Columbia University + NIH Blueprint

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

DRY AMD



All AMD Prevalence	
Global	196M[1]
U.S.	20M[2]

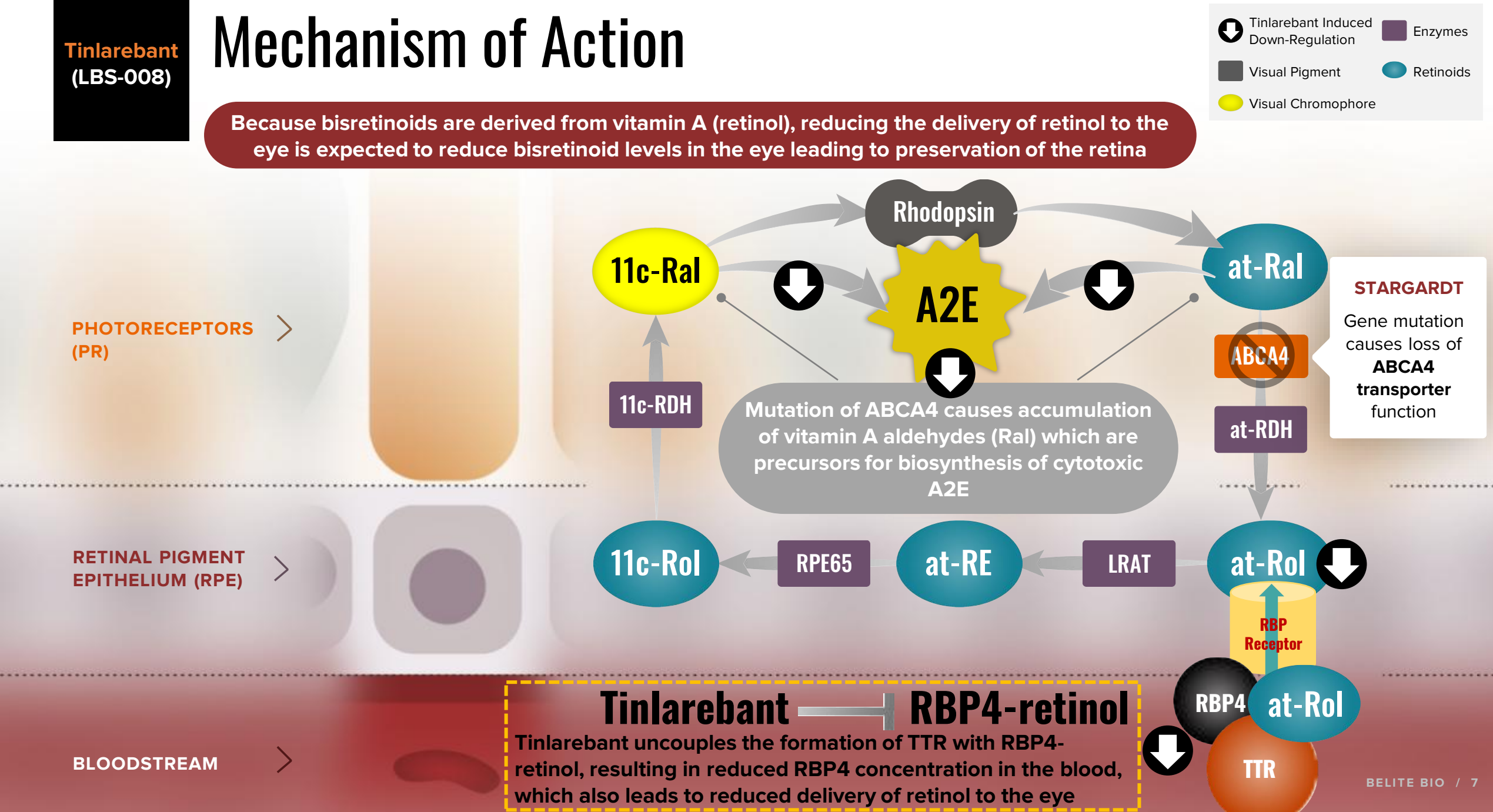
- **AMD patient population is expected to grow from 196M in 2020 to 288M in 2040**[1]

Reference: (1) Wan LingWong et al. Global prevalence of AMD and disease burden projection for 2020 and 2040. 2014; (2) Prevalence Estimates Vision and Eye Health Surveillance System Vision Health Initiative (VHI) CDC, 2022

Tinlarebant (LBS-008)

Mechanism of Action

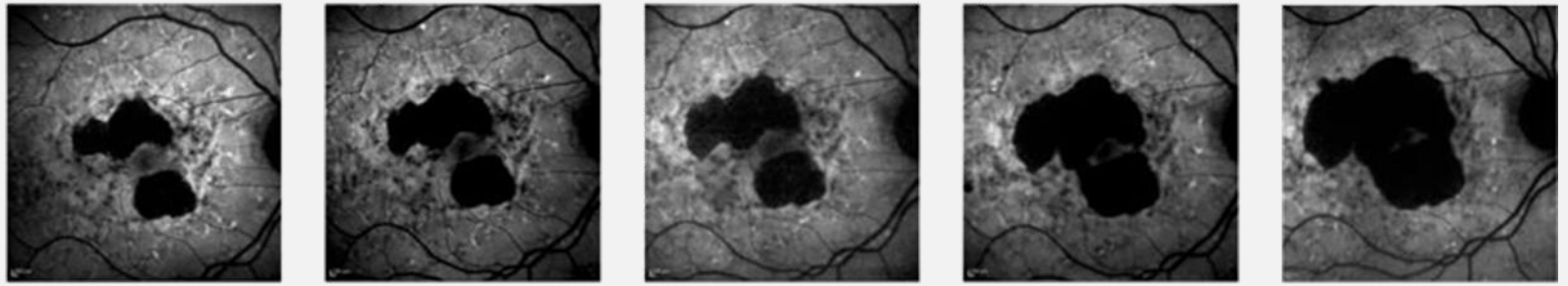
Because bisretinoids are derived from vitamin A (retinol), reducing the delivery of retinol to the eye is expected to reduce bisretinoid levels in the eye leading to preservation of the retina



Similar Pathophysiology in STGD1 & Dry AMD

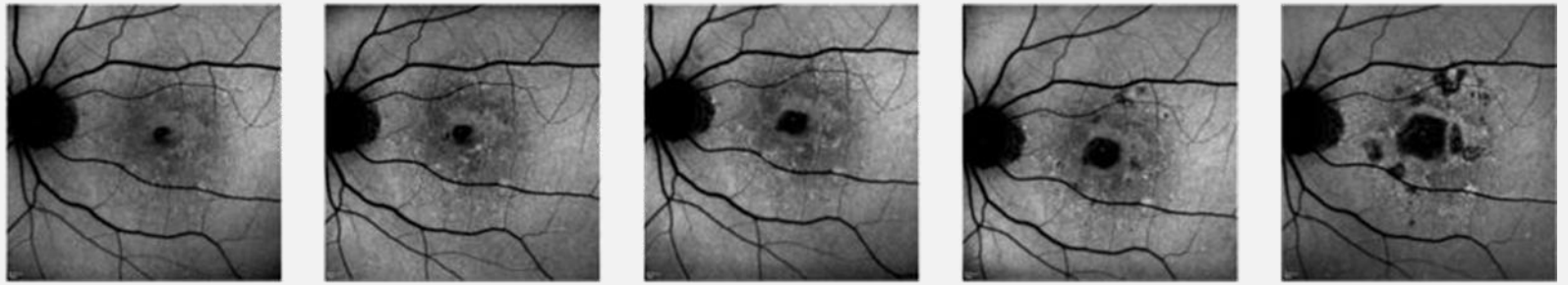
- **STGD1 and dry AMD share a similar pathophysiology** characterized by excessive accumulation of cytotoxic bisretinoids, retinal cell death, and loss of vision
- **Vision loss occurs slowly**, despite peripheral expansion of 'dead retina', until the disease reaches the center of the eye (the macula)
- **Slowing or halting the spread of 'dead retina'** is the intended **effect of Tinlarebant 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 | +57 Months: 0.5 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 | +55 Mo: 0.6 LogMAR

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.

Tinlarebant (LBS-008)

Planned Clinical Development Pathway

Reduction in Lesion Growth Rate as Measured by Retinal Imaging is an FDA Accepted Primary Endpoint in STGD1 and Geographic Atrophy (GA)

Ph1b/2 Adolescent STGD1 (2-year treatment)

- Dose finding Phase 1b completed; open label Phase 2 ongoing
- Ph1b (1-mo, AU/TW): 11 subjects completed
- Ph2 (2-yr, AU/TW): 13 subjects (11 from Ph1b)
- **Top line data expected in Q4 2023**
- **Achieved a mean RBP4 reduction of > 70% without severe adverse events**

Ph3 Adolescent STGD1 (2-year treatment)

- Initiated in June 2022, recruiting
- Randomized, double-masked, global study: 90 subjects (2:1, active, placebo)
- 42 subjects enrolled
- Primary Endpoint: Lesion growth rate
- Secondary Endpoint: BCVA

Ph3 GA (2-year treatment)

- Phase 3 study in early-stage Geographic Atrophy
- Randomized, double-masked, global study: 430 subjects (2:1, active, placebo)
- **Endpoints same as in STGD1**
- **Expect to enroll mid 2023**

Ph3 STGD1 Planned Completion

- NDA filing in STGD1 planned in H1 2026
- FDA may require another clinical trial depending on the data from the ongoing Phase 3 study
- **PRV sale pending NDA approval in STGD1**
- Previous 3 years shows PRV price range of $95-$125 million

Ph3 GA Planned Completion

- Additional Phase 3 study expected to be required prior to NDA filing

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Fenretinide Proof-of-Concept Study

Reduction of RBP4 Slows Lesion Growth in GA Subjects

Sirion's Ph 2 Proof-of-Concept Fenretinide Study in GA Reinforces Tinlarebant Potential

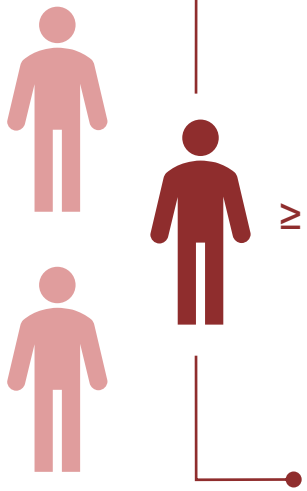
Fenretinide is a synthetic retinoid with **broad retinoid pathway capabilities**

- Developed as an anti-cancer drug
- Competing with retinol for RBP4 binding is a side effect

Tinlarebant is designed to overcome the lower potency and limited bioavailability of fenretinide

Agent	Ki RBP4
Tinlarebant	**2 nM**
Fenretinide	200 nM

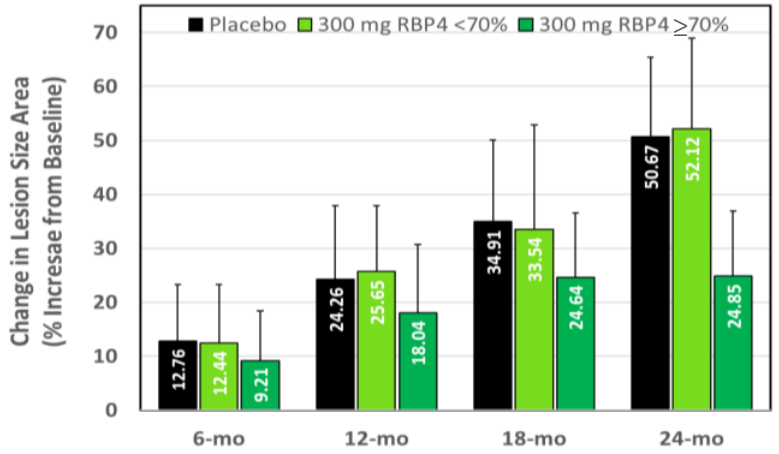
Only **1 out of 3** subjects treated with 300 mg of fenretinide **achieved RBP4 reduction ≥ 70%** relative to baseline

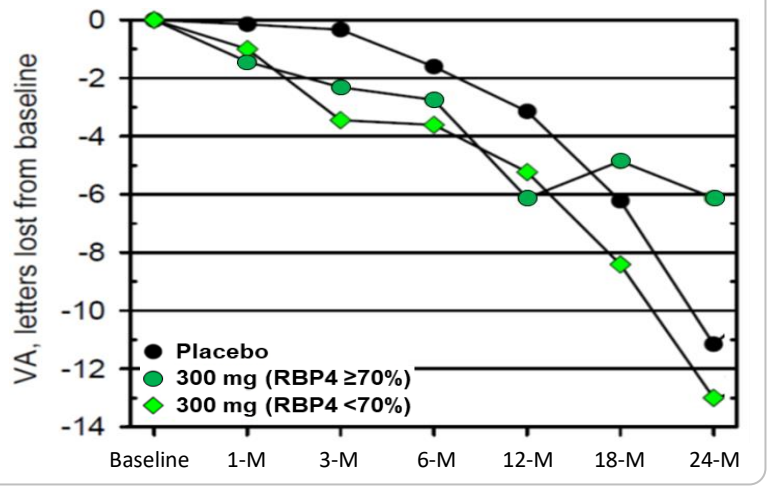


~25% statistically significant **slowing of lesion growth** vs placebo

≥ 70% RBP4 reduction

2-line gain in visual acuity at end of study





Reference: Mata et al. Investigation of oral fenretinide for treatment of geographic atrophy in age-related macular degeneration. Retina. 2013 Mar;33(3):498-507.

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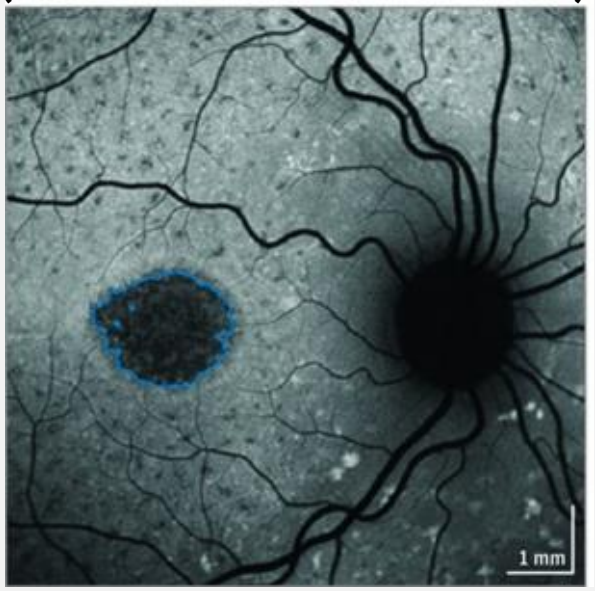
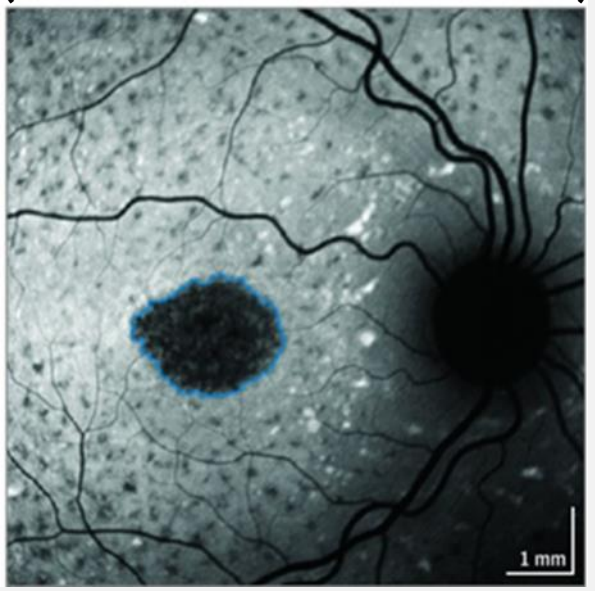
Growth Rates of Retinal Lesions in STGD1

Progression of Questionably Decreased Autofluorescence (QDAF) Lesion in STGD1

Baseline
(QDAF lesion size = 2.45 mm²)



Month 12
(QDAF lesion size = 2.90 mm²)



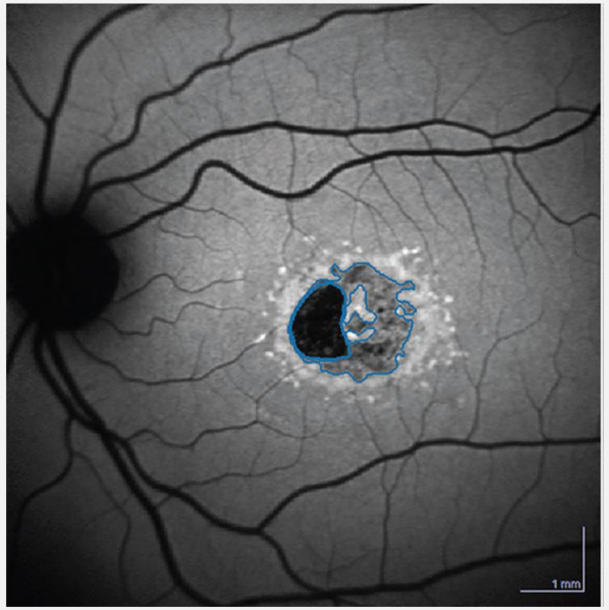
A lesion of questionably decreased autofluorescence at baseline (2.45 mm^2) enlarges to 2.90 mm^2 over 12 months of observation.

The calculated QDAF growth rate is 0.45 mm^2/year.

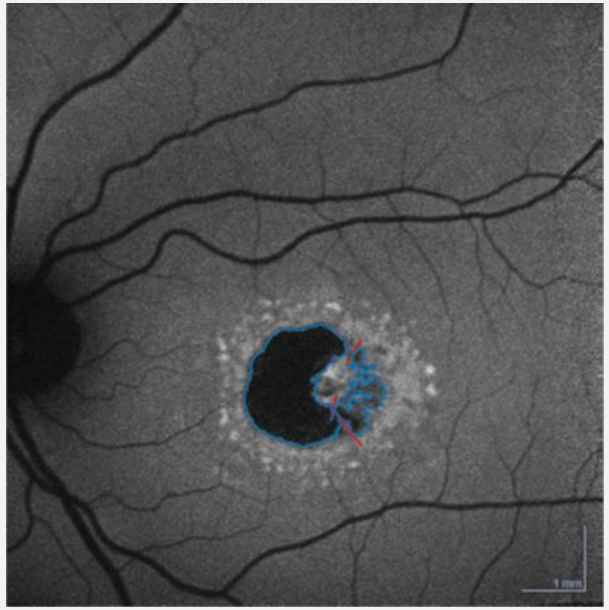
Source: Strauss et al. (ProgStar Study Group). Progression of Stargardt Disease as Determined by Fundus Autofluorescence Over a 12-Month Period: ProgStar Report No. 11. JAMA Ophthalmol. 2019; 137(10):1134-1145.

QDAF Lesion Transformation to Definitely Decreased Autofluorescence (DDAF) Lesion in STGD1

Baseline
(DDAF lesion size = 0.82 mm²)
(QDAF lesion size = 1.53 mm²)



Month 22
(DDAF lesion size = 2.09 mm²)
(QDAF lesion size = 0.45 mm²)



The image data show transformation from QDAF into DDAF. The total area (DDAF + QDAF) enlarged from 2.35 to 2.54 mm².

Calculated Lesion Growth Rates
DDAF: 0.692 mm²/year expansion; QDAF 0.588 mm²/year reduction

Source: Strauss et al. (ProgStar Study Group). Progression of Stargardt Disease as Determined by Fundus Autofluorescence in the Retrospective Progression of Stargardt Disease Study (ProgStar Report No. 9). JAMA Ophthalmol. 2017; 135(11):1232-1241.

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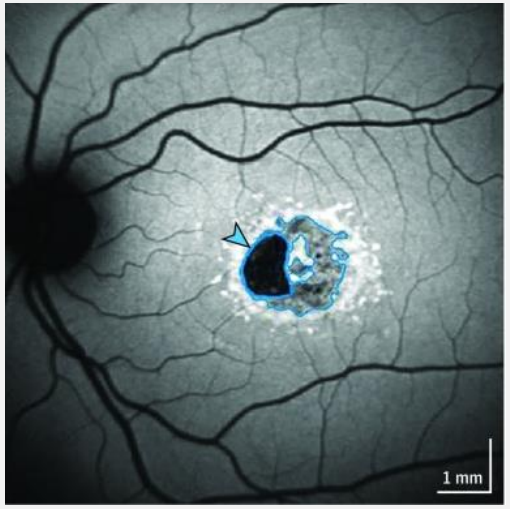
STGD1 Clinical Trials

Tinlarebant (LBS-008)

Interim Phase 2 Results: Change in DDAF & QDAF Lesion Size During Tinlarebant



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

DDAF [1] During Tinlarebant				
Subject No.	**Ph1b baseline (mm^2)**	**Ph2 baseline (mm^2)**	**Ph2 6-m (mm^2)**	**Ph2 12-m (mm^2)**
1	0	0	0	0
2	0	0	0	0
3	-	0	0	0
4	0	0	0	0
5	0	0	0	0
6	0	0	0	0
7	0	0	0	0
8	-	0	0	0
9	0	0	0	0
10	0	0	0	0
11	**0**	**0**	**0.32**	**0.44**
12	0	0	0	0
13	0	0	0	0
			Cohort Mean	**0.03**

Sources	Mean lesion growth rate (DDAF+QDAF[2])
The Prospective Cohort Study of Childhood-Onset STGD1 by Georgiou et al. 2020[2]	0.69 ± 0.72 mm^2/year, n=53
Belite Bio 1-year data	**0.26 ± 0.38 mm^2/year**
Belite Bio 1-year data **Distribution of DDAF and QDAF Lesion Growth**	**DDAF: 0.03 ± 0.12 mm^2/year** **QDAF: 0.23 ± 0.40 mm^2/year**

Note: (1) Lesion growth data in the Table shows the average lesion growth of both eyes in each subject.
(2) The combined QDAF + DDAF lesion size area is referred to as decreased autofluorescence (DAF). Georgiou et al. Am J Ophthalmol. 2020 Mar;211:159-175.

Tinlarebant
(LBS-008)

Interim Phase 2 Results: Well-Tolerated Drug-Related Adverse Events

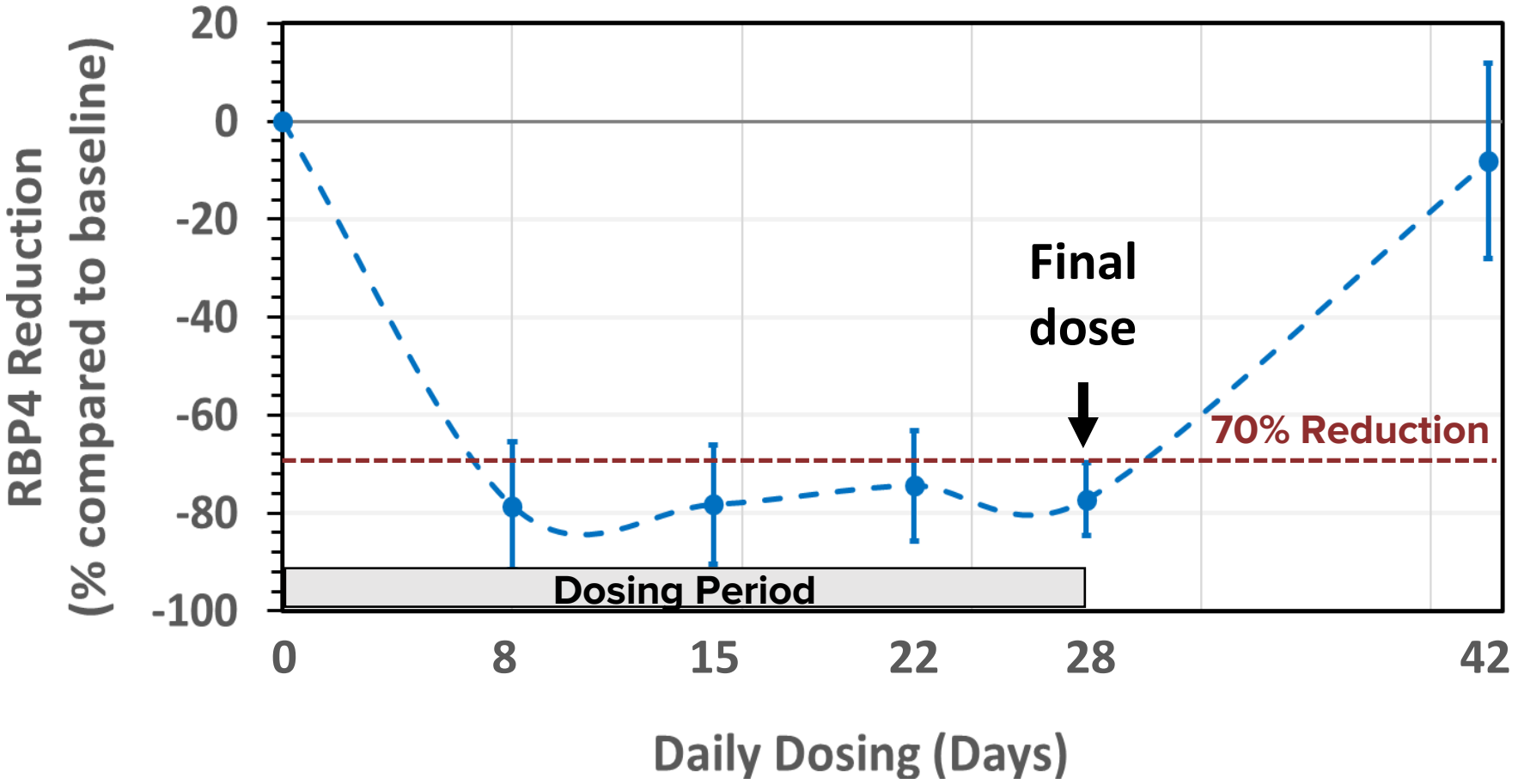
Adverse Events	Severity	Relationship to Drug	Frequency (#patients)	% Recovered	% On-going
Xanthopsia	Mild	Definitely Related	10/13	6/10 (60%)	4/10 (40%)
Delayed Dark Adaptation	Mild	Definitely Related	9/13	1/9 (11%)	8/9 (89%)
Night Vision Impairment	Mild	Definitely Related	1/13	0/1	1/1 (100%)
Increasing error score on FM100	Mild	Probably Related	1/13	0/1	1/1 (100%)

- All subjects have received **at least 12 months** of Tinlarebant treatment to date
- 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

Tinlarebant
(LBS-008)

Tinlarebant: ≥ 70% Reduction of RBP4

Phase 1b, 5mg Daily Dosing in Adolescent STGD1: Mean Percent Reduction of RBP4



Note: 6 subjects in Australian sites only as data of 5 subjects in Taiwan could not be collected due to COVID-19 restrictions at the NTUH site in Taiwan

Tinlarebant (LBS-008)

Clinical Trial Design Overview in STGD1

Reduction in Lesion Growth Rate (DDAF) as Measured by Retinal Imaging is an FDA Accepted Primary Endpoint in STGD1 and GA

	STGD1 Phase 2 *(12-Month Interim Data Available)*	STGD1 "Dragon" Phase 3* *(Enrolling)*
Enrollment	13 subjects (QDAF, no DDAF)	At least 90 subjects (must have DDAF)
Sites	Australia & Taiwan	Global
Masking	Open Label	Double Blind
Placebo	N/A	2:1 ratio (Tinlarebant : Placebo)
Treatment duration	2 years	2 years
Primary measures	Safety & tolerability, optimal dose	Efficacy as measured through DDAF lesion growth rate, safety & tolerability
Other measures	DDAF, QDAF, BCVA, SD-OCT, microperimetry	QDAF, BCVA, SD-OCT, microperimetry
Interim analysis	Yes	Yes
Key inclusion criteria	12-20 years old, diagnosed STGD1 with at least one mutation identified in the ABCA4 gene	12-20 years old, diagnosed STGD1 with at least 1 mutation identified in the ABCA4 gene, atrophic lesion size within 3 disc areas (7.62 mm^2), a BCVA of 20/200 or better

*FDA may require another clinical trial depending on the data from the ongoing Phase 3 study

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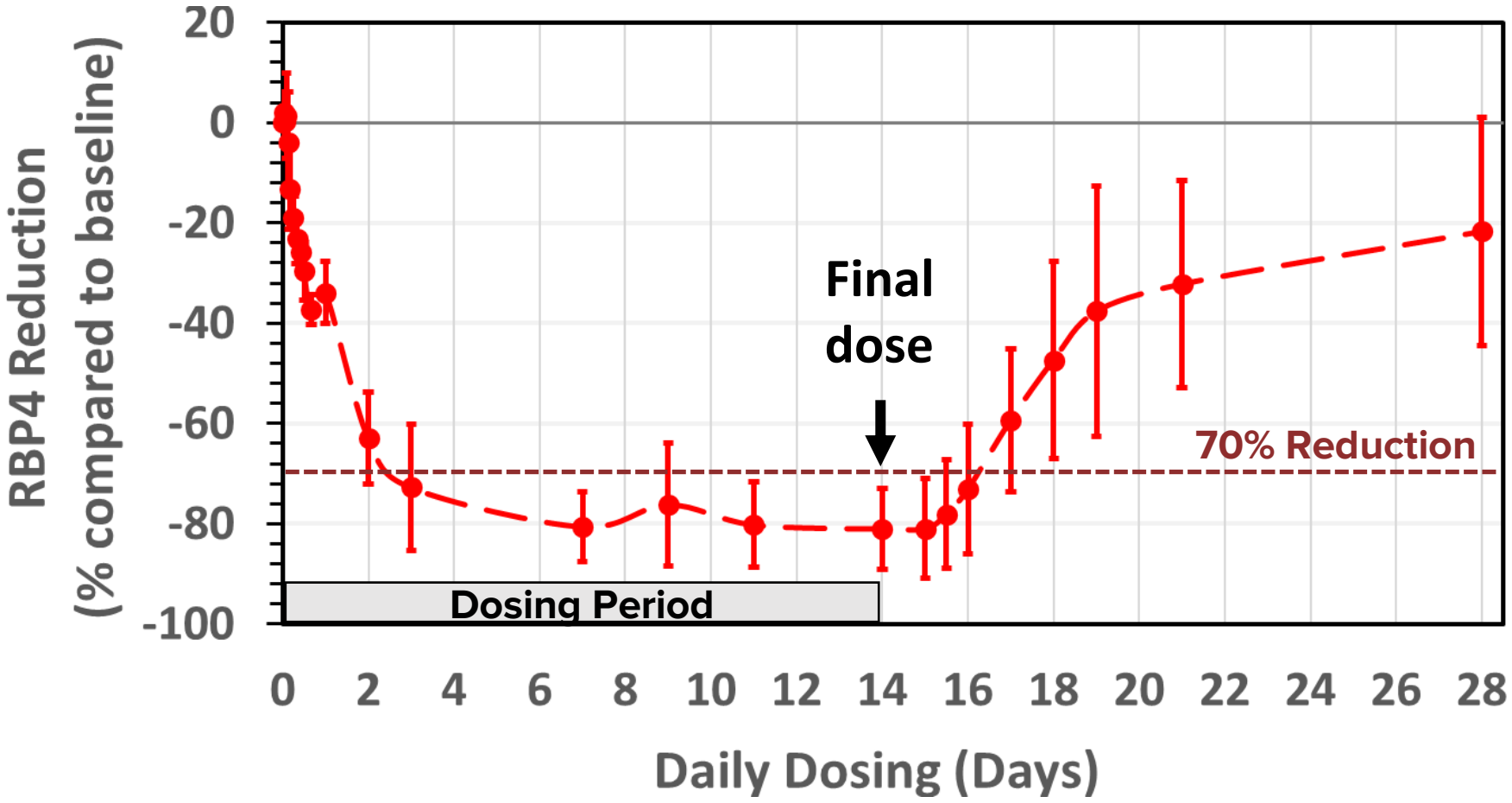
Phase 3
Advanced Dry AMD

Tinlarebant
(LBS-008)

Tinlarebant: ≥ 70% Reduction of RBP4

Phase 1, 5mg Daily Dosing in Healthy Adults: Mean Percent Reduction of RBP4 (excludes placebo)



Tinlarebant (LBS-008)

Clinical Trial Design Overview in GA

- **Established Efficacy Endpoint** – Reduction in Lesion Growth Rate (DDAF) as Measured by Retinal Imaging is the FDA Accepted Primary Endpoint for STGD1 and GA
- **Early Intervention** – Targeting patients with small lesion size to potentially slow or halt disease progress at an early stage
- **Oral Once a Day Treatment** – well suited for long term treatment for chronic diseases
- **Broad Potential** – Primary focus on GA; potential to treat earlier stages (e.g., intermediate AMD)

	GA Phase 3 "Phoenix"*
Enrollment	Approximately 430 subjects
Sites	Global
Masking	Double Blind
Placebo	2:1 ratio (Tinlarebant : Placebo)
Treatment duration	2 years
Primary measures	Efficacy as measured through DDAF lesion growth rate, safety & tolerability
Other measures	QDAF, BCVA, SD-OCT, microperimetry
Interim analysis	Yes

*Additional Phase 3 study expected to be required prior to NDA filing

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2022 Full-Year Financial Results

For more info please visit: www.belitebio.com

2022 Full-Year Financial Results

(In thousand USD)	For the years ended December 31	
	2021	2022
Total operating expenses	9,797	12,821
- R&D	7,419	8,869
- G&A	2,378	3,952
Net loss	(9,818)	(12,844)

- IPO net proceeds: $38.0 million including the overallotment
- Cash: $42.1 million

2023 Key Anticipated Milestones

Q1

- Initiated PHOENIX Phase 3 study in GA ✓
- 42 subjects enrolled in DRAGON Phase 3 study in STGD1 ✓

Q2

- April 25 - ARVO Presentation of 18-month Phase 2 efficacy and safety data in STGD1
- May 3 - KOL event to discuss 18-month Phase 2 efficacy and safety data in STGD1
- Initiate enrollment in PHOENIX Phase 3 study in GA

H2

- Topline 24-month Phase 2 efficacy and safety data in STGD1
- Complete enrollment in DRAGON Phase 3 study in STGD1

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QA

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