Belite BIO

Q1 2023 Financial Results Conference Call

May 11, 2023
Nasdaq: BLTE

Forward-Looking Statements and Legal Disclaimer

This presentation (including any oral briefing and any question-and-answer in connection with it) is not intended to, and does not constitute, represent or form part of any offer, invitation or solicitation of any offer to purchase, otherwise acquire, subscribe for, exchange, sell or otherwise dispose of, any securities of Belite Bio Inc ("Belite Bio") from any investor or in any jurisdiction in which such an offer or solicitation is not authorized or would be unlawful. No shares or other securities of Belite Bio are being offered to the public by means of this presentation. No offering of securities shall be made in the United States except pursuant to registration under the U.S. Securities Act of 1933, as amended, or an exemption therefrom. This presentation is being given (together with any further information which may be provided to the recipient) on the condition that it is for use by the recipient for information purposes and to evaluate Belite Bio and the proposed offering of securities of Belite Bio and for no other purpose. Any failure to comply with these restrictions may constitute a violation of applicable securities laws.

Any statements in this presentation about Belite Bio's future expectations, plans and prospects constitute forward-looking statements for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements about the strategy, operations and future expectations and plans and prospects for the Company, and any other statements containing the words "expect," "intend", "plan," "predict," "target," "will," "could," "should," "continue," and similar expressions.

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.

Market data and industry information used throughout this presentation are based on the knowledge of the industry and the good faith estimates of Belite Bio's management. The Company also relied, to the extent available, upon management's review of independent industry surveys and publications and other publicly available information prepared by a number of third-party sources. All of the market data and industry information used in this presentation involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Although the Company believes that these sources are reliable, it cannot guarantee the accuracy or completeness of, and has not independently conducted verification of the relevant market data and industry information used herein. While the Company believes the estimated market position, market opportunity and market size information included in this presentation are generally reliable, such information, which is derived in part from the management's estimates and beliefs, is inherently uncertain and imprecise. No representations or warranties are made by the Company or any of its affiliates as to the accuracy of any such statements or projections. Projections, assumptions and estimates of our future performance and the future performance of the industry in which the Company operates are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described above. These and other factors could cause results to differ materially from those expressed in our estimates and beliefs and in the estimates prepared by independent parties.

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

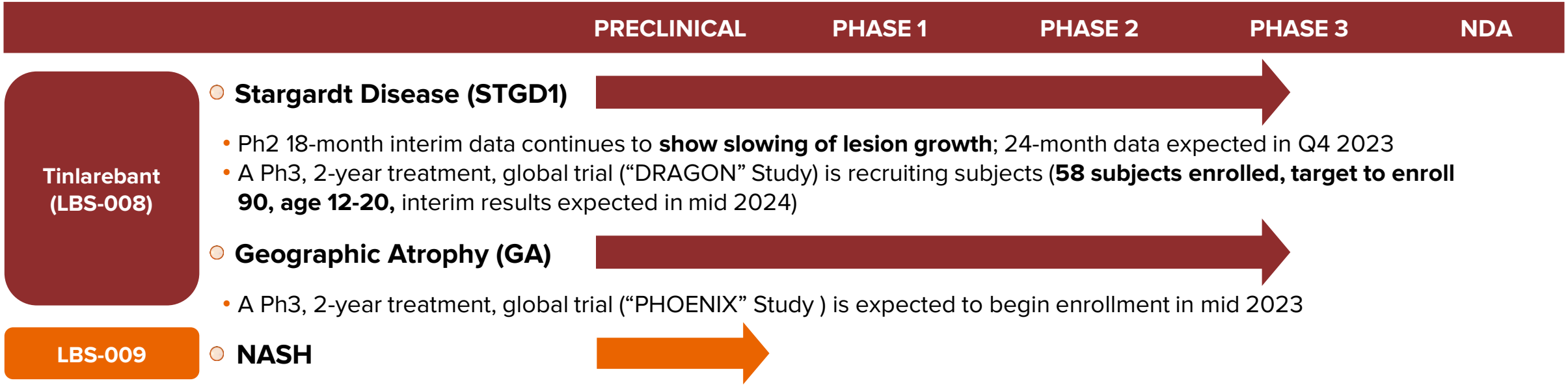
Nathan Mata, PhD
(CSO)

- 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 STGD1
- Introduced the industry's first STGD1 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 disease progression in **STGD1 & GA in Dry AMD**
- **Unmet Market Opportunity:**
  - No FDA approved treatments for STGD1
  - No FDA 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

STGD1 Clinical Trials

Tinlarebant (LBS-008)

Clinical Trial Design Overview in STGD1

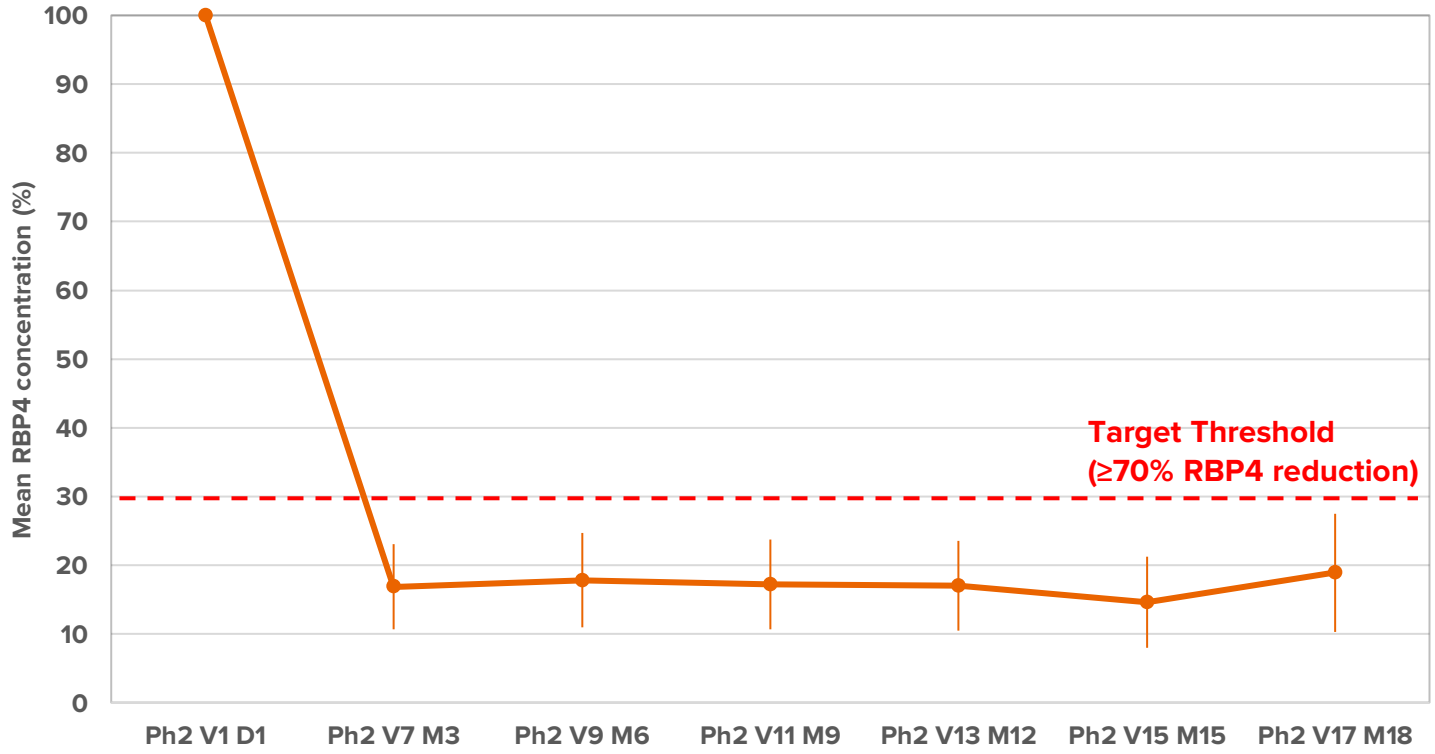
Reduction in Lesion Growth Rate (DDAF) as Measured by Retinal Imaging is the FDA Accepted Primary Endpoint in STGD1 and GA

	STGD1 Phase 2 "LBS-008-CT02" *(Preliminary 18-Month Interim Data Available)*	STGD1 "Dragon" Phase 3* *(Enrolling)*
Enrollment	13 subjects (QDAF, no DDAF)	At least 90 subjects targeted (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	12-18 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

Tinlarebant (LBS-008)

Ph2 18-month: Reduction of Plasma RBP4 Levels

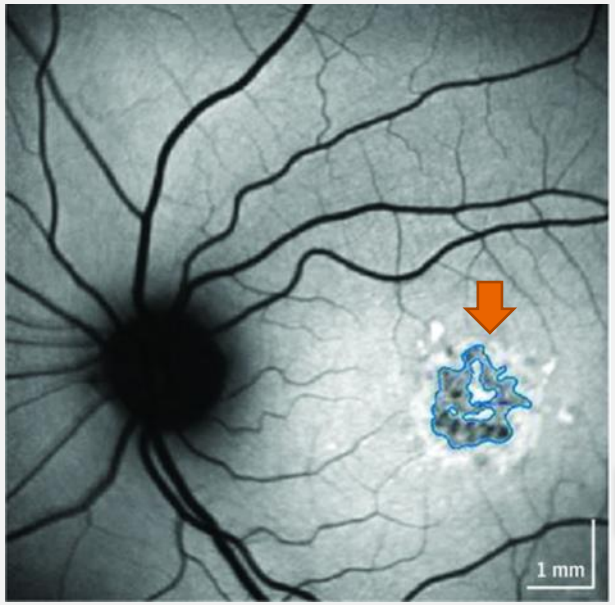


- Plasma RBP4 was reduced by approximately **80%** relative to baseline during daily dosing at **5 mg** over 18 months

Note: Preliminary data and is subject to data verification and clean-up

Tinlarebant (LBS-008)

Ph2 18-month: Change in combined lesion size



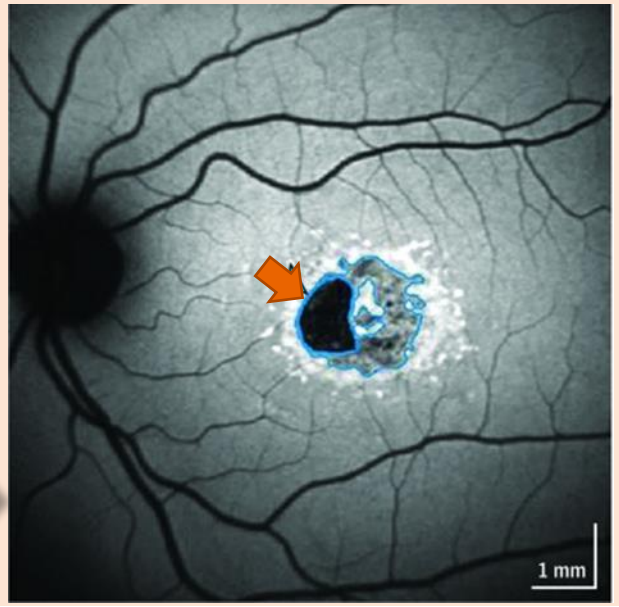
QDAF lesion (boundary outlined in blue) in STGD1 patient as measured by fundus autofluorescence (FAF) imaging.

QDAF lesions may be amenable to rescue.

DDAF lesion ("dead retina") in STGD1 patient as measured by FAF imaging.

DDAF lesions indicate irreversible loss of photoreceptor cells.

Transition of QDAF to DDAF lesion



- The combined QDAF and DDAF lesion area is termed decreased autofluorescence (DAF)
- Comparison of mean DAF lesion growth rates between Georgiou et al. (2020) and subjects in LBS-008-CT02 revealed a 60% reduction among subjects in LBS-008-CT02

Data Source	Mean DAF lesion growth rate (DAF = DDAF+QDAF)
The Prospective Cohort Study of Childhood-Onset STGD1 by Georgiou et al. 2020[1]	0.69 ± 0.72 mm^2/year, n=53
Belite Bio 18-month data	**0.28 ± 0.28 mm^2/year, n=12**

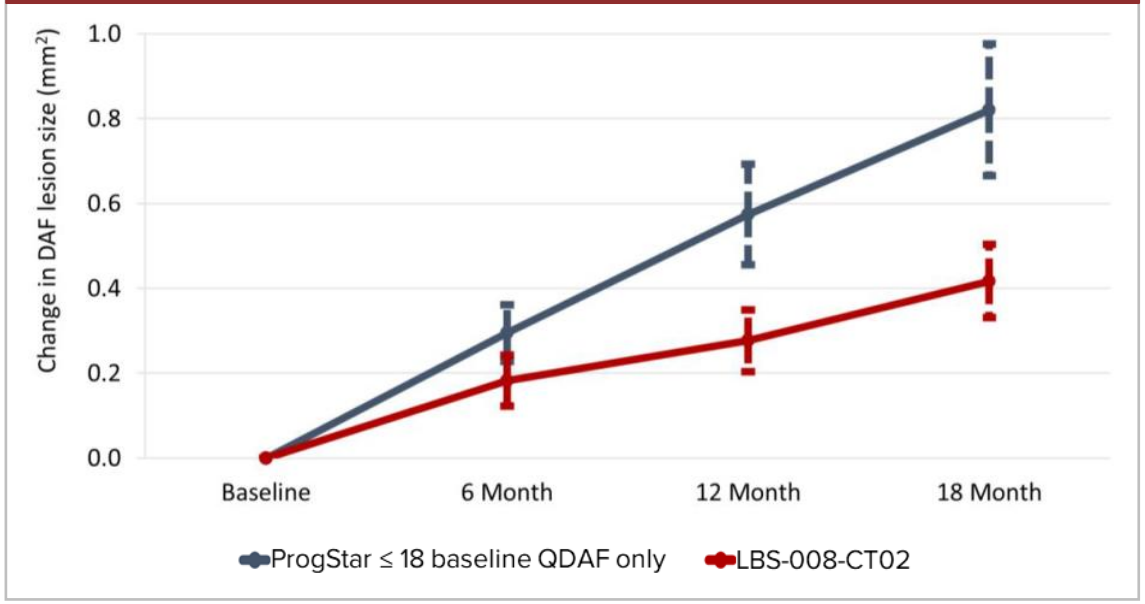
Reference: (1) Georgiou M, et al. Am J Ophthalmol. 2020;211:159-175. FAF images from: Strauss et al. JAMA Ophthalmol. 2017; 135(7):687-695.

Tinlarebant (LBS-008)

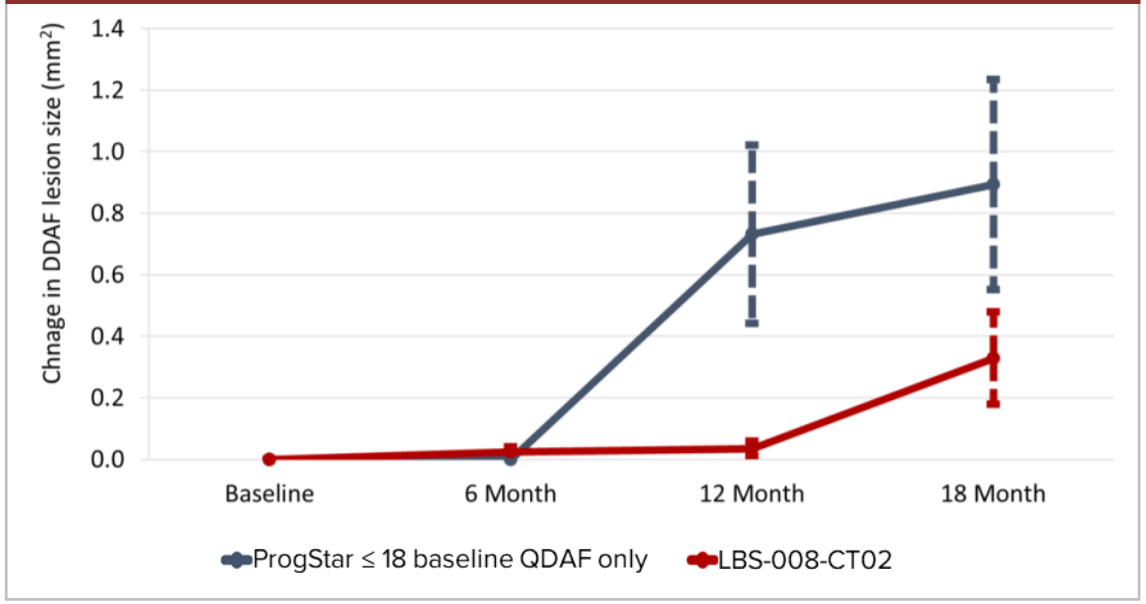
Ph2 18-month: Lesion growth rates versus ProgStar

- A comparison of DAF and DDAF lesion growth among ProgStar subjects with similar baseline characteristics as subjects in LBS-008-CT02 (i.e, ≤ 18 years old with no DDAF at baseline) was performed

DAF Lesion Growth from Baseline



DDAF Lesion Growth from Baseline

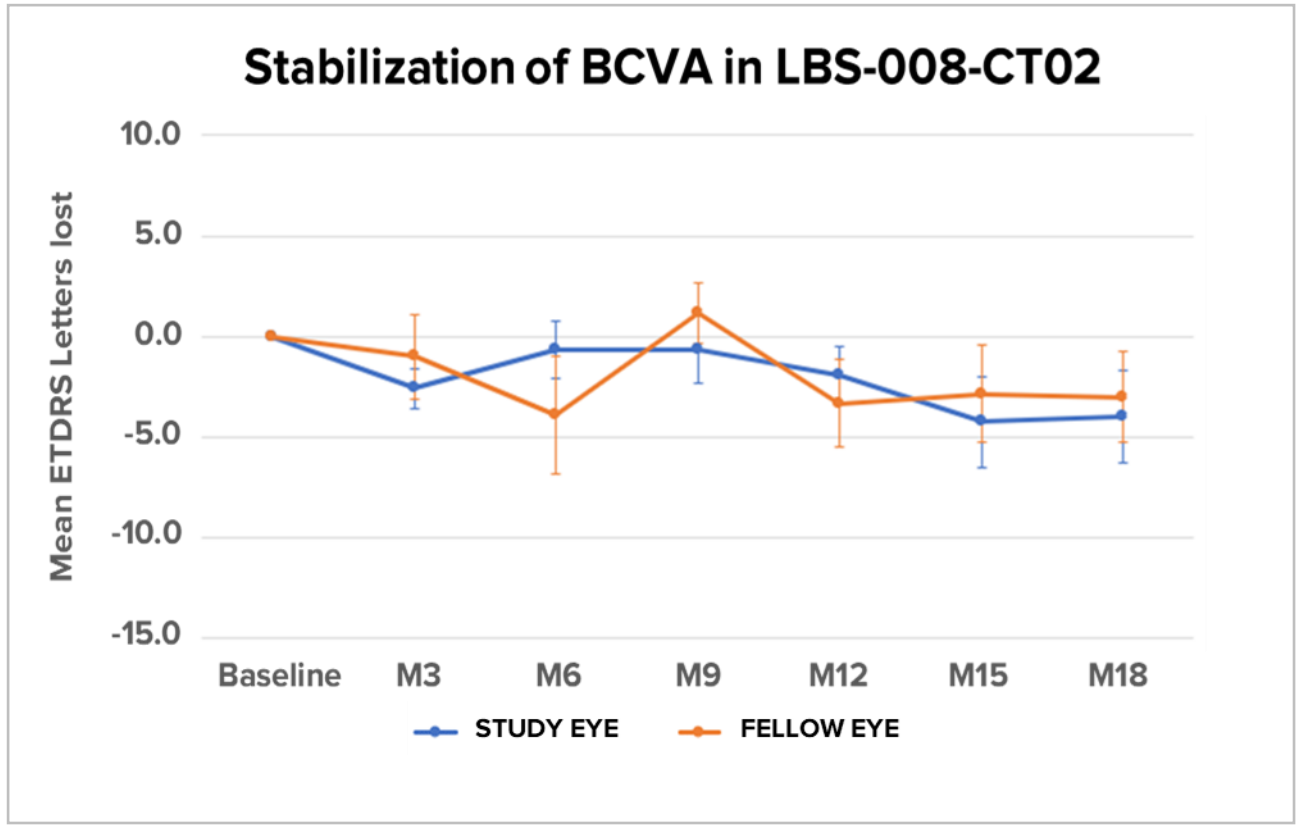


- **No development of DDAF** in 7 of 12 subjects (58.3%) at the 18-month timepoint
- Comparing to ProgStar subjects ≤ 18 years old with no DDAF at baseline, LBS-008-CT02 subjects showed reduced expansion of both DAF and DDAF lesions from baseline

Note: Preliminary data and is subject to data verification and clean-up

Tinlarebant (LBS-008)

Ph2 18-month: Visual Acuity Data



- **A trend for maintaining BCVA** in a majority of subjects was observed following 18 months of treatment
- Mean change in BCVA (ETDRS letters lost) within the study cohort over 18 months of treatment was **-3 ± 1** letters in the Study eye and **-2 ± 2 letters** in the Fellow eye

Note: Preliminary data and is subject to data verification and clean-up

Tinlarebant
(LBS-008)

Ph2 18-month: Well-Tolerated Drug-Related Adverse Events

Adverse Events	Severity	Frequency (#patients)	% Recovered
Xanthopsia/Chromatopsia	Mild	9/12 (75%)	6/9 (66.7%)
Delayed Dark Adaptation	Mild	9/12 (75%)	1/9 (11.1%)
Night Vision Impairment	Mild	1/12 (8.3%)	0

- Tinlarebant (5 mg p.o., daily) continues to be **safe** and **well tolerated** in adolescent STGD1 patients
- Tinlarebant treatment produced a mean **80% reduction of RBP4** (from baseline) throughout the study
- Delayed Dark Adaptation and Xanthopsia/Chromatopsia are the most common drug related ophthalmic AEs
- All instances of Delayed Dark Adaptation, Night Vision Impairment, and Xanthopsia/Chromatopsia were **mild** and **transient**
- No severe and moderate drug related AEs reported and no AEs requiring discontinuation of treatment
- No clinically significant findings in relation to vital signs, physical exams, cardiac health, or organ functions

Belite BIO

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

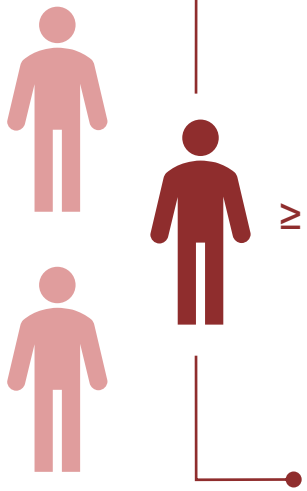
Fenretinide is a synthetic retinoid with **broad retinoid pathway capabilities**

- 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

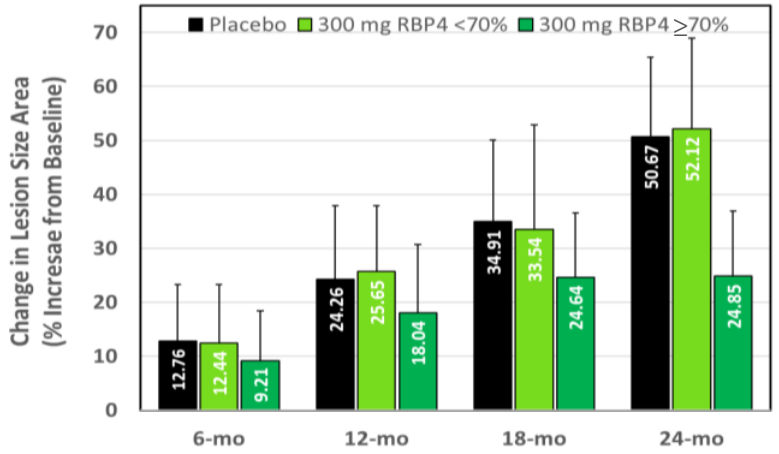
Only **1 out of 3** subjects treated with 300 mg of fenretinide **achieved RBP4 reduction ≥ 70%** relative to baseline

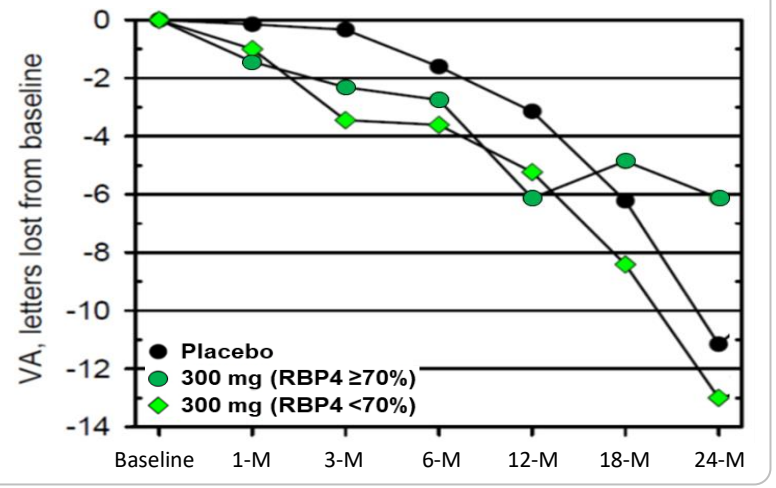


~25% statistically significant **slowing of lesion growth** vs placebo

≥ 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.

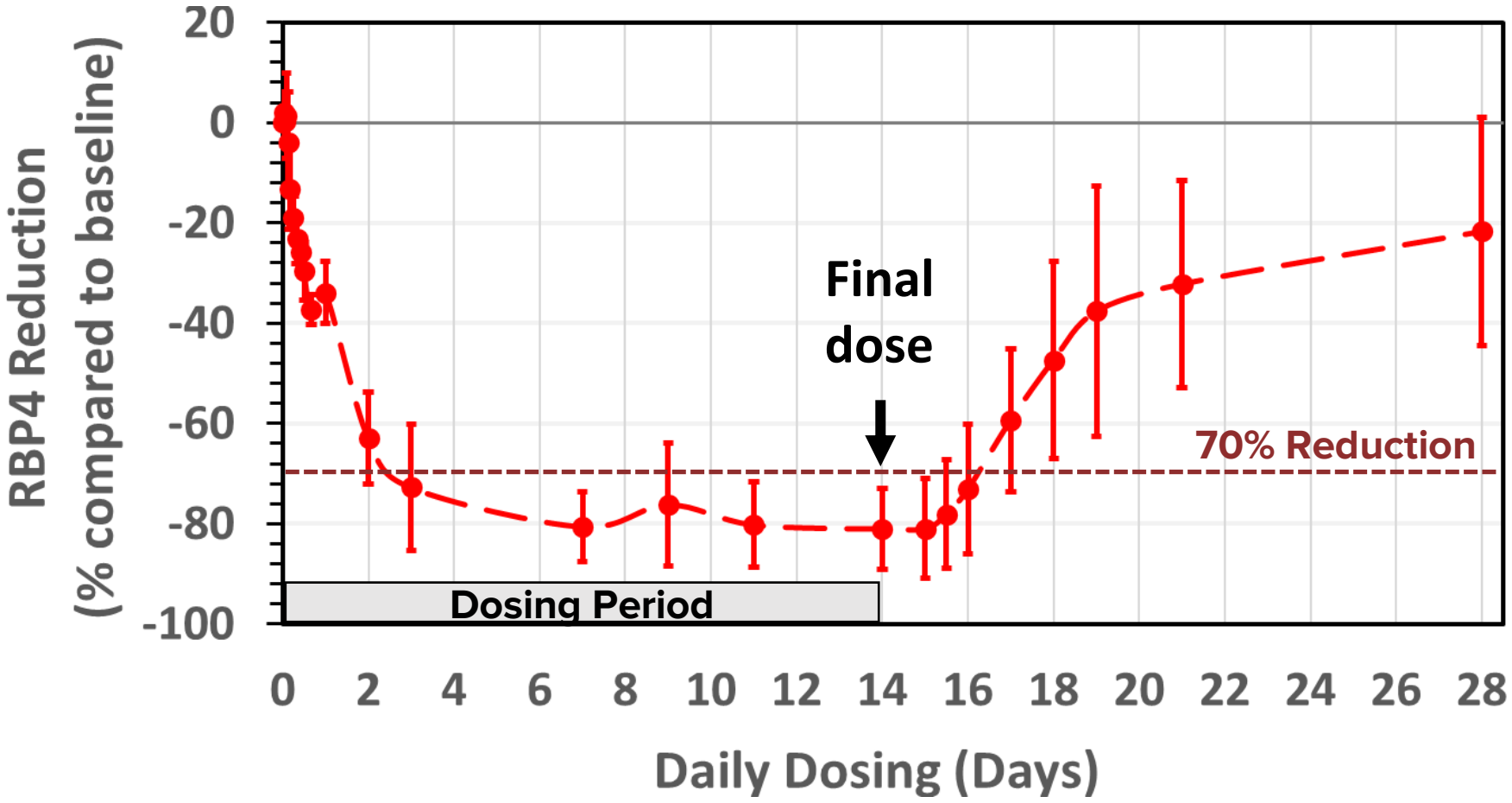
Belite BIO

Phase 3 Geographic Atrophy

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 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 targeted (Expected to begin enrolling in mid-2023)
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

Belite BIO

Q1 2023 Financial Results

For more info please visit: www.belitebio.com

Q1 2023 Financial Results

(In thousands of USD)	For the Three Months Ended March 31	
	2022	2023
Total operating expenses	1,053	6,881
- R&D	878	5,723
- G&A	175	1,158
Net loss	(1,070)	(6,895)

- Cash: $37.8 million

Belite BIO

Key Milestones

For more info please visit: www.belitebio.com

Key Milestones

Q1, 23

- Initiated Phase 3 PHOENIX study in GA ✓

Q2, 23

- April 25 - ARVO Presentation of 18-month data from Phase 2 study in STGD1 ✓
- 58 subjects enrolled in Phase 3 DRAGON study in STGD1 ✓
- Expect to initiate enrollment in Phase 3 PHOENIX study in GA

H2, 23

- Topline 24-month data from Phase 2 study in STGD1 expected
- Anticipate completing enrollment in Phase 3 DRAGON study in STGD1

H1, 24

- Interim results from Phase 3 DRAGON study in STGD1 expected

Belite BIO

QA

For more info please visit: www.belitebio.com