Belite BIO

Q3 2023 Financial Results Conference Call

November 14, 2023
Nasdaq: BLTE

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Belite Participants

Management Team

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

- 10+ years of executive management roles in biotech
- Over 10 new drug developments in multiple therapeutic areas including ophthalmology
- University of Sydney, University of Melbourne, Harvard Medical School, Columbia University, London Business School, HK University

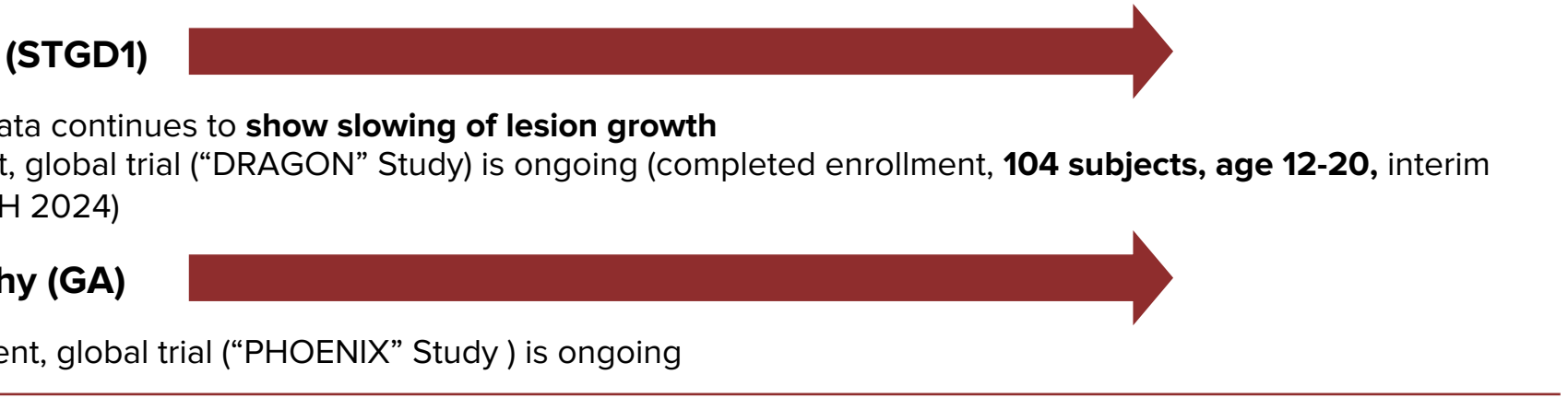
Nathan Mata, PhD
(CSO)

- 15+ years of ophthalmic drug development experience across numerous indications, including two NDAs (Durezol and Zirgan)
- Led clinical development efforts for the first RBP antagonist in advanced dry AMD and the first visual cycle modulator in dry AMD and STGD1
- Introduced the industry's first STGD1 ABCA4 knockout mice model
- University of Texas

Hao-Yuan Chuang, CFA, MBA, FRM
(CFO)

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

Belite Bio Pipeline Overview



- **Tinlarebant** is a **novel, once daily oral tablet** designed to bind to serum **retinol binding protein 4 (RBP4)** as a means to specifically reduce retinol delivery to the eye. This approach is intended to **slow or halt the formation of the toxic retinol-derived by-products** that are generated in the visual cycle and are **implicated in progression of STGD1 and GA.**
- Belite Bio believes that **early intervention directed at emerging retinal pathology**, which is not mediated by inflammation, would be the best approach to potentially slow disease progression in STGD1 & GA.
- **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
- **14 active patent families**; composition of matter patent until at least **2040** without patent term extension

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STGD1 Clinical Trials

Tinlarebant (LBS-008)

Clinical Trial Design Overview in STGD1

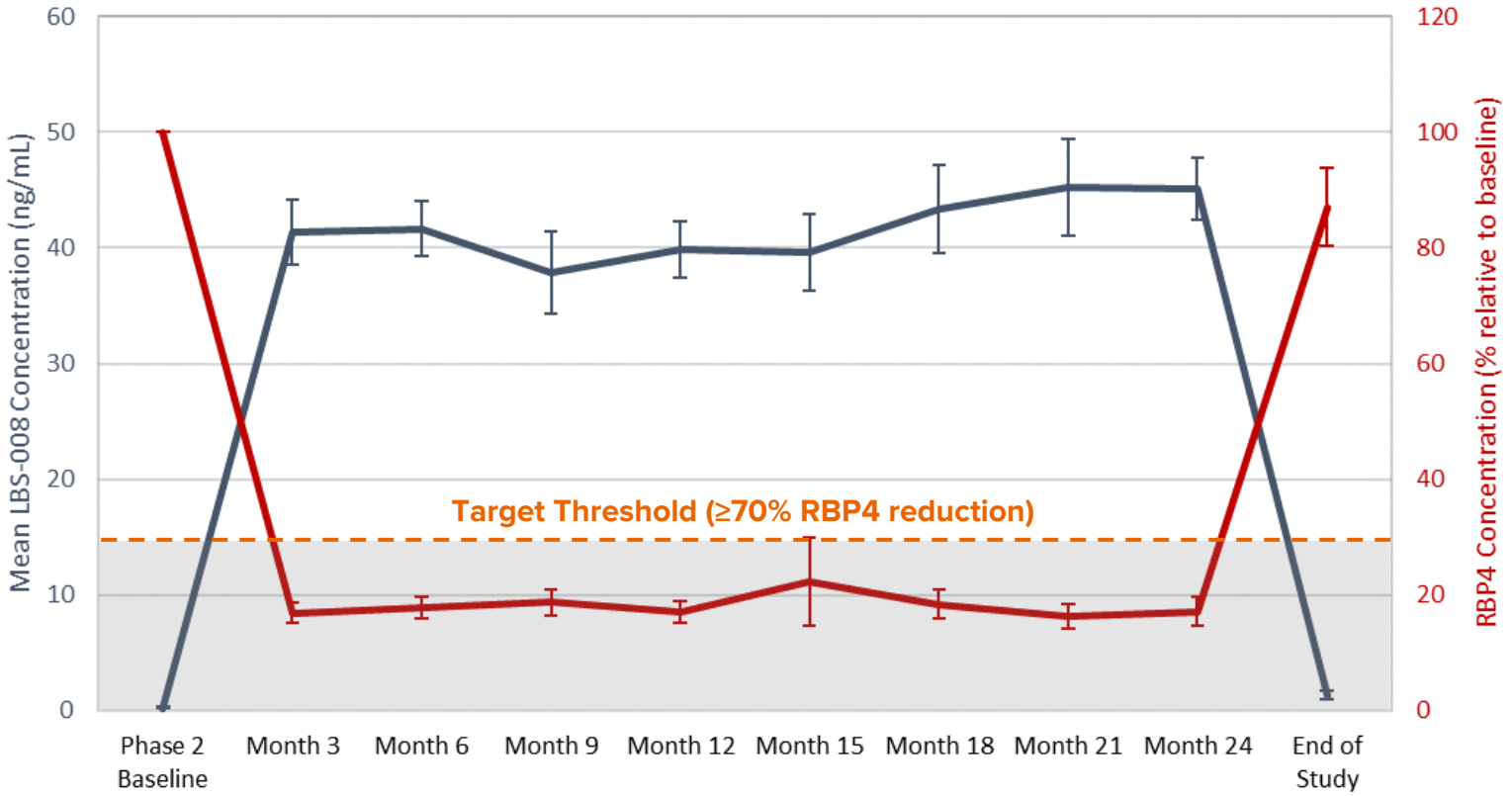
Reduction in Lesion Growth Rate (DDAF) as Measured by Retinal Imaging is the FDA Accepted Primary Endpoint in STGD1 and GA

	STGD1 Phase 2 "LBS-008-CT02" *(Preliminary 24-Month Data Available)*	STGD1 "Dragon" Phase 3*
Enrollment	13 subjects** (QDAF, no DDAF)***	104 subjects (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.
**LBS-008-CT02 initially enrolled 13 subjects in Australia and Taiwan. One subject in Australia was lost to follow up, therefore 12 subjects with complete 24-month data were evaluated.
***DDAF = definitely decreased autofluorescence; QDAF = questionably decreased autofluorescence.

Tinlarebant (LBS-008)

Ph2 24-month: Reduction of Plasma RBP4 Levels



- The 5 mg daily dose was effective to reduce RBP4 level by a mean of approximately 80% relative to baseline
- RPB4 levels returned to 87% of the baseline value at End of Study (28-days following drug cessation)
- Recovery of RBP4 concentration correlated well with the decreased tinlarebant exposure

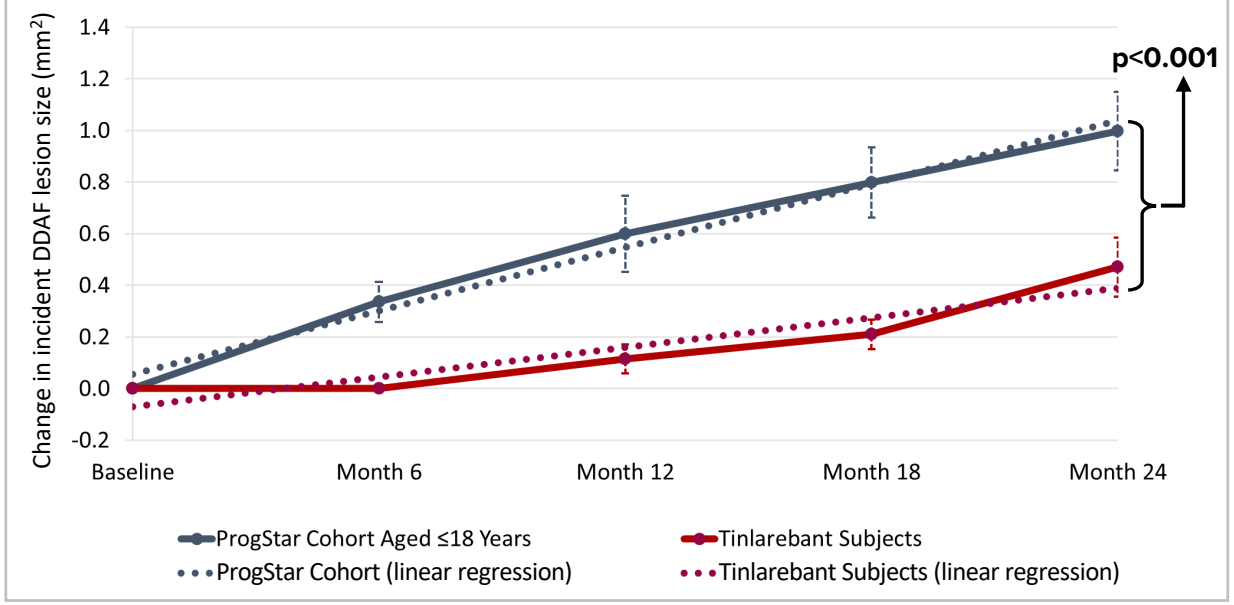
Note: Preliminary data and is subject to data verification and clean-up

Tinlarebant (LBS-008)

Ph2 24-month: Sustained Lower Lesion Growth Compared to ProgStar

- A comparison of incident DDAF lesion growth among ProgStar subjects with similar baseline characteristics as subjects in LBS-008-CT02 (i.e, ≤ 18 years old) was performed

Growth of Incident DDAF Retinal Lesions



	LBS-008-CT02	ProgStar Cohort [1, 2]
Patient Pool	**N=12**	**N=51* (aged ≤18 years)**
Mean change in incident DDAF lesion size at Month 24	**0.51± 0.4 mm²**	**1.00 ± 1.3 mm²**

Note:

** Only 50 patients from ProgStar Cohort (aged ≤18) were included in the analysis due to one subject having ungradable screening FAF data*

1. Strauss RW, Ho A, Muñoz B, et al. ProgStar Report No. 1. Ophthalmology. 2016;123(4):817-28.

2. Strauss RW, Muñoz B, Ho A, et al. ProgStar Report No. 9. JAMA Ophthalmol. 2017; 135(11):1232-1241.

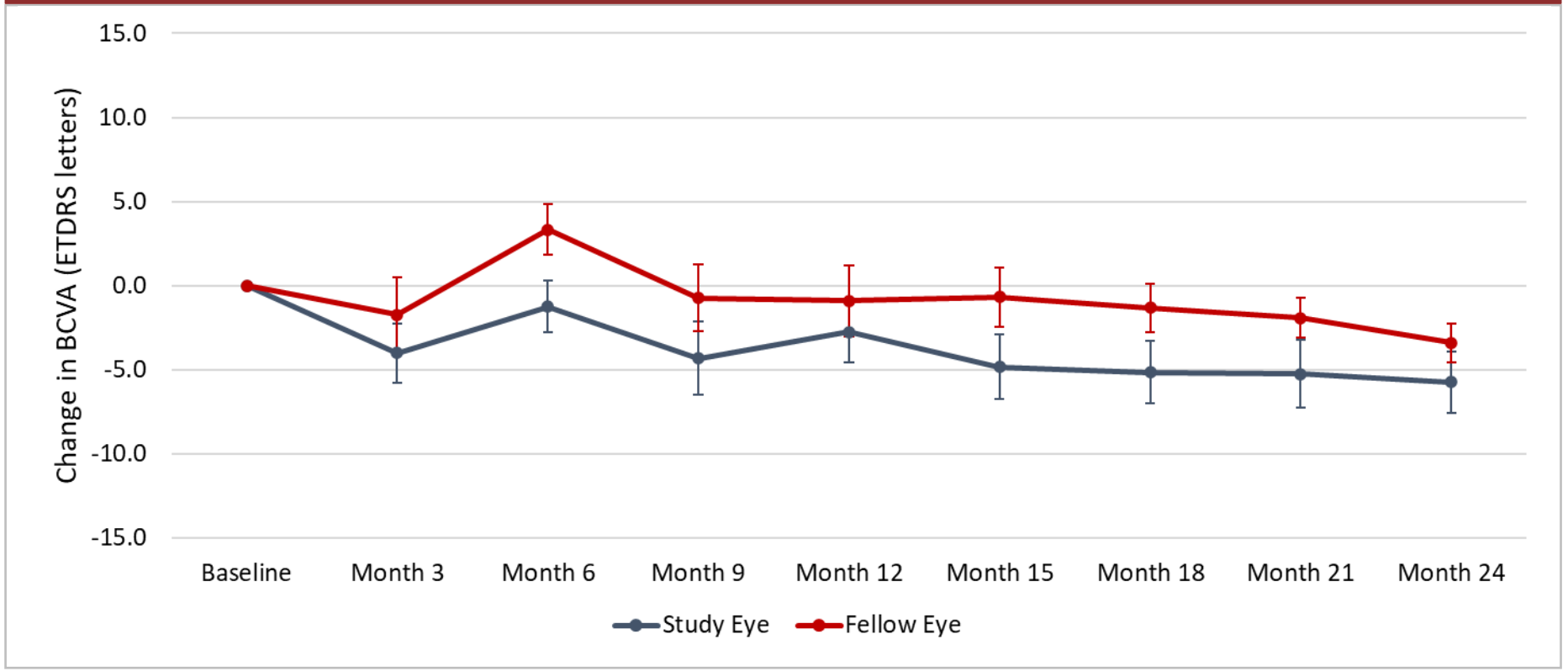
- **No development of DDAF** in 5 of 12 subjects at the 24-month timepoint
- A comparison of the 24-month DDAF lesion growth between Tinlarebant-treated subjects and ProgStar participants possessing similar baseline characteristics (aged ≤18 years) showed a sustained lower DDAF lesion growth in Tinlarebant-treated subjects over the 24-month treatment period (p<0.001)

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

Tinlarebant
(LBS-008)

Ph2 24-month: Visual Acuity Data

Stabilization of BCVA in LBS-008-CT02



- **Visual acuity** was stabilized in majority of subjects during the study with a mean loss of **5 letters** following 24 months of treatment (a loss of <10 letters is not considered clinically significant)

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

Tinlarebant
(LBS-008)

Ph2 24-month: Well-Tolerated Drug-Related Adverse Events

Adverse Events	Severity	Frequency (# and % of patients)
Xanthopsia/Chromatopsia	Mild	10/13 (76.9%)
Delayed Dark Adaptation	Mild	9/13 (69.2%)
Night Vision Impairment	Mild	1/13 (7.7%)
Increasing error score in FM100	Mild	1/13 (7.7%)
Intermittent headaches	Mild	2/13 (15.4%)

- 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

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Phase 3 Geographic Atrophy

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 (Enrolling)
Sites	Global
Masking	Double Blind
Placebo	2:1 ratio (Tinlarebant : Placebo)
Treatment duration	2 years
Primary measures	Slowing of atrophic lesion growth, safety & tolerability
Other measures	BCVA, SD-OCT, microperimetry
Interim analysis	Yes

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

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Q3 2023 Financial Results

For more info please visit: www.belitebio.com

Q3 2023 Financial Results

(In thousands of USD)	For the Three Months Ended September 30	
	2022	**2023**
Total operating expenses	2,540	10,961
- R&D	1,185	8,743
- G&A	1,355	2,218
Net loss	(2,403)	(10,935)

- Cash: $54.5 million

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

H2, 23

- Completed the enrollment of Phase 3 DRAGON study in STGD1
- November 5 – AAO Presentation of 24-month data from Phase 2 study in STGD1

H2, 24

- Interim results from Phase 3 DRAGON study in STGD1 expected

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Q&A to begin shortly

For more info please visit: www.belitebio.com