



Q3 2024 Financial Results Conference Call

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Nasdaq: BLTE

For more info please visit: www.belitebio.com

Belite Participants



Belite 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, Hong Kong University



Hendrik Scholl, MD, MA
(CMO)

- 25+ years of expertise in treating retinal diseases, including Stargardt disease and AMD
- Coordinating principal investigator of the largest natural history study of Stargardt disease (ProgStar Study)
- Participated in over 10 clinical studies both in Stargardt disease and AMD, over 280 publications in peer-reviewed journals
- University Eye Hospital Tübingen, University Eye Hospital Bonn, Wilmer Eye Institute at Johns Hopkins, University Eye Hospital Basel, Medical University of Vienna



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

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Belite Bio Pipeline Overview



PRECLINICAL

PHASE 1

PHASE 2

PHASE 3

NDA

Tinlarebant

○ Stargardt Disease (STGD1)

- Ph2 24-month final data continues to **show slowing of lesion growth**
- Ph3, 2-year treatment, global trial (“DRAGON” Study) is ongoing (completed enrollment, **104 subjects, age 12-20**, interim analysis expected by end of 2024 or early 2025)
- Ph2/3, 2-year treatment, global trial (“DRAGON II” Study) is ongoing (**60 subjects, age 12-20**)

○ Geographic Atrophy (GA)

- A Ph3, 2-year treatment, global trial (“PHOENIX” Study, **429 subjects**) is ongoing

- **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** designation in US / EU / JP, **Pioneer Drug** designation in JP, for STGD1
- **14 active patent families**; composition of matter patent until at least **2040** without patent term extension

3Q 2024 Highlights



- **Dr. Hendrik Scholl joined as CMO**
- **DRAGON II in adolescent Stargardt patients:**
 - Completed Phase 1b trial in Japan
 - Successfully dosed first patient in Phase 2/3 trial
- **PHOENIX in geographic atrophy patients:**
 - Enrolled more than 280 subjects to date

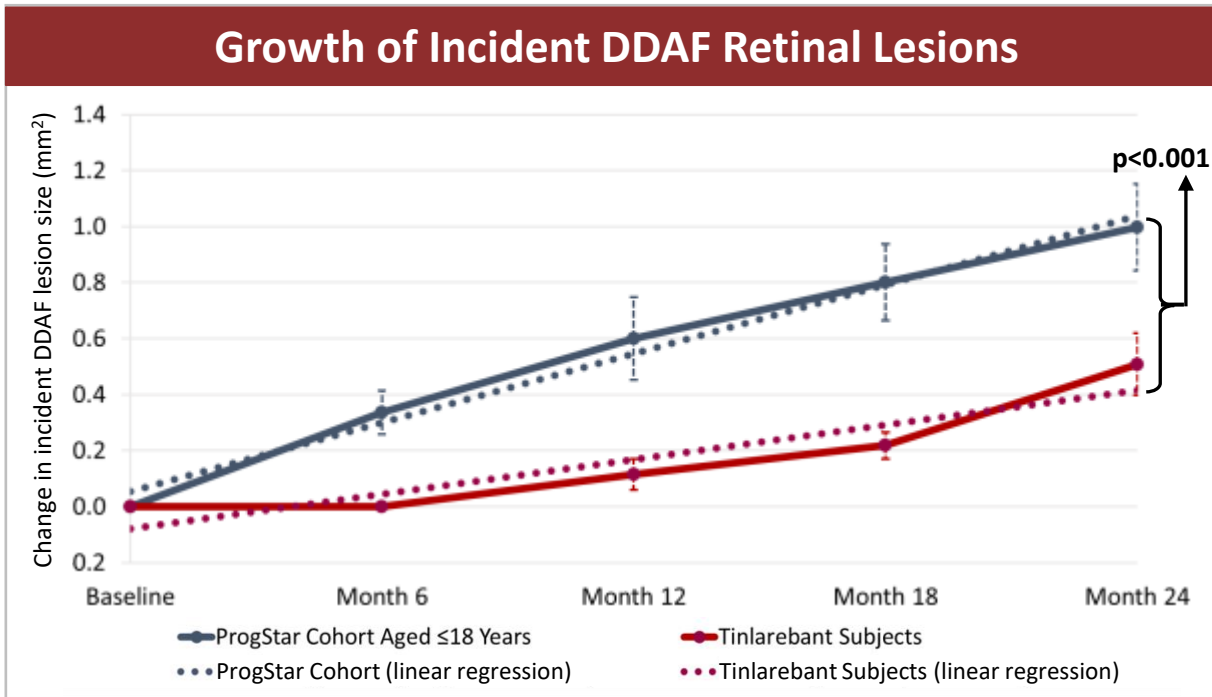


Phase 2 STGD1 Trial

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



	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 mm ²	1.00 ± 1.3 mm ²

Note:

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

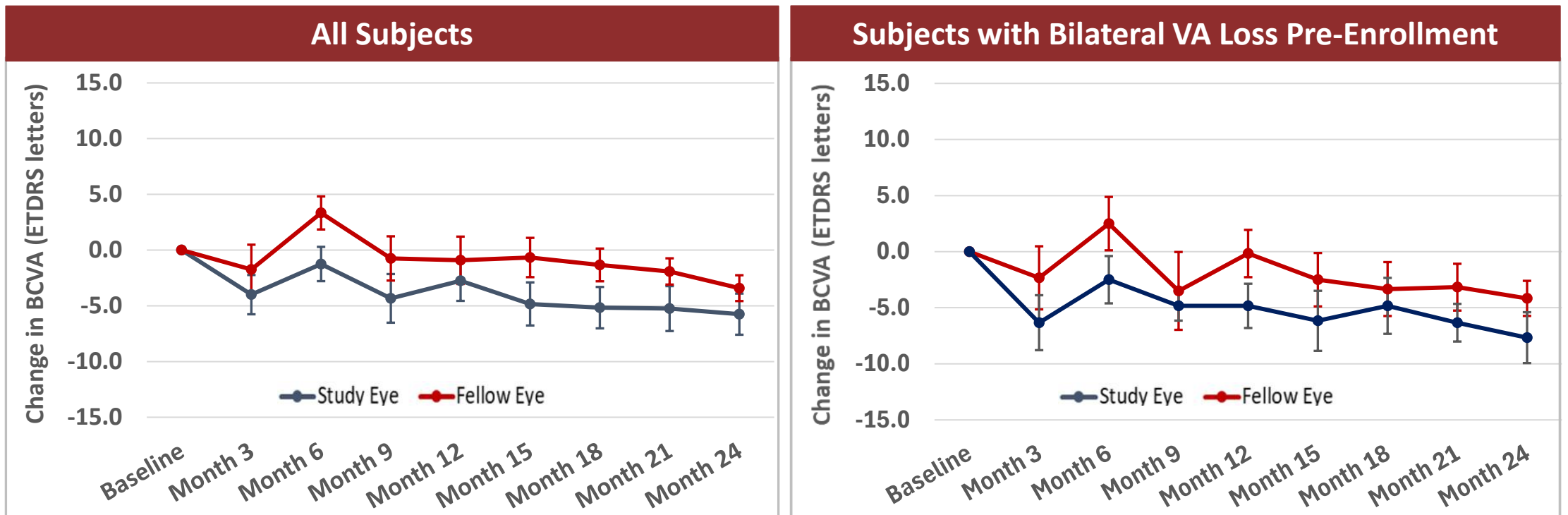
- Strauss RW, Ho A, Muñoz B, et al. ProgStar Report No. 1. *Ophthalmology*. 2016;123(4):817-28.
- Strauss RW, Muñoz B, Ho A, et al. ProgStar Report No. 9. *JAMA Ophthalmol*. 2017; 135(11):1232-1241.

- 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 ($p < 0.001$)



Visual Acuity Outcomes During the Phase 2 Study

- Visual acuity was stabilized during the study with a mean loss of 5 letters in the cohort over 24 months of treatment (2.5 letters lost/year, left panel)*
- For the 6 subjects with prior BCVA loss:
 - **Pre-enrollment, mean BCVA loss pre-enrollment was ~10 letters/year**
 - **Following 24 months of treatment, mean BCVA loss of was 6.1 letters (3 letters/year, right panel)***



*Mean BCVA values at each timepoint were used to calculate the mean BCVA change over 24 months

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



DRAGON & DRAGON II STGD1 Trials

DRAGON & DRAGON II Clinical Trial Design in STGD1



Reduction in lesion growth rate (DDAF) as measured by retinal imaging is the FDA accepted primary endpoint in STGD1 and GA

	STGD1 “DRAGON” Phase 3 ⁽¹⁾	STGD1 “DRAGON II” Phase 1b/2/3
Enrollment	104 subjects (have DDAF)	60 subjects (have DDAF)
Sites	Global	Japan, US, UK
Randomization	2:1 ratio (Tinarebant : Placebo)	1:1 ratio (Tinarebant : Placebo)
Masking	Double Blind	
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	
Key inclusion criteria	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	

⁽¹⁾ FDA may require another clinical trial depending on the data from the ongoing Phase 3 study.



Phase 3 PHOENIX Trial in Geographic Atrophy

Clinical Trial Design Overview in GA



The Phase 3 study design in GA is very similar to the Phase 3 study designs in STGD1

	GA Phase 3 “PHOENIX” ⁽¹⁾
Enrollment	Approximately 430 subjects targeted (Enrolling)
Sites	Global
Masking	Double Blind
Placebo	2:1 ratio (Tinarebant : Placebo)
Treatment duration	2 years
Primary measures	Slowing of atrophic lesion growth, safety & tolerability
Other measures	BCVA, SD-OCT, microperimetry
Interim analysis	Yes

⁽¹⁾ Additional Phase 3 study expected to be required prior to NDA filing



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2024 Third-Quarter Financial Results



(In thousand USD)	For the Three Months ended September 30	
	2023	2024
Total operating expenses	10,961	9,740
- R&D	8,743	6,842
- G&A	2,218	2,898
Net loss	(10,935)	(8,679)

- Cash, money market fund, time deposits and U.S treasury bills: \$109.0 million



Q&A to begin shortly

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