Belite BIO

Q1 2025 Financial Results Conference Call

May 15, 2025, 4:30 p.m. ET
Nasdaq: BLTE

For more info please visit: www.belitebio.com

Belite Bio 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

Forward-Looking Statements and Legal Disclaimer

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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.

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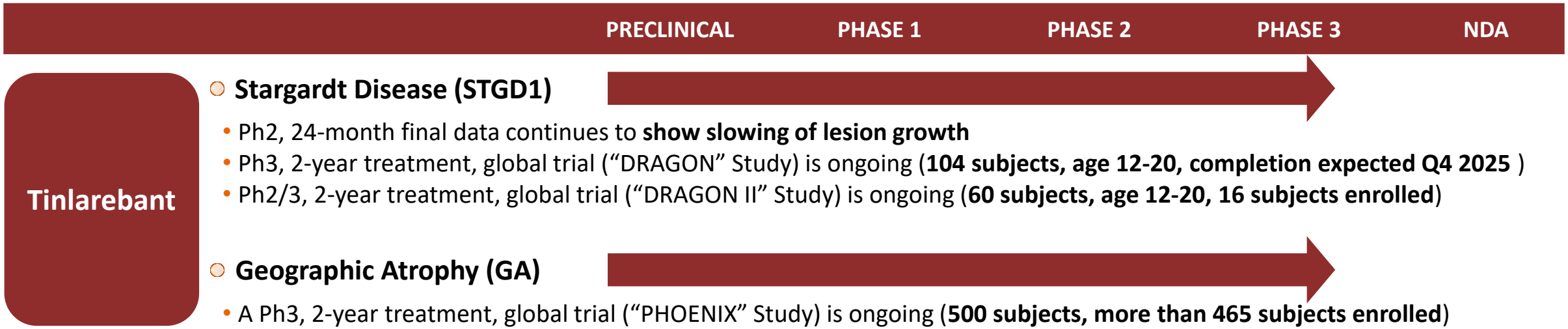
Belite Bio Pipeline Overview



- **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; **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

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DRAGON Clinical Trial Interim Analysis

Tinlarebant

DRAGON & DRAGON II Clinical Trial Design in STGD1

Reduction in atrophic lesion growth rate 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	60 subjects
Sites	Global	Japan, US, UK
Randomization	2:1 ratio (Tinlarebant : Placebo)	1:1 ratio (Tinlarebant : Placebo)
Masking	Double Blind	
Treatment duration	2 years	
Primary measures	Slowing of atrophic lesion growth, 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.

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DRAGON Clinical Trial
Demographics and Baseline Characteristics

	Mean (SD), Total N=104
Age (Years)	15.4 (2.47)
Baseline Height (cm)	168.12 (10.349)
Baseline Weight (kg)	61.75 (16.891)
Baseline BMI (kg/m2)	21.62 (4.578)

	N (%), Total N=104
Sex	
Male	65 (62.5%)
Female	39 (37.5%)
Race	
White	38 (36.5%)
Asian	58 (55.8%)
Multiple	1 (1.0%)
Other	7 (6.7%)

Tinlarebant

DRAGON Interim Analysis Conclusions

- **No modification of the study is required**
- **Continue the study without sample size increase**
- **Tinlarebant (5 mg p.o., daily) continues to be safe and well tolerated in adolescent STGD1 patients**
- **At the time of the Interim Analysis, the overall withdrawal rate was 9.6% (10 of 104 Subjects); the withdrawal rate due to ocular adverse events was 3.8 % (4 of 104 Subjects)**
- **Visual acuity was stabilized in the majority of subjects, with mean change from baseline of less than three letters under both standard and low luminance throughout the two-year study**

- **Additional DSMB comments:**
  - **It is recommended to submit the data for further regulatory review for drug approval**

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DRAGON Interim Safety Data
Treatment-Emergent Adverse Events

Adverse Events	Severity	Frequency N=104 (# and % of patients)
Xanthopsia	Mild	28 (26.9%)
Delayed Dark Adaptation	Mild	27 (26.0%)
Night Vision Impairment	Mild	15 (14.4%)
Headache	Mild	8 (7.7%)

- Tinlarebant (5 mg p.o., daily) continues to be **safe** and **well tolerated** in adolescent STGD1 patients
- Xanthopsia and Delayed Dark Adaptation are the most common drug related ophthalmic AEs
- Majority of Xanthopsia, Delayed Dark Adaptation and Night Vision Impairment were **mild**; some resolved while on treatment
- Headache is the most common treatment-related non-ocular AE
- No severe or serious treatment-related AEs reported
- No clinically significant findings in relation to vital signs, physical exams, cardiac health, or organ functions

Note: Data Extraction Date as of 11Feb2025; for ocular AE, only frequency > 10% is listed and for non-ocular AE, only frequency > 7% is listed

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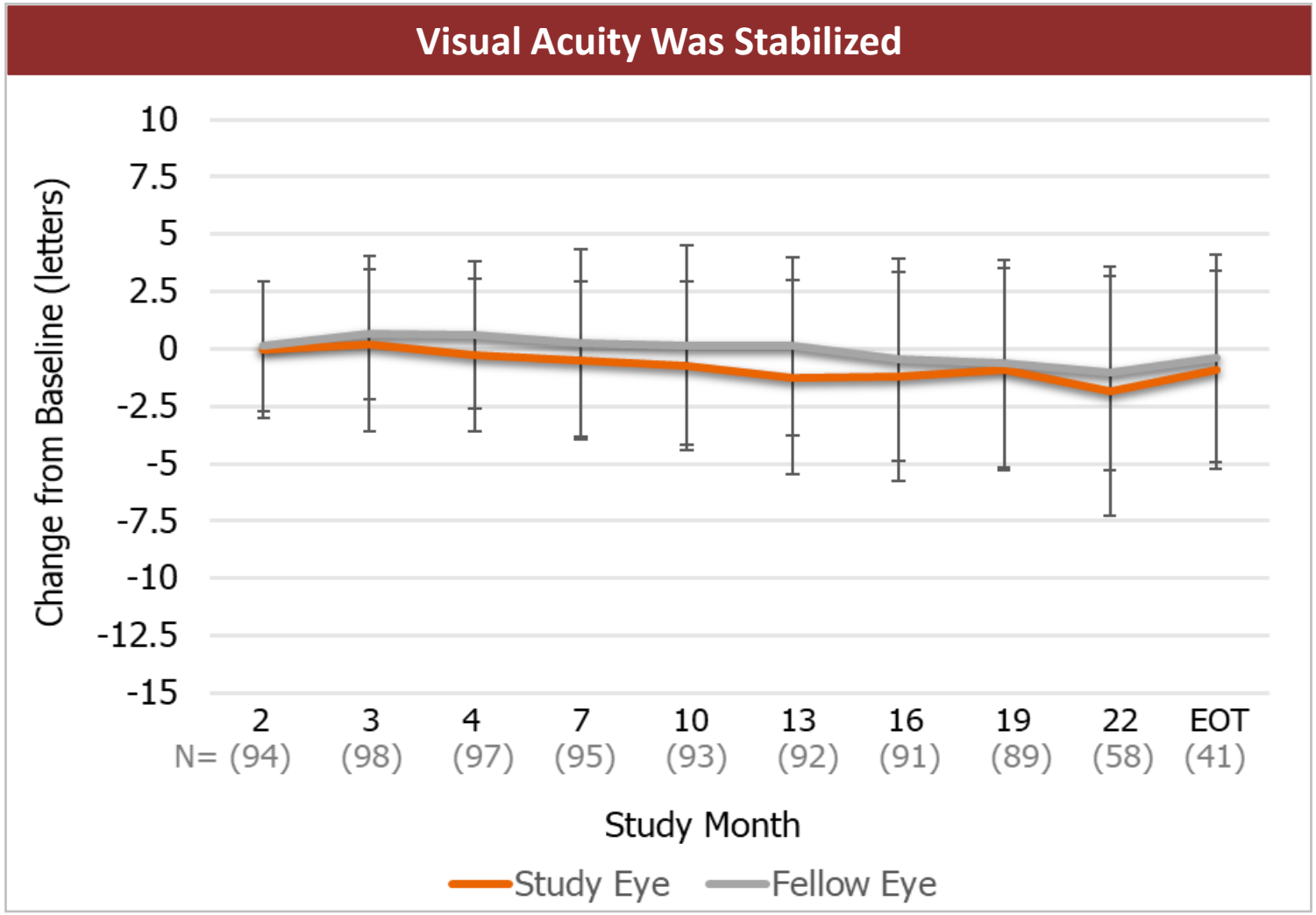
DRAGON Interim Visual Acuity Data
Change from Baseline (ETDRS Letter Score, Mean)



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Phase 3 PHOENIX Trial in Geographic Atrophy

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Clinical Trial Design Overview in GA

- **Established Efficacy Endpoint** – Reduction in atrophic lesion growth rate as measured by retinal imaging is the FDA accepted primary endpoint
- **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" (1)
Enrollment	Approximately 500 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

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

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2025 First-Quarter Financial Results

(In thousand USD)	For the Three Months Ended March 31	
	2025	2024
Total operating expenses	$15,517	$8,328
- R&D	$9,396	$6,765
- G&A	$6,121	$1,563
Net loss	($14,277)	($7,871)

Company further bolstered its balance sheet:

- Raised $15 million in gross proceeds in a registered direct offering on February 5, 2025
- Cash, liquidity fund, time deposits and U.S. treasury bills: $157.4 million

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Q&A

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