



# 2024 Full-Year Financial Results Conference Call

March 17, 2025  
Nasdaq: BLTE

# 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



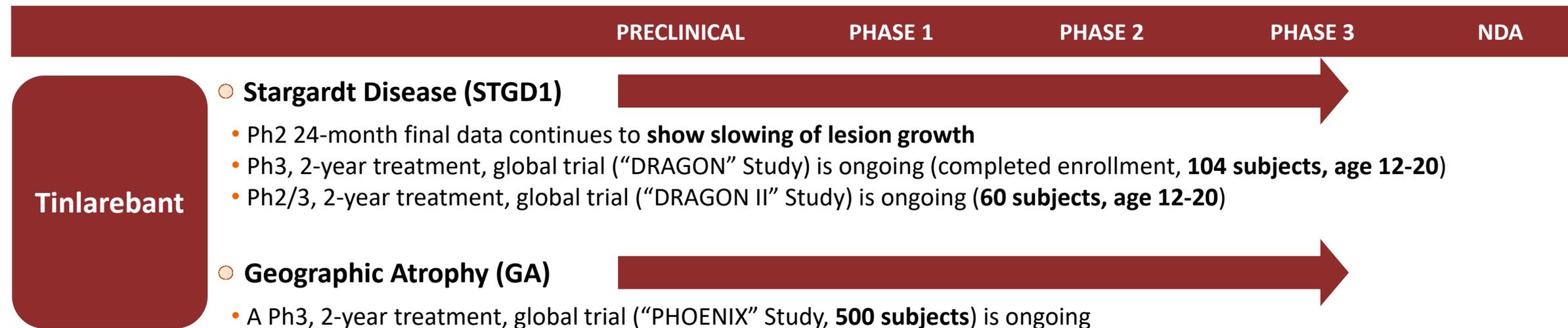
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# Belite Bio Pipeline Overview



- **Tinarebant** 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



# DRAGON Clinical Trial Interim Analysis

# 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 <sup>(1)</sup>	STGD1 “DRAGON II” Phase 1b/2/3
<b>Enrollment</b>	104 subjects	60 subjects
<b>Sites</b>	Global	Japan, US, UK
<b>Randomization</b>	2:1 ratio (Tinarebant : Placebo)	1:1 ratio (Tinarebant : Placebo)
<b>Masking</b>	Double Blind	
<b>Treatment duration</b>	2 years	
<b>Primary measures</b>	Slowing of atrophic lesion growth, safety & tolerability	
<b>Other measures</b>	QDAF, BCVA, SD-OCT, microperimetry	
<b>Interim analysis</b>	Yes	
<b>Key inclusion criteria</b>	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 <sup>2</sup> ), a BCVA of 20/200 or better	

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

# 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/m <sup>2</sup> )	21.62 (4.578)

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

# DRAGON Interim Analysis Conclusions



- **No modification of the study is required**
  - **Continue the study without sample size increase**
  - **Tinarebant (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**
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- **Additional DSMB comments:**
    - **It is recommended to submit the data for further regulatory review for drug approval**

# DRAGON Interim Safety Data

## Treatment-Emergent Adverse Events



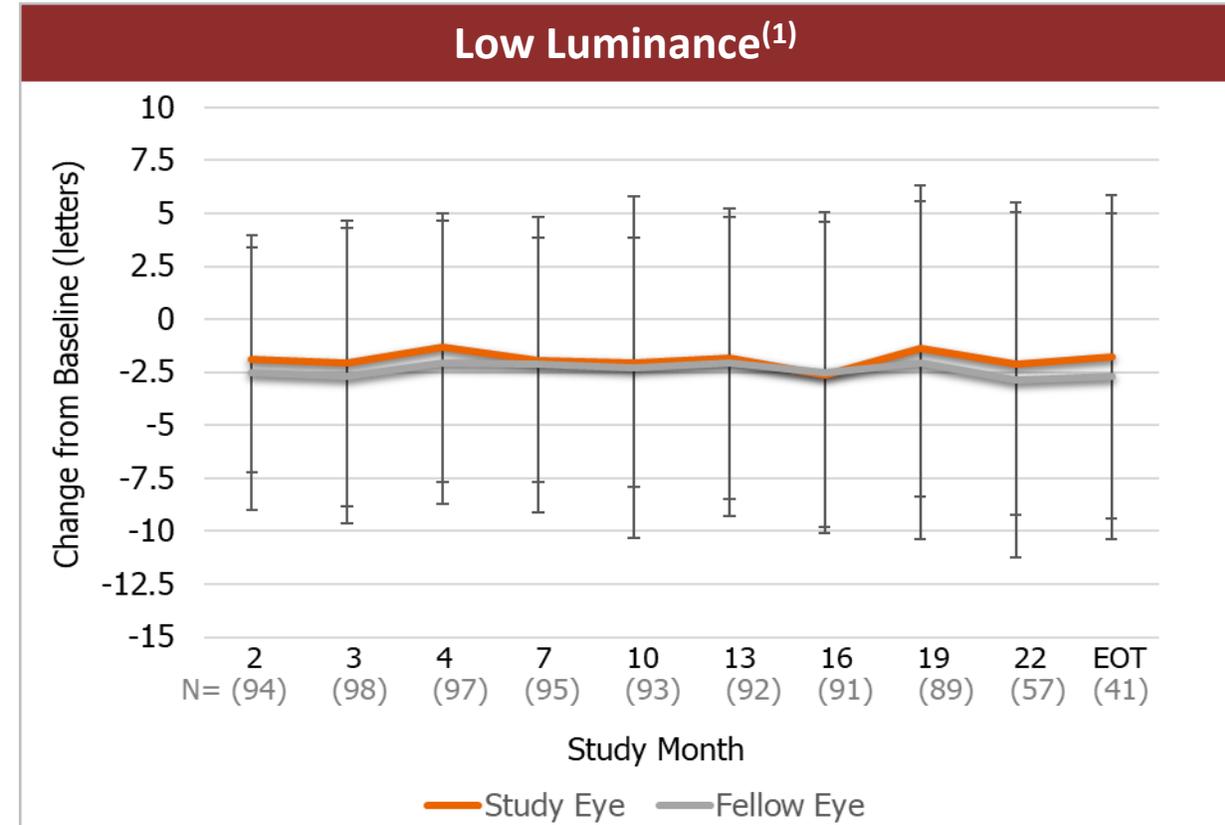
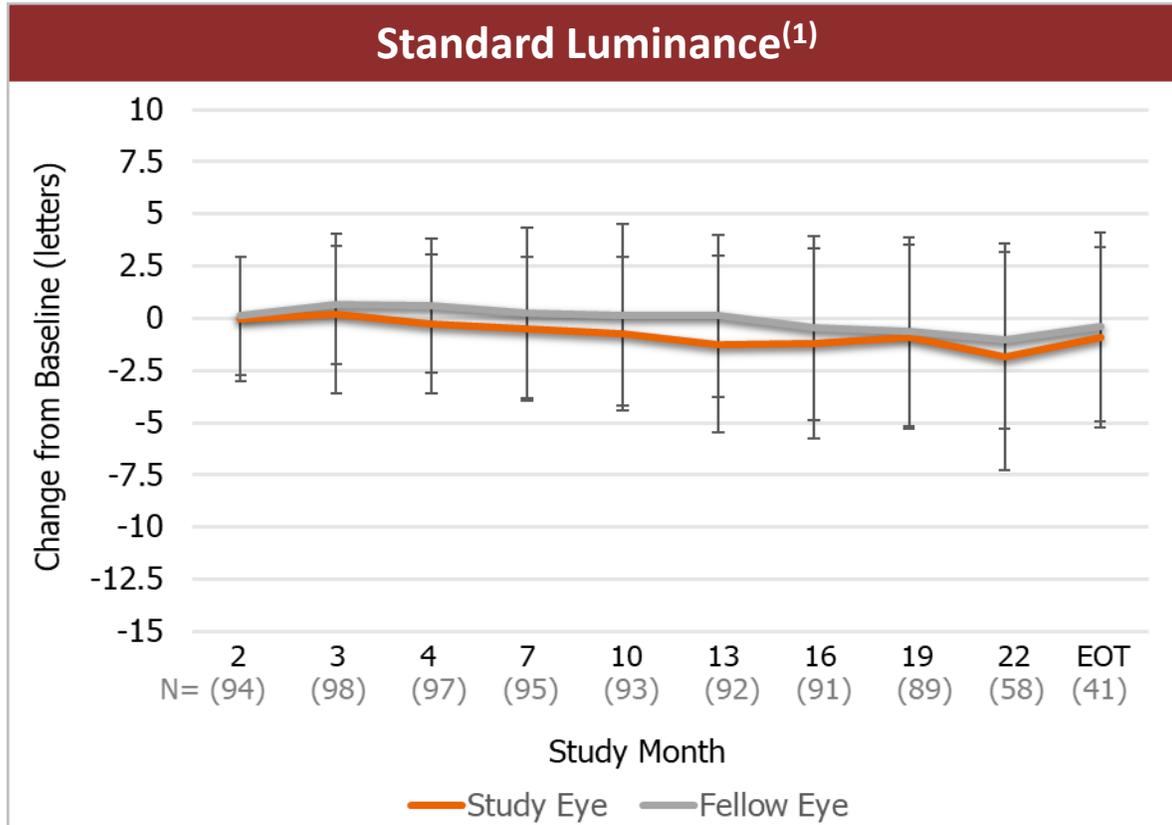
Adverse Events	Severity	Frequency N=104 (# and % of patients)
Xanthopsia	Mild	28 (26.9%)
Delayed Dark Adaptation	Mild	27 (26.0%)
Night Vision Impairment	Mild	15 (14.4%)
Headache	Mild	8 (7.7%)

- 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

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



- Visual acuity was stabilized for the study duration, under both standard luminance and low luminance.



(1) Data converted according to **LogMar Score = 1.7 - 0.02 × Number of Letter Read** (Visual acuity score conversion chart. Diabetic Retinopathy Clinical Research Network website) [http://drcrnet.jaeb.org/ViewPage.aspx?PageName=Investig\\_Info](http://drcrnet.jaeb.org/ViewPage.aspx?PageName=Investig_Info). Accessed July 5, 2014.



# Phase 3 PHOENIX Trial in Geographic Atrophy

# 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” <sup>(1)</sup>
<b>Enrollment</b>	Approximately 500 subjects targeted (Enrolling)
<b>Sites</b>	Global
<b>Masking</b>	Double Blind
<b>Placebo</b>	2:1 ratio (Tinarebant : Placebo)
<b>Treatment duration</b>	2 years
<b>Primary measures</b>	Slowing of atrophic lesion growth, safety & tolerability
<b>Other measures</b>	BCVA, SD-OCT, microperimetry
<b>Interim analysis</b>	Yes

<sup>(1)</sup> Additional Phase 3 study expected to be required prior to NDA filing



# 2024 Full-Year Financial Results

For more info please visit: [www.belitebio.com](http://www.belitebio.com)

# 2024 Full-Year Financial Results



(In thousand USD)	For the years ended December 31	
	2023	2024
<b>Total operating expenses</b>	31,668	39,996
- R&D	24,844	29,939
- G&A	6,824	10,057
<b>Net loss</b>	(31,632)	(36,144)

- Cash, liquidity fund, time deposits and U.S. treasury bills: \$145.2 million



# Q&A

For more info please visit: [www.belitebio.com](http://www.belitebio.com)