Belite BIO

Q1 2024 Financial Results Conference Call

May 14, 2024, 4:30 p.m. ET
Nasdaq: BLTE

For more info please visit: www.belitebio.com

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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, HK University

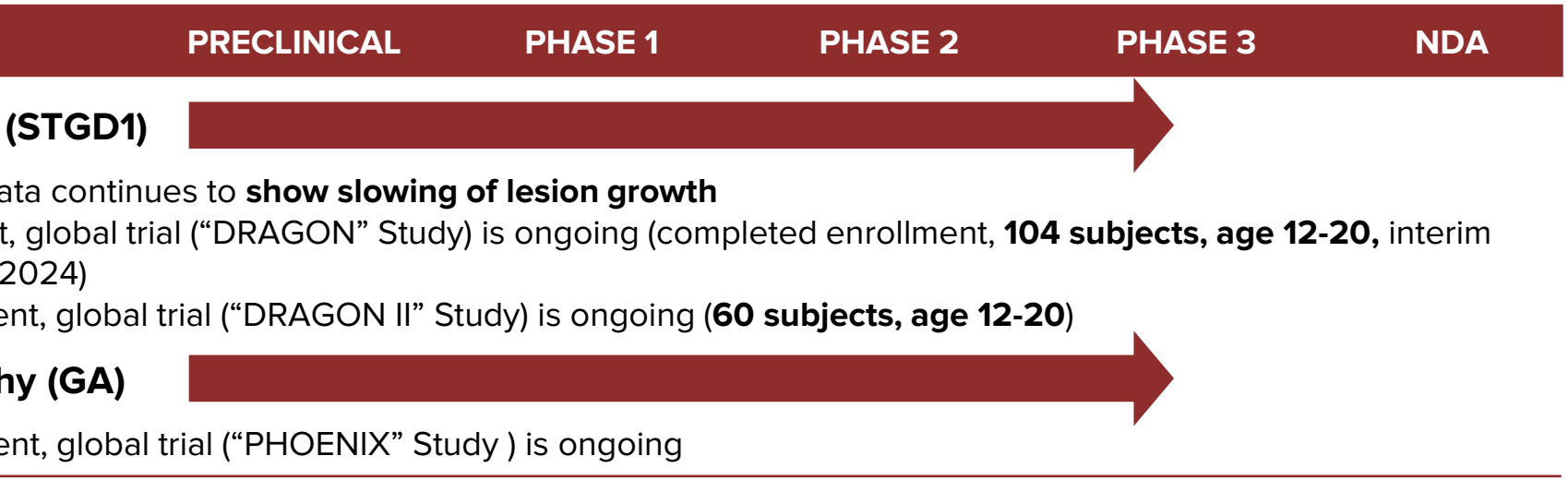
Nathan Mata, PhD
(CSO)

- 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 / JP for STGD1
- **14 active patent families**; composition of matter patent until at least **2040** without patent term extension

Belite BIO

STGD1 Clinical Trials

Tinlarebant (LBS-008)

Analysis of ABCA4 Mutations in the Phase 2 Study Cohort

- Severe biallelic ABCA4 mutations were found in 11 of 13 subjects (Subjects 3 and 5 harbored one moderate allele each)

Subject	cDNA change	Protein change	CADD v1.6[1]	Assessment	Function tested in vitro	ClinVar
1	c.1922G>C	p.Cys641Ser	25.7	likely severe		not provided
1	c.2905A>G	p.Lys969Glu	28.9	likely severe		Pathogenic
2	c.768G>T	p.(Leu257Valfs*17)	23.1	severe	yes	Pathogenic/Likely pathogenic
2	c.[1532G>A;6006-1G>C]	p.[Arg511His;?]	15.3; 34	severe		not provided
3	c.4539+2028C>T	p.[=,Arg1514Leufs*36]	1.79	moderate	yes	Pathogenic/Likely pathogenic
3	c.2894A>G	p.Asn965Ser	24.8	severe	yes	Pathogenic
4	c.2576del	p.Gln859Argfs*41	N/A	severe		Pathogenic
4	c.[2588G>C;5603A>T]	p.[Gly863Ala;Asn1868Ile]	31; 23.3	moderate/severe	yes; yes	Likely pathogenic
5	c.3260A>G	p.Glu1087Gly	29.5	likely severe		Pathogenic
5	c.5714+5G>A	p.[=,Glu1863Leufs*33]	19.1	moderate	yes	Pathogenic/Likely pathogenic
6	c.5461-10T>C	p.[Thr1821Aspfs*6,Thr1821Valfs*13]	16.8	severe	yes	Pathogenic
6	c.6079C>T	p.Leu2027Phe	27.6	severe	yes	Pathogenic/Likely pathogenic
7	c.634C>T	p.Arg212Cys	26.3	severe	yes	Pathogenic/Likely pathogenic
7	c.2894A>G	p.Asn965Ser	24.8	severe	yes	Pathogenic
8	c.161G>A	p.Cys54Tyr	33	severe	yes	Pathogenic/Likely pathogenic
8	c.4139C>T	p.Pro1380Leu	25.3	moderate/severe	yes	Pathogenic/Likely pathogenic
9	c.1804C>T	p.Arg602Trp	24.7	severe	yes	Pathogenic/Likely pathogenic
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(1) Combined Annotation–Dependent Depletion (CADD)
Variants with CADD score >20 predicted to be among the 1% most deleterious
https://cadd.gs.washington.edu/

N/A: Not available

Tinlarebant (LBS-008)

Analysis of ABCA4 Mutations in the Phase 2 Study Cohort

- Subjects 1, 3, 4, 12, and 13
  - Did not develop atrophic lesions during the Phase 2 study
  - Despite harboring severe or likely severe alleles

Subject	cDNA change	Protein change	CADD v1.6[1]	Assessment	Function tested in vitro	ClinVar
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Tinlarebant (LBS-008)

Analysis of ABCA4 Mutations in the Phase 2 Study Cohort (cont.)

- Subjects 9 & 10 (brothers)
- Subjects 12 & 13 (brother/sister)
- Harbor identical mutations
- Different phenotypes

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1	c.1922G>C	p.Cys641Ser	25.7	likely severe		not provided
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N/A: Not available

Tinlarebant (LBS-008)

Visual Acuity Outcomes - Background

- A subgroup of 6 subjects
  - mean bilateral BCVA loss of ~10 letters/year prior to enrollment
- The natural history would predict significant visual loss over 2 yrs
- Foveal-involved QDAF leads to visual acuity compromise

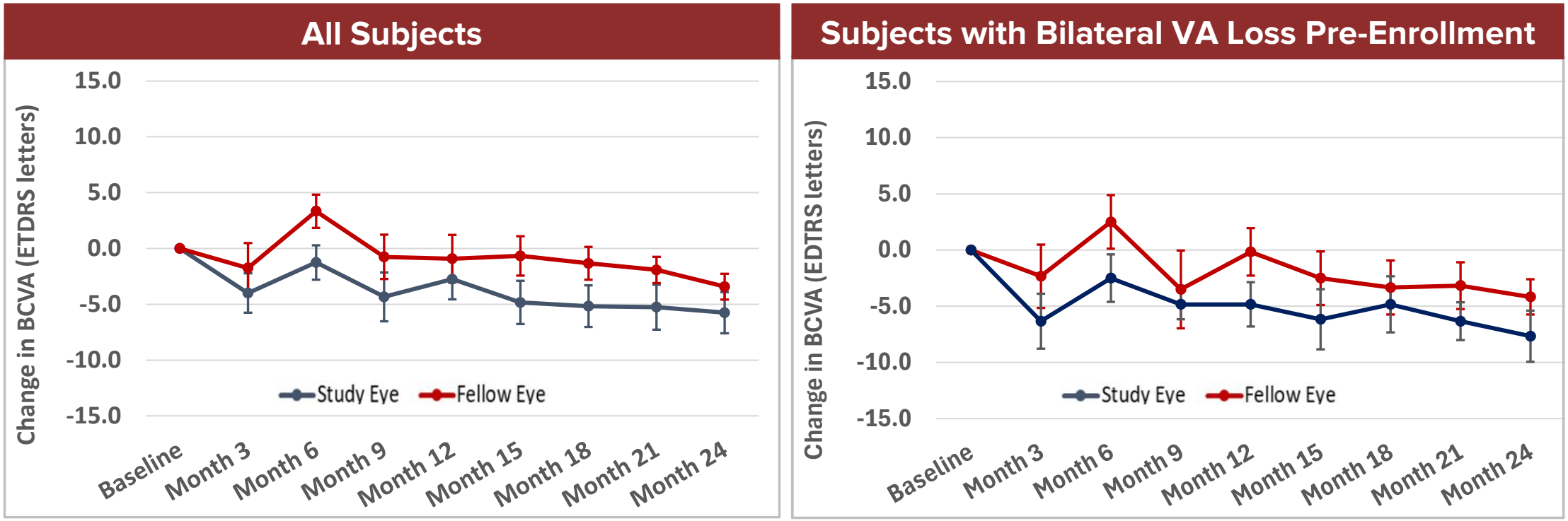
Subject	Race	Gender	Age at First Exam	Age at Enrollment	Disease Duration (yrs)	BCVA at Diagnosis Exam (Right / Left)	BCVA at Enrollment (Right/Left)	Annual Letter Loss (Right/Left)
1	Caucasian	Female	13	15	2	36/37	34/36	-
2	Caucasian	Female	11	12	1	33/39	40/42	-
3	Asian/ Caucasian	Female	13	13	<1	49/44	49/48	-
4	Caucasian	Female	14	15	1	39/44	45/45	-
5*	**Caucasian**	**Female**	**12**	**13**	**1**	**70/61**	**45/55**	**25/6**
6*	**Caucasian**	**Female**	**13**	**18**	**5**	**70/65**	**35/36**	**7/6**
7	Caucasian	Male	15	15	<1	59/75	69/40	-
8*	**Caucasian**	**Male**	**8**	**13**	**5**	**57/57**	**31/31**	**5/5**
9	Asian	Male	12	13	1	50/35	45/35	-
10*	**Asian**	**Male**	**11**	**12**	**1**	**50/59**	**45/35**	**5/24**
11*	**Asian**	**Female**	**13**	**14**	**1**	**59/59**	**50/50**	**9/9**
12	Asian	Female	10	18	8	35/44	35/35	-
13*	**Asian**	**Male**	**10**	**12**	**2**	**59/59**	**35/35**	**12/12**

*Subjects showing annual bilateral BCVA loss prior to Phase 2 enrollment; BCVA loss for subjects with <1 year disease not considered

Tinlarebant (LBS-008)

Change in Best Corrected Visual Acuity

- Visual acuity was stabilized during the study with a mean loss of 5 letters in the cohort over 24 months of treatment (equivalent to 2.5 letters lost/year, left panel)*
- For the 6 subjects:
  - Pre-enrollment mean bilateral loss of ~10 letters/year
  - 24-month data mean BCVA loss was 3.8 letters (equivalent to 1.9 letters lost/year, right panel)*

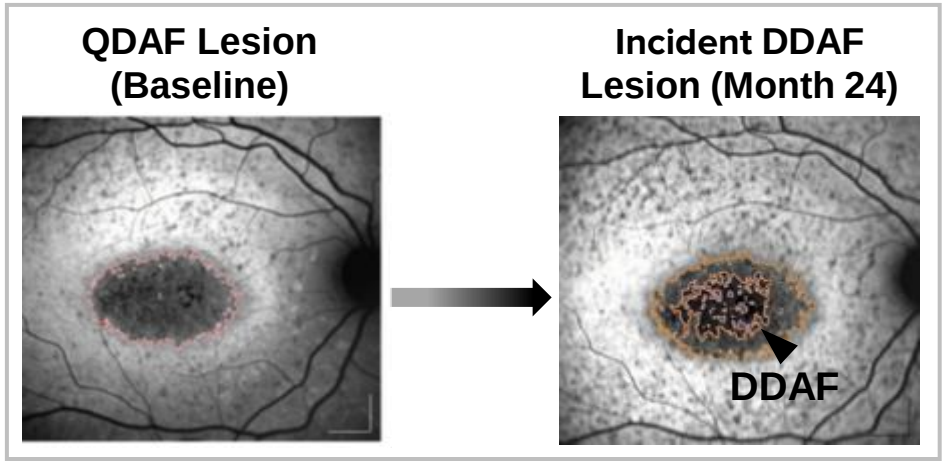


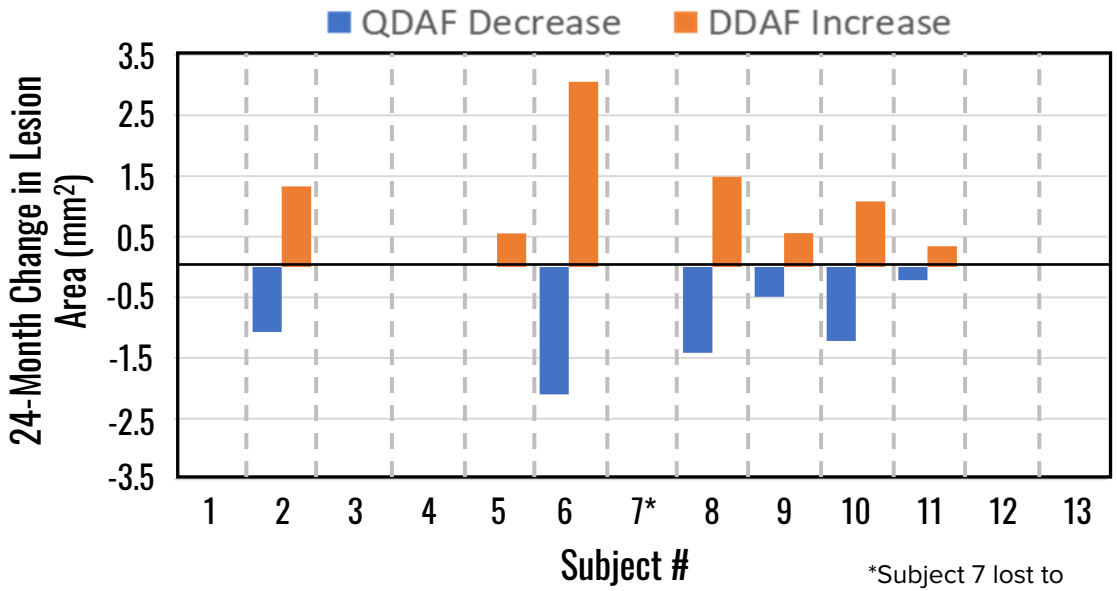
*Mean BCVA values at each timepoint were used to calculate the mean BCVA change over 24 months

Tinlarebant (LBS-008)

24-Month Change in QDAF and DDAF Lesion Size

- Transition to, and growth of, incident DDAF in cohort
- In 5 of 12 subjects (42%),
  - no change in QDAF lesion size
  - no incident DDAF lesion growth observed
- In 7 of 12 subjects (58%)
  - DDAF lesions were relatively small
  - DDAF occurred with QDAF lesions
- Only 1 subject (#5) showed a new DDAF lesion (0.5 mm^2) which was outside of the QDAF lesion area that was identified at Baseline
- Sibling subjects with identical *ABCA4* mutations and similar disease duration (9, 10, 13) showed different disease progression based on BCVA loss and QDAF/DDAF lesion growth





*Subject 7 lost to follow up at Month 12

Tinlarebant
(LBS-008)

Measurement of DDAF: Region Finder vs. Novel Method

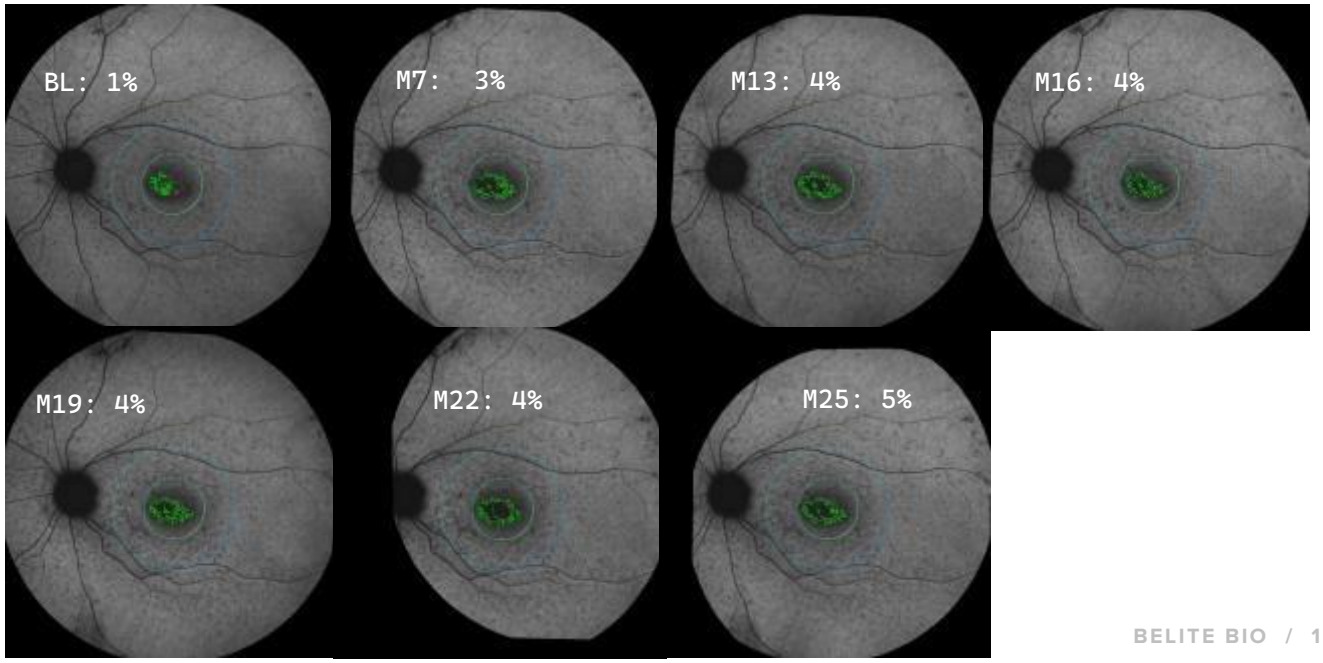
Region Finder

- Relies heavily on the grader's ability to visually determine the types and boundaries of areas with different levels of disc-derived autofluorescence (DDAF, DAF, QDAF)
- There is intra- and inter-grader variability
  - due to subjective assessment of lesion grayscale compared to the optic disc
- General assessment without specific focus on key regions
  - potentially leading to less precise measurements

Novel Lesion Size Quantification Method

- Utilizes mathematical classification of lesions based on the proximity of their gray values to that of the optic disc, reducing subjective bias
- Focuses on specific regions (macular area within central 6mm diameter and smaller zones of 1mm and 3mm ETDRS), enhancing the accuracy of localization and quantification
- Independent of initial lesion size, employing a pixel-based method that consistently evaluates the percentage of a region affected at specified DAF thresholds

DAF @ >90 %

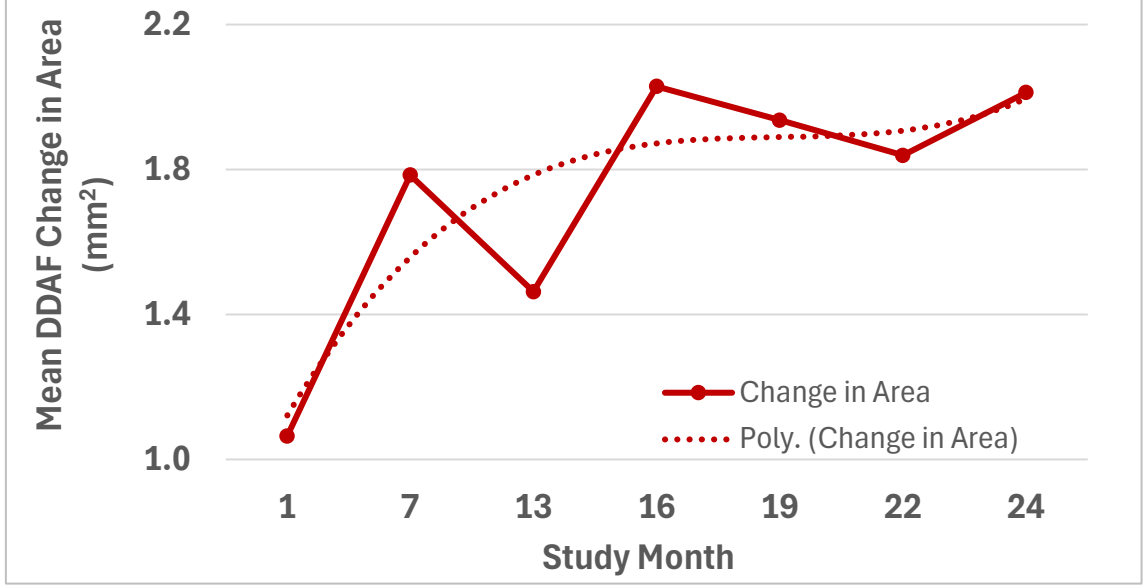


Tinlarebant (LBS-008)

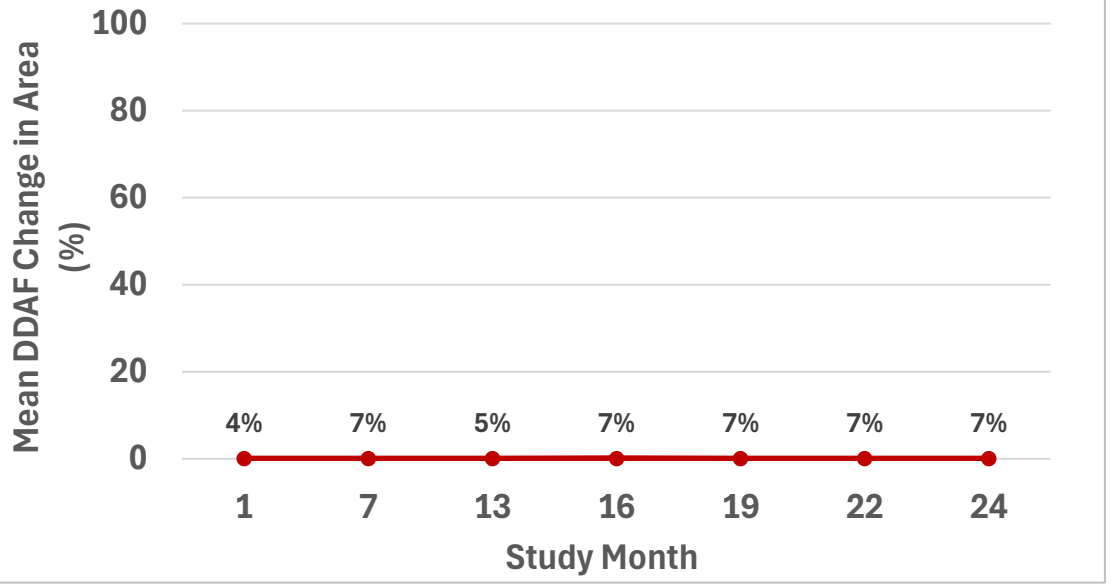
A Newly Developed Grading Algorithm Reveals Atrophic Macular Lesions

- FAF Analysis using new grading methodology showed atrophic lesions within the macula (6 mm outer ring) in 12 eyes of 8 subjects at Baseline
- In these subjects, growth of atrophic macular lesions was stabilized from Months 16 – 24
  - left panel; a 3rd order polynomial function of the lesion area data is shown
  - The extent of macular lesion involvement was ≤ 7% involvement over 24 Months (right panel)

Mean Change in Area of Macular Involvement



Mean Change in Percent of Macular Involvement



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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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Q1 2024 Financial Results

For more info please visit: www.belitebio.com

2024 First-Quarter Financial Results

(In thousand USD)	For the Three Months ended March 31	
	2023	2024
Total operating expenses	6,881	8,328
- R&D	5,723	6,765
- G&A	1,158	1,563
Net loss	(6,895)	(7,871)

- Cash & U.S treasury bills: $95.5 million
- Raised $25 million in gross proceeds in a registered direct offering in April

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Q&A to begin shortly

For more info please visit: www.belitebio.com