



Slowing the Progression of Macular Degeneration

Mission for Vision

Media and Investor Relations Contact:
Jennifer Wu /ir@belitebio.com
Tim McCarthy /tim@lifesciadvisors.com

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At-a-Glance



“Bringing Hope to Incurable Blindness”



As of 2022/7/21	Belite Bio, Inc
Share Symbol	BLTE
Stock Exchange	NASDAQ
Stock Price	\$ 41.51
Shares Outstanding	24.87 million
Market Cap	\$ 1,032.35 million

Leadership



Management



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

- 10 years of executive management role in biotech, including 2 IPO
- Over 10 new drug developments in multiple therapeutic areas, including Ophthalmology, CNS, Cardiovascular, Oncology, Immuno-Oncology, Immunotherapies, Immunosuppressants
- 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 2 NDAs for topical therapeutics (Durezol® and Zirgan®)
- Led the clinical development efforts for first RBP antagonist in advanced dry AMD and first visual cycle modulator in advanced dry AMD and STGD
- Introduced the industry's first Stargardt's ABCA4 knockout mice model
- University of Texas



Jane Chiu, MS
(VP, Clinical Operations)

- 25 years clinical operations experience in multiple therapeutical area
- 15+ years as President/Managing Director of multinational CRO, conducting over 100 studies
- 10+ years of clinical operations experience in global pharma (Astellas, Bayer, Pfizer)
- Warwick University



H.Y. Chuang, CFA, MBA, FRM
(CFO)

- 11 years of capital market experience, closed more than US\$32 billion transactions
- Wanda, Suning, CITIC Securities
- Columbia University, London Business School, HK University

Belite Bio Opportunity



Oral treatment for
an unmet market

- **Belite Bio's lead asset LBS-008** is a novel, **orally administered, Retinol Binding Protein 4 ("RBP4") antagonist** intended to slow or halt progression of vision loss in Stargardt disease (STGD1) and dry AMD. A Phase 3 trial has been initiated in adolescent STGD1 patients and a Phase 2/3 trial in dry AMD is planned in 2022.
- **Granted Fast Track Designation, Rare Pediatric Disease** in US / **Orphan Drug Disease** designation in US and EU for STGD1.
- **Priority Review Voucher (PRV)** eligible, vouchers have sold for \$80M-\$125M.
- Currently **no approved treatments** for either STGD1 or dry AMD, significant market opportunity to become **Standard of Care**.
- Ongoing **2-year Phase 2 trial (6 months** of reported **interim** safety data and preliminary efficacy data) in STGD1. Goal is to halt or slow disease progression in early-onset patients.
- **Established human proof-of-concept data** from a 2-year, Phase 2 trial of fenretinide (a retinoid-based RBP4 antagonist) **in advanced dry AMD**.
- Clinical development approach **endorsed by US NIH**, specifically **to treat dry AMD**.
- **UK NIHR's** 2018 systematic review of >7,000 publications recommends RBP4 antagonists as a **priority for clinical development to treat both STGD1 and dry AMD**.
- Highly **experienced senior management team** supported by **world-renowned advisory board** and **influential key opinion leaders** with decades of clinical development experience.

Development
of lead asset

Board of Directors



Board



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



John M. Longo, PhD
(Independent Director)

- Prof. of Rutgers Business School
- Chief Investment officer of Beacon Trust



Gary C. Biddle, PhD, CPA
(Independent Director)

- Prof. of University of Melbourne
- INED of Kingdee Software, Shui On Land Limited, Real Pet Food Company.



Ita Lu
(Independent Director)

- Managing partner of Taiwan Capital



H.Y. Chuang, CFA, MBA, FRM
(CFO)



Yvonne Chen
(Affiliated Director)

- COO of Lin Bio, our ultimate controlling shareholder



Serena Chen
(Affiliated Director)

- Associate finance director of Lin Bio, our ultimate controlling shareholder

Clinical Advisory Board



Dr. Frank Holz

- Chairman of Ophthalmology, University of Bonn



Dr. Michel Michaelides

- Ophthalmologist at Moorfields Eye Hospital
- Prof. of Ophthalmology, Univ. College London



Dr. Quan Nguyen

- Prof. of Ophthalmology, Stanford University



Dr. Hendrik P.N. Scholl

- Prof. and Chairman of the Dept. of Ophthalmology, Univ. of Basel
- Co-Director of the Institute of Molecular and Clinical Ophthalmology in Basel



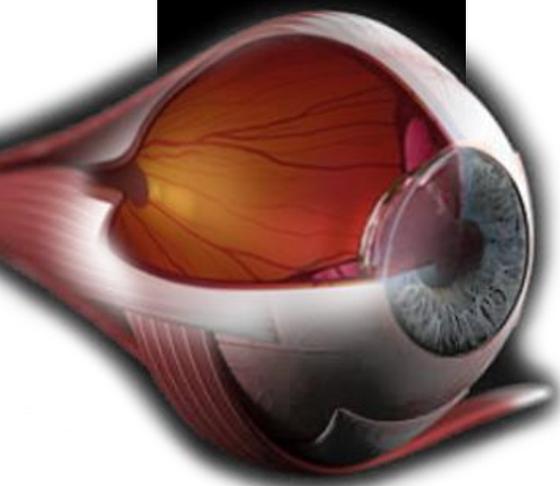
Dr. Robyn Guymer

- Prof. of Ophthalmology, University of Melbourne
- Deputy Director of the Centre for Eye Research Australia



LBS
008

- DISCOVERY
- PRE-CLINICAL
- PHASE I
- PHASE II
- **PHASE III**
- MARKET



BRING LIGHT TO INCURABLE BLINDESS

For Dry Age-Related Macular Degeneration & Stargardt Disease

KEY OPPORTUNITY

Zero Approved Treatments

FDA Fasttrack, RPD, ODD  COLUMBIA UNIVERSITY
+ EU ODD designations for STGD1

NIH Blueprint

“a promising first-in-class oral medication intended to slow or halt the progression of dry AMD”

Reference: <https://www.ninds.nih.gov/About-NINDS/Impact/Translational-Research-Success-Stories>

Dry AMD MARKET

11M

dry AMD patients in the US (90% AMD are dry AMD)

\$255B

estimated global direct healthcare cost of dry AMD

Reference: Globaldata, Lancet, Orphanet, STEM CELLS Translational Medicine

STGD1 MARKET

1 in 10,000

inherited juvenile onset macular degeneration

30,000

STGD1 patients in the US

Overview of Stargardt Disease & Dry AMD



Stargardt Disease (STGD1)

- The **most common inherited retinal dystrophy** (blurring or loss of central vision) in both adults and children
- Caused by a **dysfunctional retina-specific gene (ABCA4)** which causes massive accumulation of toxic vitamin A byproducts ('bisretinoids') in the retina leading to retinal cell death and progressive loss of central vision
- Fluorescent properties of bisretinoids and the development of **retinal imaging** help ophthalmologists identify and monitor disease progression

Dry AMD

- Shares a **similar pathophysiology with STGD1** and is a leading cause of central vision loss in people over 50



Macular degeneration
causes blurred or loss
of central vision

A cytotoxic compound known as A2E is the most abundant bisretinoid identified in the retinas from patients with STGD1 and Dry AMD; A2E has been shown to kill retinal tissue.

Reference:

www.rarediseases.info.nih.gov/diseases/181/stargardt-disease

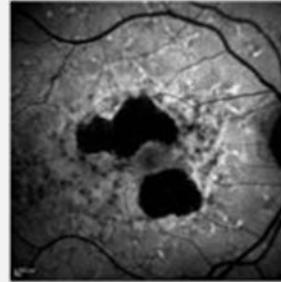
www.ncbi.nlm.nih.gov/pmc/articles/PMC2848442/

Similar Pathophysiology in STGD1 & Dry AMD

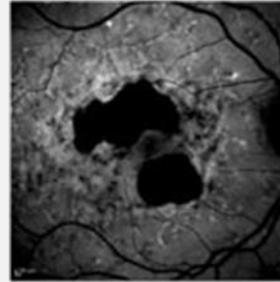


- **STGD1 and dry AMD share a similar pathophysiology** characterized by excessive accumulation of cytotoxic bisretinoids, retinal cell death, and loss of vision
- **Vision loss occurs slowly**, despite peripheral expansion of ‘dead retina’, until the disease reaches the center of the eye (the macula)
- **Slowing the spread of ‘dead retina’ is the intended effect of LBS-008 treatment**

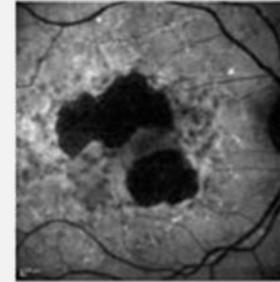
STGD1: LATE-ONSET (61-YEAR OLD FEMALE)



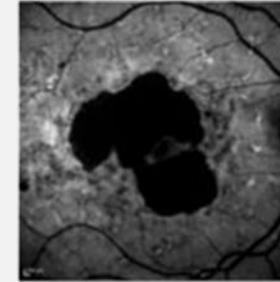
Baseline:
0.1 LogMAR



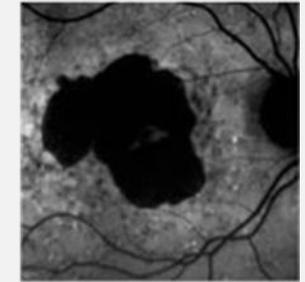
+12 Months:
0.1 LogMAR



+24 Months:
0.0 LogMAR



+36 Months:
0.1 LogMAR

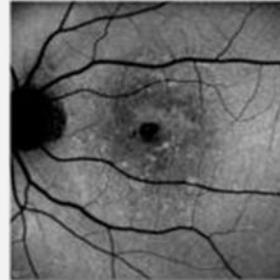


+57 Months:
0.5 LogMAR

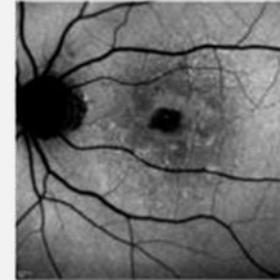
Dry AMD: ADVANCED (73-YEAR OLD FEMALE)



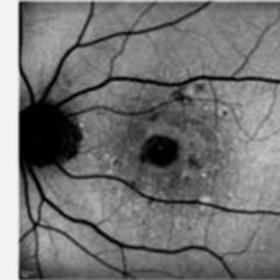
BL:
0.2 LogMAR



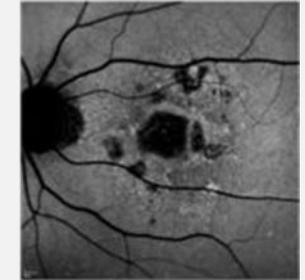
+12 Mo:
0.2 LogMAR



+ 24 Mo:
0.3 LogMAR



+ 36 Mo:
0.4 LogMAR



+55 Mo:
0.6 LogMAR

Clear Clinical Development Pathway



Reduction in Lesion Growth Rate as Measured by Retinal Imaging is an FDA Accepted Primary Endpoint in STGD1 and dry AMD

completed



- Completed, double-blind
- US SAD + AU SAD/MAD: 111 healthy adults
- Well tolerated and reduced mean RBP4 by $\geq 70\%$ from baseline

ongoing



- Open-label, Phase 1b completed, Phase 2 ongoing
- AU/TW Ph1b: 11 subjects completed
- AU/TW Ph2 (2-yr): 13 subjects
- Achieved a mean RBP4 reduction of $> 70\%$ without severe adverse events



- Initiated, double-blind
- Global study (2-yr): 60 subjects
- Primary end point: change in lesion growth rate by retinal imaging



- Expect to start in **2022**, randomized, double-blind
- Intermediate to advanced stage dry AMD
- Global study
- To evaluate the safety and efficacy

planned



- PRV sale (in the last 3 years, price range \$80-125 million)



- In-licensed 9 active patent families
- Composition of matter patents expected to expire 2034-2035 without patent term extension



Clinical Data

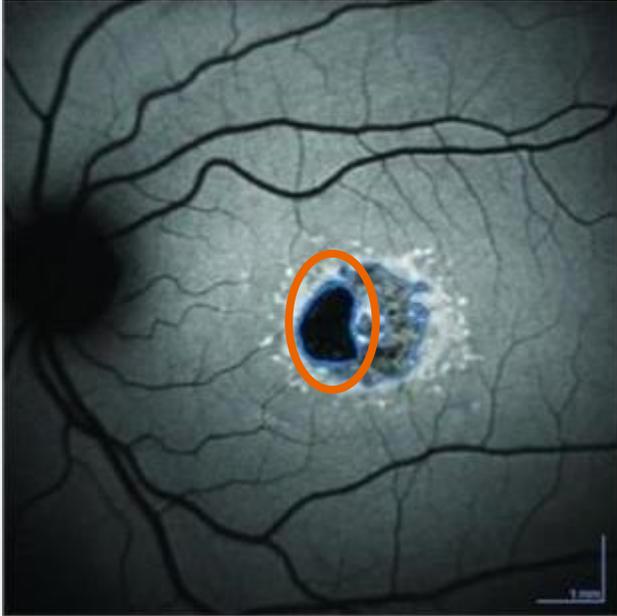
Interim Phase 2 Results: Summary of Related Adverse Events



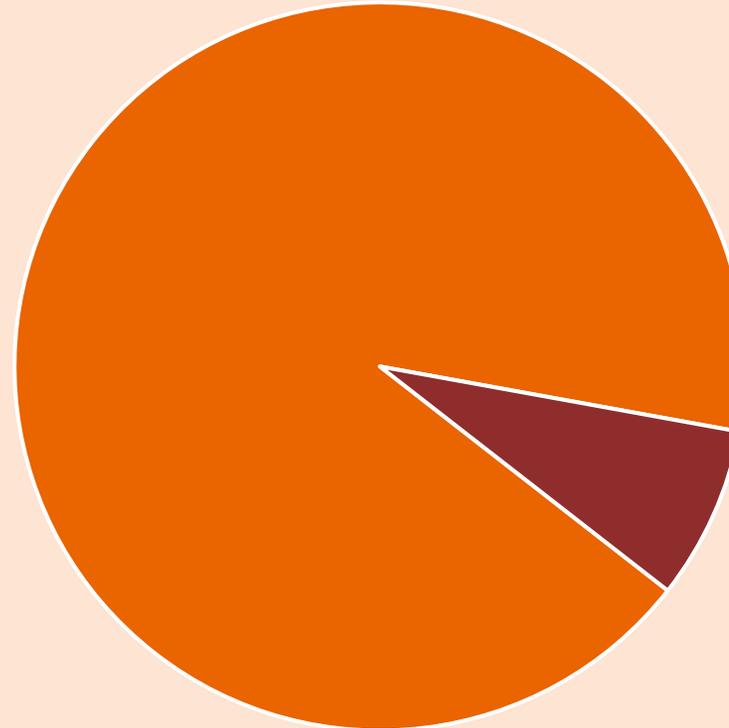
Adverse Events	Severity	Relationship to Drug	Frequency (#patients)	% Recovered	% On-going
Xanthopsia	Mild	Definitely Related	6/13	3/6 (50%)	3/6 (50%)
Delayed Dark Adaptation	Mild	Definitely Related	8/13	1/8 (12.5%)	7/8 (87.5%)
Night Vision Impairment	Mild	Definitely Related	1/13	0/1	1/1 (100%)
Increasing error score on FM100	Mild	Probably Related	1/13	0/1	1/1 (100%)

- All instances of DDA and Xanthopsia were **mild** and **transient**
- Subjects shown to have DDA based on laboratory measure were mostly **asymptomatic**
- One subject recorded to have an increasing error score on FM100 test (tests color vision and color perception) showed only a **mild** impact
- **No severe AEs or SAEs** reported and no AEs requiring discontinuation of treatment
- **No clinically significant** findings in relation to vital signs, physical exams or electrocardiograms

Interim Phase 2 Data: Change in DDAF in Adolescent STGD1 Subjects



DDAF, or lesion (“dead retina”) in STGD1 patient as measured by retinal imaging. This is the area where retinal cells and vision are lost.



92.3%

12 of 13 subjects showed no lesion growth

7.7%

1 of 13 subjects had lesion growth of 0.3 mm² in both eyes

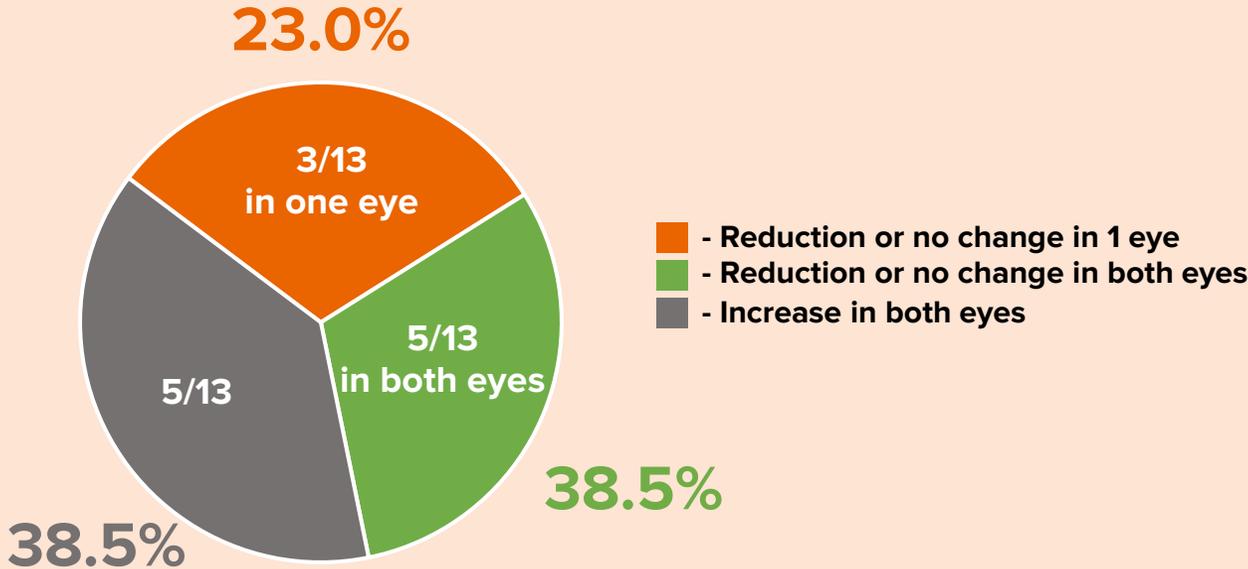
Interim Phase 2 Data: Change in QDAF in Adolescent STGD1 Subjects



Areas of QDAF progressively evolve into 'dead retina'.

8 of 13 STGD1 patients showed a reduction or no change in QDAF

Distribution of Change in QDAF

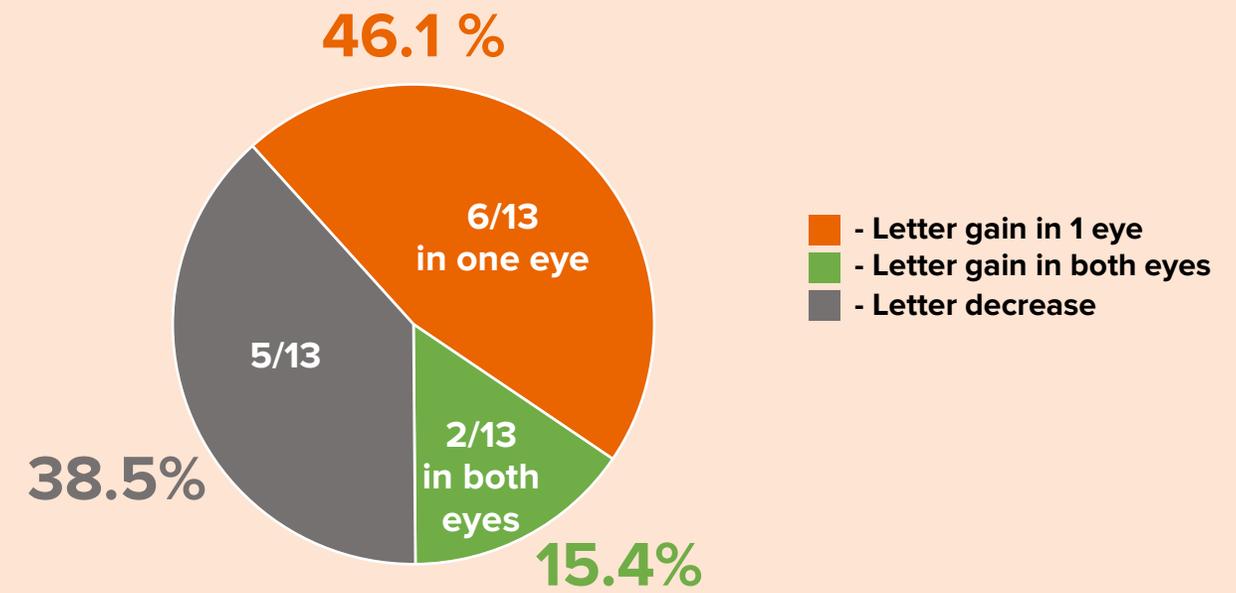


Interim Phase 2 Results: Change of Vision in Adolescent STGD1 Subjects



Best-Corrected Visual Acuity (BCVA) Test
Provides letter score for each eye

Change in BCVA BCVA gain in 8 of 13 Subjects (61.5%)



Investment Highlights



- **LBS-008 is a novel oral** treatment intended to slow or halt disease progression in both **dry AMD and STGD1**.
- **Clear Clinical Pathway:**
 - LBS-008 continues to be well-tolerated.
 - Ongoing 2-year Phase 2 trial (6 months of reported interim safety data and preliminary efficacy data) in STGD1.
 - A Phase 3 trial has been initiated in adolescent STGD1 patients.
- **Unmet Market:**
 - **No approved treatments for STGD1 and dry AMD.**
 - Dry AMD afflict 11 million patients in the US and 196 million patients worldwide.
 - Without treatment, the continual increase in the size of the elderly population will worsen the impact of this disease.



Thank You

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