Belite Bio Reports Second Quarter 2025 Financial Results and Provides a Corporate Update

August 11, 2025

- *Tinlarebant granted Breakthrough Therapy Designation for Stargardt disease (STGD1) by the U.S. Food and Drug Administration (FDA)*
- *DRAGON trial completion expected by Q4 2025 (including a three-month follow-up period)*
- *Enrollment completed with 529 subjects in the pivotal phase 3 PHOENIX trial in geographic atrophy (GA)*
- *Raised approximately $15 million in gross proceeds in a registered direct offering on August 8, 2025*
- *Conference call and webcast on Monday, August 11, 2025, at 4:30 p.m. ET*

SAN DIEGO, Aug. 11, 2025 (GLOBE NEWSWIRE) -- Belite Bio, Inc (NASDAQ: BLTE), a clinical-stage drug development company focused on advancing novel therapeutics targeting degenerative retinal diseases that have significant unmet medical needs, today announced its financial results for the second quarter ended June 30, 2025, and provided a general business update.

"This quarter, we remained on track with the strategic objectives we outlined at the start of the year, including the completion of enrollment in our pivotal Phase 3 PHOENIX trial — an important milestone in our development efforts for people living with geographic atrophy," said Dr. Tom Lin, Chairman and CEO of Belite Bio. "We also received Breakthrough Therapy Designation for Tinlarebant for the treatment of Stargardt disease from the FDA, underscoring its potential as the first-ever treatment for this patient population and acknowledging the significant unmet need for people living with this debilitating disease. With the DRAGON trial on track to complete by the end of this year, we remain focused on advancing Tinlarebant toward key clinical and regulatory milestones."

Second Quarter 2025 Business Highlights and Upcoming Milestones:

Clinical Highlights

Tinlarebant (LBS-008) is an oral, potent, once-daily, retinol binding protein 4 (RBP4) antagonist that decreases RBP4 levels in the blood and reduces vitamin A (retinol) delivery to the eye without disrupting systemic retinol delivery to other tissues. Vitamin A is critical for normal vision but can accumulate as toxic byproducts in individuals affected with STGD1 and GA, the advanced form of dry age-related macular degeneration (AMD), leading to retinal cell death and loss of vision.

- **Stargardt disease (STGD1):** Accumulation of cytotoxic vitamin A byproducts (bisretinoids) compounds has been implicated in the onset and progression of STGD1, for which there is no approved treatment. Tinlarebant has been granted Breakthrough Therapy, Fast Track and Rare Pediatric Disease Designations in the U.S.; Orphan Drug Designation in the U.S., Europe, and Japan; and Sakigake (Pioneer Drug) Designation in Japan for the treatment of STGD1.
  - DRAGON Trial: Ongoing, 24-month, randomized (2:1, active: placebo), double-masked, placebo-controlled, global, multi-center, pivotal Phase 3 trial in adolescent STGD1 patients.
    - Primary efficacy endpoint is the growth rate of atrophic lesions; safety and tolerability will also be assessed.
    - Following a pre-specified interim analysis, an independent Data Safety Monitoring Board (DSMB) recommended trial continuation without modifications, maintaining a sample size of 104 subjects, and recommended submission of the data for regulatory review for drug approval.
    - The Breakthrough Therapy Designation was supported by the interim data of the DRAGON trial. The designation is based on preliminary clinical evidence indicating that a drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Currently STGD1 has no approved treatment.
    - Belite expects trial completion by Q4 2025 (including a three-month follow-up period) and plans to submit DRAGON trial data for drug approval.
  - DRAGON II Trial: Combination of a Phase 1b open-label trial to evaluate the pharmacokinetics and pharmacodynamics of Tinlarebant in adolescent Japanese STGD1 patients and a Phase 2/3, 24-month, randomized (1:1, active: placebo), double-masked, placebo-controlled, multicenter trial in adolescent STGD1 patients.
    - The Company enrolled 17 subjects in the Phase 2/3 trial, with a target enrollment of approximately 60

subjects, aged 12 to 20 years old, including approximately 10 Japanese subjects. Data from the Japanese subjects are intended to facilitate a future new drug application in Japan.
    - Primary efficacy endpoint is the growth rate of atrophic lesions; safety and tolerability will also be assessed.
- **Geographic Atrophy (GA):** GA is a chronic degenerative disease of the retina that leads to blindness in the elderly. Accumulation of bisretinoids has been implicated in the progression of GA. There are currently no FDA-approved, orally administered treatments for GA.
    - PHOENIX Trial: Ongoing, 24-month, randomized (2:1, active: placebo), double-masked, placebo-controlled, global, multi-center, pivotal Phase 3 trial in GA patients.
        - Enrollment completed with 529 subjects.
        - Primary efficacy endpoint is the growth rate of atrophic lesions; safety and tolerability will also be assessed.
        - The Company expects to conduct an interim analysis.

Corporate Highlights

- On August 8, 2025, the Company completed a registered direct offering of its American Depositary Shares with an existing institutional investor of the Company, raising gross proceeds of approximately $15 million with potential additional proceeds of approximately $15 million if the accompanying warrants were exercised in full.

Second Quarter 2025 Financial Results:

Current Assets:

As of June 30, 2025, the Company had $149.2 million in cash, liquidity funds, time deposits, and U.S treasury bills.

R&D Expenses:

For the three months ended June 30, 2025, research and development expenses were $11.0 million compared to $9.1 million for the same period in 2024. For the six months ended June 30, 2025, research and development expenses were $20.4 million compared to $15.8 million for the same period in 2024. The increase in research and development expenses in both the quarter and year-to-date was primarily attributable to (i) higher pass-through expenses related to the PHOENIX trial and manufacturing expenses payments, partially offset by lower DRAGON trial expenses and a development milestone payment for the completion of a phase 2 trial in 2024; (ii) an increase in share-based compensation expenses.

G&A Expenses:

For the three months ended June 30, 2025, general and administrative expenses were $6.5 million compared to $1.4 million for the same period in 2024. For the six months ended June 30, 2025, general and administration expenses were $12.7 million compared to $3.0 million for the same period in 2024. The increase in general and administrative expenses in both the quarter and year-to-date was primarily due to an increase in share-based compensation expenses.

Other Income:

For the three months ended June 30, 2025, other income was $1.3 million compared to $1.0 million for the same period in 2024. For the six months ended June 30, 2025, other income was $2.5 million compared to $1.4 million for the same period in 2024. The increase in both the quarter and year-to-date was attributed to interest from time deposits and U.S. treasury bills.

Net Loss:

For the three months ended June 30, 2025, the Company reported a net loss of $16.3 million, compared to a net loss of $9.5 million for the same period in 2024. For the six months ended June 30, 2025, the Company reported a net loss of $30.6 million, compared to a net loss of $17.4 million for the same period in 2024.

Webcast Information

Belite Bio will host a webcast on Monday, August 11, 2025, at 4:30 p.m. Eastern Time to discuss the Company's financial results and provide a business update. To join the webcast, please visit https://events.q4inc.com/attendee/127464226. A replay will be available for approximately 90 days following the event.

About Belite Bio

Belite Bio is a clinical-stage drug development company focused on advancing novel therapeutics targeting degenerative retinal diseases that have significant unmet medical need, such as Stargardt disease type 1 (STGD1) and Geographic Atrophy (GA) in advanced dry age-related macular degeneration (AMD), in addition to specific metabolic diseases. Belite's lead candidate, Tinlarebant, an oral therapy intended to reduce the accumulation of toxins in the eye, is currently being evaluated in a Phase 3 study (DRAGON) and a Phase 2/3 study (DRAGON II) in adolescent STGD1 subjects and a Phase 3 study (PHOENIX) in subjects with GA. For more information, follow us on X, Instagram, LinkedIn, and Facebook or visit us at www.belitebio.com.

Important Cautions Regarding Forward Looking Statements

This press release contains forward-looking statements about future expectations and plans, as well as other statements regarding matters that are not historical facts. These statements include but are not limited to 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, and any other statements containing the words "expect", "hope" and similar expressions. 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 timing to complete relevant clinical trials and/or to receive the interim/final data of such clinical trials; the timing to submit trial data to regulatory authorities for drug approval; the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of Belite Bio's drug candidates; the potential efficacy of Tinlarebant, 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.

BELITE BIO, INC
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Amounts in thousands of US Dollars, except share and per share amounts)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	**2025**	**2024**	**2025**
Expenses				
Research and development	9,078	11,049	15,843	20,445
General and administrative	1,393	6,547	2,956	12,668
Total operating expenses	10,471	17,596	18,799	33,113
Loss from operations	(10,471)	(17,596)	(18,799)	(33,113)
Other income:				
Total other income, net	977	1,276	1,440	2,516
Loss before income tax	(9,494)	(16,320)	(17,359)	(30,597)
Income tax expense	-	-	6	-
Net loss	(9,494)	(16,320)	(17,365)	(30,597)
Other comprehensive income (loss)				
Foreign currency translation adjustments, net of nil tax	(10)	128	(106)	146
Total comprehensive loss	(9,504)	(16,192)	(17,471)	(30,451)
Weighted average number of ordinary shares used in per share calculation:				
- Basic and Diluted	30,324,132	32,585,043	30,000,653	32,335,958
Net loss per ordinary share				
- Basic and Diluted	$ (0.31)	$ (0.50)	$ (0.58)	$ (0.95)

BELITE BIO, INC
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(Amounts in thousands of US Dollars, except share amounts)

	December 31, 2024	June 30, 2025
Current assets	$ 147,073	$ 150,970
Other assets	5,059	5,437
TOTAL ASSETS	$ 152,132	$ 156,407
TOTAL LIABILITIES	$ 6,311	$ 6,522
TOTAL SHAREHOLDERS' EQUITY	145,821	149,885
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 152,132	$ 156,407
Ordinary shares authorized	400,000,000	400,000,000
Ordinary shares issued	31,857,802	32,631,133
Ordinary shares outstanding	31,826,549	32,599,298

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