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

November 10, 2025

- *Completed enrollment with 530 subjects in the pivotal phase 3 PHOENIX trial in geographic atrophy (GA)*
- *Completed $15 million registered direct offering and $125 million private placement with potential for up to an additional $165 million upon full warrant exercise*
- *Completed pivotal phase 3 DRAGON trial in Stargardt disease (STGD); final topline data expected in Q4 2025*
- *China's NMPA has agreed to accept New Drug Application with priority review for Tinlarebant for the treatment of Stargardt disease based on the interim analysis results of DRAGON trial*
- *UK's MHRA has agreed to accept Conditional Marketing Authorization application for Tinlarebant for the treatment of Stargardt disease based on the interim analysis results of DRAGON trial*
- *Conference call and webcast on Monday, November 10, 2025, at 4:30 p.m. ET*

SAN DIEGO, Nov. 10, 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 third quarter ended September 30, 2025, and provided a general business update.

"We continued to make meaningful progress this quarter toward our goal of delivering the first approved treatment for people living with Stargardt disease," said Dr. Tom Lin, Chairman and CEO of Belite Bio. "We are very encouraged by China NMPA's and UK MHRA's response to accept New Drug Application for Tinlarebant based on Phase 3 interim results. We remain on track to report final DRAGON topline data in the fourth quarter. In parallel, the completion of our $15 million registered direct offering and $125 million private placement further strengthens our financial position and enables us to continue advancing Tinlarebant toward upcoming regulatory milestones and potential commercial readiness."

Third Quarter 2025 Business Highlights and Upcoming Milestones:

Clinical Highlights

Tinlarebant 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: Completed, 24-month, 104 subjects, 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.
    - Independent Data Safety Monitoring Board (DSMB) recommended trial continuation without modifications at interim analysis, and supported data submission for regulatory review for drug approval.
    - Granted Breakthrough Therapy Designation by the US FDA supported by interim analysis results.
    - Center for Drug Evaluation of China's National Medical Products Administration ("NMPA") has agreed to accept New Drug Application with priority review for Tinlarebant for the treatment of Stargardt disease based on the interim analysis results.
    - United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) has agreed to accept Conditional Marketing Authorization application for Tinlarebant for the treatment of Stargardt disease based on the interim analysis results.
    - Trial completed, final topline data remains on track for Q4 2025.
  - 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 has enrolled 34 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 530 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

- Company closed a $15 million registered direct offering and a $125 million private placement with leading healthcare investors, with potential additional proceeds of up to total $165 million upon the full exercise of accompanying warrants.

Third Quarter 2025 Financial Results:

Current Assets:

As of September 30, 2025, the Company had $275.6 million in cash, liquidity funds, and U.S. treasury bills.

R&D Expenses:

For the three months ended September 30, 2025, research and development expenses were $10.3 million compared to $6.8 million for the same period in 2024. The increase in research and development expenses in the quarter was primarily attributable to (i) expenses related to the DRAGON trial and PHOENIX trial, partially offsetting the Australian research and development tax incentive, which is recognized as a reduction to research and development expenses; (ii) share-based compensation expenses. For the nine months ended September 30, 2025, research and development expenses were $30.8 million compared to $22.7 million for the same period in 2024. The increase in research and development expenses was primarily attributable to (i) expenses related to the PHOENIX trial; (ii) share-based compensation expenses; and (iii) manufacturing expenses, partially offset by the non-recurrence of a royalty payment recognized in 2024 for completion of a Phase 2 trial.

G&A Expenses:

For the three months ended September 30, 2025, general and administrative expenses were $12.7 million compared to $2.9 million for the same period in 2024. For the nine months ended September 30, 2025, general and administration expenses were $25.4 million compared to $5.9 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 September 30, 2025, other income was $1.3 million compared to $1.1 million for the same period in 2024. For the nine months ended September 30, 2025, other income was $3.8 million compared to $2.5 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 September 30, 2025, the Company reported a net loss of $21.7 million, compared to a net loss of $8.7 million for the same period in 2024. For the nine months ended September 30, 2025, the Company reported a net loss of $52.3 million, compared to a net loss of $26.0 million for the same period in 2024.

Webcast Information

Belite Bio will host a webcast on Monday, November 10, 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/847711723. 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 STGD1 and GA in advanced dry AMD, in addition to specific metabolic diseases. Belite's lead candidate, Tinlarebant, an oral therapy intended to reduce the accumulation of bisretinoid 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, the ability of Tinlarebant to treat Stargardt disease and geographic atrophy, 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. In addition, New Drug Application for Tinlarebant for the treatment of Stargardt disease, if submitted to the NMPA in China or the MHRA in the United Kingdom by the Company, would be subject to certain conditions set by NMPA/MHRA, respectively, including but not limited to submission of final data of the Phase 3 DRAGON trial when available and the consistency between the interim analysis results and the final data. 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 September 30,		For the Nine Months Ended September 30,	
	2024	2025	2024	2025
Expenses				
Research and development	6,842	10,307	22,685	30,753
General and administrative	2,898	12,711	5,854	25,378
Total operating expenses	9,740	23,018	28,539	56,131
Loss from operations	(9,740)	(23,018)	(28,539)	(56,131)
Other income:				
Total other income, net	1,061	1,328	2,501	3,844
Loss before income tax	(8,679)	(21,690)	(26,038)	(52,287)
Income tax expense	-	-	6	-
Net loss	(8,679)	(21,690)	(26,044)	(52,287)
Other comprehensive income (loss)				
Foreign currency translation adjustments, net of nil tax	79	82	(27)	228
Total comprehensive loss	(8,600)	(21,608)	(26,071)	(52,059)
Weighted average number of ordinary shares used in per share calculation:				
- Basic and Diluted	30,687,305	33,223,232	30,231,207	32,634,966
Net loss per ordinary share				
- Basic and Diluted	$ (0.28)	$ (0.65)	$ (0.86)	$ (1.60)

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

	December 31, 2024	September 30, 2025
Current assets	$ 147,073	$ 277,213
Other assets	5,059	5,180
TOTAL ASSETS	$ 152,132	$ 282,393
TOTAL LIABILITIES	$ 6,311	$ 8,311
TOTAL SHAREHOLDERS' EQUITY	145,821	274,082

TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 152,132	$ 282,393
Ordinary shares authorized	400,000,000	400,000,000
Ordinary shares issued	31,857,802	34,903,104
Ordinary shares outstanding	31,826,549	34,890,991

Media and Investor Relations Contact:

Jennifer Wu
ir@belitebio.com

Julie Fallon
belite@argotpartners.com