Belite Bio Reports Preliminary, Unaudited Fourth Quarter and Full Year 2025 Financial Results and Provides a Corporate Update

March 2, 2026

- *Following positive topline results from the pivotal, global Phase 3 DRAGON trial of tinlarebant in adolescents with Stargardt disease type 1 (STGD1), the Company is on track to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in Q2 2026*
- *Completed enrollment in the Phase 2/3 DRAGON II trial in STGD1*
- *Completed a $402 million underwritten public offering of American Depositary Shares*
- *Conference call and webcast on Monday, March 2, 2026, at 4:30 p.m. ET*

SAN DIEGO, March 02, 2026 (GLOBE NEWSWIRE) -- Belite Bio, Inc (NASDAQ: BLTE) ("Belite Bio" or the "Company"), a clinical-stage drug development company focused on advancing novel therapeutics targeting degenerative retinal diseases that have significant unmet medical needs, today announced its preliminary, unaudited financial results for the fourth quarter and full-year ended December 31, 2025, and provided a business update.

"2025 marked a defining year for Belite, highlighted by positive topline results from our pivotal Phase 3 DRAGON trial, establishing tinlarebant as a potential first-in-class therapy for Stargardt disease," said Dr. Tom Lin, Chairman and CEO of Belite Bio. "Combined with the completion of our $402 million public offering, we believe the Company is well positioned for the next phase of execution, and we remain on track to submit an NDA to the FDA in the second quarter of 2026 as we advance toward our goal of bringing the first approved treatment for Stargardt disease to people living with this debilitating disease."

Full Year 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 geographic atrophy (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, aged 12 to 20 years old, randomized (2:1, active: placebo), double-masked, placebo-controlled, global, multi-center, pivotal Phase 3 trial in adolescent STGD1 patients
  - Met its primary efficacy endpoint, demonstrating a statistically significant and clinically meaningful 35.7% reduction in the growth rate of macular lesions, measured as definitely decreased autofluorescence (DDAF) by fundus autofluorescence imaging, compared with placebo.
  - Achieved statistical significance when applying the pre-specified analysis (p-value = 0.0033).
  - Demonstrated in a post-hoc analysis that the treatment effect remained (35.4%) consistent with a p-value < 0.0001 when considering the progressive nature typically seen in STGD1.
  - On track to submit an NDA to the FDA in the second quarter of 2026.
- 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, multi-center trial in adolescent STGD1 patients aged 12 to 20 years old across Japan, the U.S., and the United Kingdom.
  - Targeted enrollment of 60 subjects was reached in January 2026.
  - Subjects who passed screening before enrollment cut off are allowed to be enrolled in the trial through early March.

72 subjects were enrolled as of February 27, 2026.
- Trial design and inclusion of Japanese patients are intended to facilitate a future NDA 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
  - Completed enrollment 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

- Completed a $402 million underwritten public offering of American Depositary Shares with overallotment fully exercised by the underwriters, with net proceeds intended to support commercialization preparation, development and expansion of pipelines, and general corporate purposes.

Preliminary and Unaudited Fourth Quarter and Full Year 2025 Financial Results

Cash and Cash Equivalents: As of December 31, 2025, the Company had $352.9 million in cash and cash equivalents, compared with $31.7 million on December 31, 2024.

Investments: As of December 31, 2025, the Company had $419.7 million in U.S. treasury bills and U.S. treasury notes, compared to $113.5 million in liquidity funds, time deposits, and U.S. treasury bills as of December 31, 2024.

R&D Expenses:

For the three months ended December 31, 2025, research and development expenses were $14.6 million compared to $7.3 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 II trial, (ii) lower Australian research and development tax incentive received and recognized as a reduction to research and development expenses in Q4 2025 as compared to Q4 2024; and (iii) Active Pharmaceutical Ingredient (“API”) manufacturing expense. For the year ended December 31, 2025, research and development expenses were $45.4 million compared to $29.9 million for the same period in 2024. The increase was primarily attributable to (i) expenses related to the PHOENIX trial; (ii) share-based compensation expenses; and (iii) API manufacturing expenses, partially offset by the non-recurrence of a royalty payment recognized in 2024 for completion of a Phase 2 trial.

On a non-GAAP basis, excluding share-based compensation expenses, non-GAAP research and development expenses for the three months and year ended December 31, 2025, were $12.2 million and $36.2 million compared to $5.7 million and $26.2 million for the same periods in 2024, respectively.

Selling, G&A Expenses:

For the three months ended December 31, 2025, selling, general and administrative expenses were $13.5 million compared to $4.2 million for the same period in 2024. For the year ended December 31, 2025, selling, general and administration expenses were $38.8 million compared to $10.1 million for the same period in 2024. The increase in selling, general and administrative expenses in both the quarter and the full year was primarily due to increases in share-based compensation expenses and professional service fees.

On a non-GAAP basis, excluding share-based compensation expenses, non-GAAP selling, general and administrative expenses for the three months ended December 31, 2025, were $4.2 million compared to $1.5 million for the same period in 2024. For the full year 2025, non-GAAP selling, general and administrative expenses were $9.1 million compared to $4.8 million for the full year 2024.

Other Income:

For the three months ended December 31, 2025, other income was $2.8 million compared to $1.4 million for the same period in 2024. For the year ended December 31, 2025, other income was $6.6 million compared to $3.9 million for the same period in 2024. The increase in both the quarter and full year was primarily due to interest income from bank deposits, time deposits and U.S. treasury bills.

Net Loss:

For the three months ended December 31, 2025, the Company reported a GAAP net loss of $25.3 million, compared to a GAAP net loss of $10.1 million for the same period in 2024. For the year ended December 31, 2025, the Company reported a GAAP net loss of $77.6 million, compared to a GAAP net loss of $36.1 million for the same period in 2024.

On a non-GAAP basis, excluding share-based compensation expenses, the Company reported a non-GAAP net loss of $13.6 million for the three months ended December 31, 2025, compared to a non-GAAP net loss $5.9 million for the same period in 2024. For the year ended December 31, 2025, the non-GAAP net loss was $38.7 million, compared to a non-GAAP net loss of $27.2 million for the same period in 2024.

Webcast Information

Belite Bio will host a webcast on Monday, March 2, 2026, 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/547616305. 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 Bio's lead candidate, tinlarebant, is an oral therapy intended to reduce the accumulation of bisretinoid toxins in the eye. The Company has completed a Phase 3 trial (DRAGON) in adolescent STGD1 subjects and is currently being evaluated in a Phase 2/3 trial (DRAGON II) in adolescent STGD1 subjects and a Phase 3 trial (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 regarding future expectations, plans and prospectus, 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 STGD1 and GA, 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, as well as any other statements regarding matters that are not historical facts, and any other statements containing the words "expect", "believe", "target", "plan", "hope" "potential" and other similar expressions. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors related to Belite Bio's business, 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; expectations for the timing of initiation, enrollment and completion of, and data relating to, its clinical trials; the timing to complete any ancillary clinical trials and/or to receive the interim/final data of such clinical trials; the timing to communicate with and submit trial data to regulatory authorities for drug approval in various jurisdictions; the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of Belite Bio's drug candidates; timing for Belite Bio to share additional data at upcoming medical meetings; the potential efficacy of tinlarebant to set a new benchmark for future research in inherited retinal disorders, 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.

Discussion of Non-GAAP Financial Measures

To supplement the Company's unaudited condensed consolidated financial results prepared in accordance with GAAP, the Company discloses certain non-GAAP financial measures that exclude share-based compensation, including research and development (non-GAAP), selling, general and administrative (non-GAAP), total operating expenses (non-GAAP), loss from operations (non-GAAP), net loss (non-GAAP), weighted average number of ordinary shares used in per share (non-GAAP) and net loss per ordinary share basic and diluted (non-GAAP).

The Company believes that these non-GAAP measures provide supplemental information that may be helpful in understanding period-to-period trends in operating expenses and results when considered together with, and not as a substitute for, the corresponding GAAP financial measures. These measures are intended to increase transparency into expense items that may vary from period to period for reasons such as the timing, structure, and valuation of equity awards. These measures are not intended to replace GAAP financial information and are not considered by management to be superior to GAAP measures.

At the Company's current stage of development as a clinical-stage biotechnology company, the primary expenditures relate to the execution of clinical trials, regulatory activities (including preparation for potential NDA submissions), and the management of ongoing operations. In this context, management believes that the supplemental presentation of operating expenses excluding certain non-cash charges, such as share-based compensation, may assist users in understanding the nature and scale of cash-based operating activities by reducing period-to-period volatility from non-cash items. However, these non-GAAP measures are not intended to represent, and should not be viewed as, measures of liquidity, cash burn rate, or cash flows.

Non-GAAP measures have inherent limitations and may differ from similarly titled measures used by other companies. Accordingly, these measures should be viewed as supplemental and evaluated together with the Company's GAAP results and the reconciliations to the most directly comparable GAAP measures presented in this release.

Explanation of Adjustment – Share-based compensation:

Share-based compensation expense consists of non-cash charges related to the fair value of equity awards awarded to employees and other non-employees. The amount recognized in any period may vary based on factors such as grant timing, award structure, and valuation assumptions, which may not be directly correlated with the timing or magnitude of cash payments related to the Company's clinical, regulatory, and operational activities. The exclusion of share-based compensation in the Company's non-GAAP measures is intended to supplementally illustrate operating expense trends and facilitate period-to-period comparisons of cash-based expenditures. The Company recognizes that share-based compensation is an important component of total compensation, and does not view non-GAAP measures as a replacement for GAAP results, which include the full impact of share-based compensation.

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 December 31,		For the Year Ended December 31,	
	2024	2025	2024	2025
Expenses				

Research and development	7,254	14,624	29,939	45,377
Selling, general and administrative	4,203	13,453	10,057	38,831
Total operating expenses	11,457	28,077	39,996	84,208
Loss from operations	(11,457)	(28,077)	(39,996)	(84,208)
Other income:				
Total other income, net	1,357	2,753	3,858	6,597
Loss before income tax	(10,100)	(25,324)	(36,138)	(77,611)
Income tax expense	—	—	6	—
Net loss	(10,100)	(25,324)	(36,144)	(77,611)
Other comprehensive income (loss)				
Foreign currency translation adjustments, net of nil tax	(259)	(104)	(286)	124
Total comprehensive loss	(10,359)	(25,428)	(36,430)	(77,487)
Weighted average number of ordinary shares used in per share calculation:				
- Basic and Diluted	31,453,211	36,218,289	30,538,378	33,538,160
Net loss per ordinary share				
- Basic and Diluted	$ (0.32)	$ (0.70)	$ (1.18)	$ (2.31)

BELITE BIO, INC
RECONCILIATION OF GAAP TO NON-GAAP UNAUDITED OPERATING RESULTS
(Amounts in thousands of US Dollars, except share and per share amounts)

	For the Three Months Ended December 31,		For the Year Ended December 31,	
	2024	**2025**	**2024**	**2025**
Expenses				
GAAP Research and development	7,254	14,624	29,939	45,377
Share-based compensation expense	(1,510)	(2,452)	(3,775)	(9,147)
Non-GAAP research and development	5,744	12,172	26,164	36,230
GAAP Selling, general and administrative	4,203	13,453	10,057	38,831
Share-based compensation expense	(2,696)	(9,263)	(5,212)	(29,772)
Non-GAAP selling, general and administrative	1,507	4,190	4,845	9,059
GAAP Total operating expenses	11,457	28,077	39,996	84,208
Share-based compensation expense	(4,206)	(11,715)	(8,987)	(38,919)
Non-GAAP Total operating expense	7,251	16,362	31,009	45,289
GAAP Loss from operations	(11,457)	(28,077)	(39,996)	(84,208)
Share-based compensation expense	4,206	11,715	8,987	38,919
Non-GAAP Loss from operations	(7,251)	(16,362)	(31,009)	(45,289)
GAAP Net loss	(10,100)	(25,324)	(36,144)	(77,611)
Share-based compensation expense	4,206	11,715	8,987	38,919
Non-GAAP Net Loss	(5,894)	(13,609)	(27,157)	(38,692)
Weighted average number of ordinary shares used in per share Calculation GAAP and Non-GAAP:				
- Basic and Diluted	31,453,211	36,218,289	30,538,378	33,538,160
Net loss per ordinary share				
- Basic and Diluted GAAP	$ (0.32)	$ (0.70)	$ (1.18)	$ (2.31)
- Basic and Diluted Non-GAAP	$ (0.19)	$ (0.38)	$ (0.89)	$ (1.15)

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

	December 31, 2024	December 31, 2025
Current assets	$ 147,073	$ 494,272
Other assets	5,059	286,284
TOTAL ASSETS	$ 152,132	$ 780,556

TOTAL LIABILITIES	$ 6,311	$ 10,070
TOTAL SHAREHOLDERS' EQUITY	145,821	770,486
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 152,132	$ 780,556
Ordinary shares authorized	400,000,000	400,000,000
Ordinary shares issued	31,857,802	39,353,365
Ordinary shares outstanding	31,826,549	39,339,960

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