Belite Bio Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Corporate Update

March 17, 2025

- *Following a pre-specified interim analysis, the Data Safety Monitoring Board (DSMB) recommended the DRAGON trial, a pivotal Phase 3 trial in adolescent Stargardt 1 (STGD1) subjects, proceed without any modification; trial completion expected Q4 2025 (including a three-month follow-up period)*
- *Pivotal global Phase 3 PHOENIX trial of Tinlarebant in geographic atrophy (GA) subjects is ongoing with 406 subjects enrolled*
- *Raised $15 million in gross proceeds in a registered direct offering on February 5, 2025*
- *Conference call and webcast on Monday, March 17, 2025, at 4:30 p.m. ET*

SAN DIEGO, March 17, 2025 (GLOBE NEWSWIRE) -- Belite Bio, Inc (NASDAQ: BLTE), a clinical-stage biopharmaceutical 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 fourth quarter and full-year ended December 31, 2024, and provided a business update.

"We made exciting progress in our clinical development efforts over the past year, and the recent completion of the interim analysis of the Phase 3 DRAGON trial was an important milestone that brought us one step closer to realizing Tinlarebant's potential to slow progression of STGD1," said Dr. Tom Lin, Chairman and CEO of Belite. "We are very excited with the DSMB's recommendation and the safety profile of Tinlarebant, and we remain on track to complete the trial by the fourth quarter of 2025. With the continued execution in our Phase 3 trials and the close of our recent $15 million registered direct offering on February 5, 2025, we remain well positioned through key milestones as we advance Tinlarebant as a novel therapeutic for people living with degenerative retinal diseases."

Full Year 2024 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) has been implicated in the onset and progression of STGD1, for which there are no approved treatments. Tinlarebant has been granted 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 subjects
    - Following a pre-specified interim analysis, an independent DSMB recommended trial continuation without modifications, maintaining a sample size of 104 subjects
    - In addition, the DSMB recommended to submit the data for further regulatory review for drug approval
    - Primary efficacy endpoint is the growth rate of atrophic lesions; safety and tolerability will also be assessed
    - Trial completion expected by Q4 2025 (including a three-month follow-up period)
  - DRAGON II Trial: Combination of a Phase 1b open-label trial to evaluate the pharmacokinetics and pharmacodynamics of Tinlarebant in Japanese adolescent STGD1 subjects and a Phase 2/3, 24-month, randomized (1:1, active: placebo), double-masked, placebo-controlled, multicenter trial in adolescent STGD1 subjects
    - Completed the Phase 1b portion of the trial with six subjects evaluated in Japan in Q3 of 2024
    - Enrolled 11 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 is 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 toxic vitamin A byproducts (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 subjects
        - Sample size increased from approximately 430 subjects to 500 subjects. 406 subjects have been enrolled
        - Primary efficacy endpoint is the growth rate of atrophic lesions; safety and tolerability will also be assessed
        - Company expects to conduct an interim analysis

Corporate Highlights

- In February 2025, the Company completed a registered direct offering priced at the market, raising gross proceeds of $15 million, with the potential for additional proceeds of approximately $15 million from the exercise of five-year warrants issued in the offering.

Audited Full Year 2024 and Reviewed Fourth Quarter 2024 Financial Results:

Cash: As of December 31, 2024, the Company had $31.7 million in cash, as compared with $88.2 million on December 31, 2023.

Investments: As of December 31, 2024, the Company had $113.5 million in liquidity fund, time deposits and U.S treasury bills, as compared with nil on December 31, 2023.

R&D Expenses:

For the three months ended December 31, 2024, research and development expenses were $7.3 million compared to $4.9 million for the same period in 2023. The increase resulted primarily from share-based compensation granted in the third quarter of 2024 and higher R&D expenses in the fourth quarter of 2024 as the PHOENIX trial reached certain milestones.

For the year ended December 31, 2024, research and development expenses were $29.9 million compared to $24.8 million for the same period in 2023. The increase in research and development expenses was primarily attributable to (i) an increase in royalty payments for the completion of a Phase 2 trial, (ii) an increase in share-based compensation granted in the third quarter of 2024 and (iii) a decrease in clinical trial expenses, which was mainly attributed to fewer contract research organization milestone payments related to the DRAGON trial, partially offset by the increase in the DRAGON II trial expenses and the Australian research and development tax incentive, which is recognized as a reduction to research and development expenses.

G&A Expenses:

For the three months ended December 31, 2024, general and administration expenses were $4.2 million compared to $2.1 million for the same period in 2023. For the year ended December 31, 2024, general and administration expenses were $10.1 million compared to $6.8 million for the same period in 2023. The increase for both the quarter and full year was primarily driven by an increase in share-based compensation granted in the third quarter of 2024.

Other Income (expense):

For the three months ended December 31, 2024, other income was $1.4 million compared to other expense $0.04 million for the same period in 2023. For the year ended December 31, 2024, other income was $3.9 million compared to $0.05 million for the same period in 2024. The increase in other income was interest derived from cash in banks, our investments in liquidity funds, U.S. treasury bills, and time deposits from financial institutions.

Net Loss:

For the three months ended December 31, 2024, the Company reported a net loss of $10.1 million or ($0.32) per share compared to $7.0 million or ($0.25) per share for the same period in 2023. For the year ended December 31, 2024, the Company reported a net loss of $36.1 million or ($1.18) per share, compared to a net loss of $31.6 million or ($1.19) per share for the same period in 2023.

Webcast Information

Belite Bio will host a webcast on Monday, March 17, 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/481614529. A replay will be available for approximately 90 days following the event at the Company's Investor Relations website at https://investors.belitebio.com/presentations-events/events.

About Belite Bio

Belite Bio is a clinical-stage biopharmaceutical 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 Twitter, Instagram, LinkedIn, 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 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
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Amounts in thousands of US Dollars, except share and per share amounts)

	For the Year Ended December 31,	
	2023	**2024**
Expenses		
Research and development	24,844	29,939
General and administrative	6,824	10,057
Total operating expenses	31,668	39,996
Loss from operations	(31,668)	(39,996)
Other income		
Total other income, net	45	3,858
Loss before income tax	(31,623)	(36,138)
Income tax expense	9	6
Net loss	(31,632)	(36,144)
Other comprehensive income (loss)		
Foreign currency translation adjustments, net of nil tax	18	(286)
Total comprehensive loss	(31,614)	(36,430)
Weighted average number of ordinary shares used in per share calculation:		
- Basic and Diluted	26,593,673	30,538,378
Net loss per ordinary share		
- Basic and Diluted	$ (1.19)	$ (1.18)

	For the Three Months Ended December 31,	
	2023	**2024**
	(Unaudited and Unreviewed)	**(Unaudited)**
Expenses		
Research and development	4,862	7,254
General and administrative	2,093	4,203
Total operating expenses	6,955	11,457
Loss from operations	(6,955)	(11,457)
Other expense		
Total other income (expense), net	(36)	1,357
Loss before income tax	(6,991)	(10,100)
Income tax expense	-	-
Net loss	(6,991)	(10,100)
Other comprehensive income (loss)		
Foreign currency translation adjustments, net of nil tax	133	(259)
Total comprehensive loss	(6,858)	(10,359)
Weighted average number of ordinary shares used in per share calculation:		
- Basic and Diluted	28,316,251	31,453,211
Net loss per ordinary share		
- Basic and Diluted	$ (0.25)	$ (0.32)

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

	December 31	
	2023	**2024**
ASSETS		
Current Assets		
Cash	$ 88,157	$ 31,677
Investments	-	113,472
Other receivables	818	575
Prepayments and other current assets	947	1,349
Other receivables due from related parties	18	-
Total current assets	89,940	147,073
Property and equipment, net	490	444
Intangible assets	-	31
Prepayments and other non-current assets	3,297	3,960
Security deposits	104	103
Operating lease right-of-use asset, net	811	521
TOTAL ASSETS	$ 94,642	$ 152,132
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accrued expenses and other liabilities	3,325	5,761
Other payables to related parties	-	13
Operating lease liabilities – current	308	276
Total current liabilities	3,633	6,050
Non-current liabilities		
Operating lease liabilities –non – current	578	261
TOTAL LIABILITIES	4,211	6,311
Shareholders' equity		
Ordinary shares, par value of US$0.0001 per share; 400,000,000 shares authorized; 29,184,475 and 31,857,802 shares issued; 29,149,444 and 31,826,549 shares outstanding as of December 31, 2023 and 2024, respectively	3	3
Additional paid-in capital	162,305	254,125
Accumulated other comprehensive loss	(374)	(660)
Accumulated deficit	(71,503)	(107,647)
Total shareholders' equity	90,431	145,821
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 94,642	$ 152,132

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