Belite Bio Reports Third Quarter 2024 Financial Results and Provides a Corporate Update

November 12, 2024

- *Dosed first patient in Phase 2/3 DRAGON II trial of Tinlarebant for the treatment of Stargardt disease (STGD1)*
- *Pivotal global Phase 3 PHOENIX trial of Tinlarebant in geographic atrophy (GA) subjects is ongoing with more than 280 subjects enrolled*
- *Appointed Hendrik P.N. Scholl, MD, MA, a globally recognized leader in the field of ophthalmology and the coordinating principal investigator of the largest natural history study of Stargardt disease, as Chief Medical Officer*
- *Interim analysis from the pivotal global Phase 3 DRAGON trial of Tinlarebant in adolescent STGD1 subjects anticipated by end of 2024 or early 2025*
- *Company to host webcast on Tuesday, November 12, 2024, at 4:30 p.m. EST*

SAN DIEGO, Nov. 12, 2024 (GLOBE NEWSWIRE) -- Belite Bio, Inc (NASDAQ: BLTE) ("Belite" or the "Company"), 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 third quarter ended September 30, 2024, and provided a general business update.

"I am pleased with the continued progress we made across our clinical programs. The pace of enrollment for the PHOENIX trial remains strong, and in the quarter, we completed the Phase 1b DRAGON II trial of Tinlarebant in Stargardt disease in Japan and dosed the first patient in the Phase 2/3 portion of the trial. We are well-positioned to achieve critical milestones and look forward to providing an update on the interim analysis from our pivotal Phase 3 DRAGON trial toward the end of 2024 or early 2025," said Dr. Tom Lin, Chairman and CEO of Belite. "In the quarter, we were also excited to welcome Dr. Scholl, a leading global expert in Stargardt disease and age-related macular degeneration, as our Chief Medical Officer. Dr. Scholl's decision to join Belite following his experience as Chair of the Data and Safety Monitoring Board for both our Phase 2 and Phase 3 Stargardt disease trials further validates our belief in Tinlarebant's immense potential."

Third Quarter 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 to normal vision but can accumulate as toxic byproducts in individuals affected with STGD1 and GA (the advanced form of dry age-related macular degeneration (dry 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. Tinlarebant has been granted Fast Track Designation and Rare Pediatric Disease Designation 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
    - Completed enrollment with 104 subjects in 11 countries
    - Primary efficacy endpoint is slowing of atrophic lesion growth rate; safety and tolerability will also be assessed
    - Company expects to report interim analysis by end of 2024 or early 2025
  - DRAGON II Trial: Combination of Phase 1b open-label trial to evaluate the pharmacokinetics and pharmacodynamics of Tinlarebant in Japanese adolescent STGD1 subjects and a Phase 2/3, double-masked, placebo-controlled, multicenter, trial in adolescent STGD1 subjects
    - Completed Phase 1b portion of the trial with six subjects evaluated in Japan
    - Dosed first patient in 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 slowing of atrophic lesion growth rate; 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; n~430 subjects), double-masked, placebo-controlled, global, multi-center, pivotal Phase 3 trial in patients with GA
        - More than 280 subjects have been enrolled as of November 11, 2024
        - Primary efficacy endpoint is slowing of atrophic lesion growth rate; safety and tolerability will also be assessed
        - Company expects to conduct interim analysis at the mid-point of the trial

Corporate Highlights

Hendrik P. N. Scholl, MD, MA, was appointed as the Company's Chief Medical Officer. Dr. Scholl is the foremost globally recognized authority on Stargardt disease and age-related macular degeneration and brings to Belite decades of expertise in treating retinal diseases, including the two key indications targeted by Tinlarebant.

Belite also recently announced the exercise of warrants by certain holder of Belite's outstanding warrants, pursuant to which Belite received total gross proceeds of approximately $28.75 million, which are expected to be used for general corporate purposes.

Third Quarter 2024 Financial Results:

Current Assets:

As of September 30, 2024, the Company had $109.0 million in cash, money market fund, time deposits and U.S treasury bills.

R&D Expenses:

For the three months ended September 30, 2024, research and development expenses were $6.8 million compared to $8.7 million for the same period in 2023. This decrease 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. For the nine months ended September 30, 2024, research and development expenses were $22.7 million compared to $20.0 million for the same period in 2023. The increase in research and development expenses was primarily attributable to (i) a royalty payment for completion of a Phase 2 trial, and (ii) share-based compensation granted in the third quarter of 2024.

G&A Expenses:

For the three months ended September 30, 2024, general and administrative expenses were $2.9 million compared to $2.2 million for the same period in 2023. For the nine months ended September 30, 2024, general and administration expenses were $5.9 million compared to $4.7 million for the same period in 2023. The increase in G&A expenses was primarily due to an increase in share-based compensation granted in the third quarter of 2024.

Other Income:

For the three months ended September 30, 2024, other income was $1.1 million compared to $0.03 million for the same period in 2023. For the nine months ended September 30, 2024, other income was $2.5 million compared to $0.08 million for the same period in 2023. The increase in other income was attributable to accrued interest from time deposits and U.S. treasury bills.

Net Loss:

For the three months ended September 30, 2024, the Company reported a net loss of $8.7 million, compared to a net loss of $10.9 million for the same period in 2023. For the nine months ended September 30, 2024, the Company reported a net loss of $26.0 million, compared to a net loss of $24.6 million for the same period in 2023.

Webcast Information

Belite Bio will host a webcast on Tuesday, November 12, 2024, 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://wsw.com/webcast/cc/blte5/1423080. A replay will be available following the event.

About Belite Bio

Belite Bio is a clinical-stage biopharmaceutical drug development company focused on advancing novel therapeutics targeting retinal degenerative eye diseases that have significant unmet medical needs such as Stargardt disease type 1, or 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, and 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 http://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
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,	
	2023	**2024**	**2023**	**2024**
Expenses				
Research and development	8,743	6,842	19,982	22,685
General and administrative	2,218	2,898	4,731	5,854
Total operating expenses	10,961	9,740	24,713	28,539
Loss from operations	(10,961)	(9,740)	(24,713)	(28,539)
Other income:				
Total other income, net	27	1,061	81	2,501
Loss before income tax	(10,934)	(8,679)	(24,632)	(26,038)
Income tax expense	1	-	10	6
Net loss	(10,935)	(8,679)	(24,642)	(26,044)
Other comprehensive income (loss)				
Foreign currency translation adjustments, net of nil tax	(55)	79	(115)	(27)
Total comprehensive loss	(10,990)	(8,600)	(24,757)	(26,071)
Weighted average number of ordinary shares used in per share calculation:				
- Basic and Diluted	27,315,550	30,687,305	26,013,012	30,231,207
Net loss per ordinary share				
- Basic and Diluted	$ (0.40)	$ (0.28)	$ (0.95)	$ (0.86)

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

	December 31, 2023	September 30, 2024
Current assets	$ 89,940	$ 111,268
Other assets	4,702	4,553
TOTAL ASSETS	$ 94,642	$ 115,821
TOTAL LIABILITIES	$ 4,211	$ 3,621
TOTAL SHAREHOLDERS' EQUITY	90,431	112,200
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 94,642	$ 115,821
Ordinary shares authorized	400,000,000	400,000,000
Ordinary shares issued	29,184,475	30,931,247
Ordinary shares outstanding	29,149,444	30,879,332

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