Belite Bio Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Corporate Update

March 12, 2024

- Tinlarebant is Belite Bio's orally administered tablet intended to slow disease progression in patients affected with Stargardt Disease (STGD1) and Geographic Atrophy (GA) in advanced Dry Age-related Macular Degeneration (Dry AMD)
- Data from a 24-month Phase 2 trial in adolescent STGD1 subjects showed a sustained lower atrophic lesion growth in Tinlarebant-treated subjects compared to ProgStar participants possessing similar baseline characteristics (aged ≤18 years) ($p<0.001$)
- In the Phase 2 trial, 42% of Tinlarebant-treated subjects (5 out of 12) did not develop atrophic retinal lesions during the 24-month treatment period
- Enrollment of a pivotal global Phase 3 trial of Tinlarebant in adolescent STGD1 subjects ("DRAGON") has been completed with 104 subjects across 11 countries
- Interim data from the "DRAGON" trial expected in 4Q 2024
- Dosed first subject in pivotal global Phase 3 trial of Tinalrebant in GA subjects ("PHOENIX") and received approval to initiate PHOENIX trial in eight countries
- As of December 31, 2023, the Company had $88.2 million in cash.
- Conference Call and Webcast on Tuesday, March 12, 2024, at 4:30 p.m. ET

SAN DIEGO, March 11, 2024 (GLOBE NEWSWIRE) -- Belite Bio, Inc (NASDAQ: BLTE) ("Belite Bio" 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 audited financial results for full-year 2023 and the unaudited and unreviewed financial results for the quarter ended December 31, 2023, and provided a business update.

"2023 was a productive year for Belite, from the initiation of our Phase III trial in GA, enrollment completion of our Phase III Stargardt disease trial, to the exciting 24-month data from our Phase II Stargardt disease trial," said Dr. Tom Lin, Chairman and CEO of Belite Bio. "These milestones continue to underscore the therapeutic potential of Tinlarebant, not only in Stargardt disease, for which there is still no approved treatment, but for patients suffering from GA, for which an oral treatment would be game changing. As we enter 2024, we remain focused on our mission to develop oral therapies for eye diseases with significant unmet medical needs and are well positioned to execute with our strong balance sheet. We expect to share additional analysis from our Phase 2 Stargardt disease trial at the annual meeting of The Association for Research in Vision and Ophthalmology (ARVO) in May, and to receive one-year interim data from our Phase 3 DRAGON trial later this year. We also look forward to sharing additional enrollment updates on our Phase III PHOENIX trial in GA as the year progresses."

Full Year 2023 Business Highlights and Upcoming Milestones:

Clinical Highlights

Tinlarebant (LBS-008) is designed to be 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 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 and Rare Pediatric Disease (RPD) designations by the U.S. Food and Drug Administration (FDA) and orphan drug designation (ODD) in the U.S., Europe, and Japan for STGD1. There are currently no FDA-approved treatments for STGD1.
- LBS-008-CT02 Trial: Completed, open label, 24-month Phase 2 trial in adolescent STGD1 subjects and presented end of trial data at the American Association of Ophthalmology (AAO) annual meeting in November 2023
    - Tinlarebant was safe and well tolerated with no withdrawals due to adverse events
    - The 24-month data showed a sustained lower atrophic lesion growth in Tinlarebant-treated subjects compared to ProgStar participants possessing similar baseline characteristics (aged ≤18 years) ($p<0.001$)

    - 42% of Tinlarebant-treated subjects (5 out of 12) did not develop atrophic retinal lesions
    - Visual acuity was stabilized in the majority of subjects during the trial with a mean loss of five letters following 24 months of treatment (a loss of <10 letters is not considered clinically significant)
- 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
    - Interim data expected in 4Q 2024
- Geographic Atrophy (GA): GA, the advanced form of Dry AMD, 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
        - Primary efficacy endpoint is slowing of atrophic lesion growth rate; safety and tolerability will also be assessed
        - First patient dosed in the third quarter of 2023
        - Has enrolled 56 subjects
        - Interim data expected at mid-point of the trial

Corporate Highlights

- Completed an underwritten public offering of American Depositary Shares of the Company (“ADSs”) and warrants (the “Follow-on Offering”) for gross proceeds of $30 million in June 2023
- Initiated an at-the-market offering program of additional ADSs (the “ATM Offering”) with an aggregate offering price of up to $100 million in June 2023
- Raised $22 million from the exercise of warrants issued in the Follow-on Offering and $29 million from ATM Offering as of December 31, 2023

Audited Full Year 2023 and Unaudited and Unreviewed Fourth Quarter 2023 Financial Results:

Cash: As of December 31, 2023, the Company had $88.2 million in cash, as compared with $42.1 million on December 31, 2022.

R&D Expenses:

For the three months ended December 31, 2023, research and development expenses were $4.9 million compared to $5.2 million for the same period in 2022. The decrease resulted primarily from higher R&D expenses in the fourth quarter of 2022 as the DRAGON trial reached certain milestones in such quarter. For the year ended December 31, 2023, research and development expenses were $24.8 million compared to $8.9 million for the same period in 2022. The increase in research and development expenses was primarily attributable to increases in expenses related to conducting the DRAGON and PHOENIX trials.

G&A Expenses:

For the three months ended December 31, 2023, general and administration expenses were $2.1 million compared to $1.5 million for the same period in 2022. The increase resulted primarily from an increase in share-based compensation granted in 2023. For the year ended December 31, 2023, general and administration expenses were $6.8 million compared to $4.0 million for the same period in 2022. The increase resulted also primarily from an increase in share-based compensation granted in 2023 and an increase in professional service fees.

Net Loss:

For the three months ended December 31, 2023, the Company reported a net loss of $7.0 million or ($0.25) per share compared to $6.8 million or ($0.27) per share for the same period in 2022. For the year ended December 31, 2023, the Company reported a net loss of $31.6 million or ($1.19) per share, compared to a net loss of $12.6 million or ($0.63) per share for the same period in 2022.

Webcast Information

Belite Bio will host a webcast on Tuesday, March 12, 2023, 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/blte2/1419894. 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 retinal degenerative eye diseases which have significant unmet medical needs such as (i) atrophic age-related macular degeneration (AMD), commonly known as Geographic Atrophy (GA) in advanced dry AMD, and (ii) autosomal recessive Stargardt disease type 1, or STGD1, in addition to specific metabolic diseases. 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,	
	2022	**2023**
	(Audited)	(Audited)
Expenses		
Research and development	8,869	24,844
General and administrative	3,952	6,824
Total operating expenses	12,821	31,668
Loss from operations	(12,821)	(31,668)
Other income		
Total other income, net	173	45
Loss before income tax	(12,648)	(31,623)
Income tax expense	-	9
Net loss	(12,648)	(31,632)
Other comprehensive income (loss)		
Foreign currency translation adjustments, net of nil tax	(196)	18
Total comprehensive loss	(12,844)	(31,614)
Weighted average number of ordinary shares used in per share calculation:		
- Basic and Diluted	19,976,596	26,593,673
Net loss per ordinary share		
- Basic and Diluted	$ (0.63)	$ (1.19)

	For the Three Months Ended December 31,	
	2022	**2023**
	(Unaudited and Unreviewed)	(Unaudited and Unreviewed)
Expenses		
Research and development	5,226	4,862
General and administrative	1,495	2,093
Total operating expenses	6,721	6,955
Loss from operations	(6,721)	(6,955)
Other expense		
Total other expense, net	(62)	(36)
Loss before income tax	(6,783)	(6,991)
Income tax expense	-	-
Net loss	(6,783)	(6,991)
Other comprehensive income (loss)		
Foreign currency translation adjustments, net of nil tax	127	133
Total comprehensive loss	(6,656)	(6,858)
Weighted average number of ordinary shares used in per share calculation:		
- Basic and Diluted	24,889,136	28,316,251
Net loss per ordinary share		
- Basic and Diluted	$ (0.27)	$ (0.25)

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

	December 31	
	2022	**2023**
	(Audited)	**(Audited)**
ASSETS		
Current Assets		
Cash	$ 42,089	$ 88,157
Other receivables	—	818
Prepayments and other current assets	716	947
Other receivables due from related parties	2	18
Total current assets	42,807	89,940
Property and equipment, net	541	490
Prepayments and other non-current assets	31	3,297
Security deposits	88	104
Operating lease right-of-use asset, net	806	811
TOTAL ASSETS	$ 44,273	$ 94,642
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accrued expenses and other liabilities	1,906	3,325
Operating lease liabilities – current	198	308
Total current liabilities	2,104	3,633
Non-current liabilities		
Operating lease liabilities –non – current	668	578
TOTAL LIABILITIES	2,772	4,211
Shareholders' equity		
Ordinary shares, par value of US$0.0001 per share; 400,000,000 shares authorized; 24,898,908 and 29,184,475 shares issued; 24,898,908 and 29,149,444 shares outstanding as of December 31, 2022 and 2023, respectively	3	3
Additional paid-in capital	81,761	162,305
Accumulated other comprehensive loss	(392)	(374)
Accumulated deficit	(39,871)	(71,503)
Total shareholders' equity	41,501	90,431
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 44,273	$ 94,642

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