Belite Bio Reports Full-Year 2022 Operational Highlights and Financial Results

March 31, 2023

- 12-month interim data from the ongoing 2-year, Phase 2 Stargardt disease (STGD1) study continues to show halting or slowing of lesion growth; 18-month efficacy and safety update expected during the 2023 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting on April 25
- 42 subjects have been enrolled for the pivotal Phase 3 “DRAGON” trial evaluating oral tinlarebant in adolescent STGD1; at least 90 subjects are targeted for enrollment
- The first patient of the pivotal Phase 3 “PHOENIX” trial in Geographic Atrophy (GA) is expected to be enrolled during mid-2023
- Webcast Monday, April 3, 2023, at 4:30 p.m. ET

SAN DIEGO, March 31, 2023 (GLOBE NEWSWIRE) -- Belite Bio, Inc (NASDAQ: BLTE) (“Belite” or the “Company”), a San Diego based clinical stage biopharmaceutical drug development company targeting eye diseases with significant unmet medical needs, today announced its financial results for the full-year ended December 31, 2022 and provided a general business update.

“2022 was a transformative year for Belite, with achievements across key clinical and corporate milestones including the closing of our successful initial public offering, enrollment in over 11 countries for our pivotal Phase 3 DRAGON trial, and Phase 2 efficacy data reinforcing the potential for tinlarebant to slow down disease progression in Stargardt disease,” said Dr. Tom Lin, Belite’s Chairman and CEO. “As we look towards 2023, we remain focused on late-stage advancement of tinlarebant with continued enrollment in the DRAGON trial and the first patient of the Phase 3 PHOENIX trial in GA is expected to be enrolled during mid-year. We also expect to present the 18-month efficacy and safety data from our two-year Phase 2 trial in Stargardt disease during ARVO this year. With our balance sheet strengthened, we are well-positioned to execute across our near-term catalysts and work towards our mission of developing oral therapies for eye diseases with significant unmet medical needs.”

Full Year 2022 Business Highlights and Upcoming Milestones:

Clinical Highlights

Tinlarebant (LBS-008) is an oral, once daily, retinol binding protein 4 (RBP4) antagonist that decreases RBP4 levels in the blood and selectively lowers vitamin A (retinol) delivery to the eye as a means to potentially reduce the accumulation of toxic vitamin A byproducts within the eye leading to preservation of the retina. Vitamin A is critical for normal vision but it can be converted to toxic byproducts (bisretinoids) in degenerative retinal diseases such as STGD1 and GA leading to photoreceptor cell death and vision loss.

- **Stargardt disease (STGD1):** Accumulation of cytotoxic 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. and Europe for STGD1. There are currently no FDA approved treatments for STGD1.

    - Ongoing, open-label, 2-year Phase 2 trial in adolescent STGD1 subjects:
        - 13 subjects enrolled at clinical sites in Australia and Taiwan.
        - No atrophic retinal lesions in the 13 subjects at study start; only 1 subject developed bilateral retinal lesions (~0.44 mm^2 mean size) at the 12-month interval.
        - ARVO 2023, April 25: Expect to present 18-month efficacy and safety data.

- Pivotal DRAGON Trial: 2-year, randomized, double-masked, placebo-controlled, global, multi-center, pivotal Phase 3 trial in adolescent STGD1 subjects:
    - Trial initiated in the U.S., the United Kingdom, Germany, Belgium, France, Switzerland, China, Hong Kong, Taiwan, Australia, and the Netherlands, with 42 subjects enrolled; at least 90 subjects are targeted for enrollment.
    - Upper age range for enrollment increased from 18 to 20 years.
    - Primary efficacy endpoint is slowing of lesion growth rate; safety and tolerability will also be assessed.
    - Mid 2024: Interim efficacy and safety data expected.

- **Geographic Atrophy (GA):** GA, an advanced form of Dry Age-Related Macular Degeneration (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.
    - Pivotal PHOENIX Trial: initiated; a 2-year prospective, randomized (2:1, active:placebo, n ~430 subjects), double-masked, placebo-controlled, global, multi-center, Phase 3 trial in patients with GA.
    - Primary efficacy endpoint is slowing of lesion growth rate; safety and tolerability will also be assessed.
    - Interim analysis expected at mid-point of the study.
    - Mid 2023: Enrollment of first patient in pivotal Phase 3 PHOENIX trial expected

Corporate Highlights

- Completed initial public offering in April 2022. Belite Bio (NASDAQ: BLTE) became listed on Nasdaq and raised net proceeds of approximately $38.0 million including the overallotment. The Company expects to use the net proceeds to fund the Phase 3 clinical trial of Tinlarebant for STGD1 and GA, working capital and other general corporate purposes.

Full Year 2022 Financial Results:

Cash and Cash Equivalents: As of December 31, 2022, the Company had $42.1 million in cash.

R&D Expenses:
For the year ended December 31, 2022, research and development expenses were $8.9 million compared to $7.4 million for the same period in 2021. Research and development expense increase was primarily attributable to an increase in wages and salaries due to our R&D team expansion and increased share-based compensation expenses.

G&A Expenses:
For the year ended December 31, 2022, general and administration expenses were $4.0 million compared to $2.4 million for the same period in 2021. General and Administration expenses increased by approximately $1.6 million from the year ended December 31, 2021, to the year ended December 31, 2022, which was primarily due to an increase in professional service fees incurred, an increase of D&O insurance expense, and increase of wages and salaries.

Net Loss:
For the year ended December 31, 2022, the Company reported a net loss of $12.6 million, compared to a net loss of $9.7 million for the same period in 2021.

Webcast Information

Belite Bio will host a webcast to discuss the Company's financial results and provide a business update. The call is scheduled for Monday, April 3, 2023, at 4:30 p.m. Eastern Time. To join the live webcast please click here. A replay will be available approximately two hours after the event for 90 days.

About Belite Bio

Belite Bio is a San Diego based clinical stage biopharmaceutical drug development company targeting eye diseases with significant unmet medical needs, such as advanced dry age-related macular degeneration (commonly known as Geographic Atrophy, or advanced Dry AMD), Stargardt disease, and 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, plans and prospects, as well as any 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, clinical development, regulatory milestones, and commercialization of its product candidates, and any other statements containing the words "expect", "will", "believe", "target", and other 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 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
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Amounts in thousand US Dollars, except share and per share amounts)

	For the Years Ended December 31,		
	2020	**2021**	**2022**
Expenses			
Research and development	3,688	7,419	8,869
General and administrative	2,055	2,378	3,952

Total operating expenses	5,743	9,797	12,821
Loss from operations	(5,743)	(9,797)	(12,821)
Other income (expense):			
Total other (expense) income, net	(9)	131	173
Loss before income tax	(5,752)	(9,666)	(12,648)
Income tax expense	(1)	—	—
Net loss	(5,753)	(9,666)	(12,648)
Other comprehensive income (loss)			
Foreign currency translation adjustments, net of nil tax	6	(152)	(196)
Total comprehensive loss	$ (5,747)	$ (9,818)	(12,844)
Weighted average number of ordinary shares used in per share calculation:			
− Basic and Diluted	8,790,397	9,569,932	19,976,596
Net loss per ordinary share			
− Basic and Diluted	$ (0.65)	$ (1.01)	$ (0.63)

SELECTED CONSOLIDATED BALANCE SHEET
(Amounts in thousand US Dollars)

	December 31,	
	2021	**2022**
Current assets	$ 17,431	$ 42,807
Other assets	917	1,466
TOTAL ASSETS	$ 18,348	$ 44,273
TOTAL LIABILITIES	$ 1,635	$ 2,772
Total convertible preferred shares	31,806	—
Total shareholders' (deficit) equity	(15,093)	41,501
TOTAL LIABILITIES, CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' (DEFICIT) EQUITY	$ 18,348	$ 44,273
SUPPLEMENTAL DISCLOSURE		
Ordinary shares authorized	492,179,086	492,179,086
Ordinary shares issued and outstanding	10,274,403	24,898,908

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