Belite Bio Reports First Half 2022 Operational Highlights and Financial Results

August 11, 2022

- *LBS-008 (aka Tinlarebant) is Belite Bio's orally administered tablet for the treatment of Stargardt disease (STGD1) and Dry AMD*
- *A 2-year Phase 2 trial in adolescent STGD1 and a global Phase 3 trial in adolescent STGD1 are ongoing*
- *The Phase 3, Multicenter, Randomized, **D**ouble Masked, Placebo Controlled Study to Evaluate the Safety and Efficacy of Tinla**R**ebant in the Treatment of St**A**r**G**ardt Disease in Ad**O**lesce**N**t Subjects (DRAGON) trial has commenced in the U.S., the United Kingdom, Germany, Belgium, Switzerland, Hong Kong, Taiwan, and Australia, and several patients have been enrolled*
- *LBS-008, Belite Bio's lead asset, has been granted fast track designation, rare pediatric disease designation (RPD) in the U.S., and orphan drug designation (ODD) in the U.S. and Europe for STGD1*
- *Conference Call and Webcast Today, August 11, 2022, at 4:30 p.m. ET*

SAN DIEGO, Aug. 10, 2022 (GLOBE NEWSWIRE) -- Belite Bio, Inc (NASDAQ: BLTE), a San Diego based clinical stage biopharmaceutical drug development company targeting untreatable eye diseases, today announced its financial results for the first six months ended June 30, 2022 and provided a general business update.

"We are pleased to be listed on Nasdaq to further progress LBS-008's clinical trials," said Dr. Tom Lin, Belite's Chairman and CEO. "With the promising results from the Phase 2 trial in early-onset STGD1 subjects, we have initiated the global Phase 3 trial for LBS-008 and believe that we are on a clear clinical development pathway to accelerate and bring forward a promising treatment for STGD1 and dry AMD."

First Half 2022 Business Highlights and Upcoming Milestones:

Therapeutics Programs Targeting STGD1 and Dry AMD

LBS-008 (aka Tinlarebant): orally administered RBP4 antagonist

- LBS-008 is an orally-available, small molecule retinol binding protein 4 (RBP4) antagonist that selectively reduces the delivery of vitamin A (retinol) to the eye leading to a reduction of toxic vitamin A byproducts (bisretinoids) that have been implicated in the onset and progression of STGD1. Sponsored by the NIH Blueprint program to treat non-neovascular age-related macular degeneration (Dry AMD), LBS-008 is also endorsed by NIH as a promising first-in-class oral medication to slow or halt the progression of Dry AMD, a disease which primarily affects the elderly and shares a similar pathophysiology as STGD1.
- There are currently no approved treatments for STGD1 or Dry AMD by the U.S. Food and Drug Administration (FDA).
- LBS-008 has been granted FDA fast track designation, rare pediatric disease designation (RPD) in the U.S., and orphan drug designation (ODD) in the U.S. and Europe for STGD1.
- Belite has completed three randomized, double-blind, placebo-controlled, Phase 1 trials of LBS-008 in healthy adult subjects, including a single ascending dose, or SAD trial in 40 subjects in the U.S., and a SAD trial in 39 subjects and a multiple ascending dose, or MAD, trial in 32 healthy adult subjects in Australia. These trials were conducted to confirm the safety, toxicity, PK, and PD of LBS-008 on a range of SAD (10-50 mg in the U.S.; 25-400 mg in Australia) / MAD (5-25 mg in Australia) levels in healthy adult subjects in fasted / fed conditions.
- Belite is currently conducting a 2-year Phase 2 trial and a 2-year Phase 3 (DRAGON) trial of LBS-008 in adolescent STGD1 subjects.
- The Phase 2 trial has enrolled a total of 13 subjects at clinical sites in Australia and Taiwan. Preliminary data from the Phase 2 trial at the first 6-month interval shows that 8 of the 13 patients (or 61.5%) recorded a gain in best-corrected visual acuity (BCVA) in at least one eye, including 2 patients who recorded a BCVA gain in both eyes. In addition, there were no atrophic lesions in any of the 13 subjects at study start and only 1 subject showed evidence of a retinal lesion (~0.3mm^2 in size) at 6-months. Belite expects the next data readout of this Phase 2 trial to occur in the last quarter of 2022 when all subjects have completed 12 months of treatment.
- An Investigational New Drug (IND) application to initiate the DRAGON trial in the U.S. was submitted to the FDA on July 19, 2022. The DRAGON trial is a 2-year, randomized, double-masked, placebo-controlled, global, multi-center, study designed to evaluate the safety and efficacy of LBS-008 in adolescent STGD1 patients. Currently, the DRAGON trial has *commenced in the U.S., the United Kingdom, Germany, Belgium, Switzerland, Hong Kong, Taiwan, and Australia, and several patients have been enrolled*. Belite has additional plans to submit trial

applications across other jurisdictions. (For more information, visit clinicaltrials.gov at https://www.clinicaltrials.gov/ct2/show/NCT05244304?term=belite+bio&draw=2&rank=1)

- Because the accumulation of toxic bisretinoids has also been implicated in the progression of Dry AMD, Belite believes LBS-008 has the potential to be effective for the treatment of Dry AMD as well. Belite plans to initiate a Phase 2/3 clinical trial for Dry AMD in the 4th quarter of 2022.

The Company strengthened its balance sheet with an initial public offering

Belite Bio (NASDAQ: BLTE) became listed on Nasdaq on April 29, 2022 and raised net proceeds of approximately $36.1 million including the overallotment. The Company expects to use the net proceeds to fund the Phase 3 clinical trial of LBS-008 for STGD1, further clinical development of LBS-008 for Dry AMD, working capital and other general corporate purposes.

First half 2022 Financial Results:

- **Cash and Cash Equivalents:** As of June 30, 2022, the Company had $48.7 million in cash.
- **R&D Expenses:** For the six months ended June 30, 2022, research and development expenses were $2.5 million compared to $3.6 million for the same period in 2021. Research and development expenses decreased primarily due to higher drug manufacturing and tox study costs incurred for STGD1 Phase 3 preparation in the first half of 2021.
- **G&A Expenses:** For the six months ended June 30, 2022, general and administration expenses were $1.1 million compared to $1.2 million for the same period in 2021.
- **Net Loss:** For the six months ended June 30, 2022, the Company reported a net loss of $3.5 million or ($0.23) per share, compared to a net loss of $4.7 million or ($0.49) per share for the same period in 2021.

Conference Call/Webcast Information

Belite Bio will host a conference call/webcast to discuss the Company's financial results and provide a business update. The call is scheduled for August 11, 2022, at 4:30 p.m. Eastern Time.

Webcast Link Instructions

You can join a live webcast of the conference at https://edge.media-server.com/mmc/p/duiw3n7s or the "Presentations & Events" section of the Company's Investor Relations website at https://investors.belitebio.com/presentations-events/events. A replay will be available approximately two hours after the event for 30 days.

Phone Registration Instructions

To participate in the live call, please register at https://register.vevent.com/register/BI1ef44339069942b696cb9a1a54d14d41. Once registered, you will receive dial-in numbers and unique PIN numbers via email. At the time of the call, you will dial in using the numbers from the confirmation email, and upon entering the unique PIN, will be routed into the call.

About Belite Bio

Belite Bio is a San Diego based clinical stage biopharmaceutical drug development company targeting untreatable eye diseases, such as atrophic age-related macular degeneration (commonly known as Dry AMD) and Stargardt disease, and metabolic diseases. For more information, follow us on Twitter, Instagram, LinkedIn, Facebook or visit us at www.belitebio.com.

Forward-looking Statements

This press release contains forward-looking statements, including 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. 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; Belite Bio's ability to achieve commercial success for its drug candidates, if approved; Belite Bio's ability to obtain and maintain protection of intellectual property for its technology and drugs; Belite Bio's reliance on third parties to conduct drug development, manufacturing and other services; Belite Bio's limited operating history and Belite Bio's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; Belite Bio's ability to enter into additional collaboration agreements beyond its existing strategic partnerships or collaborations, and the impact of the COVID-19 pandemic on Belite Bio's clinical development, commercial and other operations, 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

(in thousand US Dollars, except share and per share amounts)

	For the Six Months

	Ended June 30,	
	2021	2022
Operating Expenses		
Research and development	3,640	2,457
General and administrative	1,158	1,102
Total operating expenses	4,798	3,559
Loss from operations	(4,798)	(3,559)
Total Other income, net	77	98
Loss before income tax	(4,721)	(3,461)
Income tax expense	—	—
Net loss	(4,721)	(3,461)
Other comprehensive loss		
Foreign currency translation adjustments, net of nil tax	(87)	(157)
Total comprehensive loss	$ (4,808)	$ (3,618)
Weighted average number of ordinary shares used in per share calculation:		
– Basic and Diluted	9,567,997	14,992,848
Net loss per ordinary share		
– Basic and Diluted	$ (0.49)	$ (0.23)

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEET

	December 31, 2021	June 30 ,2022
Current assets	$ 17,431	$ 49,927
Other assets	917	1,130
Total assets	$ 18,348	$ 51,057
Total liabilities	$ 1,635	$ 1,426
Total convertible preferred shares	31,806	—
Total shareholders' equity (deficit)	(15,093)	49,631
Total liabilities, convertible preferred shares and shareholders' equity (deficit)	$ 18,348	$ 51,057
SUPPLEMENTAL DISCLOSURE		
Ordinary shares authorized	492,179,086	492,179,086
Ordinary shares issued and outstanding	10,274,403	24,867,408

Media and Investor Relations Contact:
Jennifer Wu /ir@belitebio.com
Tim McCarthy /tim@lifesciadvisors.com