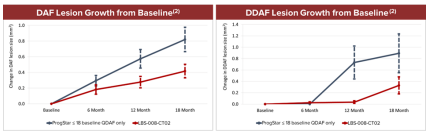
Belite Bio Reports First-Quarter 2023 Operational Highlights and Financial Results

May 10, 2023

- In 18-month interim data from ongoing 2-year, Phase 2 Stargardt disease (“STGD1”) trial (“LBS-008-CT02”), we continued to observe that oral Tinlarebant is safe and well tolerated in adolescent STGD1 subjects
- A continued trend of slowing expansion of autofluorescence was observed and the growth rate of incident atrophic retinal lesions was reduced with Tinlarebant in LBS-008-CT02 compared to a natural history study of the disease (“ProgStar”)
- Stabilization of visual acuity with no significant loss and no clinically significant changes in retinal thickness observed over 18 months of treatment with Tinlarebant in LBS-008-CT02
- 58 subjects have been enrolled in the pivotal Phase 3 “DRAGON” trial evaluating Tinlarebant in adolescent STGD1; at least 90 subjects are targeted for enrollment
- Enrollment of first patient in pivotal Phase 3 “PHOENIX” trial for Geographic Atrophy (GA) is expected in mid-2023
- Conference Call and Webcast Monday, May 11, 2023, at 8:00 a.m. ET

Lesion Growth from Baseline



Lesion Growth from Baseline

SAN DIEGO, May 10, 2023 (GLOBE NEWSWIRE) -- Belite Bio, Inc (NASDAQ: BLTE) (“Belite” or the “Company”), a clinical stage biopharmaceutical drug development company focused on advancing novel therapeutics targeting retinal degenerative eye diseases which have significant unmet medical needs, today announced its financial results for the first quarter ended March 31, 2023 and provided a general business update.

“The promising interim data after 18 months of treatment in our Phase 2 trial further reinforces the potential of Tinlarebant, an oral, once daily retinol binding protein antagonist, to slow disease progression in STGD1,” said Dr. Tom Lin, Belite’s Chairman and CEO. “We remain focused on advancing late-stage development of Tinlarebant and are pleased with the 60% enrollment seen to date in our pivotal Phase 3 DRAGON trial. We remain on track to enroll the first patient in our Phase 3 PHOENIX trial in GA in mid-2023.”

Dr. Nathan L. Mata, Chief Scientific Officer of Belite Bio added, “The 18-month data from our Phase 2 trial presented at ARVO are encouraging and highlight the ability of Tinlarebant to slow expansion of autofluorescence and the majority of the subjects showed no transition to atrophic (DDAF) lesions. Among the minority subjects who did transition to DDAF lesions, Tinlarebant slowed the rate of progression compared to those reported in a natural history study. We believe these 18-month Phase 2 data continue to reinforce the potential of Tinlarebant to be a transformative oral treatment for patients with STGD1.”

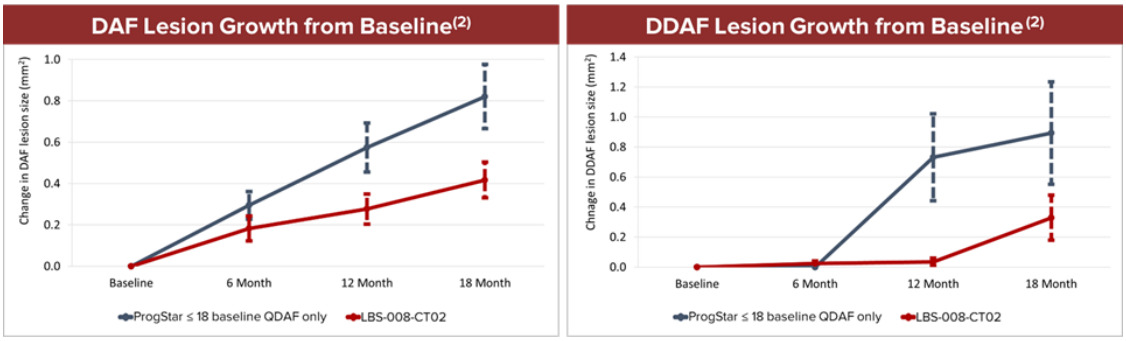
First Quarter 2023 Business Highlights and Upcoming Milestones:

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 selectively lowers vitamin A (retinol) delivery to the eye without disrupting systemic lipoprotein delivery to other tissues. Vitamin A is critical to normal vision but can accumulate as toxic byproducts and lead to retinal cell death and vision loss in certain eye diseases like STGD1 and GA, the advanced form of dry Age-Related Macular Degeneration (dry AMD).

- **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.
    - LBS-008-CT02 trial: Ongoing, open-label, 2-year Phase 2 trial in adolescent STGD1 subjects
        - 18-month data presented at 2023 Association for Research in Vision and Ophthalmology (ARVO)
        - 12 subjects have completed 18 months of treatment
        - Tinlarebant continues to be safe and well tolerated
        - Nearly 60% of subjects (7 out of 12) had no incident atrophic retinal lesions as assessed by fundus autofluorescence (FAF) imaging after 18 months
        - Visual acuity was stabilized, with no significant loss and no clinically significant changes in retinal thickness observed over 18 months of treatment
        - When compared with participants from the Prospective Cohort Study of Childhood-Onset STGD1 by Georgiou (2020), subjects in LBS-008-CT02 showed a reduced expansion of decreased autofluorescence (DAF) lesions from baseline to 18 months (0.69 ± 0.72 mm^2/year versus 0.28 ± 0.28 mm^2/year, respectively)[(1)]; DAF represents the combined

sizes of questionably decreased autofluorescence (QDAF) + definitely decreased autofluorescence (DDAF) lesions
- When compared with ProgStar study participants ≤ 18 years old with only QDAF lesions at baseline, after 18 months[1]:
  - LBS-008-CT02 subjects again showed reduced expansion of DAF lesion size from baseline;
  - LBS-008-CT02 subjects also exhibited a reduced expansion in DDAF lesion size from baseline



  - 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, Netherlands, Belgium, France, Switzerland, China, Hong Kong, Taiwan, and Australia with 58 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 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: 2-year prospective, randomized (2:1, active:placebo, n ~430), 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 trial
    - Mid 2023: Enrollment of first patient in pivotal Phase 3 PHOENIX trial expected

Corporate Highlights

- Hosted two key opinion leader (KOL) events on STGD1 disease:
  - On May 3, the Company hosted a KOL event featuring Professor Hendrik Scholl, M.D. (Chairman of the Department of Ophthalmology, University of Basel) who discussed STGD1 overview and the 18-month data from the LBS-008-CT02 trial evaluating Tinlarebant for the treatment of STGD1
  - On May 10, the Company hosted a KOL event featuring Professor Michel Michaelides, M.D. (Professor of Ophthalmology at the UCL Institute of Ophthalmology) who discussed the progression of childhood-onset STGD1 and the relevance of Tinlarebant's LBS-008-CT02 trial 18-month data

First Quarter 2023 Financial Results:

Cash and Cash Equivalents: As of March 31, 2023, the Company had $37.8 million in cash.

R&D Expenses:
For the three months ended March 31, 2023, research and development expenses were $5.7 million compared to $0.9 million for the same period in 2022. The increase in research and development expenses was primarily attributable to an increase in (i) research for and activities related to conducting DRAGON and PHOENIX trials, and (ii) wages and salaries due to our R&D team expansion.

G&A Expenses:
For the three months ended March 31, 2023, general and administration expenses were $1.2 million compared to $0.2 million for the same period in 2022. The increase in general and administration expenses was primarily due to increases in professional service fees, insurance premium for directors' and officers' liability insurance, and wages and salaries.

Net Loss:
For the three months ended March 31, 2023, the Company reported a net loss of $6.9 million, compared to a net loss of $1.1 million for the same period in 2022.

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 Thursday, May 11, 2023, at 8:00 a.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 clinical stage biopharmaceutical drug development company focused on advancing novel therapeutics targeting retinal degenerative eye diseases with significant unmet medical needs, such as STGD1 and GA in advanced dry AMD, 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, 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; expectations for the timing of initiation, enrollment and completion of, and data relating to, its clinical trials; the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of Belite Bio's drug candidates; whether additional clinical trials may be required for DRAGON or PHOENIX studies based on their respective data; 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 March 31,	
	2022	**2023**
Expenses		
Research and development	878	5,723
General and administrative	175	1,158
Total operating expenses	1,053	6,881
Loss from operations	(1,053)	(6,881)
Other income (expense):		
Total other (expense) income, net	(17)	(8)
Loss before income tax	(1,070)	(6,889)
Income tax expense	-	6
Net loss	(1,070)	(6,895)
Other comprehensive income (loss)		
Foreign currency translation adjustments, net of nil tax	25	16
Total comprehensive loss	$ (1,045)	(6,879)
Weighted average number of ordinary shares used in per share calculation:		
- Basic and Diluted	10,274,403	20,950,240
Net loss per ordinary share		
- Basic and Diluted	$ (0.10)	$ (0.33)

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

	December 31, 2022	**March 31, 2023**
Current assets	$ 42,807	$ 38,423
Other assets	1,466	1,395
TOTAL ASSETS	$ 44,273	$ 39,818
TOTAL LIABILITIES	$ 2,772	$ 4,649
TOTAL SHAREHOLDERS' EQUITY	41,501	35,169
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 44,273	$ 39,818
Ordinary shares authorized	492,179,086	400,000,000
Ordinary shares issued and outstanding	24,898,908	24,914,741

Media and Investor Relations Contact:
Jennifer Wu /ir@belitebio.com

Tim McCarthy /tim@lifesciadvisors.com

Note: (1) Although we have compared the published data for the above studies to our interim data in the LBS-008-CT02 trial, the value of such comparisons is limited because they are derived from studies conducted under different protocols, at different sites, with different patient populations, and results were analyzed using non-standardized methods. We note our future trials may not confirm the comparisons or analyses we have made to date.
(2) For each subject, the mean lesion size between eyes was determined and the average value for the lesion sizes within each study group was calculated. The data show mean lesion sizes within each group ± standard error of the mean at each timepoint.

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/729308da-8c18-4067-b087-e5ec2da8e3df