89bio Reports First Quarter 2023 Financial Results and Provides Corporate Update

May 4, 2023

– Positive topline results from ENLIVEN Phase 2b trial of pegozafermin in NASH demonstrated high statistical significance on both primary histology endpoints supporting advancement to Phase 3; discussions with regulatory agencies planned for the second half of 2023 –

– SHTG Phase 3 trial expected to be initiated in the second quarter of 2023 –

– Completed underwritten public offering with $316.2 million in gross proceeds; cash balance of $480.9 million as of March 31, 2023 –

SAN FRANCISCO, May 04, 2023 (GLOBE NEWSWIRE) -- 89bio, Inc. (Nasdaq: ETNB), a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of liver and cardio-metabolic diseases, today reported its financial results for the first quarter ended March 31, 2023.

“In the first quarter we reported highly statistically significant topline results from the ENLIVEN Phase 2b NASH trial of pegozafermin, which we believe further de-risks our late-stage clinical development program and supports advancement to Phase 3,” said Rohan Palekar, Chief Executive Officer of 89bio. “We look forward to discussing next steps with the regulatory agencies in the second half of 2023. We intend to evaluate pegozafermin in F2/3 patients as well as in compensated cirrhosis (F4) patients, who have the most severe subset of the disease and highest unmet need.”

Mr. Palekar continued, “Additionally, we plan to advance pegozafermin in SHTG with initiation of the first of two recommended Phase 3 trials in the second quarter of this year. Following the recent public offering we are well positioned to execute on key priorities in both NASH and SHTG, bringing us one step closer to delivering a potentially transformational and highly differentiated treatment option to patients.”

Recent Highlights and Anticipated Milestones

Nonalcoholic Steatohepatitis (NASH)

- ENLIVEN is a Phase 2b trial designed to evaluate the safety and efficacy of a weekly (15mg and 30mg) or every two-week (44mg) dose of pegozafermin compared to placebo for the treatment of patients with fibrosis stage F2 - F3 NASH and NAS ≥ 4 for 24 weeks. All patients will continue treatment in a blinded extension phase for an additional 24 weeks for a total treatment period of 48 weeks.
- The 44 mg every-two-week and the 30 mg weekly dose groups both met with high statistical significance, both of the primary histology endpoints per the U.S. Food and Drug Administration (FDA) guidance on endpoints for accelerated approval in non-cirrhotic NASH patients. The 30mg weekly and 44mg every two-week dose groups also demonstrated statistically significant and clinically meaningful improvements in liver fat, non-invasive markers of liver fibrosis and inflammation as well as meaningful improvements in other metabolic and lipid markers. The every-two-week dose data reinforces pegozafermin’s potential to be a differentiated treatment ideally suited for a chronic, asymptomatic disease like NASH. Pegozafermin was generally well tolerated with a favorable safety profile consistent with prior studies.
- The ENLIVEN study also included 14 biopsy-confirmed NASH patients with compensated cirrhosis (F4 patients) who were not part of the primary analysis but continued in the study. 12 of these 14 patients underwent a follow-up biopsy at week 24. In a descriptive analysis of these data, five out of 11 pegozafermin-treated patients experienced at least one-stage improvement in liver fibrosis with no worsening of NASH by week 24 compared with zero out of one patient on placebo. An additional two pegozafermin-treated patients experienced at least one-stage improvement in liver fibrosis with no worsening of ballooning or inflammation.
- The Company intends to meet with the FDA in the second half of 2023 and to pursue EU scientific advice in parallel. Subject to regulatory approval, the Company’s proposed clinical development plans include a Phase 3 trial evaluating F2/F3 patients with a histology endpoint for accelerated approval and a Phase 3 trial evaluating F4 patients in parallel with an outcomes endpoint for full approval. The planned SHTG Phase 3 trials are expected to satisfy safety database requirements.

Severe Hypertriglyceridemia (SHTG)

- The first Phase 3 trial is planned to be initiated in the second quarter of 2023. The FDA agreed to the proposed primary endpoint of reduction in triglycerides (TG) from baseline without the need for a clinical outcome study. The FDA also agreed to the proposed doses and proposed secondary endpoints and were generally aligned with other trial parameters. The primary endpoint in the planned Phase 3 trials is anticipated to be assessed at week 26.
- Developed a new pre-filled syringe implementing the approved liquid formulation, which will be utilized in the planned SHTG Phase 3 trial in the second quarter of 2023.

Corporate Updates

- Completed underwritten public offering of common stock raising approximately $316.2 million in gross proceeds.

First Quarter 2023 Financial Results

Cash Position. As of March 31, 2023, 89bio had cash, cash equivalents, and short-term investments totaling $480.9 million.

Research and Development (R&D) Expenses. R&D expenses were $22.3 million for the three months ended March 31, 2023, compared to $19.8 million for the three months ended March 31, 2022. The increase in R&D expenses was primarily driven by increases in contract manufacturing and personnel expenses offset by decreases in clinical development costs.

General and Administrative (G&A) Expenses. G&A expenses were $6.2 million for the three months ended March 31, 2023, compared to $5.3 million for the three months ended March 31, 2022. The increase in G&A expenses was primarily due to an increase in costs related to professional services and stock-based compensation.

Net Loss. 89bio reported a net loss of $28.8 million for the three months ended March 31, 2023, compared to a net loss of $25.6 million for the three months ended March 31, 2022. The increase in net loss is primarily attributable to increased R&D expenses for our programs and increased G&A expenses associated with operating as a public company.

About 89bio
89bio is a clinical-stage biopharmaceutical company dedicated to the development of best-in-class therapies for patients with liver and cardiometabolic diseases who lack optimal treatment options. The company is focused on rapidly advancing its lead candidate, pegozafermin, through clinical development for the treatment of non-alcoholic steatohepatitis (NASH) and severe hypertriglyceridemia (SHTG). Pegozafermin is a specifically engineered, potentially best-in-class fibroblast growth factor 21 (FGF21) analog with unique glycoPEGylated technology that optimizes biological activity through an extended half-life. The company is headquartered in San Francisco. For more information, visit www.89bio.com or follow the company on LinkedIn.

Forward-looking Statements
Certain statements in this press release may constitute "forward-looking statements" within the meaning of the federal securities laws, including, but not limited to, statements regarding the therapeutic potential, efficacy and clinical benefits of pegozafermin, the safety and tolerability profile of pegozafermin, clinical development plans and timing for pegozafermin, including the Phase 3 trial in SHTG and commencement of a Phase 3 trial based on results from the Phase 2b ENLIVEN trial, the timing for meeting with regulatory authorities and expectations regarding the time period over which 89bio's capital resources will be sufficient to fund its anticipated operations. Words such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "anticipate," "goal," "opportunity," "develop," "plan" or the negative of these terms, and similar expressions, or statements regarding intent, belief, or current expectations, are forward looking statements. While 89bio believes these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-looking statements, which are based on information available to us on the date of this release. These forward-looking statements are based upon current estimates and assumptions and are subject to various risks and uncertainties (including, without limitation, those set forth in 89bio's filings with the SEC), many of which are beyond 89bio's control and subject to change. Actual results could be materially different. Risks and uncertainties include: expectations regarding the initiation of the Phase 3 trial in SHTG and NASH; 89bio's ability to execute on its strategy; positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; 89bio's substantial dependence on the success of it lead product candidate; competition from competing products; the impact of general economic, health, industrial or political conditions in the United States or internationally; the sufficiency of 89bio's capital resources and its ability to raise additional capital; and other risks and uncertainties identified in 89bio's Annual Report on Form 10-K for the year ended December 31, 2022 and other subsequent disclosure documents filed with the SEC. 89bio claims the protection of the Safe Harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. 89bio expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

89bio, Inc.
Condensed Consolidated Statement of Operations Data
(Unaudited)
(In thousands, except share and per share amounts)

	Three months Ended March 31, 2023	Three months Ended March 31, 2022
Operating expenses:		
Research and development	$ 22,306	$ 19,849
General and administrative	6,218	5,259
Total operating expenses	28,524	25,108
Loss from operations	28,524	25,108
Interest expense	2,075	408
Interest income and other, net	(1,763)	48
Net loss before tax	28,836	25,564
Income tax expense	—	1
Net loss	$ 28,836	$ 25,565
Comprehensive loss	$ 28,726	$ 25,757

Net loss per share, basic and diluted	$ 0.54	$ 1.26
Weighted-average shares used to compute net loss per share, basic and diluted	53,171,370	20,339,416

89bio, Inc.
Condensed Consolidated Balance Sheet Data
(Unaudited)
(In thousands)

	March 31, 2023	December 31, 2022
Cash, cash equivalents and short-term investments	$ 480,883	$ 188,160
Total assets	494,319	196,824
Total current liabilities	24,015	24,614
Non current liabilities	24,474	20,378
Total stockholders' equity (deficit)	445,830	151,832
Total liabilities and stockholders' equity	$ 494,319	$ 196,824

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