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

August 9, 2023

– Published data from ENLIVEN Phase 2b trial of pegozafermin in NASH in The New England Journal of Medicine; presented the data in a late-breaker session at the EASL International Liver Congress –

– Discussions with regulatory agencies regarding Phase 3 NASH program are planned for the second half of 2023 –

– Initiated ENTRUST Phase 3 trial of pegozafermin in patients with severe hypertriglyceridemia (SHTG) –

– Published positive results from Phase 2 ENTRIGUE trial of pegozafermin in SHTG in Nature Medicine –

SAN FRANCISCO, Aug. 09, 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 cardiometabolic diseases, today reported its financial results for the second quarter ended June 30, 2023.

“Progress in our late-stage clinical development programs in both NASH and SHTG further position pegozafermin as a potentially leading FGF21 analog treatment option,” said Rohan Palekar, Chief Executive Officer of 89bio. “The importance of the Phase 2b ENLIVEN trial data in NASH was further validated with the recent *New England Journal of Medicine (NEJM)* publication. Specifically, the histology data and positive results seen across markers of total liver health in the overall trial population and in patients on background GLP-1 therapies continue to support the therapeutic utility of pegozafermin and highlight the potential opportunity for a combination approach in patients with comorbidities. As we continue to advance towards Phase 3 development, we look forward to discussions with regulatory agencies planned in the second half of 2023.”

Mr. Palekar continued, “In the second quarter of 2023, we initiated ENTRUST, the Phase 3 trial of pegozafermin in patients with SHTG, signifying entry of the first FGF21 analog into Phase 3 development. Results from our previous trials in SHTG, including the recently published Phase 2 ENTRIGUE data in *Nature Medicine*, highlight the therapeutic potential of pegozafermin to offer a highly differentiated treatment option that is supportive of adoption and compliance.”

Recent Highlights and Anticipated Milestones

Nonalcoholic Steatohepatitis (NASH)

- Data from the Phase 2b ENLIVEN trial evaluating treatment with pegozafermin in patients with NASH were published online in *NEJM.* The data were simultaneously presented in a late-breaking oral session at the EASL Congress 2023 in Vienna, Austria and were also selected for inclusion in the Best of EASL Congress summary.
    - New analyses presented at EASL showed pegozafermin resulted in significant benefit across several key sub populations of NASH patients, including type 2 diabetes status, fibrosis stage (F2 or F3), and ALT levels. Adding pegozafermin to patients taking GLP-1 therapies improved key NASH measures, including liver markers of fibrosis, improvements in liver fat, ALT levels as well as metabolic (HbA1c) markers.
    - A subgroup of patients on background GLP-1 therapy saw improvements in key markers in the pooled pegozafermin group versus placebo for ELF score (-0.4 vs. +0.3 points), VCTE (-2.1 vs. -0.4 kPa), ALT (-22.3 vs. -12.4 U/L), MRI-PDFF (-54% vs. -28%), and hemoglobin A1c (HbA1c; -0.4 vs. -0.1). While GLP-1 therapies are promising for early-stage disease, there remains an unmet need for liver targeted therapies that demonstrate a fibrosis benefit like pegozafermin for medium-high risk (F2/F3) non-cirrhotic patients and compensated cirrhotic patients.
    - Across all patients, treatment with pegozafermin demonstrated statistically significant improvements on hepatic inflammation and fibrosis, which is consistent with previously reported markers. Further, there were no clinically relevant changes observed on vital signs, bone biomarkers or dual x-ray absorptiometry (DEXA) scans.
- The Company intends to meet with the U.S. Food and Drug Administration in the second half of 2023 and to pursue European Union scientific advice in parallel. Subject to regulatory feedback, the Company’s proposed clinical development plans include a Phase 3 trial evaluating F2/F3 NASH patients with a histology endpoint for accelerated approval and a Phase 3 trial in parallel with an outcomes endpoint for full approval. The SHTG Phase 3 program is expected to also support the safety database requirements at the time of BLA submission.

Severe Hypertriglyceridemia (SHTG)

- The Company initiated ENTRUST, a Phase 3 trial evaluating the efficacy, safety and tolerability of pegozafermin in patients with SHTG.
    - ENTRUST is a randomized, double-blind, placebo-controlled global trial that is planned to enroll up to 360 SHTG

patients randomized in a 3:3:2 ratio of pegozafermin (30 mg, 20 mg or placebo) given once weekly by subcutaneous injection for 52 weeks. The primary endpoint is the percent change from baseline in fasting triglycerides at Week 26 compared to placebo. Secondary endpoints include the assessment of liver fat measured by MRI-PDFF, non-HDL-C, HDL-C, apo-B, VLDL-C, HbA1c for those with baseline ≥ 6.5%, and total cholesterol at Week 26 compared to placebo.

- Previously reported positive data from the Phase 2 ENTRIGUE trial of pegozafermin in patients with SHTG were published online in *Nature Medicine*.

Second Quarter 2023 Financial Results

Cash Position. As of June 30, 2023, 89bio had cash, cash equivalents and short-term available-for-sale securities totaling $478.0 million.

Research and Development (R&D) Expenses. R&D expenses were $34.9 million for the three months ended June 30, 2023, compared to $19.7 million for the three months ended June 30, 2022. The increase in R&D expenses was primarily driven by increases in contract manufacturing costs, personnel expenses, and clinical development costs.

General and Administrative (G&A) Expenses. G&A expenses were $7.2 million for the three months ended June 30, 2023, compared to $5.1 million for the three months ended June 30, 2022. The increase in G&A expenses was primarily due to an increase in costs related to professional services and stock-based compensation, offset in part by a decrease in insurance-related costs.

Net Loss. 89bio reported a net loss of $38.4 million for the three months ended June 30, 2023, compared to a net loss of $25.1 million for the three months ended June 30, 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 therapeutic candidate, pegozafermin, through clinical development for the treatment of non-alcoholic steatohepatitis (NASH) and severe hypertriglyceridemia (SHTG). 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 and utility, efficacy and clinical benefits of pegozafermin, the safety and tolerability profile of pegozafermin, trial designs, clinical development plans and timing for pegozafermin, including the SHTG Phase 3 program, the ENTRUST Phase 3 trial in SHTG and the NASH Phase 3 trial, the timing for meeting with regulatory authorities, the use of the SHTG Phase 3 program to support safety database requirements 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 Securities and Exchange Commission (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 NASH; expectations regarding the timing and outcome of the ENTRUST Phase 3 trial in SHTG; 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 34,915	$ 19,686	$ 57,221	$ 39,535
General and administrative	7,214	5,052	13,432	10,311
Total operating expenses	42,129	24,738	70,653	49,846
Loss from operations	(42,129)	(24,738)	(70,653)	(49,846)
Interest expense	(894)	(434)	(2,969)	(842)
Interest income and other, net	4,630	118	6,393	70
Net loss before income tax	(38,393)	(25,054)	(67,229)	(50,618)

Income tax expense	—	—	—	(1)
Net loss	$ (38,393)	$ (25,054)	$ (67,229)	$ (50,619)
Comprehensive loss	$ (38,747)	$ (25,116)	$ (67,473)	$ (50,873)
Net loss per share, basic and diluted	$ (0.52)	$ (1.23)	$ (1.06)	$ (2.49)
Weighted-average shares used to compute net loss per share, basic and diluted	74,126,569	20,351,560	63,706,856	20,345,521

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

	June 30, 2023	December 31, 2022
Cash and cash equivalents and short-term investments	$ 477,995	$ 188,160
Total assets	492,511	196,824
Total current liabilities	25,944	24,614
Non current liabilities	24,581	20,378
Total stockholders' equity	441,986	151,832
Total liabilities and stockholders' equity	$ 492,511	$ 196,824

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