89bio Reports First Quarter 2025 Financial Results and Corporate Updates

May 1, 2025

– Topline histology data from ENLIGHTEN-Fibrosis and ENLIGHTEN-Cirrhosis Phase 3 trials are expected in 1H 2027 and in 2028, respectively; each trial is designed to support accelerated approval to treat patients with metabolic dysfunction-associated steatohepatitis (MASH) –

– The Phase 3 ENTRUST trial in severe hypertriglyceridemia (SHTG) has been fully enrolled and topline data are expected in 1Q 2026 –

– Cash, cash equivalents, and marketable securities totaled $638.8 million as of March 31, 2025; completed follow-on equity offering in 1Q 2025 with gross proceeds of $287.5 million –

SAN FRANCISCO, May 01, 2025 (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 first quarter ended March 31, 2025, and provided corporate updates.

"We have entered 2025 with strong momentum, fueled by continued progress in our two global Phase 3 trials in advanced MASH. Both trials are actively screening and enrolling patients across more than 20 countries, with most sites now activated and strong investigator enthusiasm driving enrollment," said Rohan Palekar, Chief Executive Officer of 89bio. "A recently published meta-analysis in *Hepatology*[1] ranked pegozafermin among the most effective agents for achieving fibrosis improvement and MASH resolution—reinforcing its differentiated profile and the growing recognition of its potential. With best-in-class relative risk reduction, a favorable safety and tolerability profile, and convenient dosing, we believe pegozafermin is well positioned as a leading candidate to treat this large and underserved patient population."

"Looking ahead, we continue to expect topline results from our Phase 3 ENTRUST trial in SHTG in first quarter of 2026, followed by data readouts from ENLIGHTEN-Fibrosis in the first half of 2027 and ENLIGHTEN-Cirrhosis in 2028—the latter two of which are intended to support the accelerated approval of pegozafermin to treat patients with F2-F3 and compensated F4 MASH," added Mr. Palekar. "To support our development and commercial readiness efforts, we have implemented a flexible, global manufacturing strategy with optionality for our manufacturing footprint across geographies, including the United States for the drug product."

Recent Highlights and Anticipated Milestones

Metabolic dysfunction-associated steatohepatitis (MASH)

- The Phase 3 *ENLIGHTEN-Fibrosis* trial in non-cirrhotic (F2-F3) MASH and Phase 3 *ENLIGHTEN-Cirrhosis* trial in compensated cirrhotic (F4) MASH continue to enroll patients, with topline data from the histology cohorts of these trials expected in the first half of 2027 and in 2028, respectively.
- Based on previous alignment obtained with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), the Company designed its Phase 3 *ENLIGHTEN* trials to generate data from the histology cohorts of each trial to support accelerated approval in both F2-F3 and compensated F4 MASH. Both trials will continue for outcomes, to potentially support full approval.

[1] Souza, Matheus et al. (2025) Comparison of pharmacological therapies in metabolic dysfunction–associated steatohepatitis for fibrosis regression and MASH resolution: Systematic review and network meta-analysis. *Hepatology*. DOI: 10.1097/HEP.0000000000001254

Severe Hypertriglyceridemia (SHTG)

- *ENTRUST* is a randomized, double-blind, placebo-controlled global Phase 3 trial evaluating the efficacy, safety and tolerability of pegozafermin in SHTG patients randomized to pegozafermin (30 mg, 20 mg) or placebo in a 3:3:2 ratio given once weekly (QW) for 52 weeks.
- Topline data from the Phase 3 *ENTRUST* trial are expected in the first quarter of 2026.

Corporate Updates

- Completed follow-on equity offering in the first quarter of 2025 with gross proceeds of $287.5 million. The Company also has a $150 million credit facility with K2 HealthVentures, of which a total of $35 million has been drawn down.
- The Company's global manufacturing strategy provides resilience and flexibility due to its diversified supply chain with alternative contract development and manufacturing organizations for each step in the supply chain to mitigate against macroeconomic and geopolitical environment changes.

First Quarter 2025 Financial Results

Cash Position. As of March 31, 2025, 89bio had cash, cash equivalents and marketable securities of approximately $638.8 million.

Research and Development (R&D) Expenses. R&D expenses were $64.4 million for the three months ended March 31, 2025, compared to $47.4 million for the three months ended March 31, 2024. The increase in R&D expenses was primarily driven by increases in clinical development of the Phase 3 ENLIGHTEN trials in MASH and personnel-related expenses, including stock-based compensation driven by higher headcount.

General and Administrative (G&A) Expenses. G&A expenses were $11.5 million for the three months ended March 31, 2025, compared to $9.8 million for the three months ended March 31, 2024. The increase was primarily attributable to an increase in personnel-related expenses including stock-based compensation driven by higher headcount.

Net Loss. 89bio reported a net loss of $71.3 million for the three months ended March 31, 2025, compared to a net loss of $51.7 million for the three months ended March 31, 2024. The increase in net loss was primarily attributable to higher R&D expenses related to advancing our Phase 3 programs and increased G&A expenses driven by higher headcount and other costs associated with supporting our expanded operations.

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 in Phase 3 trials for its lead candidate, pegozafermin, for the treatment of metabolic dysfunction-associated steatohepatitis (MASH) with advanced fibrosis, including patients with compensated cirrhosis, 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 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 topline histology data from the ENLIGHTEN-Fibrosis and ENLIGHTEN-Cirrhosis Phase 3 trials in patients with non-cirrhotic (F2-F3) and compensated cirrhotic (F4) MASH, topline results from the ENTRUST Phase 3 trial in SHTG and the possibility of obtaining accelerated approval in the United States and conditional approval in Europe in non-cirrhotic MASH (F2-F3) patients and compensated cirrhosis (F4) MASH patients and the possibility of outcomes data supporting full approval. 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 timing and outcome of the ENLIGHTEN-Fibrosis Phase 3 trial and Phase 3 ENLIGHTEN-Cirrhosis trial in MASH and 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, including recently announced tariffs and potential additional tariffs; FDA and comparable foreign regulatory authorities changes in leadership or policies or issuing additional regulations or revising existing regulations; 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, 2024 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.

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

	Three Months Ended March 31,	
	2025	**2024**

Operating expenses:		
Research and development	$ 64,394	$ 47,428
General and administrative	11,515	9,849
Total operating expenses	75,909	57,277
Loss from operations	(75,909)	(57,277)
Interest expense	(1,267)	(863)
Interest income and other, net	6,038	6,556
Net loss before income tax	(71,138)	(51,584)
Income tax expense	(137)	(97)
Net loss	$ (71,275)	$ (51,681)
Comprehensive loss	$ (71,453)	$ (52,390)
Net loss per share, basic and diluted	$ (0.49)	$ (0.54)
Weighted-average shares used to compute net loss per share, basic and diluted	146,365,115	95,846,740

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

	March 31, 2025	December 31, 2024
Cash, cash equivalents and marketable securities	$ 638,780	$ 439,955
Total assets	685,031	478,685
Total current liabilities	37,884	36,129
Non current liabilities	41,689	41,767
Total stockholders' equity	605,458	400,789
Total liabilities and stockholders' equity	$ 685,031	$ 478,685