



89bio Reports Fourth Quarter and Full Year 2024 Financial Results and Corporate Updates

February 27, 2025

- ENLIGHTEN-Fibrosis and ENLIGHTEN-Cirrhosis Phase 3 trials in patients with non-cirrhotic (F2-F3) and compensated cirrhotic (F4) metabolic dysfunction-associated steatohepatitis (MASH) continue to advance with topline histology data expected in 1H 2027 and 2028, respectively –
- The Phase 3 ENTRUST trial in severe hypertriglyceridemia (SHTG) will be unblinded after study completion at Week 52 vs. Week 26 following discussions with the U.S. Food and Drug Administration (FDA); topline data are now expected in 1Q 2026 –
- Cash, cash equivalents, and marketable securities totaled \$440.0 million as of December 31, 2024; a follow-on offering in the 1Q 2025 resulted in gross proceeds of \$287.5 million –

SAN FRANCISCO, Feb. 27, 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 fourth quarter and full year ended December 31, 2024, and provided corporate updates.

"2024 marks a tremendous year of execution and progress for 89bio, highlighted by the initiation of two global pivotal trials targeting advanced MASH patients, as well as completion of enrollment in our Phase 3 ENTRUST trial in SHTG," stated Rohan Palekar, Chief Executive Officer of 89bio. "As we look toward 2025 and beyond, we look forward to executing on our clinical trials and completing all scale-up and regulatory activities to position us for a successful Biologics License Application (BLA) filing, pending positive results in the Phase 3 trials. With its robust fibrosis benefit shown in clinical trials to date, potential best-in-class tolerability and safety profile, and convenient dosing, pegozafermin has the potential to significantly impact the lives of patients suffering from advanced MASH including those with cirrhosis, as well as SHTG."

Recent Highlights and Anticipated Milestones

Metabolic dysfunction-associated steatohepatitis (MASH)

- The Company initiated the Phase 3 ENLIGHTEN-Fibrosis trial in non-cirrhotic (F2-F3) MASH and Phase 3 ENLIGHTEN-Cirrhosis trial in compensated cirrhotic (F4) MASH in the first half of 2024. 89bio expects topline data from the histology cohorts of ENLIGHTEN-Fibrosis and ENLIGHTEN-Cirrhosis in the first half of 2027 and 2028, respectively.
- The data from the histology cohorts of both trials are intended to support accelerated approval in the United States and conditional approval in Europe in their respective indications, based on previously obtained alignment with the FDA and European Medicines Agency (EMA). Both trials will continue for outcomes, to potentially support full approval.
- Data analyses from the Phase 2b ENLIVEN trial highlighting the potential anti-fibrotic effects and the potential utility of non-invasive tests correlating with histological endpoints were presented at the 75th Annual American Association for the Study of Liver Diseases (AASLD) The Liver Meeting® in November 2024.

Severe Hypertriglyceridemia (SHTG)

- Enrollment has been completed in the Phase 3 ENTRUST trial with a total of 369 patients. ENTRUST is a randomized, double-blind, placebo-controlled global trial evaluating the efficacy, safety and tolerability of pegozafermin in SHTG patients randomized into pegozafermin (30 mg, 20 mg) or placebo in a 3:3:2 ratio given once weekly (QW) for 52 weeks.
- The trial will now be unblinded after study completion at Week 52 vs. Week 26 following discussions with the FDA. The primary endpoint remains percentage change from baseline in fasting triglycerides (TG) at Week 26 compared to placebo, but it will now be analyzed after study unblinding at Week 52 to minimize any potential bias that may be introduced due to the unblinding of data prior to completion of the trial. As a result, 89bio now expects to report topline data from ENTRUST in the first quarter of 2026. This approach is aligned with the company's strategy of prioritizing MASH and filing for SHTG after MASH.

Corporate Updates

- Completed follow-on equity offerings in 4Q 2024 and 1Q 2025 for gross proceeds of \$143.7 million and \$287.5 million, respectively.
- Obtained regulatory feedback from the FDA and the EMA on clinical, nonclinical, as well as Chemistry, Manufacturing, and Controls (CMC) requirements for marketing authorization filings for pegozafermin. The Company remains on track for potential BLA and Marketing Authorization Application (MAA) filings, pending positive clinical data.

Fourth Quarter and Full Year 2024 Financial Results

Cash Position. As of December 31, 2024, 89bio had cash, cash equivalents and marketable securities totaling \$440.0 million, as compared to \$578.9 million as of December 31, 2023.

Research and Development (R&D) Expenses. R&D expenses were \$111.3 million and \$345.0 million for the three months and year ended December 31, 2024, respectively, compared to \$33.6 million and \$122.2 million for the three months and year ended December 31, 2023, respectively. The increases in R&D expenses in both the current quarter and the current year were primarily driven by increases in contract manufacturing costs, including one-time milestone payments under the Company's agreement with Bibo of \$40.5 million and \$121.5 million in the three months and year ended December 31, 2024 respectively, as well as contract manufacturing costs related to the supply of pegozafermin and clinical materials for the Company's three Phase 3 clinical trials, clinical development costs with the initiation of the Phase 3 MASH program, and personnel-related expenses.

General and Administrative (G&A) Expenses. G&A expenses were \$10.7 million and \$39.6 million for the three months and year ended December 31, 2024, respectively, compared to \$7.6 million and \$29.0 million for the three months and year ended December 31, 2023, respectively. The increase in G&A expenses in both the current quarter and the current year was primarily due to an increase in personnel-related expenses, including stock-based compensation expense, reflecting higher headcount to support the Company's growth, increased consultant and professional fees, and increase in facilities and other costs.

Net Loss. 89bio reported a net loss of \$118.4 million and \$367.1 million for the three months and year ended December 31, 2024, respectively, compared to a net loss of \$40.2 million and \$142.2 million for the three months and year ended December 31, 2023, respectively. The increased net loss in both the current quarter and the current year was primarily driven by higher research and development expenses associated with contract manufacturing and the advancement of the Company's Phase 3 programs, along with increased general and administrative expenses due to expanded operations and headcount growth. These increases were partially offset by higher interest income for the full year ending December 31, 2024.

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, 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, and plans for scale-up and regulatory activities ahead of a potential BLA filing. 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 its 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 Quarterly Report on Form 10-Q for the quarter ended November 30, 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 Data
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 111,303	\$ 33,592	\$ 345,037	\$ 122,230
General and administrative	10,702	7,614	39,619	28,974
Total operating expenses	<u>122,005</u>	<u>41,206</u>	<u>384,656</u>	<u>151,204</u>
Loss from operations	(122,005)	(41,206)	(384,656)	(151,204)
Interest expense	(1,191)	(866)	(5,290)	(4,794)
Interest income and other, net	5,099	5,704	23,559	17,676
Net loss before income tax	<u>(118,097)</u>	<u>(36,368)</u>	<u>(366,387)</u>	<u>(138,322)</u>
Income tax expense	(257)	(3,867)	(692)	(3,867)
Net loss	<u>\$ (118,354)</u>	<u>\$ (40,235)</u>	<u>\$ (367,079)</u>	<u>\$ (142,189)</u>
Comprehensive loss	<u>\$ (119,060)</u>	<u>\$ (39,498)</u>	<u>\$ (366,706)</u>	<u>\$ (141,649)</u>
Net loss per share, basic and diluted	<u>\$ (1.02)</u>	<u>\$ (0.50)</u>	<u>\$ (3.51)</u>	<u>\$ (2.00)</u>
Weighted-average shares used to compute net loss per share, basic and diluted	<u>115,955,933</u>	<u>80,696,621</u>	<u>104,714,613</u>	<u>71,172,870</u>

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

	December 31, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	\$ 439,955	\$ 578,870
Total assets	478,685	596,269
Total current liabilities	36,129	29,611
Non-current liabilities	41,767	30,352
Total stockholders' equity	400,789	536,306
Total liabilities and stockholders' equity	\$ 478,685	\$ 596,269