89bio Reports Second Quarter 2025 Financial Results and Corporate Updates

August 7, 2025

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

– ENTRUST Phase 3 topline data in severe hypertriglyceridemia (SHTG) expected in 1Q 2026 –

– Cash, cash equivalents, and marketable securities totaled $561.2 million as of June 30, 2025 –

SAN FRANCISCO, Aug. 07, 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 second quarter ended June 30, 2025, and provided corporate updates.

"As we enter the second half of 2025, we remain diligently focused on execution across our three global Phase 3 trials for pegozafermin in MASH and SHTG. In SHTG, we continue to expect topline data from our Phase 3 *ENTRUST* trial in the first quarter of 2026," said Rohan Palekar, Chief Executive Officer of 89bio. "In MASH, we expect topline histology data from *ENLIGHTEN-Fibrosis* in the first half of 2027, and *ENLIGHTEN-Cirrhosis* in 2028, underpinning our accelerated-approval filings for patients with F2-F3 and F4 MASH, respectively. As our clinical development program in MASH continues to progress, we believe pegozafermin is poised to potentially deliver best-in-class relative risk ratio on histology endpoints, a favorable safety and tolerability profile, and a convenient dosing approach to the large and underserved MASH patient population."

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.
- The Company anticipates data from the histology cohorts of the Phase 3 *ENLIGHTEN* trials to support accelerated approval in both non-cirrhotic (F2-F3) and compensated cirrhotic (F4) MASH, based on alignment with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA). Both trials will continue for outcomes, to potentially support full approval.

Severe Hypertriglyceridemia (SHTG)

- *ENTRUST* is a randomized, double-blind, placebo-controlled global study 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. The primary endpoint of the trial is the percent change from baseline in fasting triglycerides at Week 26 compared to placebo.
- Topline data from the Phase 3 *ENTRUST* trial in SHTG are expected in the first quarter of 2026.

Second Quarter 2025 Financial Results

Cash Position. As of June 30, 2025, 89bio had cash, cash equivalents, and marketable securities of approximately $561.2 million.

Research and Development (R&D) Expenses. R&D expenses were $103.9 million for the three months ended June 30, 2025, compared to $44.9 million for the three months ended June 30, 2024. The increase in R&D expenses was driven by the Phase 3 *ENLIGHTEN* trials in MASH and a non-recurring payment of $42.4 million related to the cost of construction of the commercial-scale production facility for pegozafermin. Construction of this facility remains on schedule to support the Biologics License Application (BLA) filing for pegozafermin. The Company's remaining obligation for the facility is limited to a final milestone payment of $13.5 million to be paid in 2026 upon completion of the construction of the facility.

General and Administrative (G&A) Expenses. G&A expenses were $11.9 million for the three months ended June 30, 2025, compared to $8.6 million for the three months ended June 30, 2024. The increase in G&A expenses 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 $111.5 million for the three months ended June 30, 2025, compared to a net loss of $48.0 million for the three months ended June 30, 2024. The increased net loss was primarily driven by higher R&D expenses associated with contract manufacturing, the advancement of the Company's Phase 3 MASH programs, and personnel-related expenses, including stock-based compensation, driven by higher headcount.

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 June 30,		Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 103,902	$ 44,865	$ 168,296	$ 92,293
General and administrative	11,922	8,571	23,437	18,420
Total operating expenses	115,824	53,436	191,733	110,713
Loss from operations	(115,824)	(53,436)	(191,733)	(110,713)
Interest expense	(1,137)	(874)	(2,404)	(1,737)
Interest income and other, net	6,210	6,473	12,248	13,029
Net loss before income tax	(110,751)	(47,837)	(181,889)	(99,421)
Income tax expense	(753)	(134)	(890)	(231)
Net loss	$ (111,504)	$ (47,971)	$ (182,779)	$ (99,652)
Comprehensive loss	$ (111,767)	$ (48,135)	$ (183,220)	$ (100,525)
Net loss per share, basic and diluted	$ (0.71)	$ (0.48)	$ (1.20)	$ (1.02)
Weighted-average shares used to compute net loss per share, basic and diluted	157,880,203	99,831,111	152,154,469	97,838,926

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

	June 30, 2025	December 31, 2024
Cash, cash equivalents and marketable securities	$ 561,164	$ 439,955
Total assets	603,485	478,685
Total current liabilities	39,611	36,129
Non current liabilities	42,141	41,767
Total stockholders' equity	521,733	400,789
Total liabilities and stockholders' equity	$ 603,485	$ 478,685