89bio Reports Third Quarter 2024 Financial Results and Corporate Updates

November 7, 2024

– The Phase 3 ENLIGHTEN program in patients with non-cirrhotic (F2-F3) and compensated cirrhotic (F4) metabolic dysfunction-associated steatohepatitis (MASH) continues to enroll patients across both trials –

– Topline data from the Phase 3 ENTRUST trial in patients with severe hypertriglyceridemia (SHTG) are expected in 2025 –

– Strengthened the Board of Directors and Executive Leadership Team with the appointments of Charles McWherter, Ph.D. to the Board of Directors, Francis Sarena as Chief Operating Officer, and Teresa Perney, Ph.D. as Chief Regulatory and Quality Officer –

SAN FRANCISCO, Nov. 07, 2024 (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 third quarter ended September 30, 2024.

"We continue to execute on our three pivotal Phase 3 trials for pegozafermin in MASH and SHTG," stated Rohan Palekar, CEO of 89bio. "Building on the positive momentum from ENLIGHTEN and ENTRUST, we have made strategic additions to our Board of Directors and Executive Leadership Team, as well as bolstered our financial position with support from K2 HealthVentures. These efforts collectively underscore our confidence in pegozafermin's anti-fibrotic and broad metabolic effects across multiple indications where significant opportunities remain to offer better treatment for those living with MASH and SHTG."

Recent Highlights and Anticipated Milestones

Metabolic dysfunction-associated steatohepatitis (MASH)

- *ENLIGHTEN-Fibrosis* and *ENLIGHTEN-Cirrhosis* are global Phase 3 trials in non-cirrhotic (F2-F3) MASH patients with fibrosis and in compensated cirrhotic (F4) MASH patients, respectively. The histology endpoints of both trials could potentially support accelerated approval in the United States and conditional approval in Europe. Both trials will continue for outcomes, to potentially support full approval. The trials were initiated earlier this year and are continuing to enroll patients.

- New analyses of data from the *ENLIVEN* Phase 2b trial will be presented at the upcoming 75th Annual American Association for the Study of Liver Diseases (AASLD) The Liver Meeting® 2024 being held November 15 to 19, 2024. The details on these upcoming presentations can be found here.

Severe Hypertriglyceridemia (SHTG)

- Enrollment is ongoing in *ENTRUST*, the Phase 3 trial evaluating the efficacy, safety and tolerability of pegozafermin in patients with SHTG. 89bio expects to report topline data from this trial in 2025.

Corporate Updates

- Charles McWherter, Ph.D. was appointed to the Board of Directors, effective July 30, 2024. Dr. McWherter is a seasoned biotech industry veteran who brings decades of biotech and pharmaceutical experience, most recently serving as Chief Scientific Officer and President of Research and Development at CymaBay Therapeutics, Inc.

- Francis Sarena joined the Company as Chief Operating Officer, effective August 5, 2024. Mr. Sarena is a seasoned C-suite, biotech executive with over 25 years of experience. Before joining 89bio, he served as President and Chief Operating Officer at Apexigen, Inc.

- Teresa Perney, Ph.D. was appointed Chief Regulatory and Quality Officer, effective September 16, 2024. Dr. Perney brings over 20 years of relevant experience in the biotech and pharmaceutical industry. She previously had been in leadership roles within Regulatory and Quality at EQRx, Inc., Myovant Sciences Ltd. and Medivation, Inc.

- In September, 89bio secured an amended credit facility with K2 HealthVentures, a healthcare-focused specialty finance company, which provides an aggregate principal amount 89bio may borrow up to $150 million, of which 89bio drew $35 million at close, a portion of which was used to refinance the previously existing $25 million loan with K2 HealthVentures. An additional $35 million is available to draw at the Company's discretion through June 30, 2025. Furthermore, 89bio may also draw two additional tranches totaling up to $80 million subject to the achievement of a certain time-based clinical

milestone or the approval of K2 HealthVentures.

Third Quarter 2024 Financial Results

Cash Position. As of September 30, 2024, 89bio had cash, cash equivalents and marketable securities of $423.8 million.

Research and Development (R&D) Expenses. R&D expenses were $141.4 million for the three months ended September 30, 2024, compared to $31.4 million for the three months ended September 30, 2023. The increase in R&D expenses was primarily driven by a payment for the achievement of milestones totaling $81.0 million to BiBo Biopharma Engineering Co., Ltd. (“BiBo”), with whom the Company entered into a collaboration agreement earlier this year for the commercial supply of pegozafermin. The increase in R&D expenses was also driven by an increase in clinical development costs, contract manufacturing costs, and personnel-related expenses, including stock-based compensation due to higher headcount.

General and Administrative (G&A) Expenses. G&A expenses were $10.5 million for the three months ended September 30, 2024, compared to $7.9 million for the three months ended September 30, 2023. The increase in G&A expenses was primarily due to an increase in personnel-related expenses including stock-based compensation driven by higher headcount, professional fees and facilities and other expenses.

Net Loss. 89bio reported a net loss of $149.1 million for the three months ended September 30, 2024, compared to a net loss of $34.7 million for the three months ended September 30, 2023. The increase in net loss was primarily attributable to increased R&D expenses to advance the Company's Phase 3 clinical trials, milestone payments to BiBo, increased G&A expenses associated with higher headcount, and expenses to support the Company's 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 studies for its lead candidate, pegozafermin, for the treatment of metabolic dysfunction-associated steatohepatitis (MASH) 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 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 (fibrosis stage F2-F3) patients and compensated cirrhosis (F4) MASH patients, and enrollment in clinical trials, including enrollment of the Phase 3 ENLIGHTEN-Fibrosis trial and Phase 3 ENLIGHTEN-Cirrhosis trial in MASH and ENTRUST Phase 3 trial in SHTG. 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; 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 June 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.

Investor Contact:
Annie Chang
89bio, Inc.
annie.chang@89bio.com

PJ Kelleher
LifeSci Advisors, LLC
+1-617-430-7579
pkelleher@lifesciadvisors.com

Media Contact:
Sheryl Seapy
Real Chemistry
sseapy@realchemistry.com

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 141,441	$ 31,417	$ 233,734	$ 88,638
General and administrative	10,497	7,928	28,917	21,360
Total operating expenses	151,938	39,345	262,651	109,998
Loss from operations	(151,938)	(39,345)	(262,651)	(109,998)
Interest expense	(2,362)	(959)	(4,099)	(3,928)
Interest income and other, net	5,431	5,579	18,460	11,972
Net loss before income tax	(148,869)	(34,725)	(248,290)	(101,954)
Income tax expense	(204)	—	(435)	—
Net loss	$ (149,073)	$ (34,725)	$ (248,725)	$ (101,954)
Comprehensive loss	$ (147,121)	$ (34,678)	$ (247,646)	$ (102,151)
Net loss per share, basic and diluted	$ (1.39)	$ (0.45)	$ (2.46)	$ (1.50)
Weighted-average shares used to compute net loss per share, basic and diluted	107,075,197	76,336,050	100,940,155	67,962,848

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

	September 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 423,774	$ 578,870
Total assets	458,297	596,269
Total current liabilities	39,131	29,611
Non current liabilities	41,064	30,352
Total stockholders’ equity	378,102	536,306
Total liabilities and stockholders' equity	$ 458,297	$ 596,269