89bio Reports Second Quarter 2024 Financial Results and Corporate Updates

August 5, 2024

–The Phase 3 ENLIGHTEN-Fibrosis trial in patients with non-cirrhotic metabolic dysfunction-associated steatohepatitis (MASH) and the Phase 3 ENLIGHTEN-Cirrhosis trial in patients with compensated cirrhosis (F4) are enrolling patients–

–Phase 3 ENTRUST trial for patients with severe hypertriglyceridemia (SHTG) continues to enroll patients and topline data is expected in 2025–

SAN FRANCISCO, Aug. 05, 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 second quarter ended June 30, 2024.

“We are thrilled to have initiated two pivotal Phase 3 trials addressing non-cirrhotic MASH (ENLIGHTEN-Fibrosis in F2-F3) and MASH with compensated cirrhosis (ENLIGHTEN-Cirrhosis in F4), which have the potential for accelerated approval using histology in both trials,” stated Rohan Palekar, CEO of 89bio. “In parallel to executing on three Phase 3 trials in both MASH and SHTG, we continue to take important steps forward that we believe will strategically enhance our preparedness for potential commercialization of pegozafermin including commercial manufacturing readiness. We believe in the prospects of pegozafermin in MASH, given the urgent medical need for more severe patients with advanced fibrosis and cirrhosis, in addition to the significant opportunity in SHTG to help patients who are refractory to current standard of care."

Recent Highlights and Anticipated Milestones

Metabolic dysfunction-associated steatohepatitis (MASH)

- ENLIGHTEN-Cirrhosis, a Phase 3 trial of pegozafermin in MASH patients with compensated cirrhosis (F4), was initiated in the second quarter.
    - ENLIGHTEN-Cirrhosis is a global Phase 3, randomized, double-blind, placebo-controlled trial evaluating pegozafermin for the treatment of MASH patients with compensated cirrhosis (F4). The trial will enroll approximately 760 patients, who will be randomized in a 1:1 ratio to either receive 30mg of pegozafermin administered weekly or a placebo. A subset of the 760 patients will be evaluated at 24 months to assess fibrosis regression, potentially supporting an accelerated approval filing in the United States and conditional approval in Europe. The primary endpoint of fibrosis regression is defined as an improvement in fibrosis from F4 to an earlier stage. The primary endpoint for the final analysis will be a clinical outcome composite and is expected to form the basis for confirmatory or full approval.
- Data from the ENLIVEN Phase 2b trial was presented at the European Association for the Study of the Liver Congress (EASL) and was selected for the Poster Tour, a dedicated discussion session.

Severe Hypertriglyceridemia (SHTG)

- Enrollment is ongoing in ENTRUST, the Phase 3 trial evaluating the efficacy, safety and tolerability of pegozafermin in patients with SHTG.
- Topline results from this trial are expected to be reported in 2025.

Corporate Update

- Dr. Charles McWherter joined the Board of Directors, effective July 30, 2024. Dr. McWherter most recently served as Chief Scientific Officer and President of Research and Development of CymaBay Therapeutics, until it was acquired by Gilead Sciences in March 2024.

Second Quarter 2024 Financial Results

Cash Position. As of June 30, 2024, 89bio had cash, cash equivalents and marketable securities of $531.4 million, which does not include $19.4 million and $5.3 million of proceeds received by the Company subsequent to June 30, 2024 from the exercise of common stock warrants prior to June 30, 2024 and on July 1, 2024, respectively.

Research and Development (R&D) Expenses. R&D expenses were $44.9 million for the three months ended June 30, 2024, compared to $34.9 million for the three months ended June 30, 2023. The increase in R&D expenses was primarily driven by increases in clinical development, contract manufacturing, and personnel-related expenses, including stock-based compensation driven by higher headcount.

General and Administrative (G&A) Expenses. G&A expenses were $8.6 million for the three months ended June 30, 2024, compared to $7.2 million for the three months ended June 30, 2023. The increase in G&A expenses was primarily due to an increase in professional fees and personnel-related

expenses including stock-based compensation driven by higher headcount.

Net Loss. 89bio reported a net loss of $48.0 million for the three months ended June 30, 2024, compared to a net loss of $38.4 million for the three months ended June 30, 2023. The increase in net loss was primarily attributable to increased R&D expenses to advance the company's Phase 3 clinical trials, increased G&A expenses associated with higher headcount, and expenses to support the Company's expanded operations. These increases in operating expenses were offset in part by the increase in net interest income and other to $6.5 million for the three months ended June 30, 2024 from $4.6 million for the three months ended June 30, 2023, mainly due to a change in interest rates and an increase in the average invested balances.

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 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 March 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.

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,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 44,865	$ 34,915	$ 92,293	$ 57,221
General and administrative	8,571	7,214	18,420	13,432
Total operating expenses	53,436	42,129	110,713	70,653
Loss from operations	(53,436)	(42,129)	(110,713)	(70,653)
Interest expense	(874)	(894)	(1,737)	(2,969)
Interest income and other, net	6,473	4,630	13,029	6,393
Net loss before income tax	(47,837)	(38,393)	(99,421)	(67,229)
Income tax expense	(134)	—	(231)	—
Net loss	$ (47,971)	$ (38,393)	$ (99,652)	$ (67,229)
Comprehensive loss	$ (48,135)	$ (38,747)	$ (100,525)	$ (67,473)
Net loss per share, basic and diluted	$ (0.48)	$ (0.52)	$ (1.02)	$ (1.06)
Weighted-average shares used to compute net loss per share, basic and diluted	99,831,111	74,126,569	97,838,926	63,706,856

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

(In thousands)

	June 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 531,384	$ 578,870
Total assets	582,138	596,269
Total current liabilities	41,653	29,611
Non current liabilities	25,568	30,352
Total stockholders' equity	514,917	536,306
Total liabilities and stockholders' equity	$ 582,138	$ 596,269

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