89bio Reports First Quarter 2024 Financial Results and Provides Corporate Update

May 9, 2024

–Initiated Phase 3 ENLIGHTEN-Fibrosis trial in non-cirrhotic (F2-F3) metabolic dysfunction-associated steatohepatitis (MASH) patients–

–Expect to initiate ENLIGHTEN-Cirrhosis trial this quarter in MASH patients with compensated cirrhosis (F4)–

–Granted Priority Medicines (PRIME) status from the European Medicines Agency (EMA) for pegozafermin in the treatment of MASH with fibrosis and compensated cirrhosis–

–Data from the 48-Week Extension Phase of the ENLIVEN Phase 2b Trial to be presented at the European Association for the Study of the Liver Congress (EASL)–

SAN FRANCISCO, May 09, 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 first quarter ended March 31, 2024.

"We are excited to have initiated ENLIGHTEN-Fibrosis, the first of two pivotal Phase 3 trials addressing MASH, and we are on track to begin the ENLIGHTEN-Cirrhosis trial for compensated cirrhotic MASH patients in the second quarter," stated Rohan Palekar, CEO of 89bio. "Because of its demonstrated anti-fibrotic and metabolic benefits, we believe that pegozafermin has the potential to be the leading therapy in treating advanced MASH patients with fibrosis. We are focused on the execution of our Phase 3 trials for MASH and our synergistic Phase 3 trial in severe hypertriglyceridemia (SHTG), which we anticipate topline data from in 2025. These key clinical developments, coupled with our agreement for commercial supply, are designed to strategically enhance our readiness for potential commercialization."

Recent Highlights and Anticipated Milestones

Metabolic dysfunction-associated steatohepatitis (MASH)

- Initiated ENLIGHTEN-Fibrosis, the first of two Phase 3 trials in the ENLIGHTEN program evaluating the efficacy and safety of pegozafermin in non-cirrhotic MASH patients with fibrosis stage F2-F3.
    - The co-primary endpoints are a one-point or greater improvement in fibrosis with no worsening of MASH, and MASH resolution with no worsening of fibrosis. The co-primary endpoints will be assessed at week 52, in a subset of patients, and are intended to support a filing for accelerated approval in the U.S. and conditional approval in Europe in non-cirrhotic patients. Patients are expected to continue to be treated beyond the 52-week assessment through outcomes in approximately 1,000 patients to support full approval. ENLIGHTEN-Fibrosis aims to enroll MASH patients, including those on background GLP-1-based therapies, where pegozafermin has demonstrated additional anti-fibrotic and metabolic effects.
    - ENLIGHTEN-Cirrhosis, the second trial in the program, is planned to evaluate patients with compensated cirrhosis and is expected to initiate in the second quarter of 2024.
- The European Medicines Agency (EMA) granted Priority Medicines (PRIME) status to pegozafermin for the treatment of MASH with fibrosis and MASH with compensated cirrhosis. The PRIME status was supported by positive data from the ENLIVEN Phase 2b trial of pegozafermin in patients with non-cirrhotic MASH with fibrosis and in those with compensated cirrhosis.
- Data from the 48-Week Extension Phase of the ENLIVEN Phase 2b Trial will be presented at the European Association for the Study of the Liver Congress (EASL), on Saturday June 8th at 10:45-12:00 CET and 8:30-17:00 CET, respectively.
    - **Abstract #943**: Week 48 results from the Phase 2b ENLIVEN extension study investigating pegozafermin for the treatment of metabolic dysfunction-associated steatohepatitis with fibrosis
      Presenting Author: Rohit Loomba, M.D., MHSc, Chief of the Division of Gastroenterology and Hepatology at University of California San Diego School of Medicine, and lead investigator of the ENLIGHTEN program
    - **Abstract #1268**: Pegozafermin added to background GLP-1 therapy in patients with metabolic dysfunction-associated steatohepatitis with F2/F3 fibrosis: ENLIVEN 48-week extension data
      Presenting Author: Arun J. Sanyal, MBBS, M.D., Director of the Stravitz-Sanyal Institute for Liver Disease and Metabolic Health, Virginia Commonwealth University and lead investigator of the ENLIVEN trial

Severe Hypertriglyceridemia (SHTG)

- Enrollment continues to progress well 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 in 2025.

Corporate Update

- 89bio entered into a collaboration agreement with BiBo Biopharma Engineering Co., Ltd. (“BiBo”) under which BiBo will construct a production facility in China specifically designed to produce pegozafermin for commercial supply, if approved.
- Appointed Martin Babler to its Board of Directors, who brings over 30 years of pharmaceutical and biotech experience to 89bio.
- 89bio will host a key opinion leader webinar on pegozafermin’s potential as a leading and potentially best-in-class FGF21 in the evolving MASH landscape on Thursday, May 16, 2024, at 10am EDT. The webinar will feature a presentation from Arun J. Sanyal, MBBS, M.D., Professor, Departments of Medicine, Physiology, and Molecular Pathology, Virginia Commonwealth University. The webinar can be accessed from the investors section of the 89bio website.

First Quarter 2024 Financial Results

Cash Position. As of March 31, 2024, 89bio had cash, cash equivalents and marketable securities of approximately $562.3 million.

Research and Development (R&D) Expenses. R&D expenses were $47.4 million for the three months ended March 31, 2024, compared to $22.3 million for the three months ended March 31, 2023. The increase in R&D expenses was primarily driven by increases in contract manufacturing, clinical development and personnel-related expenses, including stock-based compensation driven by higher headcount.

General and Administrative (G&A) Expenses. G&A expenses were $9.8 million for the three months ended March 31, 2024, compared to $6.2 million for the three months ended March 31, 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 $51.7 million for the three months ended March 31, 2024, compared to a net loss of $28.8 million for the three months ended March 31, 2023. The increase in net loss was primarily attributable to increased R&D expenses to advance the company's programs, 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 focused on rapidly advancing its lead candidate, pegozafermin, through clinical development 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 initiation of the Phase 3 ENLIGHTEN-Cirrhosis trial in MASH and 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 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 initiation of the ENLIGHTEN-Cirrhosis Phase 3 trial in MASH; expectations regarding the timing and outcome of the ENLIGHTEN-Fibrosis Phase 3 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 Annual Report on Form 10-K for the year ended December 31, 2023 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 March 31, 2024	Three months Ended March 31, 2023

Operating expenses:		
Research and development	$ 47,428	$ 22,306
General and administrative	9,849	6,218
Total operating expenses	57,277	28,524
Loss from operations	(57,277)	(28,524)
Interest expense	(863)	(2,075)
Interest income and other, net	6,556	1,763
Net loss before income tax	(51,584)	(28,836)
Income tax expense	(97)	—
Net loss	$ (51,681)	$ (28,836)
Comprehensive loss	$ (52,390)	$ (28,726)
Net loss per share, basic and diluted	$ (0.54)	$ (0.54)
Weighted-average shares used to compute net loss per share, basic and diluted	95,846,740	53,171,370

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

	March 31, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 562,288	$ 578,870
Total assets	577,322	596,269
Total current liabilities	38,241	29,611
Non current liabilities	28,542	30,352
Total stockholders' equity	510,539	536,306
Total liabilities and stockholders' equity	$ 577,322	$ 596,269

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