# 89bio Reports First Quarter 2022 Financial Results and Provides Corporate Update

May 11, 2022

*- ENTRIGUE Phase 2 trial of pegozafermin in severe hypertriglyceridemia (SHTG) patients remains on track with topline data expected in the second quarter of 2022 -*

*- ENLIVEN Phase 2b NASH trial enrollment completion expected in the third quarter of 2022 followed by topline data in the first half of 2023 -*

SAN FRANCISCO, May 11, 2022 (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 cardio-metabolic diseases, today reported its financial results for the quarter ended March 31, 2022.

“Our team continued to execute very well in the first quarter and we are now well positioned to deliver on multiple upcoming milestones,” said Rohan Palekar, Chief Executive Officer of 89bio. “We plan to report topline data from the ENTRIGUE trial in SHTG this quarter. We are excited about the opportunity in this indication given pegozafermin’s unique profile to potentially reduce triglyceride levels and treat other metabolic co-morbidities associated with SHTG. On our NASH program, we now expect to complete enrollment in the ENLIVEN trial in the third quarter of 2022, and have implemented changes to the ENLIVEN protocol to maximize the probability of success in this trial.”

**Recent Highlights and Anticipated Milestones**

*SHTG*

**Topline data for the Phase 2 ENTRIGUE trial of pegozafermin in SHTG patients expected in the second quarter of 2022.**

- ENTRIGUE is a proof-of-concept study designed to assess the impact of pegozafermin on triglycerides as well as other metabolic markers. A total of 85 SHTG patients were enrolled in the trial. Positive results would support moving into a Phase 3 program in 2023 following regulatory discussions.

**Hosted key opinion leader webinar on SHTG that reinforced pegozafermin’s unique proposition in this patient population.**

- The webinar featured presentations from KOLs Harold Bays, MD, President, Louisville Metabolic and Atherosclerosis Research Center, Inc., and Deepak L. Bhatt, MD, MPH, Brigham and Women’s Health and Harvard Medical School.
- The discussion highlighted the importance of treating the highly prevalent co-morbidities associated with SHTG and the potential differentiated profile that pegozafermin offers.
- An archived replay of the webinar is available on the company website and can be accessed from the investors section of the 89bio website.

*NASH*

**Expect to complete enrollment in the third quarter of 2022 with ~200 patients in the ENLIVEN Phase 2b trial; topline data expected in the first half of 2023.**

- ENLIVEN is a Phase 2b trial designed to evaluate the safety and efficacy of weekly or every two-week pegozafermin for the treatment of patients with fibrosis stage F2 - F3 NASH and NAS ≥ 4

**Implemented modifications to the ENLIVEN protocol to optimize the trial including:**

- Redistribution of patients across treatment arms with a focus on the higher dosing groups. The planned approximate randomization is 4 : 4 : 2.5 : 1 (placebo : 30mg QW : 44mg Q2W : 15mg QW)
- Inclusion of additional composite histology endpoints to potentially help stabilize the placebo response and better identify the drug benefit
- Adoption of a three-panel consensus read for biopsies, the industry best-in-class approach, to improve the accuracy of biopsy analysis

**First Quarter 2022 Financial Results**

**Cash Position.** As of March 31, 2022, 89bio had cash, cash equivalents, and short-term investments of $126.1 million. Based upon current

projections, 89bio believes it has sufficient cash to fund operations into the second half of 2023.

**Research and Development (R&D) Expenses.** R&D expenses were $19.8 million for the three months ended March 31, 2022, compared to $10.1 million for the three months ended March 31, 2021. The increase in R&D expenses was primarily driven by increases in clinical development costs, contract manufacturing and personnel expenses.

**General and Administrative (G&A) Expenses.** G&A expenses were $5.3 million for the three months ended March 31, 2022, compared to $4.6 million for the three months ended March 31, 2021. The increase in G&A expenses was primarily due to an increase in costs related to personnel expenses, offset by a reduction in expenses for professional services.

**Net Loss.** 89bio reported a net loss of $25.6 million for the three months ended March 31, 2022, compared to a net loss of $14.8 million for the three months ended March 31, 2021. The increase in net loss is primarily attributable to increased R&D expenses for our programs and increased G&A expenses associated with operating as a public company.

**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 non-alcoholic steatohepatitis (NASH) 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 with operations in Herzliya, Israel. 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, the therapeutic potential and clinical benefits of pegozafermin, clinical development plans and timing for pegozafermin, including the Phase 2b ENLIVEN trial and Phase 2 ENTRIGUE trial, the expected trial design for the ENLIVEN trial, including patient enrollment, dosing schedules and trial endpoints, the timing for topline data for the ENLIVEN trial and the Phase 2 ENTRIGUE trial, and expectations regarding the time period over which 89bio's capital resources will be sufficient to fund its anticipated operations. 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 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 Phase 2b ENLIVEN trial in NASH and Phase 2 ENTRIGUE trial in SHTG; expectations regarding the timing of topline data; 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 effect of the COVID-19 pandemic on 89bio's clinical trials and business operations, and 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, 2022 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 Data**
**(Unaudited)**
**(In thousands, except share and per share amounts)**

| | Three months Ended March 31, 2022 | Three months Ended March 31, 2021 |
|---|---|---|
| Operating expenses: | | |
| Research and development | $ 19,849 | $ 10,131 |
| General and administrative | 5,259 | 4,608 |
| Total operating expenses | 25,108 | 14,739 |
| Loss from operations | 25,108 | 14,739 |
| Other expenses, net | (456) | (43) |
| Net loss before tax | 25,564 | 14,782 |
| Income tax expense | 1 | — |
| Net loss | $ 25,565 | $ 14,782 |
| Comprehensive loss | $ 25,757 | $ 14,775 |
| Net loss per share, basic and diluted | $ 1.26 | $ 0.74 |
| Weighted-average shares used to compute net loss per share, basic and diluted | 20,339,416 | 20,010,412 |

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

| | March 31, 2022 | December 31, 2021 |
|---|---|---|
| Cash, cash equivalents and short-term investments | $ 126,111 | $ 150,745 |
| Total assets | 135,765 | 162,422 |
| Total current liabilities | 18,400 | 19,537 |
| Non current liabilities | 14,624 | 16,928 |
| Total stockholders’ equity (deficit) | 102,741 | 125,957 |
| Total liabilities and shtockholders' equity | $ 135,765 | $ 162,422 |

**Investor Contact:**
Ryan Martins
Chief Financial Officer
investors@89bio.com