89bio Reports Third Quarter 2022 Financial Results and Provides Corporate Update

November 10, 2022

-Completed enrollment in ENLIVEN Phase 2b NASH trial with topline data expected in the first quarter of 2023-

-Presented additional post-hoc exploratory analyses from the Phase 1b/2a NASH study of pegozafermin at AASLD The Liver Meeting® 2022-

-Reported additional positive data from ENTRIGUE Phase 2 trial of pegozafermin in severe hypertriglyceridemia patients at European Society of Cardiology Congress 2022-

SAN FRANCISCO, Nov. 10, 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 third quarter ended September 30, 2022.

"We are pleased with the progress across our late-stage clinical development program for pegozafermin and believe we are well positioned to achieve multiple value-driving milestones," said Rohan Palekar, Chief Executive Officer of 89bio. "We successfully completed enrollment in our Phase 2b ENLIVEN trial in NASH and expect to report topline data in the first quarter of 2023. Additionally, we look forward to initiating our Phase 3 SHTG program in the first half of 2023, pending our meeting with the FDA in the fourth quarter of 2022."

Recent Highlights and Anticipated Milestones

NASH

Successfully completed enrollment in the ENLIVEN Phase 2b trial; topline data expected in the first quarter of 2023.

- ENLIVEN is a Phase 2b trial designed to evaluate the safety and efficacy of weekly (15mg and 30mg) or every two-week (44mg) pegozafermin for the treatment of patients with fibrosis stage F2 – F3 NASH and NAS ≥ 4.

Presented additional post-hoc exploratory analyses of cohort 7 data from the Phase 1b/2a NASH study of pegozafermin at AASLD The Liver Meeting® 2022

- Additional exploratory analyses of cohort 7 data using a three-reader pathologist panel showed that 6/19 patients scored as having fibrosis stage 4 at baseline (putative F4). Excluding these putative F4 patients resulted in a higher proportion of patients meeting the registration enabling histological endpoints compared to the primary analysis based on the central reader (NASH resolution without worsening of fibrosis was ~46%; fibrosis improvement ≥ 1 stage without worsening of NASH was ~38%). Pegozafermin also demonstrated encouraging pharmacological activity in the small group of F4 patients.

SHTG

Initiation of Phase 3 trial of pegozafermin in SHTG patients expected in the first half of 2023.

- FDA meeting planned in the fourth quarter of 2022 to gain alignment and feedback based on regulatory precedent for approval of drugs in SHTG.

Presented additional positive results from ENTRIGUE Phase 2 trial of pegozafermin at European Society of Cardiology (ESC) Congress 2022.

- Results were featured in a late-breaking oral presentation demonstrating that treatment with pegozafermin had consistent and significant benefits in triglyceride (TG) reduction as well as improvements in liver fat and glycemic control.

Third Quarter 2022 Financial Results

Cash Position. As of September 30, 2022, 89bio had cash, cash equivalents, and short-term investments of $193.3 million. This includes $88.2 million in net proceeds from the sale of common stock and warrants in a public offering in July 2022.

Research and Development (R&D) Expenses. R&D expenses were $22.2 million and $61.7 million for the three and nine months ended September 30, 2022, respectively, compared to $23.6 million and $49.4 million for the three and nine months ended September 30, 2021, respectively. The decrease and increase in R&D expenses for the three and nine months, respectively, was primarily driven by increases in clinical development costs related to our ongoing clinical trials and personnel-related expenses, offset in part by a decrease in contract manufacturing costs and lower overhead costs.

General and Administrative (G&A) Expenses. G&A expenses were $4.8 million and $15.2 million for the three and nine months ended September

30, 2022, respectively, compared to $4.6 million and $14.2 million for the three and nine months ended September 30, 2021, respectively. The increase in G&A expenses was primarily due to an increase in costs related to personnel expenses and professional services.

Net Loss. 89bio reported a net loss of $26.8 million and $77.4 million for the three and nine months ended September 30, 2022, respectively compared to $28.3 million and $63.8 million for the three and nine months ended September 30, 2021, respectively. The decrease in net loss for the three-month period is mainly due to decreased R&D expenses relating to a decrease in contract manufacturing costs offset by an increase in clinical development costs and increased G&A expenses. The increase in the net loss for the nine-month period 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, the clinical benefit, safety and tolerability profile of pegozafermin, clinical development plans and timing for pegozafermin, including the Phase 2b ENLIVEN trial, the timing for topline data for the ENLIVEN trial, the timing for the initiation of the Phase 3 trial in SHTG 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; expectations regarding the timing of topline data; expectations regarding the initiation of the 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 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 September 30, 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 22,197	$ 23,590	$ 61,732	$ 49,351
General and administrative	4,844	4,622	15,155	14,151
Total operating expenses	27,041	28,212	76,887	63,502
Loss from operations	27,041	28,212	76,887	63,502
Other (income) expenses, net	(238)	117	534	332
Net loss before tax	26,803	28,329	77,421	63,834
Income tax expense	2	—	3	—
Net loss	$ 26,805	$ 28,329	$ 77,424	$ 63,834
Comprehensive loss	$ 26,927	$ 28,327	$ 77,800	$ 63,818
Net loss per share, basic and diluted	$ 0.57	$ 1.41	$ 2.63	$ 3.18
Weighted-average shares used to compute net loss per share, basic and diluted	47,253,527	20,092,094	29,413,421	20,043,301

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

(In thousands)

	September 30, 2022	December 31, 2021
Cash, cash equivalents and short-term investments	$ 193,341	$ 150,745
Total assets	200,580	162,422
Total current liabilities	34,423	19,537
Non current liabilities	13,582	16,928
Total stockholders’ equity	152,575	125,957
Total liabilities and stockholders' equity	$ 200,580	$ 162,422

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