89bio Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update

March 24, 2022

– Reported positive topline results from cohort 7 in the Phase 1b/2a trial including data from new analyses demonstrating the promising therapeutic utility of pegozafermin for the treatment of NASH –

– ENLIVEN Phase 2b NASH trial on track for topline data in first half of 2023 –

– Closed enrollment in the Phase 2 ENTRIGUE trial of pegozafermin in SHTG patients with topline data expected in the second quarter of 2022 –

SAN FRANCISCO, March 24, 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 and full year ended December 31, 2021.

“In 2021, we took important steps to advance our ongoing clinical development program for pegozafermin which was highlighted by positive topline data from cohort 7 of the Phase 1b/2a NASH trial that demonstrated meaningful changes on histology endpoints, multiple non-invasive liver tests, cardiovascular markers and glycemic control,” said Rohan Palekar, Chief Executive Officer of 89bio. “We are also pleased to have closed enrollment in the Phase 2 ENTRIGUE trial in severe hypertriglyceridemia (SHTG) and expect to present topline data in the second quarter of 2022. Positive results would position pegozafermin to be the first metabolic hormone to enter Phase 3 for this indication with the potential to offer a compelling profile to address the significant unmet needs in this population.”

Recent Highlights and Anticipated Milestones

NASH Program

Positive topline results with pegozafermin from cohort 7 in the Phase 1b/2a proof-of-concept NASH trial; data from new analyses of cohort 7 reinforce pegozafermin’s promising profile in NASH

- Histology results, based on a single expert central reader, showed 74% of patients achieved a 2-point or greater improvement in NAFLD Activity Score (NAS), 63% of patients achieved 2-point or greater improvement in NAS without worsening of fibrosis, and 32% and 26% percent of patients achieved clinically meaningful improvements on registration-enabling endpoints of NASH resolution and fibrosis improvement, respectively. Clinically meaningful and significant changes were observed across key non-invasive tests (FAST, VCTE, FIB-4 and Pro-C3) associated with fibrosis, risk of fibrosis and/or NASH resolution.
- Data from a new analysis of the same histology slides by a panel of an additional three expert liver pathologists, showed rates of:
  - NASH resolution without worsening of fibrosis up to 47% (range: 26-47%)
  - ≥ 1-stage improvement in fibrosis without worsening of NASH up to 42% (range: 12-42%)
  - 2-point NAS improvement up to 79% (range: 68-79%)
- New data also showed pegozafermin significantly increased adiponectin (+87%) at week 20 compared to baseline. Adiponectin is an insulin-sensitizing hormone that regulates lipid and glucose metabolism and has been shown to have anti-inflammatory and anti-fibrotic activity in the liver.

“These data increase our confidence in the potential of pegozafermin to show a strong beneficial effect in our ongoing and future NASH trials. We are making good progress in our Phase 2b ENLIVEN trial and expect to report topline data in the first half of 2023,” said Hank Mansbach, MD, Chief Medical Officer of 89bio. “Based on learnings from our recent cohort, developments in the field, and feedback from our steering committee, we are working on steps to optimize the ENLIVEN trial.”

SHTG Program

Closed enrollment in the Phase 2 ENTRIGUE trial of pegozafermin in SHTG; topline data expected in the second quarter of 2022

- Closed enrollment with 85 SHTG patients either on stable background therapy with prescription fish oil and/or statins and/or fibrates or not on any background therapy. Positive results would support moving into a Phase 3 program following regulatory discussions.
- ENTRIGUE is a proof-of-concept study designed to assess the impact pegozafermin given weekly or every two-weeks will have on reduction in triglycerides, as well as other metabolic benefits including changes in lipids and reduction of liver fat,

which our recent data suggest is highly prevalent in these patients. Screening in the fibrate cohort was stopped along with the main study and patients enrolled will be analyzed as part of the main ENTRIGUE trial.

Manufacturing Update

- Scaled-up manufacturing at a contract manufacturing vendor including transfer of some key reagents for manufacturing from Teva Pharmaceuticals.
- Developed a liquid formulation of pegozafermin currently being used in the ENLIVEN trial.
- Development of a pre-filled syringe to enable convenient self-administration by patients, which is intended to be the commercial presentation, is ongoing and expected to be completed prior to the initiation of the Phase 3 program in NASH.

Fourth Quarter and Full Year 2021 Financial Results

Cash Position. As of December 31, 2021, 89bio had cash, cash equivalents, and short-term investments totaling $150.7 million compared to $204.7 million as of December 31, 2020.

Research and Development (R&D) Expenses. R&D expenses were $21.0 million and $70.3 million for the three months and year ended December 31, 2021, respectively, compared to $8.8 million and $36.2 million for the three months and year ended December 31, 2020, respectively. The increase in R&D expenses was primarily driven by increases in clinical development, contract manufacturing and personnel expenses.

General and Administrative (G&A) Expenses. G&A expenses were $5.3 million and $19.4 million for the three months and year ended December 31, 2021, respectively, compared to $3.8 million and $13.2 million for the three months and year ended December 31, 2020, respectively. The increase in G&A expenses for the year ended December 31, 2021 was primarily due to an increase in costs related to personnel expenses, insurance-related expenses, and expenses for professional services.

Net Loss. 89bio reported a net loss of $26.3 million and $90.1 million for the three and twelve months ended December 31, 2021, respectively, compared to a net loss of $12.6 million and $49.5 million for the comparable periods in 2020, respectively. The increase in net loss is primarily attributable to increased R&D expenses for our programs and increased G&A expenses associated with our growth and 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 timing for topline data, the expected trial design for the ENLIVEN trial and the ENTRIGUE trial, and the timing for the development of a pre-filled syringe. 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 89bio’s initiation 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; and other risks and uncertainties identified in 89bio's Annual Report on Form 10-K for the year ended December 31, 2021 to be filed with the SEC 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 December 31,	Three months Ended December 31,	Year Ended December 31,	Year Ended December 31,

	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 20,979	$ 8,770	$ 70,330	$ 36,199
General and administrative	5,262	3,777	19,413	13,156
Total operating expenses	26,241	12,547	89,743	49,355
Loss from operations	26,241	12,547	89,743	49,355
Other expenses, net	194	116	526	203
Net loss before tax	26,435	12,663	90,269	49,558
Income tax (benefit)	(147)	(82)	(147)	(59)
Net loss	$ 26,288	$ 12,581	$ 90,122	$ 49,499
Comprehensive loss	$ 26,358	$ 12,588	$ 90,176	$ 49,509
Net loss per share, basic and diluted	$ 1.30	$ 0.63	$ 4.48	$ 3.08
Weighted-average shares used to compute net loss per share, basic and diluted	20,261,662	19,895,952	20,098,340	16,087,785

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

	December 31, 2021	December 31, 2020
Cash and cash equivalents	$ 150,745	$ 204,654
Total Assets	162,422	211,074
Total current liabilities	19,537	8,113
Non-current liabilities	16,928	—
Total stockholders' equity	125,957	202,961
Total liabilities and stockholders' equity	$ 162,422	$ 211,074

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