89bio Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Corporate Updates

February 29, 2024

– Plan to initiate the Phase 3 ENLIGHTEN NASH program for non-cirrhotic (F2-F3) and cirrhotic (F4) patients in the first and second quarters of 2024, respectively –

– Long-term data from Phase 2b ENLIVEN trial demonstrated sustained benefits of pegozafermin at week 48 in patients with advanced NASH, which was consistent across patient sub-groups –

– Data from Phase 2b ENLIVEN trial in patients with cirrhotic NASH were featured in an oral presentation during American Association for the Study of Liver Diseases The Liver Meeting® (AASLD) –

– Completed follow-on offering in the fourth quarter 2023 for $172.5 million in gross proceeds; cash, cash equivalents and marketable securities totaled $578.9 million as of December 31, 2023 –

SAN FRANCISCO, Feb. 29, 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 fourth quarter and full year ended December 31, 2023, and provided corporate updates.

“In 2023, we advanced our late-stage clinical development programs and demonstrated the anti-fibrotic and metabolic benefits of pegozafermin, aligned our Phase 3 NASH program with regulatory agencies in the United States and Europe, initiated our Phase 3 trial for SHTG, and strengthened our financial position,” said Rohan Palekar, Chief Executive Officer of 89bio. “We are highly encouraged by the Phase 2b ENLIVEN data and the long-term efficacy and tolerability data, which demonstrated positive, sustained benefits over a 48-week period, which together, positions pegozafermin as a potential best-in-class FGF21. As we continue to pursue a new therapeutic option and standard of care for patients through the promise of pegozafermin, our team is focused on the execution of our planned Phase 3 trials in NASH and the ongoing Phase 3 trial in SHTG.”

Recent Highlights and Anticipated Milestones

Nonalcoholic Steatohepatitis (NASH), or Metabolic dysfunction-associated steatohepatitis (MASH)

- Successful end-of-Phase 2 meetings (EOP2) with the U.S. Food & Drug Administration (FDA), and initial scientific advice received from the European Medicines Agency (EMA) supports the advancement of pegozafermin into Phase 3 in NASH.
    - The ENLIGHTEN program is expected to include two Phase 3 trials evaluating patients with NASH. ENLIGHTEN-Fibrosis is expected to enroll non-cirrhotic patients with fibrosis stage F2-F3 and ENLIGHTEN-Cirrhosis is expected to enroll NASH patients with compensated cirrhosis (F4).
    - ENLIGHTEN-Fibrosis and ENLIGHTEN-Cirrhosis are expected to initiate in the first and second quarter of 2024, respectively.
- Long-term data from the ENLIVEN Phase 2b trial demonstrated statistically significant improvements across key markers of fibrosis and liver health and at week 48 in NASH patients. Pegozafermin continued to demonstrate a favorable safety and tolerability profile consistent with previously reported data.
- Data from the Phase 2b ENLIVEN trial of NASH patients with compensated cirrhosis (F4) were featured in an oral presentation during AASLD, showing clinically meaningful reductions in key non-invasive tests (NITs) of liver inflammation and fibrosis.

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 Updates

- Completed follow-on offering in the fourth quarter of 2023 for $172.5 million in gross proceeds.

Fourth Quarter 2023 Financial Results

Cash Position. As of December 31, 2023, 89bio had cash, cash equivalents and marketable securities totaling $578.9 million, as compared to $188.2

million as of December 31, 2022.

Research and Development (R&D) Expenses. R&D expenses were $33.6 million and $122.2 million for the three months and year ended December 31, 2023, respectively, compared to $19.1 million and $80.8 million for the three months and year ended December 31, 2022, respectively. The increase in R&D expenses for the year was primarily driven by increases in contract manufacturing costs and personnel-related expenses.

General and Administrative (G&A) Expenses. G&A expenses were $7.6 million and $29.0 million for the three months and year ended December 31, 2023, respectively, compared to $6.3 million and $21.5 million for the three months and year ended December 31, 2022, respectively. The increase in G&A expenses for the year ended December 31, 2023, was primarily due to an increase in personnel-related expenses, employee headcount, including stock-based compensation expense, and increased consultant and professional service fees, partially offset by a decrease in insurance-related costs.

Net Loss. 89bio reported a net loss of $40.2 million and $142.2 million for the three months and year ended December 31, 2023, respectively, compared to a net loss of $24.6 million and $102.0 million for the three months and year ended December 31, 2022, respectively. The increase in net loss is primarily attributable to increased R&D expenses to advance the company's programs, increased G&A expenses associated with additions in headcount, and expenses in support of the company's expanded operations, offset by an increase in interest income.

The foregoing financial information is unaudited and subject to change, and actual results may vary from the foregoing.

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 nonalcoholic 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. Pegozafermin has been granted Breakthrough Therapy Designation for the treatment of NASH with fibrosis from U.S. Food and Drug Administration (FDA). 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-Fibrosis trial and Phase 3 ENLIGHTEN-Cirrhosis trial in NASH and the topline results from the ENTRUST Phase 3 trial in SHTG, and enrollment in clinical trials. 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 Phase 3 trials in NASH; expectations regarding the timing and outcome of the 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, 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 December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 33,592	$ 19,064	$ 122,230	$ 80,796
General and administrative	7,614	6,298	28,974	21,453
Total operating expenses	41,206	25,362	151,204	102,249
Loss from operations	(41,206)	(25,362)	(151,204)	(102,249)
Interest expense	(866)	(545)	(4,794)	(1,922)
Interest income and other, net	5,704	1,321	17,676	2,164
Net loss before income tax	(36,368)	(24,586)	(138,322)	(102,007)
Income tax expense	(3,867)	(16)	(3,867)	(19)
Net loss	$ (40,235)	$ (24,602)	$ (142,189)	$ (102,026)

Comprehensive loss	$ (39,498)	$ (24,512)	$ (141,649)	$ (102,312)
Net loss per share, basic and diluted	$ (0.50)	$ (0.48)	$ (2.00)	$ (2.93)
Weighted-average shares used to compute net loss per share, basic and diluted	80,696,621	50,809,279	71,172,870	34,806,349

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

	December 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 578,870	$ 188,160
Total assets	596,269	196,824
Total current liabilities	29,611	24,614
Non-current liabilities	30,352	20,378
Total stockholders' equity	536,306	151,832
Total liabilities and stockholders' equity	$ 596,269	$ 196,824

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