UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 10, 2023

89bio, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39122**	**36-4946844**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

142 Sansome Street, Second Floor
San Francisco, CA 94104
(Address of principal executive offices, including zip code)

(415) 432-9270
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	ETNB	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On March 10, 2023, 89bio, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 31, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

This Item 2.02 and the Press Release attached hereto as Exhibit 99.1, insofar as they disclose information regarding the Company's results of operations and financial condition for the quarter and year ended December 31, 2022, are being furnished to the Securities and Exchange Commission.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits*. The following exhibit is being furnished herewith:

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated March 10, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

89bio, Inc.

Date: March 10, 2023

By: /s/ Rohan Palekar
Rohan Palekar
Chief Executive Officer

89bio Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Update

– Topline results from ENLIVEN Phase 2b NASH trial on track for first quarter of 2023 –

– Feedback from FDA supports advancement of Phase 3 program for pegozafermin in SHTG; plan to initiate first of two SHTG Phase 3 trials in the second quarter of 2023 –

– Published results of Phase 1b/2a study of pegozafermin for the treatment of NASH in The Lancet Gastroenterology & Hepatology –

SAN FRANCISCO, March 10, 2023 (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 fourth quarter and full year ended December 31, 2022.

"In 2022, we made significant advancements across our late-stage clinical development program for pegozafermin, and with our extended cash runway, are well positioned to execute on our key priorities and achieve multiple value-driving milestones in both SHTG and NASH," said Rohan Palekar, Chief Executive Officer of 89bio. "We are encouraged by the feedback from the FDA supporting the advancement of pegozafermin in SHTG and plan to initiate the first of two recommended Phase 3 trials in the second quarter of this year. In parallel, we remain on track to deliver topline results from ENLIVEN, our Phase 2b NASH trial, this quarter, which could support advancing into Phase 3 development in NASH. We have developed plans to optimize the clinical development program across both indications and expect to finalize these plans after we have reviewed the results from ENLIVEN."

Recent Highlights and Anticipated Milestones

Nonalcoholic Steatohepatitis (NASH)
ENLIVEN Phase 2b trial topline data on track for 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 compared to placebo for the treatment of patients with fibrosis stage F2—F3 NASH and NAS ≥ 4.
- The primary analysis will evaluate the effect of pegozafermin at week 24 on the two histology endpoints that can support accelerated approval by the FDA. The primary analysis population will include patients who met histologic entry criteria [F2/F3 patients and NAS ≥4] based on the three-panel consensus read of biopsies at baseline.

Published results from the Phase 1b/2a study of pegozafermin for the treatment of NASH in *The Lancet Gastroenterology & Hepatology*

- Data from cohorts 1-6 in the proof-of-concept study showed pegozafermin had a beneficial therapeutic effect in reducing liver fat and improving markers of liver injury, fibrosis and lipids and was generally well tolerated.

Severe Hypertriglyceridemia (SHTG)

Initiation of the first Phase 3 trial planned in the second quarter of 2023 based on feedback from the FDA

- The FDA agreed that the pre-clinical and clinical data package support the advancement of pegozafermin into Phase 3, with the proposed primary endpoint of reduction in triglycerides (TG) from baseline without the need for a clinical outcome study. The FDA also agreed to the proposed doses and proposed secondary endpoints and were generally aligned with other study parameters. The primary endpoint in the planned Phase 3 trials is anticipated to be assessed at week 26.

Presented new analysis of data from the ENTRIGUE Phase 2 trial highlighting the beneficial effects of pegozafermin in SHTG patients at the American College of Cardiology's Annual Scientific Session

- Results from a post-hoc analysis were featured in a poster demonstrating that treatment with pegozafermin significantly reduced TGs and other atherogenic lipids in patients with SHTG regardless of their background lipid-modifying therapy status.

Other Updates

- 89bio has developed a new pre-filled syringe using its approved liquid formulation and intends to utilize this presentation in its planned SHTG Phase 3 trial in the second quarter of 2023.
- 89bio entered into a loan and security agreement with K2 HealthVentures LLC, for an aggregate principal amount of up to $100 million, of which $25 million was drawn at closing.

Fourth Quarter and Full Year 2022 Financial Results

Cash Position. As of December 31, 2022, 89bio had cash, cash equivalents, and short-term investments totaling $188.2 million compared to $150.7 million as of December 31, 2021.

Research and Development (R&D) Expenses. R&D expenses were $19.1 million and $80.8 million for the three months and year ended December 31, 2022, respectively, compared to $21.0 million and $70.3 million for the three months and year ended December 31, 2021, respectively. The increase in R&D expenses for the year was primarily driven by increases in clinical development and personnel expenses offset by a decrease in contract manufacturing costs.

General and Administrative (G&A) Expenses. G&A expenses were $6.3 million and $21.5 million for the three months and year ended December 31, 2022, respectively, compared to $5.3 million and $19.4 million for the three months and year ended December 31, 2021, respectively. The increase in G&A expenses for the year ended December 31, 2022 was primarily due to an increase in costs related to personnel expenses and expenses for professional services offset by a decrease in insurance related costs.

Net Loss. 89bio reported a net loss of $24.6 million and $102.0 million for the three and year ended December 31, 2022, respectively, compared to a net loss of $26.3 million and $90.1 million for the three months and year ended December 31, 2021, 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. 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 clinical benefits of pegozafermin, the clinical benefit, safety and tolerability profile of pegozafermin, clinical development plans and timing for pegozafermin, including the Phase 3 trial in SHTG, 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 public health crises 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 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.

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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,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 19,064	$ 20,979	$ 80,796	$ 70,330
General and administrative	6,298	5,262	21,453	19,413
Total operating expenses	25,362	26,241	102,249	89,743
Loss from operations	25,362	26,241	102,249	89,743
Other (income) expenses, net	(776)	194	(242)	526
Net loss before income tax	24,586	26,435	102,007	90,269
Income tax (expense) benefit	16	(147)	19	(147)
Net loss	$ 24,602	$ 26,288	$ 102,026	$ 90,122
Comprehensive loss	$ 24,512	$ 26,358	$ 102,312	$ 90,176
Net loss per share, basic and diluted	$ 0.48	$ 1.30	$ 2.93	$ 4.48
Weighted-average shares used to compute net loss per share, basic and diluted	50,809,279	20,261,662	34,806,349	20,098,340

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

	December 31, 2022	December 31, 2021
Cash, cash equivalents and short-term investments	$ 188,160	$ 150,745
Total assets	196,824	162,422
Total current liabilities	24,614	19,537
Non current liabilities	44,992	16,928
Total stockholders' equity	151,832	125,957
Total liabilities and stockholders' equity	$ 196,824	$ 162,422

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