# 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): November 8, 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 November 8, 2023, 89bio, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2023. 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 ended September 30, 2023, 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 November 8, 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: November 8, 2023

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

**89bio Reports Third Quarter 2023 Financial Results and Provides Corporate Updates**

*–Pegozafermin granted Breakthrough Therapy Designation (BTD) for the treatment of nonalcoholic steatohepatitis (NASH) with fibrosis–*

*–Feedback from regulatory agencies on pegozafermin Phase 3 development program in NASH expected this quarter–*

*–Data from ENLIVEN in patients with cirrhotic (F4) NASH will be featured in an oral presentation during American Association for the Study of Liver Diseases (AASLD) The Liver Meeting®–*

SAN FRANCISCO, November 8, 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 cardiometabolic diseases, today reported its financial results for the third quarter ended September 30, 2023.

“We are making excellent progress in developing pegozafermin as a potential leading treatment for liver and cardiometabolic diseases,” stated Rohan Palekar, CEO of 89bio. “We believe the FDA’s breakthrough therapy designation is a significant milestone, and further validates pegozafermin’s potential in NASH. Pending regulatory feedback, we expect to initiate our Phase 3 program in NASH in the first half of 2024. Additionally, we are continuing to enroll patients in ENTRUST, the Phase 3 trial of pegozafermin in patients with SHTG. Together, these advancements across our late-stage clinical development programs bring us closer to addressing the significant disease burden and unmet medical needs of patients with NASH and SHTG.”

**Recent Highlights and Anticipated Milestones**

***Nonalcoholic Steatohepatitis (NASH)***

- U.S. Food and Drug Administration (FDA) granted BTD to pegozafermin for the treatment of NASH with fibrosis.
- Data from the Phase 2b ENLIVEN trial of patients with F4 NASH will be featured in an oral presentation on Sunday, November 12 during AASLD The Liver Meeting® to be held in Boston, Massachusetts.
    - **Abstract #47238:** Fibrosis improvement with pegozafermin treatment in NASH patients with F4 fibrosis: Analysis from a 24-week randomized, double-blind, placebo-controlled Phase 2 trial (ENLIVEN)
    - **Presenting Author:** Rohit Loomba, M.D., MHSc, chief of the Division of Gastroenterology and Hepatology at University of California San Diego School of Medicine
    - **Date, Time, Location:** November 12, 2023, at 12:15 p.m. ET at the Ballroom BC, Hynes Convention Center
- The Company expects to receive feedback this quarter from regulatory agencies on the pegozafermin Phase 3 NASH development program, which is planned to initiate in the first half of 2024.

***Severe Hypertriglyceridemia (SHTG)***

- Enrollment continues to progress 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.

**Third Quarter 2023 Financial Results**

**Cash Position.** As of September 30, 2023, 89bio had cash, cash equivalents and short-term available-for-sale securities totaling $448.3 million.

**Research and Development (R&D) Expenses.** R&D expenses were $31.4 million for the three months ended September 30, 2023, compared to $22.2 million for the three months ended September 30, 2022. The increase in R&D expenses was primarily driven by increases in contract manufacturing costs and personnel expenses, offset by a decrease in clinical development costs.

**General and Administrative (G&A) Expenses.** G&A expenses were $7.9 million for the three months ended September 30, 2023, compared to $4.8 million for the three months ended September 30, 2022. The increase in G&A expenses was primarily due to an increase in personnel costs, stock-based compensation, and expenses related to professional services.

**Net Loss.** 89bio reported a net loss of $34.7 million for the three months ended September 30, 2023, compared to a net loss of $26.8 million for the three months ended September 30, 2022. 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 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 SHTG Phase 3 program, the ENTRUST Phase 3 trial in SHTG and the NASH Phase 3 trial, the timing for meeting with regulatory authorities, the use of the SHTG Phase 3 program to support safety database requirements 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 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 trial 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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| Operating expenses: | | | | |
| Research and development | $ 31,417 | $ 22,197 | $ 88,638 | $ 61,732 |
| General and administrative | 7,928 | 4,844 | 21,360 | 15,155 |
| Total operating expenses | 39,345 | 27,041 | 109,998 | 76,887 |
| Loss from operations | (39,345) | (27,041) | (109,998) | (76,887) |
| Interest expense | (959) | (535) | (3,928) | (1,377) |
| Interest income and other, net | 5,579 | 773 | 11,972 | 843 |
| Net loss before income tax | (34,725) | (26,803) | (101,954) | (77,421) |
| Income tax expense | — | (2) | — | (3) |
| Net loss | $ (34,725) | $ (26,805) | $ (101,954) | $ (77,424) |
| Comprehensive loss | $ (34,678) | $ (26,927) | $ (102,151) | $ (77,800) |
| Net loss per share, basic and diluted | $ (0.45) | $ (0.57) | $ (1.50) | $ (2.63) |
| Weighted-average shares used to compute net loss per share, basic and diluted | 76,336,050 | 47,253,527 | 67,962,848 | 29,413,421 |

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

| | September 30, 2023 | December 31, 2022 |
|---|---|---|
| Cash and cash equivalents and short-term investments | $ 448,304 | $ 188,160 |
| Total assets | 460,111 | 196,824 |
| Total current liabilities | 25,212 | 24,614 |
| Non current liabilities | 24,690 | 20,378 |
| Total stockholders' equity | 410,209 | 151,832 |
| Total liabilities and stockholders' equity | $ 460,111 | $ 196,824 |


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