

**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 10, 2022

89bio, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39122
(Commission
File Number)

36-4946844
(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 10, 2022, 89bio, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 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 ended September 30, 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. | <u>Description</u> |
|--------------------|--|
| 99.1 | Press Release, dated November 10, 2022 |
| 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 10, 2022

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



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

-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, November 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 \geq 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 \geq 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 its 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 | <u>27,041</u> | <u>28,212</u> | <u>76,887</u> | <u>63,502</u> |
| 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 | <u>\$ 26,805</u> | <u>\$ 28,329</u> | <u>\$ 77,424</u> | <u>\$ 63,834</u> |
| Comprehensive loss | <u>\$ 26,927</u> | <u>\$ 28,327</u> | <u>\$ 77,800</u> | <u>\$ 63,818</u> |
| Net loss per share, basic and diluted | <u>\$ 0.57</u> | <u>\$ 1.41</u> | <u>\$ 2.63</u> | <u>\$ 3.18</u> |
| Weighted-average shares used to compute net loss per share, basic and diluted | <u>47,253,527</u> | <u>20,092,094</u> | <u>29,413,421</u> | <u>20,043,301</u> |

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 |

Investor/Media Contact:

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Chief Financial Officer
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