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): December 4, 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 7.01 Regulation FD Disclosure.

On December 4, 2023, 89bio, Inc. (the "Company") issued a press release announcing alignment with the U.S. Food and Drug Administration and the European Medicines Agency on the Company's Phase 3 program for pegozafermin in nonalcoholic steatohepatitis.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein. The exhibit furnished under Item 7.01 of this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits*.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated December 4, 2023
104	The cover page from the Company's Current Report on Form 8-K formatted in Inline XBRL

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: December 4, 2023

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

89bio Reaches Alignment with the FDA and EMA on Phase 3 Program for Pegozafermin in Nonalcoholic Steatohepatitis (NASH); Program Initiation Planned in the First Half of 2024

*—Alignment reached on key elements of the NASH development strategy, including accelerated approval pathway for **both** F4 and F2-F3 NASH patients using histology—*

—Outcomes trial in F4 cirrhotic NASH patients expected to support full approval across F2-F4 NASH; potential to accelerate timeline to outcomes readout based on agreement with FDA on modified definition of some events—

—Safety database will be inclusive of data from the ongoing SHTG Phase 3 program—

—Trials to include patients on background GLP-1 therapy to assess potential of combination with pegozafermin—

SAN FRANCISCO, December 4, 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 announced a successful end-of-Phase 2 Meeting with the U.S. Food & Drug Administration (FDA), supporting the advancement of pegozafermin into Phase 3 in NASH. The program will include two Phase 3 trials evaluating patients with NASH: ENLIGHTEN-Cirrhosis will enroll patients with compensated cirrhosis (F4) and ENLIGHTEN-Fibrosis will enroll patients with fibrosis stage F2-F3. The F2-F3 and the F4 trials are expected to initiate in the first quarter and the second quarter of 2024, respectively. Initial scientific advice received from EMA was generally aligned with the feedback from the FDA.

“We are pleased to have achieved alignment with both regulatory agencies on the development path forward for pegozafermin in NASH, featuring an innovative clinical trial approach in F4 patients,” said Hank Mansbach, Chief Medical Officer of 89bio. “Importantly, the FDA has agreed to an accelerated approval pathway in F4 patients using histology and for the outcomes portion of the trial, has agreed to modified definitions of some clinical outcomes, which could potentially expedite the timeline to readout. The agency also agreed to a trial in F2-F3 patients using histology as an endpoint for accelerated approval. Furthermore, the agency supported our strategy to leverage safety data from our ongoing SHTG Phase 3 program, eliminating the need for a separate safety study.”

The planned ENLIGHTEN program will be comprised of two randomized, double-blinded, placebo-controlled Phase 3 trials, evaluating the efficacy and safety of pegozafermin in patients with NASH.

- **ENLIGHTEN-Cirrhosis, in patients with compensated F4 NASH*:*** The trial will evaluate the efficacy and safety of pegozafermin administered 30mg weekly.
  - **Histology Portion**: The primary endpoint will be regression of fibrosis from F4 to an earlier stage of fibrosis. This endpoint is planned to be assessed at 24 months, with the potential to assess it earlier based on the evolving clinical and regulatory landscape. This primary endpoint is intended to support a filing for accelerated approval in the United States and conditional approval in Europe in F4 patients.
  - **Outcome Portion**: Patients will continue to be treated in a blinded extension phase through clinical outcome events that are expected to be predominantly decompensation events. Alignment with the FDA on modified definitions of some of these events could allow the trial to reach the final number of events more quickly and therefore accelerate the timeline to trial readout. Positive results would support full approval in F4 patients and will also serve as confirmatory full approval in F2-F3 patients.

- **ENLIGHTEN-Fibrosis, in patients with F2-F3 NASH:** The trial will evaluate the efficacy and safety of pegozafermin administered 30mg weekly and 44mg every-two-weeks.
    - **Histology Portion**: The co-primary endpoints will be a one-point improvement in fibrosis with no worsening of NASH and NASH resolution with no worsening of fibrosis. These endpoints will be assessed at week 52 and are intended to support a filing for accelerated approval in the U.S. and conditional approval in Europe in F2-F3 patients.
    - **Outcome Portion:** Patients will continue to be treated in a blinded extension phase to measure clinical outcomes to support full approval in F2-F3 patients. The clinical outcome events are expected to be primarily due to progression to cirrhosis.

Both ENLIGHTEN-Fibrosis and ENLIGHTEN-Cirrhosis will enroll a significant proportion of patients on stable doses of GLP-1 based therapies and data from these patients in the trials will evaluate the expected incremental benefit of adding pegozafermin to these therapies. Both trials will employ the three-panel consensus biopsy reading methodology, which was successfully utilized in the ENLIVEN trial, for both baseline and primary endpoint biopsy reads. Patients will self-administer pegozafermin using the planned commercial liquid formulation delivered as a single subcutaneous injection.

About pegozafermin

Pegozafermin is a specifically engineered glycoPEGylated analog of fibroblast growth factor 21 (FGF21) being developed for the treatment of nonalcoholic steatohepatitis (NASH) and severe hypertriglyceridemia (SHTG). FGF21 is an endogenous hormone that has broad effects such as regulating energy expenditure, glucose and lipid metabolism. In clinical trials, pegozafermin has demonstrated direct anti-fibrotic and anti-inflammatory effects on the liver, as well as reduced triglyceride levels, improved insulin resistance and glycemic control, and continued to demonstrate a favorable safety and tolerability profile. The FDA granted pegozafermin Breakthrough Therapy designation (BTD) for the treatment of NASH with fibrosis. Pegozafermin is advancing into the Phase 3 ENLIGHTEN trial program for NASH and is being studied in the Phase 3 ENTRUST trial for SHTG.

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 anticipated design and timing of initiation of the

NASH Phase 3 trials, the possibility of obtaining accelerated approval using histology, the ability to achieve an expedited timeline for outcomes readout based on the modified definitions of clinical outcomes for the outcome trial in cirrhotic patients and the use of the ongoing SHTG Phase 3 program to support safety database requirements. 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 design and 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; receipt of BTD for pegozafermin in NASH may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA; 89bio’s substantial dependence on the success of its 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.

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