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 11, 2021

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) 500-4614
(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 11, 2021, 89bio, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2021. 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, 2021, 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 11, 2021
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 12, 2021

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

89bio Reports Third Quarter 2021 Financial Results and Provides Corporate Update

SAN FRANCISCO, November 11, 2021 (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 quarter ended September 30, 2021.

“In the third quarter of 2021, we took important steps to advance our ongoing clinical development program for BIO89-100: a highly differentiated FGF21 analog with a validated and potentially transformational profile for patients suffering from NASH and SHTG,” said Rohan Palekar, Chief Executive Officer of 89bio. “With multiple ongoing studies in these indications, we look forward to reporting data from our open-label histology cohort in NASH patients in early to mid-January 2022 and our proof-of-concept study in SHTG in the first half of 2022. Additionally, we continue to make progress on the ENLIVEN Phase 2b study in NASH patients with F2 and F3 fibrosis.”

Recent Highlights and Anticipated Milestones

Report topline data from the open-label histology cohort in biopsy-confirmed fibrosis stage F2 – F3 NASH patients in early to mid-January 2022. The paired-biopsy, open-label histology cohort is an expansion of the Phase 1b/2a trial of BIO89-100 in NASH. In this cohort, biopsy-confirmed NASH patients are treated for 20 weeks with 27 mg of BIO89-100 once weekly. This cohort is intended to support both the clinical utility of BIO89-100 and our overall clinical development strategy in NASH.

Report topline data from the Phase 2 ENTRIGUE trial of BIO89-100 in severe hypertriglyceridemia patients in the first half of 2022. Recently presented data at the National Lipid Association (NLA) meeting in September showed patients with SHTG also had high levels of liver fat by MRI-PDFF (mean = 20%; n=14 in this sub-analysis) underscoring the potential of BIO89-100 to address the broader metabolic dysregulation seen in this patient population.

Present new analyses from the Phase 1b/2a NASH trial of BIO89-100 showing beneficial effects on spleen volume in an oral presentation at AASLD’s The Liver Meeting 2021. Data from a sub-analysis looking at the correlation of liver fat and spleen volume suggests BIO89-100 can reduce spleen volume (abstract #139). A poster with new data on population pharmacokinetics and pharmacodynamics of BIO89-100 that helped inform the dose selection for ENLIVEN will also be presented (abstract # 1931).

Continue to enroll patients in the ENLIVEN Phase 2b trial of BIO89-100 for the treatment of NASH. ENLIVEN is a multi-center, randomized, double-blind, placebo-controlled Phase 2b trial designed to evaluate the safety and efficacy of BIO89-100 for the treatment of patients with fibrosis stage F2—F3 NASH.

Third Quarter 2021 Financial Results

Cash Position. As of September 30, 2021, 89bio had cash, cash equivalents, and short-term investments of $157.4 million.

Research and Development (R&D) Expenses. R&D expenses were $23.6 million and $49.4 million for the three and nine months ended September 30, 2021, respectively, compared to $11.2 million and $27.4 million for the comparable periods in 2020, respectively. The increase in R&D expenses was primarily driven by increases in clinical development, contract manufacturing, and personnel expenses.

General and Administrative (G&A) Expenses. G&A expenses were $4.6 million and $14.2 million for the three and nine months ended September 30, 2021, respectively, compared to $3.2 million and $9.4 million for the comparable periods in 2020, respectively. The increase in G&A expenses was primarily due to an increase in costs related to personnel expenses, insurance-related expenses, and expenses for professional services.

Net Loss. 89bio reported a net loss of $28.3 million and $63.8 million for the three and nine months ended September 30, 2021, respectively, compared to a net loss of $14.6 million and $36.9 million for the comparable periods in 2020, 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, BIO89-100, through clinical development for the treatment of non-alcoholic steatohepatitis (NASH) and severe hypertriglyceridemia (SHTG). BIO89-100 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 BIO89-100, clinical development plans and timing for BIO89-100, including the Phase 2b ENLIVEN trial and Phase 2 ENTRIGUE trial, the expected trial design for the ENLIVEN trial and the ENTRIGUE trial, including patient enrollment, dosing schedules and trial endpoints, and the timing for topline data for the open-label histology cohort and the Phase 2 ENTRIGUE trial. 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 89bio’s initiation of the Phase 2b ENLIVEN trial in NASH and Phase 2 ENTRIGUE trial in SHTG; expectations regarding the timing of topline data;

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 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; and other risks and uncertainties identified in 89bio's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 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,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 23,590	$ 11,208	$ 49,351	$ 27,429
General and administrative	4,622	3,225	14,151	9,379
Total operating expenses	28,212	14,433	63,502	36,808
Loss from operations	28,212	14,433	63,502	36,808
Other expenses, net	117	146	332	87
Net loss before tax	28,329	14,579	63,834	36,895
Income tax expense (benefit)	—	24	—	23
Net loss	$ 28,329	$ 14,603	$ 63,834	$ 36,918
Comprehensive loss	$ 28,327	$ 14,606	$ 63,818	$ 36,921
Net loss per share, basic and diluted	$ 1.41	$ 0.86	$ 3.18	$ 2.49
Weighted-average shares used to compute net loss per share, basic and diluted	20,092,094	16,884,244	20,043,301	14,809,131

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

	September 30, 2021	December 31, 2020
Cash, cash equivalents and Short term investments	$ 157,358	$ 204,654
Total Assets	168,056	211,074
Total current liabilities	19,845	8,113
Total stockholders' equity	146,770	202,961

Investor Contact:

Ryan Martins
Chief Financial Officer
investors@89bio.com

Media Contact:

Peter Duckler
773-343-3069
pduckler@w2ogroup.com