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 24, 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 March 24, 2021, 89bio, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 31, 2020. 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, 2020, 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 24, 2021

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 24, 2021

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

Exhibit 99.1

89bio Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Corporate Update

- Initiation of BIO89-100 Phase 2b NASH trial planned in 1H21 -

- NASH histology cohort topline data expected by YE21 -

- Phase 2 SHTG trial (ENTRIGUE) expected to report topline data in 2H21 -

SAN FRANCISCO, March 24, 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 and full year ended December 31, 2020.

“2020 was a transformative year for 89bio, and we are encouraged by the significant progress made in advancing BIO89-100 through the clinic. This was highlighted by our Phase 1b/2a data in NASH patients that underscored the potential for BIO89-100 as a best-in-class FGF21 analog and provided the impetus for advancing BIO89-100 into a Phase 2b trial for the treatment of NASH,” said Rohan Palekar, Chief Executive Officer of 89bio. “We are anticipating some important clinical milestones in 2021 that we expect will continue to validate BIO89-100’s potential in both NASH and SHTG.”

Recent Highlights and Anticipated Milestones

- **Presented updated clinical data from Phase 1b/2a study of BIO89-100 in NASH at AASLD’s The Liver Meeting® 2020 and at ENDO 2021.** The data presented at AASLD confirmed BIO89-100’s compelling efficacy profile and favorable tolerability with weekly and every two-week dosing. New analyses demonstrated the significant correlation between relative reductions in MRI-PDFF and serum ALT in patients treated with BIO89-100. New analyses of BIO89-100’s Phase 1b/2a study data presented at ENDO 2021 demonstrated significant reductions in liver volume of up to 15% and liver fat volume of up to 65% at 13 weeks compared to baseline in treated patients as measured by MRI-PDFF.
- **Initiate the Phase 2b trial in NASH patients in the first half of 2021.**
- **Report topline data from the paired-biopsy, open-label histology cohort in NASH patients by year-end 2021.** This cohort is enrolling approximately 20 patients with biopsy-confirmed NASH and will provide an early opportunity to demonstrate BIO89-100’s benefits on histology endpoints.
- **Report topline data from the Phase 2 ENTRIGUE study of BIO89-100 in SHTG patients in the second half of 2021.** ENTRIGUE is a multi-center, randomized, double-blind, placebo-controlled study designed to evaluate safety, efficacy and tolerability in patients that will receive BIO89-100 administered weekly (9mg, 18mg or 27 mg), every two weeks (36mg) or placebo. The primary endpoint is the reduction in fasting triglycerides from baseline. Key secondary endpoints include other lipids and metabolic

markers and change in liver fat measured by MRI-PDFF. ENTRIGUE was expanded recently with an additional cohort of patients on fibrates to assess the benefit of the 27 mg weekly dose of BIO89-100 when added to background fibrates. In this additional cohort, a total of 36 patients will be randomized to either BIO89-100 or placebo. The primary endpoint and key secondary endpoints are the same as in ENTRIGUE, including change in liver fat as measured by MRI-PDFF.

Fourth Quarter and Full Year 2020 Financial Results

Cash Position. As of December 31, 2020, 89bio had cash, cash equivalents, and short-term investments totaling $204.7 million compared to $93.4 million as of December 31, 2019. This included approximately $157.7 million in estimated net proceeds from underwritten public offerings of common stock in the third quarter of 2020.

Research and Development (R&D) Expenses. R&D expenses were $8.8 million and $36.2 million for the three months and year ended December 31, 2020, respectively, compared to $7.2 million and $21.4 million for the three months and year ended December 31, 2019, respectively. The increase for the year ended December 31, 2020 was primarily driven by higher clinical development, contract manufacturing, and personnel expenses.

General and Administrative (G&A) Expenses. G&A expenses were $3.8 million and $13.2 million for the three months and year ended December 31, 2020, respectively, compared to $2.4 million and $5.3 million for the three months and year ended December 31, 2019, respectively. The increase for the year ended December 31, 2020 was primarily due to higher personnel expenses and expenses relating to first full year of operations as a public company.

About 89bio

89bio is a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of liver and cardio-metabolic diseases. The company's lead product candidate, BIO89-100, is a specifically engineered glycoPEGylated analog of FGF21. BIO89-100 is being developed for the treatment of nonalcoholic steatohepatitis (NASH) and severe hypertriglyceridemia (SHTG). 89bio is headquartered in San Francisco with operations in Herzliya, Israel.

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, the safety and tolerability of BIO89-100, clinical development plans for BIO89-100, including the Phase 2b trial and open-label paired biopsy histology cohort for NASH and the Phase 2 trial for SHTG, and the anticipated timing for such plans. Words such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "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 trial in NASH; 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; 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 Annual Report on Form 10-K for the year ended December 31, 2019 and its Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 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 December 31, 2020	Three months Ended December 31, 2019	Year Ended December 31, 2020	Year Ended December 31, 2019
Operating expenses:				
Research and development	$ 8,770	$ 7,192	$ 36,199	$ 21,346
General and administrative	3,777	2,419	13,156	5,294
Total operating expenses	12,547	9,611	49,355	26,640
Loss from operations	12,547	9,611	49,355	26,640
Other (income) expenses, net	116	9,540	203	30,562
Net loss before tax	12,663	19,151	49,558	57,202
Income tax expense	(82)	132	(59)	218
Net loss	$ 12,581	$ 19,283	$ 49,499	$ 57,420
Comprehensive loss	$ 12,588	$ 19,283	$ 49,509	$ 57,420
Net loss per share, basic and diluted	$ 0.63	$ 2.58	$ 3.08	$ 24.49
Weighted-average shares used to compute net loss per share, basic and diluted	19,895,952	7,486,577	16,087,785	2,344,191

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

	December 31, 2020	December 31, 2019
Cash, cash equivalents, and short-term investments	$ 204,654	$ 93,360
Total Assets	211,074	95,553
Total current liabilities	8,113	5,609
Total stockholders' equity	202,961	89,944

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