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): May 13, 2020

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 May 13, 2020, 89bio, Inc. issued a press release announcing its financial results for the quarter ended March 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 ended March 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 May 13, 2020

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: May 13, 2020

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

89bio Reports First Quarter 2020 Financial Results and Provides Corporate Update

- Topline results from BIO89-100's Phase 1b/2a NASH trial are expected in 2H20 -

- Announces FDA Clearance of BIO89-100 IND Application for SHTG -

San Francisco, California, May 13, 2020 – 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 March 31, 2020.

"We are excited to have closed enrollment in our Phase 1b/2a trial for nonalcoholic steatohepatitis (NASH) and look forward to reporting topline results in the second half of 2020," said Rohan Palekar, Chief Executive Officer of 89bio. "The recent clearance by the FDA of our Investigational New Drug (IND) application for severe hypertriglyceridemia (SHTG) puts us in position to initiate our Phase 2 trial of BIO89-100 for the treatment of SHTG when conditions permit safe and effective execution of the trial."

Recent Highlights and Upcoming Milestones

Closed enrollment in the Phase 1b/2a trial of BIO89-100 in NASH. In April 2020, 89bio closed enrollment in its Phase 1b/2a trial of BIO89-100 in NASH with 98% of patients enrolled. 89bio is working closely with its contract research organization partners and clinical sites to mitigate, where possible, any potential impact of the COVID-19 pandemic on the trial. In this trial, 81 patients were randomized to receive weekly or every other week subcutaneous dosing of BIO89-100 or placebo for 12 weeks. Topline results are expected in the second half of 2020.

FDA Clearance of BIO89-100's IND application for SHTG. On May 8, 2020, the Division of Diabetes, Lipid Disorders, and Obesity at the FDA cleared the IND Application for BIO89-100 in patients with SHTG. In April 2020, 89bio announced that it was delaying initiation of its Phase 2 trial of BIO89-100 for the treatment of SHTG due to the COVID-19 pandemic. 89bio is planning to complete all activities in order to be operationally prepared to enroll the trial once the external environment is conducive to executing the trial safely and effectively.

New preclinical data confirms BIO89-100's mechanism of action via potent FGF receptor agonism. In April 2020, 89bio released new preclinical data demonstrating that BIO89-100 had similar activity to recombinant human FGF21 at very low nanomolar concentrations in cells co-expressing ß-klotho and each of FGF receptors 1c, 2c or 3c. The data suggests that BIO89-100 could reproduce the beneficial metabolic benefits of the native hormone and confirming its potential to translate into clinical benefits for patients with NASH and SHTG. An EC50 could not be calculated for rhFGF21 or BIO89-100 at FGF receptor R4.

First Quarter 2020 Financial Results

Cash Position. As of March 31, 2020, 89bio had cash and cash equivalents of $85.5 million.

Research and Development (R&D) Expenses. R&D expenses were $7.8 million for the three months ended March 31, 2020, compared to $4.3 million for the three months ended March 31, 2019. The increase in R&D expenses was primarily driven by increases in clinical development, pre-clinical development and personnel expenses.

General and Administrative (G&A) Expenses. G&A expenses were $2.9 million for the three months ended March 31, 2020, compared to $0.5 million for the three months ended March 31, 2019. The increase in G&A expenses was primarily due to an increase in costs related to professional services and personnel expenses.

Net Loss. 89bio reported a net loss of $10.5 million for the three months ended March 31, 2020, compared to a net loss of $4.4 million for the three months ended March 31, 2019. The increase in net loss is primarily attributable to increased Research and Development expenses for our programs and increased General and Administrative expenses associated with our becoming a public company.

About BIO89-100

BIO89-100 is a glycoPEGylated analog of FGF21 being developed for the treatment of NASH and a trial is planned for evaluating its role in the treatment of severe hypertriglyceridemia (SHTG). 89bio has specifically engineered BIO89-100 using a proprietary glycoPEGylation technology designed to prolong the biological activity of native FGF21. In preclinical studies, BIO89-100 demonstrated consistent beneficial effects across a range of endpoints, including hepatic steatosis, injury, and fibrosis. In 89bio's Phase 1a clinical trial in healthy volunteers, BIO89-100 demonstrated a favorable tolerability profile and dose-proportional pharmacokinetics. BIO89-100 also demonstrated statistically significant improvements in key lipid parameters for two weeks after a single dose, which combined with results from the company's animal studies supports the potential for weekly or once every two weeks dosing. A proof of concept Phase 1a/2b clinical trial evaluating BIO89-100 in patients with NASH or NAFLD and a high risk of NASH is currently underway.

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 being developed for the treatment of NASH. The company also intends to develop BIO89-100 for the treatment of SHTG. BIO89-100 is a specifically engineered glycoPEGylated analog of FGF21 that is currently in a proof of concept Phase 1b/2a clinical trial in patients with NASH or NAFLD and a high risk of NASH. 89bio is headquartered in San Francisco with operations in Herzliya, Israel. Visit 89bio.com for more information.

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, 89bio's expectations regarding plans for its clinical programs and clinical studies. 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 U.S. 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 timing, completion and outcome of 89bio's Phase 1b/2a proof of concept clinical trial evaluating BIO89-100 in patients with NASH or patients with NAFLD and a high risk of NASH; expectations regarding the timing, completion and outcome of 89bio's proof of concept Phase 2 clinical trial evaluating BIO89-100 in patients with SHTG; the unpredictable relationship between preclinical study results and clinical study results; the effect of the COVID-19 pandemic on 89bio's clinical trials and business operations; liquidity and capital resources; and other risks and uncertainties identified in 89bio's Annual Report on Form 10-K for the year ended December 31, 2019, filed March 18, 2020 with the SEC 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 March 31, 2020	Three months Ended March 31, 2019
Operating expenses:		
Research and development	$ 7,778	$ 4,309
General and administrative	2,924	523
Total operating expenses	10,702	4,832
Loss from operations	10,702	4,832
Other income, net	(157)	(416)
Net loss before tax	10,545	4,416
Income tax (benefit) expense	(1)	23
Net loss and comprehensive loss	$ 10,544	$ 4,439
Net loss per share, basic and diluted	$ 0.76	$ 7.26
Weighted-average shares used to compute net loss per share, basic and diluted	13,789,786	611,226

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

	March 31, 2020	December 31, 2019
Cash and cash equivalents	$ 85,532	$ 93,335
Total assets	87,689	95,553
Total current liabilities	7,787	5,609
Total stockholders' equity	79,902	89,944

###

Investor Contact:
Ryan Martins
Chief Financial Officer
investors@89bio.com

Media Contact:
Lori Rosen
LDR Communications
917-553-6808
lori@ldrcommunications.com