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): August 12, 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 August 12, 2021, 89bio, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 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 June 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 August 12, 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: August 12, 2021

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

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

- Initiated Phase 2b ENLIVEN trial in NASH patients -
- Completed enrollment in NASH histology cohort with topline data expected by year-end 2021 -

SAN FRANCISCO, August 12, 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 June 30, 2021.

“In the second quarter of 2021, we continued to execute on our goals and took important steps in advancing BIO89-100 as a new treatment option for patients suffering from NASH,” said Rohan Palekar, Chief Executive Officer of 89bio. “We initiated our Phase 2b ENLIVEN trial in NASH and successfully completed target enrollment in the open-label histology cohort in biopsy-confirmed NASH patients. Leveraging this momentum, this quarter we are planning to initiate a pharmacokinetic study of BIO89-100 in NASH patients with compensated cirrhosis (fibrosis stage F4). As we build on the success of our clinical initiatives, we continue to add talent and depth to our leadership team to guide us through this exciting next phase of strategic growth.”

Recent Highlights and Anticipated Milestones

Initiated 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. A total of approximately 216 patients will receive either one of two different weekly doses (15mg or 30mg), or an every two-week dose (44mg) of BIO89-100 or placebo for 24 weeks followed by a blinded extension phase of an additional 24 weeks for a total treatment period of 48 weeks. The primary efficacy outcome measures at week 24 will include the two-key histology-based endpoints of NASH resolution without worsening of fibrosis and the improvement of fibrosis $\geq$ 1 stage without worsening of NASH.

Completed target enrollment of 20 patients in open-label histology cohort in biopsy-confirmed fibrosis stage F2 – F3 NASH patients. These patients will be treated for approximately 20 weeks with 27 mg of BIO89-100 once weekly. The trial will provide an early opportunity to demonstrate BIO89-100’s potential benefits on histology endpoints.

Initiate Pharmacokinetic (PK) study in NASH patients with compensated cirrhosis (fibrosis stage F4) in 3Q21. The trial is designed to evaluate the PK, safety and tolerability of BIO89-100 administered as a single 30 mg dose to these NASH patients.

Report topline data from the Phase 2 ENTRIGUE trial of BIO89-100 in severe hypertriglyceridemia patients in the first half of 2022. ENTRIGUE is a multi-center, randomized, double-blind, placebo-controlled trial designed to evaluate safety and efficacy in patients who will receive BIO89-100 administered weekly (9mg, 18mg or 27 mg), every two weeks (36mg) or placebo.

Corporate Update. The company has further strengthened its leadership team in 2021 with key hires across different functions including manufacturing, clinical development, and human resources.

Second Quarter 2021 Financial Results

Cash Position. As of June 30, 2021, 89bio had cash, cash equivalents, and short-term investments of $171.0 million.

Research and Development (R&D) Expenses. R&D expenses were $15.6 million and $25.8 million for the three and six months ended June 30, 2021, respectively, compared to $8.4 million and $16.2 million for the comparable periods in 2020. 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 $4.9 million and $9.5 million for the three and six months ended June 30, 2021, respectively, compared to $3.2 million and $6.2 million for the comparable periods in 2020. 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 $20.7 million and $35.5 million for the three and six months ended June 30, 2021, respectively, compared to a net loss of $11.8 million and $22.3 million for the comparable periods in 2020. 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 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, efficacy, and tolerability 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. 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 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; and other risks and uncertainties identified in 89bio's Quarterly Report on Form 10-Q for the quarter ended March 31, 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 15,630	$ 8,443	$ 25,761	$ 16,221
General and administrative	4,921	3,230	9,529	6,154
Total operating expenses	20,551	11,673	35,290	22,375
Loss from operations	20,551	11,673	35,290	22,375
Other (expenses) income, net	172	98	215	(59)
Net loss before tax	20,723	11,771	35,505	22,316
Income tax expense (benefit)	—	—	—	(1)
Net loss	$ 20,723	$ 11,771	$ 35,505	$ 22,315
Comprehensive loss	$ 20,716	$ 11,771	$ 35,491	$ 22,315
Net loss per share, basic and diluted	$ 1.03	$ 0.85	$ 1.77	$ 1.62
Weighted-average shares used to compute net loss per share, basic and diluted	20,060,061	13,797,356	20,017,677	13,793,544

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

	June 30, 2021	December 31, 2020
Cash, cash equivalents and short term investments	$170,988	$ 204,654
Total assets	181,711	211,074
Total current liabilities	7,580	8,113
Total stockholders' equity	172,705	202,961

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