
**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 12, 2021

89bio, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39122
(Commission
File Number)

36-4946844
(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 12, 2021, 89bio, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 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 March 31, 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 May 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: May 13, 2021

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

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

- ENLIVEN Phase 2b trial in NASH expected to be initiated in 2Q21 -

SAN FRANCISCO, May 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 March 31, 2021.

“We are pleased to have received written guidance from the U.S. Food and Drug Administration (FDA) on our planned Phase 2b ENLIVEN trial design in non-alcoholic steatohepatitis (NASH),” said Rohan Palekar, Chief Executive Officer of 89bio. “We have a well-defined work plan ahead of us and are well-funded to reach multiple clinical and regulatory milestones which we expect will continue to validate BIO89-100’s potential in both NASH and severe hypertriglyceridemia (SHTG).”

Recent Highlights and Anticipated Milestones

- **Received written guidance from the FDA on the Phase 2b ENLIVEN trial design, planned to initiate in 2Q21:** 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 2 or 3 NASH and will utilize a liquid formulation. A total of approximately 200 patients will receive either one of two different weekly doses or a every two-week dose 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 ³ 1 stage without worsening of NASH.
- **Report topline data from the paired-biopsy, open-label histology cohort in NASH patients by year-end 2021:** This cohort is enrolling patients with biopsy-confirmed NASH and is expected to provide an early opportunity to demonstrate the benefits of BIO89-100 on histology endpoints.
- **Report topline data from the Phase 2 ENTRIGUE trial of BIO89-100 in severe hypertriglyceridemia patients in 2H21:** 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. ENTRIGUE was expanded recently with an additional cohort of patients on background fibrates. While the recent COVID-19 surge in Europe has resulted in enrollment challenges in certain geographies, we are working closely with our CRO and remain optimistic that enrollment will pick up in the trial.

First Quarter 2021 Financial Results

Cash Position. As of March 31, 2021, 89bio had cash, cash equivalents, and short-term investments of \$189.6 million.

Research and Development (R&D) Expenses. R&D expenses were \$10.1 million for the three months ended March 31, 2021, compared to \$7.8 million for the three months ended March 31, 2020. The increase in R&D expenses was primarily driven by increases in contract manufacturing and personnel expenses.

General and Administrative (G&A) Expenses. G&A expenses were \$4.6 million for the three months ended March 31, 2021, compared to \$2.9 million for the three months ended March 31, 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 \$14.8 million for the three months ended March 31, 2021, compared to a net loss of \$10.5 million for the three months ended March 31, 2020. The increase in net loss is primarily attributable to increased R&D expenses for our programs and increased G&A expenses associated with 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 and tolerability of BIO89-100, clinical development plans and timing for BIO89-100, including the Phase 2b ENLIVEN trial and Phase 3 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," "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; 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, 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 March 31, 2021 | Three months Ended March 31, 2020 |
|--|--|--|
| Operating expenses: | | |
| Research and development | \$ 10,131 | \$ 7,778 |
| General and administrative | 4,608 | 2,924 |
| Total operating expenses | <u>14,739</u> | <u>10,702</u> |
| Loss from operations | 14,739 | 10,702 |
| Other (expenses) income, net | (43) | 157 |
| Net loss before tax | 14,782 | 10,545 |
| Income tax expense (benefit) | — | (1) |
| Net loss | <u>\$ 14,782</u> | <u>\$ 10,544</u> |
| Comprehensive loss | <u>\$ 14,775</u> | <u>\$ 10,544</u> |
| Net loss per share, basic and diluted | <u>\$ 0.74</u> | <u>\$ 0.76</u> |
| Weighted-average shares used to compute net loss per share, basic and diluted | <u>20,010,412</u> | <u>13,789,786</u> |

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

| | March 31, 2021 | December 31, 2020 |
|---|-------------------|----------------------|
| Cash, cash equivalents and short-term investments | \$ 189,650 | \$ 204,654 |
| Total assets | 198,654 | 211,074 |
| Total current liabilities | 8,459 | 8,113 |
| Total stockholders' equity (deficit) | 190,195 | 202,961 |

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