
**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): December 18, 2019

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.)

**535 Mission Street, 14th Floor
San Francisco, CA 94105**
(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 December 18, 2019, 89bio, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2019. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits.* The following exhibit is being furnished herewith:

EXHIBIT INDEX

| <u>Exhibit No.</u> | <u>Description</u> |
|---------------------------|--------------------------------------------------------|
| 99.1 | Press Release, dated December 18, 2019 |

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: December 18, 2019

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



89bio Reports Third Quarter 2019 Financial Results and Provides Corporate Update

- Upsized Initial Public Offering raises \$97.6 million in gross proceeds -

- BIO89-100 continues to advance in Phase 1b/2a NASH study -

San Francisco, California, December 18, 2019 – 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, 2019.

“I am proud of what the 89bio team has accomplished with the successful completion of our IPO and the advancement of BIO89-100 in the Phase 1b/2a NASH study,” said Rohan Palekar, Chief Executive Officer of 89bio. “With our strengthened capital position, we look forward to continuing to advance BIO89-100 through clinical development in NASH and initiating development of BIO89-100 in our planned Phase 2 study in severe hypertriglyceridemia (SHTG) in 2020.”

Recent Highlights and Upcoming Milestones

Initiated Phase 1b/2a Trial for BIO89-100. In the third quarter of 2019, 89bio announced that it had initiated dosing in its proof of concept Phase 1b/2a clinical trial evaluating BIO89-100 in patients with nonalcoholic steatohepatitis (NASH) or patients with nonalcoholic fatty liver disease (NAFLD) and a high risk of NASH. Topline data from this study is expected in the second half of 2020.

Completed Upsized Initial Public Offering. 89bio completed a successful, upsized IPO on November 13, 2019 that priced at \$16.00 per share. The gross proceeds of the offering were approximately \$97.6 million which included the exercise in full by the underwriters of their option to purchase additional shares of common stock. The gross proceeds were calculated before deducting underwriting discounts and commissions and other offering expenses payable by 89bio.

Presented BIO89-100 Data at The Liver Meeting 2019. 89bio presented two posters related to BIO89-100 at The Liver Meeting 2019 in November 2019. The poster presentations included one on the results from the Phase 1a clinical trial in healthy volunteers and a second poster on preclinical data demonstrating the positive effect of BIO89-100 in reducing preference for sweetened water in obese monkeys.

Issued New Composition of Matter Patent. The United States Patent and Trademark Office issued US Patent 10,407,479, entitled “Mutant FGF-21 Peptide Pegylated Conjugates and Uses Thereof” to 89bio in September 2019. The patent covers the composition of BIO89-100 as well as methods for making and using BIO89-100 for a variety of therapeutic indications including NASH or metabolic syndrome. The patent expires in 2038 not including any potential patent term extension or regulatory exclusivity that would extend this date.

Third Quarter 2019 Financial Results

Cash Position. Cash, cash equivalents and marketable securities were \$16.2 million as of September 30, 2019, compared to \$11.3 million as of December 31, 2018. Subsequent to September 30, 2019, 89bio raised gross proceeds of \$97.6 million from its IPO before deducting underwriting discounts and commissions and other offering expenses.

Research and Development (R&D) Expenses. R&D expenses were \$6.7 million and \$14.2 million for the three and nine months ended September 30, 2019, respectively, compared to \$3.3 million and \$10.0 million for the same periods in 2018, respectively. The increase in R&D expenses was mainly driven by increases in contract manufacturing, clinical development and personnel related expenses.

General and Administrative (G&A) Expenses. G&A expenses were \$1.5 million and \$2.9 million for the three and nine months ended September 30, 2019, respectively, compared to \$0.5 million and \$0.8 million for the same periods in 2018, respectively. The increase in G&A expenses was primarily due to professional services and other costs associated with preparation to become a public company and personnel related expenses

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 enrollment, completion and outcome of 89bio's proof of concept Phase 1b/2a clinical trial evaluating BIO89-100 in patients with NASH or patients with NAFLD and a high risk of NASH; expectations regarding the development of BIO89-100 for SHTG and the related Phase 2 study; the unpredictable relationship between preclinical study results and clinical study results; liquidity and capital resources; and other risks and uncertainties identified in 89bio's filings with the SEC. 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, 2019 | Three Months Ended September 30, 2018 | Nine Months Ended September 30, 2019 | Period from January 18, 2018 (inception) to September 30, 2018 |
|-------------------------------------------------------------------------------|------------------------------------------------|------------------------------------------------|-----------------------------------------------|----------------------------------------------------------------------------|
| Operating expenses: | | | | |
| Research and development | \$ 6,680 | \$ 3,289 | \$ 14,154 | \$ 9,989 |
| General and administrative | 1,518 | 497 | 2,875 | 765 |
| Total operating expenses | 8,198 | 3,786 | 17,029 | 10,754 |
| Loss from operations | 8,198 | 3,786 | 17,029 | 10,754 |
| Other (income) expenses, net | 10,470 | 379 | 21,022 | 784 |
| Net loss before tax | 18,668 | 4,165 | 38,051 | 11,538 |
| Income tax expense | 57 | — | 86 | — |
| Net loss and comprehensive loss | \$ 18,725 | \$ 4,165 | \$ 38,137 | \$ 11,538 |
| Net loss per share, basic and diluted | \$ (30.63) | \$ (6.81) | \$ (62.39) | \$ (29.79) |
| Weighted-average shares used to compute net loss per share, basic and diluted | 611,226 | 611,226 | 611,226 | 387,334 |

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

| | September 30, 2019 | December 31, 2018 |
|------------------------------------|-------------------------------------|------------------------------------|
| Cash and cash equivalents | \$ 16,226 | \$ 11,257 |
| Total Assets | 18,354 | 11,369 |
| Total current liabilities | 22,579 | 4,353 |
| Convertible preferred stock/shares | 49,746 | 23,073 |
| Total stockholders' deficit | (53,971) | (16,057) |

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

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