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): July 30, 2024

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) 432-9270
(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 5, 2024, 89bio, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2024. 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, 2024, are being furnished to the Securities and Exchange Commission.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Director Appointment

On July 30, 2024, the board of directors (the "Board") of the Company appointed Charles McWherter, Ph.D. as a member of the Board. Dr. McWherter will serve as a Class I Director until the Company's 2026 Annual Meeting of Stockholders and until his successor is duly elected and qualified, effective immediately. The Board has not yet appointed Dr. McWherter to serve on a committee.

Dr. McWherter, age 69, served as the President of Research and Development and Chief Scientific Officer of CymaBay Therapeutics ("CymaBay") (formerly, Nasdaq: CBAY), a clinical-stage biopharmaceutical company, from November 2022 until it was acquired by Gilead Sciences, Inc. (Nasdaq: GILD) in March 2024. He previously served as Chief Scientific Officer of CymaBay from 2013 until November 2022, and as Senior Vice President, Research and Preclinical Development from 2007 to 2013. From 2003 to 2007, Dr. McWherter served as Vice President and head of the cardiovascular therapeutics areas of Pfizer Inc., a biopharmaceutical company ("Pfizer"). From 2001 to 2003, he served as Vice President of Drug Discovery at Sugen, Inc., a biopharmaceutical company acquired by Pfizer. Before joining Sugen, Inc., Dr. McWherter worked at Pharmacia Cop., a pharmaceutical and biotechnological company, and its predecessor companies, G.D. Searle & Co. and Monsanto Co. He previously served as Chairman of the Board of Directors of the Greater St. Louis Division of the American Heart Association and as an adjunct assistant professor of molecular biology and pharmacology at the Washington University School of Medicine. Dr. McWherter obtained his Ph.D. from Cornell University.

Dr. McWherter will be entitled to receive compensation in accordance with the Company's non-employee director compensation policy, which is described in the Company's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 17, 2024. Dr. McWherter has entered into the Company's standard form of indemnification agreement, a form of which was previously filed by the Company as Exhibit 10.1 to the Company's Form S-1 filed on October 11, 2019.

There are no arrangements or understandings between Dr. McWherter and any other persons pursuant to which he was elected as a director of the Company. There are no family relationships between Dr. McWherter and any director or executive officer of the Company, and he has no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

Committee Appointment

As previously disclosed in the Company's Form 8-K filed on April 17, 2024, Martin Babler was appointed as a member of the Board. The Board has appointed Mr. Babler to serve on the Audit Committee, effective August 2, 2024.

Item 7.01 Regulation FD Disclosure.

On August 5, 2024, the Company issued a press release announcing Dr. McWherter's appointment. A copy of the press release is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*. The following exhibits are being furnished herewith:

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated August 5, 2024
99.2	Press Release, dated August 5, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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 5, 2024

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

89bio Reports Second Quarter 2024 Financial Results and Corporate Updates

–The Phase 3 ENLIGHTEN-Fibrosis trial in patients with non-cirrhotic metabolic dysfunction-associated steatohepatitis (MASH) and the Phase 3 ENLIGHTEN-Cirrhosis trial in patients with compensated cirrhosis (F4) are enrolling patients–

–Phase 3 ENTRUST trial for patients with severe hypertriglyceridemia (SHTG) continues to enroll patients and topline data is expected in 2025–

SAN FRANCISCO, August 5, 2024 (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 cardiometabolic diseases, today reported its financial results for the second quarter ended June 30, 2024.

“We are thrilled to have initiated two pivotal Phase 3 trials addressing non-cirrhotic MASH (ENLIGHTEN-Fibrosis in F2-F3) and MASH with compensated cirrhosis (ENLIGHTEN-Cirrhosis in F4), which have the potential for accelerated approval using histology in both trials,” stated Rohan Palekar, CEO of 89bio. “In parallel to executing on three Phase 3 trials in both MASH and SHTG, we continue to take important steps forward that we believe will strategically enhance our preparedness for potential commercialization of pegozafermin including commercial manufacturing readiness. We believe in the prospects of pegozafermin in MASH, given the urgent medical need for more severe patients with advanced fibrosis and cirrhosis, in addition to the significant opportunity in SHTG to help patients who are refractory to current standard of care.”

Recent Highlights and Anticipated Milestones

Metabolic dysfunction-associated steatohepatitis (MASH)

- ENLIGHTEN-Cirrhosis, a Phase 3 trial of pegozafermin in MASH patients with compensated cirrhosis (F4), was initiated in the second quarter.
    - ENLIGHTEN-Cirrhosis is a global Phase 3, randomized, double-blind, placebo-controlled trial evaluating pegozafermin for the treatment of MASH patients with compensated cirrhosis (F4). The trial will enroll approximately 760 patients, who will be randomized in a 1:1 ratio to either receive 30mg of pegozafermin administered weekly or a placebo. A subset of the 760 patients will be evaluated at 24 months to assess fibrosis regression, potentially supporting an accelerated approval filing in the United States and conditional approval in Europe. The primary endpoint of fibrosis regression is defined as an improvement in fibrosis from F4 to an earlier stage. The primary endpoint for the final analysis will be a clinical outcome composite and is expected to form the basis for confirmatory or full approval.
- Data from the ENLIVEN Phase 2b trial was presented at the European Association for the Study of the Liver Congress (EASL) and was selected for the Poster Tour, a dedicated discussion session.

Severe Hypertriglyceridemia (SHTG)

- Enrollment is ongoing in ENTRUST, the Phase 3 trial evaluating the efficacy, safety and tolerability of pegozafermin in patients with SHTG.
- Topline results from this trial are expected to be reported in 2025.

Corporate Update

- Dr. Charles McWherter joined the Board of Directors, effective July 30, 2024. Dr. McWherter most recently served as Chief Scientific Officer and President of Research and Development of CymaBay Therapeutics, until it was acquired by Gilead Sciences in March 2024.

Second Quarter 2024 Financial Results

Cash Position. As of June 30, 2024, 89bio had cash, cash equivalents and marketable securities of $531.4 million, which does not include $19.4 million and $5.3 million of proceeds received by the Company subsequent to June 30, 2024 from the exercise of common stock warrants prior to June 30, 2024 and on July 1, 2024, respectively.

Research and Development (R&D) Expenses. R&D expenses were $44.9 million for the three months ended June 30, 2024, compared to $34.9 million for the three months ended June 30, 2023. The increase in R&D expenses was primarily driven by increases in clinical development, contract manufacturing, and personnel-related expenses, including stock-based compensation driven by higher headcount.

General and Administrative (G&A) Expenses. G&A expenses were $8.6 million for the three months ended June 30, 2024, compared to $7.2 million for the three months ended June 30, 2023. The increase in G&A expenses was primarily due to an increase in professional fees and personnel-related expenses including stock-based compensation driven by higher headcount.

Net Loss. 89bio reported a net loss of $48.0 million for the three months ended June 30, 2024, compared to a net loss of $38.4 million for the three months ended June 30, 2023. The increase in net loss was primarily attributable to increased R&D expenses to advance the company's Phase 3 clinical trials, increased G&A expenses associated with higher headcount, and expenses to support the Company's expanded operations. These increases in operating expenses were offset in part by the increase in net interest income and other to $6.5 million for the three months ended June 30, 2024 from $4.6 million for the three months ended June 30, 2023, mainly due to a change in interest rates and an increase in the average invested balances.

About 89bio

89bio is a clinical-stage biopharmaceutical company dedicated to the development of best-in-class therapies for patients with liver and cardiometabolic diseases who lack optimal treatment options. The company is in Phase 3 studies for its lead candidate, pegozafermin, for the treatment of metabolic dysfunction-associated steatohepatitis (MASH) and severe hypertriglyceridemia (SHTG). Pegozafermin is a specifically engineered, potentially best-in-class fibroblast growth factor 21 (FGF21) analog with unique glycoPEGylated technology that optimizes biological activity through an extended half-life. The company is headquartered in San Francisco. For more information, visit www.89bio.com or follow the company on LinkedIn.

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, statements regarding the therapeutic potential and utility, efficacy and clinical benefits of pegozafermin, the safety and tolerability profile of pegozafermin, trial designs, clinical development plans and timing for pegozafermin, including the topline results from the ENTRUST Phase 3 trial in SHTG, and enrollment in clinical trials, including enrollment of the Phase 3 ENLIGHTEN-Fibrosis trial and Phase 3 ENLIGHTEN-Cirrhosis trial in MASH and ENTRUST Phase 3 trial in SHTG. 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 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 and outcome of the ENLIGHTEN-Fibrosis Phase 3 trial and Phase 3 ENLIGHTEN-Cirrhosis trial in MASH and ENTRUST Phase 3 trial in SHTG; 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 it lead product candidate; competition from competing products; the impact of general economic, health, industrial or political conditions in the United States or internationally; the sufficiency of 89bio's capital resources and its ability to raise additional capital; and other risks and uncertainties identified in 89bio's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 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 and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 44,865	$ 34,915	$ 92,293	$ 57,221
General and administrative	8,571	7,214	18,420	13,432
Total operating expenses	53,436	42,129	110,713	70,653
Loss from operations	(53,436)	(42,129)	(110,713)	(70,653)
Interest expense	(874)	(894)	(1,737)	(2,969)
Interest income and other, net	6,473	4,630	13,029	6,393
Net loss before income tax	(47,837)	(38,393)	(99,421)	(67,229)
Income tax expense	(134)	—	(231)	—
Net loss	$ (47,971)	$ (38,393)	$ (99,652)	$ (67,229)
Comprehensive loss	$ (48,135)	$ (38,747)	$ (100,525)	$ (67,473)
Net loss per share, basic and diluted	$ (0.48)	$ (0.52)	$ (1.02)	$ (1.06)
Weighted-average shares used to compute net loss per share, basic and diluted	99,831,111	74,126,569	97,838,926	63,706,856

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

	June 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 531,384	$ 578,870
Total assets	582,138	596,269
Total current liabilities	41,653	29,611
Non current liabilities	25,568	30,352
Total stockholders' equity	514,917	536,306
Total liabilities and stockholders' equity	$ 582,138	$ 596,269

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89bio Appoints Charles McWherter, Ph.D., to its Board of Directors

SAN FRANCISCO, August 5, 2024 (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 cardiometabolic diseases, today announced the appointment of Dr. Charles McWherter to its Board of Directors, effective July 30, 2024. Dr. McWherter most recently served as Chief Scientific Officer and President of Research and Development of CymaBay Therapeutics until it was acquired by Gilead Sciences in March 2024.

“We are thrilled to welcome Charles, an esteemed industry leader, to our Board of Directors,” said Rohan Palekar, CEO of 89bio. “His expertise in drug development and profound knowledge of liver inflammation and fibrosis will be highly valuable as we advance our Phase 3 trials for non-cirrhotic and cirrhotic MASH, as well as our synergistic Phase 3 trial in SHTG. Charles joins us at a pivotal moment as we continue to develop pegozafermin in Phase 3 studies, aiming to establish it as a potential cornerstone therapy in MASH and SHTG. We are excited to collaborate with him and leverage his insights to further strengthen our robust Board of Directors.”

Dr. McWherter added, “I’m honored to join 89bio’s Board during this exciting phase of its journey. The ongoing Phase 3 studies for MASH patients with advanced fibrosis and compensated cirrhosis, following the promising results from the Phase 2b ENLIVEN trial, highlight the promising potential of pegozafermin. Its demonstrated benefits in fibrosis reduction, metabolic improvement, alongside its favorable tolerability and dosing convenience, suggest that pegozafermin has the potential to become a leading treatment option for MASH. I look forward to contributing to the company’s strategic goals and supporting its continued growth.”

Dr. Charles A. McWherter, Ph.D., most recently served as Chief Scientific Officer at CymaBay Therapeutics, Inc. since 2013 and served as its President of Research and Development since November 01, 2022 until its acquisition by Gilead Sciences for $4.3 billion in March 2024. Dr. McWherter served as Senior Vice President of Research and Preclinical Development at CymaBay Therapeutics from August 2007 to November 22, 2013. From 2003 to 2007, he served as Vice President and Head of the cardiovascular therapeutics areas of Pfizer Inc. Dr. McWherter served as Vice President and Head of Pfizer, Inc.’s cardiovascular research unit in St. Louis during which his organization built a portfolio of clinical candidates for hypertension, renal disease and thrombosis. Prior to Pfizer, Inc. he served as Vice President of Drug Discovery at Sugen Inc., from 2001 to 2003 where he developed and implemented a strategic plan integrating structure-based drug design with advanced compound screening. Before joining Sugen, Dr. McWherter worked at Pharmacia Corp. and its predecessor companies, G.D. Searle & Co. and Monsanto Co., for almost two decades, rising to the position of Director for oncology research. He has also served as Chairman of the Board of Directors of the Greater St. Louis Division of the American Heart Association. Dr. McWherter has published more than 45 scientific articles and holds many U.S. patents. He previously served as an adjunct assistant professor of molecular biology and pharmacology at the Washington University School of Medicine.

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