89bio Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Corporate Update

March 18, 2020

- BIO89-100 Phase 1b/2a NASH study on track for topline data in 2H20 -

- Initiation of Phase 2 SHTG study planned in 1H20 -

SAN FRANCISCO, March 18, 2020 (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 and full year ended December 31, 2019.

"The fourth quarter of 2019 capped an exciting year for 89bio where we reported positive topline data from our single ascending dose study of BIO89-100, scaled up our operations and manufacturing, and successfully completed an upsized initial public offering," said Rohan Palekar, Chief Executive Officer of 89bio. "We expect 2020 to be another transformative year with topline data from our Phase 1b/2a nonalcoholic steatohepatitis (NASH) study expected in the second half of 2020 and planned initiation of our Phase 2 study in severe hypertriglyceridemia (SHTG) in the first half of 2020."

Recent Highlights and Upcoming Milestones

Phase 1b/2a Trial of BIO89-100 in NASH. In September 2019, 89bio announced that it had initiated dosing in its proof of concept Phase 1b/2a clinical trial evaluating BIO89-100 in patients with NASH or patients with nonalcoholic fatty liver disease (NAFLD) and a high risk of NASH. Enrollment in the study has been progressing well with topline data expected in the second half of 2020.

Phase 2 Trial of BIO89-100 in SHTG. 89bio's Phase 2 clinical trial evaluating BIO89-100 in patients with SHTG, which has a planned primary endpoint of reduction from baseline in triglycerides, is currently on track for initiation in the first half of 2020 and topline data in the first half of 2021.

Completed Successful 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.

Fourth Quarter and Full Year 2019 Financial Results

Cash Position. As of December 31, 2019, 89bio had cash and cash equivalents of $93.4 million, including the net proceeds from our IPO.

Research and Development (R&D) Expenses. R&D expenses were $7.2 million and $21.4 million for the three months and year ended December 31, 2019, respectively, compared to $3.7 million and $13.7 million for the three months and year ended December 31, 2018, respectively. The increase for the year ended December 31, 2019 was primarily driven by increases in clinical development, contract manufacturing, pre-clinical, and personnel expenses.

General and Administrative (G&A) Expenses. G&A expenses were $2.4 million and $5.3 million for the three months and year ended December 31, 2019, respectively, compared to $0.7 million and $1.5 million for the three months and year ended December 31, 2018, respectively. The increase for the year ended December 31, 2019 was primarily due to costs incurred in preparation to be a public company and personnel related costs.

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 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; liquidity and capital resources; and other risks and uncertainties identified in 89bio's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, filed December 18, 2019 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 and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	Three months Ended December 31, 2019	Three months Ended December 31, 2018	Year Ended December 31, 2019	Period from January 18, 2018 (inception) to December 31, 2018
Operating expenses:				
Research and development	$ 7,192	$ 3,692	$ 21,346	$ 13,681
General and administrative	2,419	716	5,294	1,481
Total operating expenses	9,611	4,408	26,640	15,162
Loss from operations	9,611	4,408	26,640	15,162
Other (income) expenses, net	9,540	202	30,562	986
Net loss before tax	19,151	4,610	57,202	16,148
Income tax expense	132	28	218	28
Net loss and comprehensive loss	$ 19,283	$ 4,638	$ 57,420	$ 16,176
Net loss per share, basic and diluted	$ 2.58	$ 7.59	$ 24.49	$ 36.45
Weighted-average shares used to compute net loss per share, basic and diluted	7,486,577	611,226	2,344,191	443,767

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

	December 31, 2019	December 31, 2018
Cash and cash equivalents	$ 93,360	$ 11,257
Total Assets	95,553	11,369
Total current liabilities	5,609	4,353
Convertible preferred stock/shares	—	23,073
Total stockholders' equity (deficit)	89,944	(16,057)

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