# 89bio Reports Third Quarter 2020 Financial Results and Provides Corporate Update

November 10, 2020

*– Updated clinical data from BIO89-100's Phase 1b/2a NASH trial to be presented as a late-breaking poster at upcoming AASLD Liver Meeting –*

*– Planning to initiate the Phase 2b trial as part of the Phase 2b/3 program in NASH in 1H21 –*

*– Topline results from BIO89-100's Phase 2 SHTG trial expected in 2H21 –*

SAN FRANCISCO, Nov. 10, 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 ended September 30, 2020.

"We have made significant advances across our development programs this quarter. We initiated our Phase 2 trial in SHTG and in NASH we announced impressive results from our Phase 1b/2a trial that further support our view that BIO89-100 could be the best-in-class FGF21 analog within a class that could be the mainstay of treatment for NASH," said Rohan Palekar, chief executive officer of 89bio. "BIO89-100 delivers a compelling risk-benefit profile by improving liver pathology and addressing the underlying metabolic issues while balancing these benefits with favorable tolerability and the dosing convenience necessary for adoption and compliance. We are moving forward with a comprehensive clinical development program for BIO89-100, including initiating the Phase 2b trial in the first half of 2021 and initiating in parallel a new histology cohort in the near term as part of the Phase 1b/2a trial. The data from this new cohort will provide additional supporting information on the efficacy of BIO89-100 and is not expected to affect our planned timing for initiation of the Phase 2b/3 program."

**Recent Highlights**

- Reported positive Phase 1b/2a clinical data evaluating BIO89-100 in NASH. Results observed add to a growing body of evidence demonstrating the promise of BIO89-100 for the treatment of NASH. Results showed a strong efficacy and favorable tolerability profile with weekly and every two-week dosing. Specifically, the data demonstrated
    - Statistically significant reductions in liver fat of up to 70% versus placebo with 43% of patients at the highest dose achieving normal liver fat content of <5%.
    - Up to 88% and 71% of BIO89-100 patients achieved ≥30% and ≥50% liver fat reduction respectively.
    - Significant benefit in markers of liver injury and fibrosis, with up to 44% reduction in alanine aminotransferase (ALT) and up to 27% reduction in Pro-C3. A 35 U/L decrease in patients with high ALT was observed.
    - Significant improvements in key lipid markers—triglycerides, non-HDL, and LDL. Reductions in TGs was more pronounced in patients who had higher levels of TGs at baseline.
    - Improvements in the spectrum of metabolic marker data including HOMA-IR, glucose, HbA1c, weight and adiponectin.
    - Overall, BIO89-100 demonstrated a favorable safety and tolerability profile.
        - Well tolerated across tested dose range with few adverse events that occurred in ≥ 10% of subjects.
        - Very low frequency of gastrointestinal (GI) events was observed with a similar profile to placebo.
        - No hypersensitivity or tremor were observed and no adverse effects on heart rate or blood pressure were observed.
- Initiated a Phase 2 trial of BIO89-100 in patients with SHTG.
- Completed underwritten public offerings of common stock in the third quarter, resulting in an aggregate of approximately $157.7 million in estimated net proceeds.

**Expected Upcoming Milestones**

- Present updated clinical data from the Phase 1b/2a trial as a late-breaking poster at AASLD's The Liver Meeting® 2020 being held November 13-16 highlighting BIO89-100's compelling clinical profile and preclinical data covering BIO89-100's receptor activation profile.
- Initiate a new open-label histology cohort as part of the Phase 1b/2a trial of BIO89-100 in NASH. This new cohort will enroll approximately 20 patients with biopsy-confirmed NASH that will be treated for 20 weeks with 27mg QW BIO89-100.

- The new cohort will provide an early opportunity to demonstrate BIO89-100's benefits on histology endpoints.
- This cohort is planned to start in the near term with results expected by the end of 2021.

- Initiate a Phase 2b NASH trial as part of the Phase 2b/3 program in the first half of 2021.
- Report topline data from the Phase 2 trial of BIO89-100 in SHTG in the second half of 2021.

**Third Quarter 2020 Financial Results**

**Cash Position.** As of September 30, 2020, 89bio had cash, cash equivalents and short-term investments of $219.2 million.

**Research and Development (R&D) Expenses.** R&D expenses were $11.2 million for the three months ended September 30, 2020, compared to $6.7 million for the three months ended September 30, 2019. The increase in R&D expenses was primarily driven by increases in clinical development, contract manufacturing, pre-clinical development and personnel expenses.

**General and Administrative (G&A) Expenses.** G&A expenses were $3.2 million for the three months ended September 30, 2020, compared to $1.5 million for the three months ended September 30, 2019. The increase in G&A expenses was primarily due to an increase in costs related to professional services and personnel expenses.

**Net Loss.** 89bio reported a net loss of $14.6 million for the three months ended September 30, 2020, compared to a net loss of $18.7 million for the three months ended September 30, 2019. The decrease in net loss is primarily attributable to increased R&D expenses for our programs and increased G&A expenses associated with our becoming a public company offset by a non-recurring charge in 2019 for accounting of preferred stock liability.

**About the Phase 1b/2a Study**

89bio's Phase 1b/2a trial with BIO89-100 in patients with NASH was a multicenter, randomized, double-blind, placebo-controlled, multiple ascending dose-ranging trial. It was designed to assess the safety, tolerability, and PK properties of BIO89-100 as well as change in liver fat measured by MRI-PDFF and key biomarker assessments in subjects with biopsy-proven NASH with fibrosis or subjects with phenotypical NASH (PNASH). PNASH was defined as patients with steatosis greater than 10% who have central obesity and Type 2 diabetes or central obesity and evidence of liver injury. Both populations that were enrolled had similar disease characteristics at baseline. A total of 81 subjects were randomized to receive weekly or every two weeks subcutaneous dosing of BIO89-100 or placebo for up to 12 weeks. Results showed robust reductions in liver fat and key liver and metabolic markers with a favorable tolerability profile. The positive results were observed with weekly and every two-week dosing.

**About BIO89-100**

BIO89-100 is a glycoPEGylated analog of FGF21 being developed for the treatment of NASH. 89bio has optimally engineered BIO89-100 using a proprietary glycoPEGylation technology to balance efficacy and longer dosing interval. Recent Phase 1b/2a data show BIO89-100 demonstrated a favorable safety and tolerability profile and robust reductions in liver fat and key lipid markers when dosed weekly (QW) or once every two weeks (Q2W). BIO89-100 is also being developed for the treatment of severe hypertriglyceridemia (SHTG) and is currently in a Phase 2 trial.

**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, 89bio's expectations and guidance regarding its business plans and objectives for BIO89-100, including the therapeutic potential and clinical benefits thereof, as well as the safety and tolerability of BIO89-100 and future clinical development plans; its plans to initiate an open-label histology cohort as part of the Phase 1b/2a trial of BIO89-100 in NASH; expectations regarding BIO89-100's development path with regulatory authorities and timeline; the expected timing of 89bio's Phase 2b trial; and expectations regarding 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 an open-label histology cohort and Phase 2b trial; 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, 2019 and its Quarterly Report on Form 10-Q for the quarter ended June 30, 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.

**Condensed Consolidated Statement of Operations and Comprehensive Loss**
**(Unaudited)**
**(In thousands, except share and per share amounts)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Operating expenses: | | | | |
| Research and development | $ 11,208 | $ 6,680 | $ 27,429 | $ 14,154 |
| General and administrative | 3,225 | 1,518 | 9,379 | 2,875 |
| Total operating expenses | 14,433 | 8,198 | 36,808 | 17,029 |
| Loss from operations | 14,433 | 8,198 | 36,808 | 17,029 |
| Other expenses, net | 146 | 10,470 | 87 | 21,022 |
| Net loss before tax | 14,579 | 18,668 | 36,895 | 38,051 |
| Income tax expense | 24 | 57 | 23 | 86 |
| Net loss | $ 14,603 | $ 18,725 | $ 36,918 | $ 38,137 |
| Comprehensive loss | $ 14,606 | $ 18,725 | $ 36,921 | $ 38,137 |
| Net loss per share, basic and diluted | $ 0.86 | $ 30.63 | $ 2.49 | $ 62.39 |
| Weighted-average shares used to compute net loss per share, basic and diluted | 16,884,244 | 611,226 | 14,809,131 | 611,226 |

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

| | September 30, 2020 | December 31, 2019 |
|---|---|---|
| Cash, cash equivalents and short-term investments | $ 219,153 | $ 93,335 |
| Total assets | 223,428 | 95,553 |
| Total current liabilities | 9,424 | 5,609 |
| Total stockholders' equity | 214,004 | 89,944 |

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