89bio Reports Second Quarter 2022 Financial Results and Provides Corporate Update

August 11, 2022

- Reported positive topline results from ENTRIGUE Phase 2 trial of pegozafermin in severe hypertriglyceridemia patients; initiation of Phase 3 trial expected in the first half of 2023 -

- ENTRIGUE data to be presented as a late-breaker at European Society of Cardiology Congress 2022 -

- ENLIVEN Phase 2b NASH trial enrollment completion expected in the third quarter of 2022 followed by topline data in the first quarter of 2023 -

- Completed underwritten offering, raising approximately $94.5 million in gross proceeds -

SAN FRANCISCO, Aug. 11, 2022 (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 June 30, 2022.

“In the second quarter we reported positive topline results from the ENTRIGUE Phase 2 trial of pegozafermin in patients with severe hypertriglyceridemia (SHTG) and further strengthened our financial resources, which we believe will carry us through key value-driving milestones as we transition into a late-stage company,” said Rohan Palekar, Chief Executive Officer of 89bio. “We are well positioned to drive our clinical development program forward and build on the encouraging data that underscore pegozafermin’s broad metabolic effects and favorable safety and tolerability profile. The results from the ENTRIGUE Phase 2 trial position pegozafermin as potentially the first FGF21 analog to market and bring us one step closer to providing a differentiated therapeutic option for the treatment of cardio-metabolic and liver disease. We plan to present ENTRIGUE data at the upcoming European Society of Cardiology Congress and remain on track to initiate our Phase 3 trial in SHTG in the first half of 2023 pending our end of Phase 2 meeting with the FDA. Additionally, we expect to report topline data from our Phase 2b ENLIVEN trial in NASH in the first quarter of 2023.”

Recent Highlights and Anticipated Milestones

SHTG

Data from the Phase 2 ENTRIGUE trial of pegozafermin to be presented as a late-breaker at European Society of Cardiology (ESC) Congress 2022.

- Data to be presented by Deepak L. Bhatt, MD, MPH, Brigham and Women’s Hospital and Harvard Medical School during the Late-Breaking Science-Innovation in Drug Treatment session on Friday, August 26th at 6 a.m. ET/ 3 a.m. PT/ 12 p.m. CEST.

Reported positive topline data for the Phase 2 ENTRIGUE trial of pegozafermin in SHTG patients; initiation of Phase 3 trial expected in the first half of 2023.

- Treatment with pegozafermin resulted in clinically meaningful and statistically significant reductions in triglycerides (TG) from baseline across all doses (with a 63% reduction in the highest dosing group; $p<0.001$), statistically significant improvements in key markers of cardiovascular risk (non-HDL-C and apo B), reductions in liver fat, and improvements in glycemic control markers.
- Results were consistent in patients not on background therapy or on background therapy (consistent results on statins or statin combos, prescription fish oils, and fibrates) and across various subgroups, including those with the greatest disease burden, such as patients with type 2 diabetes and those with baseline TG levels ≥750 mg/dL.
- Consistent with prior studies, pegozafermin was generally well tolerated with a favorable safety profile across doses. The most commonly reported treatment-related adverse events were nausea, diarrhea, and injection site reactions, all which were classified as mild or moderate. No tremors or transaminase elevation adverse events were observed. There were no drug-related serious adverse events and two Grade 2 treatment-related discontinuations.

NASH

Expect to complete enrollment in the third quarter of 2022 with over 200 patients in the ENLIVEN Phase 2b trial; topline data expected in the first quarter of 2023.

- ENLIVEN is a Phase 2b trial designed to evaluate the safety and efficacy of weekly or every two-week pegozafermin for the treatment of patients with fibrosis stage F2 - F3 NASH and NAS ≥ 4.

Presented additional pegozafermin data at the European Association for the Study of the Liver (EASL) International Liver Congress™ 2022.

- Three poster presentations were showcased:
  - Results from an open-label expansion cohort in the Phase 1b/2a proof-of-concept study evaluating pegozafermin for the treatment of NASH demonstrated clinically meaningful improvements on HbA1c, adiponectin, and lipid parameters with notable body weight reduction and favorable safety and tolerability observed.
  - Treatment with pegozafermin in advanced fibrosis patients, 85% of which had type 2 diabetes and were on background therapy for diabetes, hyperlipidemia or both, demonstrated significant metabolic benefits in addition to robust beneficial effects on the liver, with favorable safety and tolerability. Together, these data suggest that pegozafermin has the potential to address broader cardiometabolic risks in addition to liver related outcomes.
  - Treatment with pegozafermin demonstrated a robust pharmacokinetic/pharmacodynamic effect independent of NASH fibrosis stage, with a favorable safety and tolerability profile observed following a single 30-mg dose. These findings highlight the feasibility of assessing treatment response in F4 patients with compensated hepatic function without requiring a dose adjustment.

Corporate Updates:

- Completed underwritten public offering of common stock, warrants to purchase shares of common stock and pre-funded warrants to purchase shares of common stock, raising approximately $94.5 million in gross proceeds.

Second Quarter 2022 Financial Results

Cash Position. As of June 30, 2022, 89bio had cash, cash equivalents, and short-term investments of $139.3 million. This includes $28.2 million in proceeds from pre-funded warrants that the company received prior to the closing of the offering. Pro-forma cash as of June 30, 2022 was approximately $200 million, including the remainder of the net proceeds received from the offering.

Research and Development (R&D) Expenses. R&D expenses were $19.7 million for the three months ended June 30, 2022, compared to $15.6 million for the three months ended June 30, 2021. The increase in R&D expenses was primarily driven by increases in clinical development costs related to our ongoing clinical trials and personnel-related expenses, offset in part by a decrease in contract manufacturing costs and lower overhead costs.

General and Administrative (G&A) Expenses. G&A expenses were $5.1 million for the three months ended June 30, 2022, compared to $4.9 million for the three months ended June 30, 2021. The increase in G&A expenses was primarily due to an increase in costs related to personnel expenses.

Net Loss. 89bio reported a net loss of $25.1 million for the three months ended June 30, 2022, compared to $20.7 million for the three months ended June 30, 2021. 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 dedicated to the development of best-in-class therapies for patients with liver and cardiometabolic diseases who lack optimal treatment options. The company is focused on rapidly advancing its lead candidate, pegozafermin, through clinical development for the treatment of non-alcoholic steatohepatitis (NASH) 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 with operations in Herzliya, Israel. 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, the therapeutic potential and clinical benefits of pegozafermin, the safety and tolerability profile of pegozafermin, clinical development plans and timing for pegozafermin, including the Phase 2b ENLIVEN trial, the expected trial design for the ENLIVEN trial, including patient enrollment, dosing schedules and trial endpoints, the timing for topline data for the ENLIVEN trial, the timing for the initiation of the Phase 3 trial in SHTG and expectations regarding the time period over which 89bio's capital resources will be sufficient to fund its anticipated operations. 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 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 Phase 2b ENLIVEN trial in NASH; expectations regarding the timing of topline data; expectations regarding the initiation of the 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 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; 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 June 30, 2022 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 19,686	$ 15,630	$ 39,535	$ 25,761
General and administrative	5,052	4,921	10,311	9,529
Total operating expenses	24,738	20,551	49,846	35,290
Loss from operations	24,738	20,551	49,846	35,290
Other expenses, net	316	172	772	215
Net loss before tax	25,054	20,723	50,618	35,505
Income tax expense	—	—	1	—
Net loss	$ 25,054	$ 20,723	$ 50,619	$ 35,505
Comprehensive loss	$ 25,116	$ 20,716	$ 50,873	$ 35,491
Net loss per share, basic and diluted	$ 1.23	$ 1.03	$ 2.49	$ 1.77
Weighted-average shares used to compute net loss per share, basic and diluted	20,351,560	20,060,061	20,345,521	20,017,677

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

	June 30, 2022	December 31, 2021
Cash, cash equivalents and short-term investments	$ 139,350	$ 150,745
Total assets	147,595	162,422
Total current liabilities	26,899	19,537
Non current liabilities	40,511	16,928
Total stockholders' equity	80,185	125,957
Total liabilities and stockholders' equity	$ 147,595	$ 162,422

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