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): September 14, 2020

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) 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 7.01 Regulation FD Disclosure.

On September 14, 2020, 89bio, Inc. (the "Company") issued a press release titled "89bio Announces Positive Topline Results from its Phase 1b/2a Trial of BIO89-100 in NASH." A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01, including Exhibits 99.1 and 99.2, shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act or the Exchange Act, except as shall be expressly set forth in such registration statement or filing.

Item 8.01 Other Events.

The Company from time to time presents and/or distributes to the investment community slide presentations to provide updates and summaries of its business. A copy of the BIO89-100 Phase 1b/2a Topline Results slide presentation is being furnished herewith as Exhibit 99.2 to this Current Report on Form 8-K. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits*.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated September 14, 2020
99.2	Slide Presentation, dated September 14, 2020

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: September 14, 2020

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

89bio Announces Positive Topline Results from its Phase 1b/2a Trial of BIO89-100 in NASH

All dose groups achieved statistically significant reductions in liver fat, with relative reductions of up to 60% versus baseline and up to 70% versus placebo

Favorable safety and tolerability profile

Strong efficacy profile with every two-week dosing

Statistically significant improvements in markers of liver injury and key lipid parameters

Conference call and webcast scheduled for 8:30 am ET (5:30 am PT) today

SAN FRANCISCO, Sept. 14, 2020 — 89bio, Inc. (Nasdaq: ETNB) today announced positive topline results from its Phase 1b/2a trial with BIO89-100, an investigational FGF21 analog, in patients with nonalcoholic steatohepatitis (NASH). All dose groups demonstrated significant reductions in liver fat at week 13, with relative reductions up to 60% versus baseline and up to 70% versus placebo, as measured by magnetic resonance imaging – proton density fat factor (MRI-PDFF). A significant proportion of subjects responded to therapy with up to 88% and 71% of subjects achieving a ³30% or a ³50% reduction in liver fat versus baseline, respectively. Treatment with BIO89-100 also resulted in significant improvements in liver transaminases, with a 35 U/L decrease in ALT from baseline in subjects with elevated baseline levels, and reductions in ProC3, a marker of fibrosis. Importantly, BIO89-100 is the first FGF21 analog to show benefit in subjects with NASH with every two-week dosing. BIO89-100 was well tolerated at all doses with low incidence of adverse events that occurred in ³10% of subjects and very low frequency of gastrointestinal (GI) events relative to placebo.

The MRI-PDFF results are summarized in the table below:

		BIO89-100 (once-weekly)				BIO89-100 (once every two weeks)	
Measure	Placebo (n= 19)	3mg (n= 6)	9mg (n= 12)	18mg (n= 11)	27mg (n= 10)	18 mg (n= 14)	36 mg (n= 9)
Relative reduction/increase in liver fat vs. baseline	+10%	-37%**	-50%**	-36%**	-60%**	-43%**	-50%**
Relative reduction in liver fat vs. placebo		-47%**	-59%**	-46%**	-70%**	-53%**	-60%**
Proportion of subjects with ³30% relative reduction in liver fat	0%	60%*	82%**	60%**	86%**	69%**	88%**
Absolute change in liver fat vs. baseline	+1.4	-7.5%*	-10%**	-7.5%**	-13.5%**	-9.0%**	-9.7%**

**p<0.01; **p<0.001 vs. placebo. n based on subjects randomized. Least square mean based on MRI analysis set (N=75) and responder analysis based on subjects with MRI at Week 13. Levels of liver fat in the BIO89-100 and placebo groups at baseline were 21.2% (on a pooled basis) and 21.8%, respectively. Baseline liver fat levels and changes in liver fat were similar in biopsy-confirmed NASH and phenotypical NASH subjects.*

"The robust reductions in liver fat and key liver markers add to a growing body of evidence demonstrating the promise of BIO89-100 for the treatment of NASH and cardio-metabolic diseases," said Rohit Loomba, MD, MHSc, Director of the UC San Diego NAFLD Research Center and Director of

Hepatology at UC San Diego School of Medicine. “The magnitude of ³30% relative reduction in liver fat has been shown in the literature to translate into higher odds of histologic response and potential to deliver clinically meaningful benefit to patients with NASH.”

BIO89-100 had a favorable safety and tolerability profile with no deaths or serious adverse events related to treatment. The frequency of GI events compared favorably to placebo with diarrhea (BIO89-100 12.7% vs. placebo 22.2%) and nausea (BIO89-100 7.9% vs. placebo 16.7%) being the only GI events occurring in ³5% of BIO89-100-treated subjects. The only treatment-related adverse event that occurred in ³10% of all BIO89-100-treated subjects was mild, increased appetite (15.9%) consistent with other investigational FGF21 analogs. No adverse effects on heart rate or blood pressure were observed.

Treatment with BIO89-100 resulted in significant reductions in triglycerides (up to 28%; $p < 0.05$), non-HDL (up to 16%; $p<0.01$) and LDL-C (up to 16%; $p<0.05$). Triglycerides were reduced to a greater extent in subjects with elevated triglycerides at baseline (TG³200 mg/mL), and 53% of the BIO89-100 subjects in this group normalized triglyceride levels versus 0% in the placebo group. BIO89-100 also demonstrated significant increases in the insulin-sensitizing hormone adiponectin (up to 61%; $p<0.001$).

This study was a randomized, double-blind, placebo-controlled, multiple ascending dose-ranging trial that enrolled 81 biopsy-proven NASH or phenotypical NASH (PNASH) subjects. A total of 81 subjects were randomized to receive weekly or every two-week dosing of BIO89-100 or placebo for up to 12 weeks. Key endpoints assessed were safety, tolerability, and PK of BIO89-100 as well as change in liver fat measured by MRI-PDFF and other metabolic markers.

“The favorable safety and tolerability profile of BIO89-100 together with potential best-in-class dosing regimen could be important considerations for a NASH therapeutic given the chronic and generally asymptomatic nature of the disease,” said Hank Mansbach, MD, Chief Medical Officer, 89bio. “These factors, combined with improvements in liver fat and metabolic markers, unequivocally support advancing the clinical development of BIO89-100 in NASH and reinforce our confidence in the severe hypertriglyceridemia program. We plan to initiate our next trial in NASH in the first half of 2021.”

“We are pleased with this data that highlight BIO89-100’s promising clinical profile and its potential to be a leading FGF21 analog, in a class with the potential to become a backbone treatment approach for NASH,” said Rohan Palekar, Chief Executive Officer, 89bio. “I would like to sincerely thank all of our investigators, clinical sites, subjects, and employees who supported the trial, especially amid a pandemic that has severely impacted the global healthcare system in an unprecedented manner.”

Conference Call/Webcast Details

89bio will host a conference call and webcast with slides at 8:30am PT (5:30am PT) this morning, September 14. Details for the live conference call are as follows: Domestic – (833) 570-1145; International – (914) 987-7092; and Passcode - 5064866. To access the live webcast and slides, please visit “Events and Presentations” under the “Investors” section of 89bio’s website at https://ir.89bio.com/events-and-presentations. Following the live audio webcast, a replay will be available on the company’s website for 90 days.

About NASH

NASH is the most advanced stage of nonalcoholic fatty liver disease (NAFLD). It is a complex metabolic disorder that causes fat buildup in the liver, as well as inflammation and eventually fibrosis, and it can worsen to cirrhosis and liver failure. NASH affects more than 16 million adults in the United States, and

by 2030 its prevalence is predicted to increase by 63 percent. The exact cause of NASH is unknown, but it is commonly found in people with obesity and type 2 diabetes. While there are currently no approved treatments, the biopharmaceutical industry is actively involved in addressing this unmet medical need.

About the Phase 1b/2a Study

This clinical study 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 patients 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.

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 or once every two weeks. 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 is BIO89-100, is a specifically engineered glycoPEGylated analog of FGF21. BIO89-100 is being developed for the treatment of NASH and severe hypertriglyceridemia (SHTG). 89bio is headquartered in San Francisco with operations in Herzliya, Israel. For more information, visit www.89bio.com.

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; 89bio's statements regarding the Phase 1b/2a Trial of BIO89-100; and the potential impact of COVID-19 on patient retention, strategy, future operations and clinical trials, including the anticipated timing of the next trial in NASH. 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 the next trial in NASH; 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; regulatory developments in the United States; 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.

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Exhibit 99.2

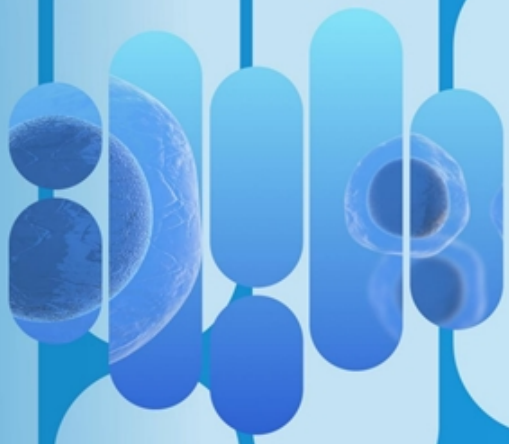
89bio

Powerful Science
Meaningful Medicines
Changing Lives

BIO89-100
Phase 1b/2a Topline Results

Nasdaq: ETNB

September 14, 2020



Disclaimer

Cautionary Note Regarding Forward-Looking Statements

This presentation contains "forward-looking statements" within the meaning of the federal securities laws, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. Other than statements of historical facts, all statements included in this presentation are forward-looking statements, including statements concerning our plans, objectives, goals, strategies, future events, future revenues or performance, financing needs, plans or intentions relating to product candidates, estimates of market size, business trends, the anticipated timing, costs, design and conduct of our planned clinical trials for BIO89-100, our only product candidate, the association of preclinical data with potential clinical benefit, the timing of anticipated milestones, the effect of the COVID-19 pandemic on our clinical trials and business operations, the timing and likelihood of regulatory filings and approvals for BIO89-100, our ability to commercialize BIO89-100, if approved, the pricing and reimbursement of BIO89-100, if approved, the potential to develop future product candidates, our ability to scale up manufacturing, the potential benefits of strategic collaborations and our intent to enter into any strategic arrangements, the timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated product development efforts and our liquidity and capital resources. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this presentation including those described more fully our most recent Form 10-K and Form 10-Q under the caption "Risk Factors" and elsewhere in such report and in other subsequent disclosure documents filed with the SEC.

We cannot assure you that we will realize the results, benefits or developments that we expect or anticipate or, even if substantially realized, that they will result in the consequences or affect us or our business in the way expected. Forward-looking statements are not historical facts, and reflect our current views with respect to future events. Given the significant uncertainties, you should evaluate all forward-looking statements made in this presentation in the context of these risks and uncertainties and not place undue reliance on these forward-looking statements as predictions of future events. All forward-looking statements in this presentation apply only as of the date made and are expressly qualified in their entirety by the cautionary statements included in this presentation. We disclaim any intent to publicly update or revise any forward-looking statements to reflect subsequent events or circumstances, except as required by law.

We obtained the industry, market and competitive position data used throughout this presentation from our own internal estimates and research, as well as from industry and general publications, and research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of the industry and market, which we believe to be reasonable. In addition, while we believe the industry, market and competitive position data included in this presentation is reliable and based on reasonable assumptions, we have not independently verified any third-party information, and all such data involve risks and uncertainties and are subject to change based on various factors.

BIO89-100: Promising Benefit-Risk Profile with Convenient Dosing

EFFICACY RESULTS

- Significant benefits across key liver parameters observed across all dose groups
  - Up to **60%** reduction in liver fat versus baseline and up to **70%** versus placebo
  - Up to **44%** reduction in ALT (**35** U/L decrease in high ALT group)
  - Up to **27%** reduction in Pro-C3
- Significant responder rates— Up to **88%** and **71%** of subjects showed fat reduction ≥30% and ≥50%
- Significant improvements in lipids—triglycerides, non-HDL and LDL

SAFETY RESULTS & TOLERABILITY

- Well tolerated at all doses with low incidence of adverse events that occurred in ≥ 10% of subjects
- Very low frequency of gastrointestinal events and similar profile to placebo
- No hypersensitivity or tremor observed: no adverse effects on heart rate or blood pressure

POTENTIAL BEST-IN-CLASS DOSING REGIMEN

- Results seen with weekly and two-week dosing

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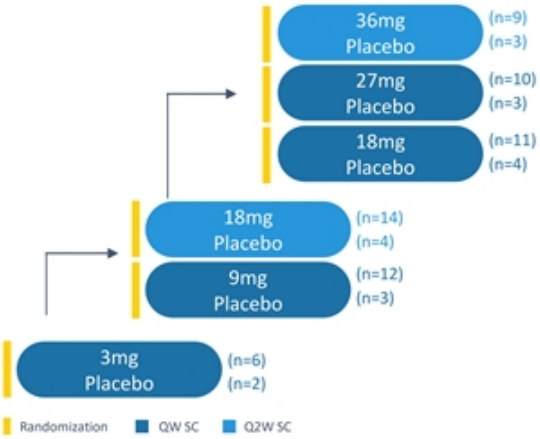
BIO89-100-002: Trial Design



- 12-week treatment duration + 4-week safety follow up
- Placebo (n=19) combined across cohorts for analysis

KEY INCLUSION CRITERIA

- NASH* or phenotypic NASH (PNASH)#
- PDFF≥10%

*Subjects with biopsy-proven F1-3

#Central obesity plus T2DM or evidence of liver injury

KEY TRIAL ENDPOINTS

- Safety, PK
- Relative changes in liver fat
- Serum lipids, liver and metabolic markers

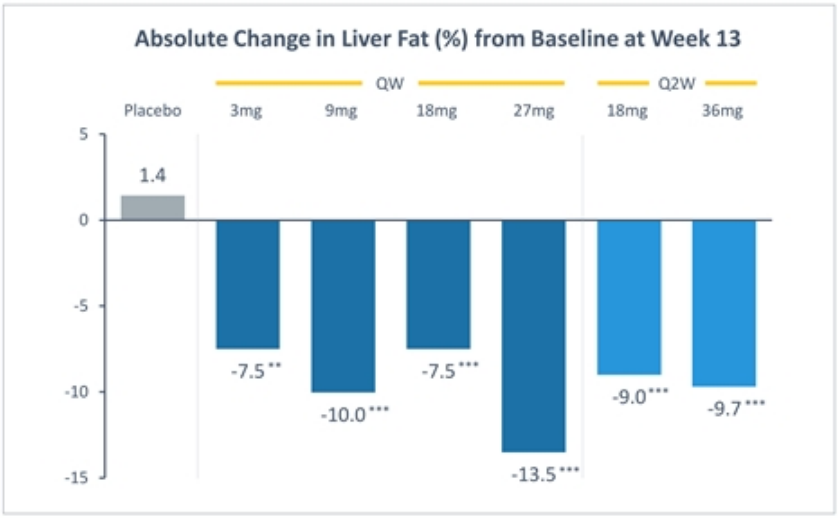
- Randomized, pharmacodynamic (PD) and safety analysis set n=81; Study completers n=71
- MRI analysis set n=75 (subjects with post-baseline MRI)

Baseline Characteristics

Parameter Mean or %	Placebo (n=19)	Pooled BIO89-100 (n=62)	3mg QW (n=6)	9mg QW (n=12)	18mg QW (n=11)	27mg QW (n=10)	18mg Q2W (n=14)	36mg Q2W (n=9)
Age (years)	52.6	51.7	56.1	49.5	51.5	52.0	51.2	52.5
Male/Female	36.8%	38.7%	16.7%	50%	27.3%	20%	28.6%	88.9%
Weight (kg)	93.6	93.6	87.9	87.2	87.1	94.0	101.5	101.1
BMI (kg/m^2)	33.8	34.8	34.3	32.7	32.8	36.8	37.0	34.8
Type 2 Diabetes	63.2%	40.3%	83.3%	33.3%	63.6%	40.0%	21.4%	22.2%
ALT (U/L)	38.8	42.3	45.0	32.8	38.4	53.3	39.1	50.4
AST (U/L)	29.0	31.5	34.5	22.8	30.9	39.0	28.8	38.1
MRI-PDFF (%)	21.8	21.2	22.4	21.4	19.3	22.0	21.6	20.9

Baseline characteristics were similar between NASH (n=15) and PNASH (n=66) subjects

BIO89-100 Significantly Reduces Liver Fat Across All Dose Groups

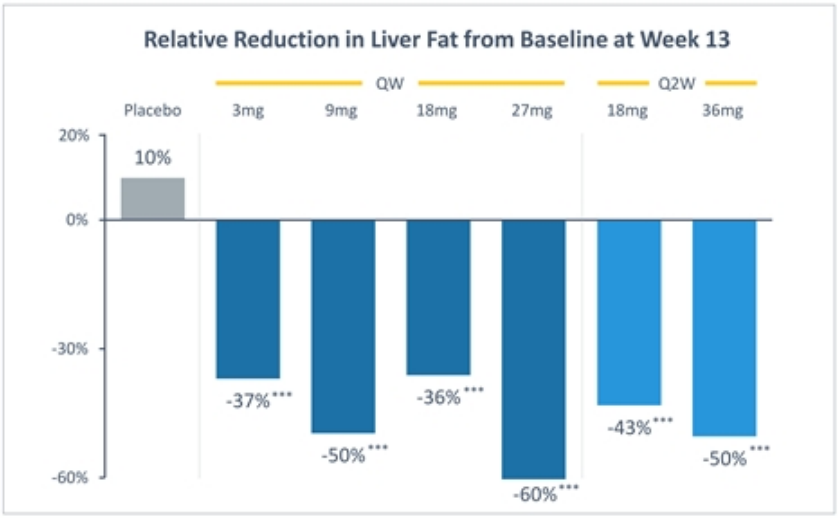


- Up to **43%** of subjects normalized their liver fat (<5%)
- BIO89-100 significantly reduced liver volume up to 15%
- Changes in liver fat were similar between NASH and PNASH subjects

89bio

MRI Analysis Set; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo

BIO89-100 Reduces Liver Fat in Significant Percentage of Subjects



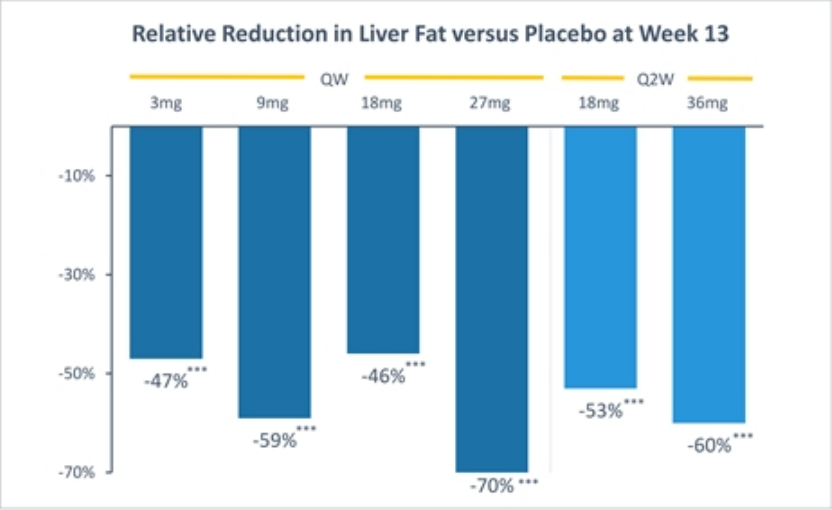
Proportion of Subjects with ≥30% Relative Reduction in Liver Fat

	Placebo	0%
QW	3mg	60%**
QW	9mg	82%***
QW	18mg	60%**
QW	27mg	86%***
Q2W	18mg	69%**
Q2W	36mg	88%***

89bio

MRI Analysis Set; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo

Majority of Subjects on BIO89-100 Achieved ≥50% Reduction in Liver Fat



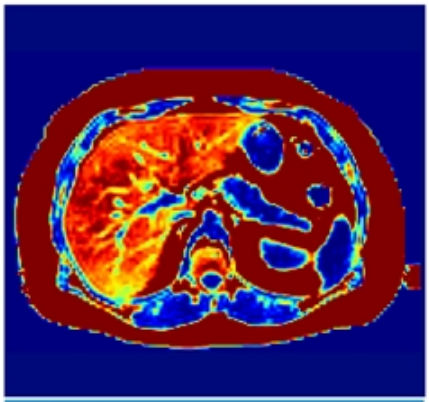
Proportion of Subjects with ≥50% Relative Reduction in Liver Fat

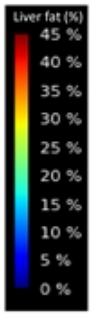
	Placebo	0%
QW	3mg	20%
QW	9mg	54%**
QW	18mg	50%**
QW	27mg	71%***
Q2W	18mg	39%**
Q2W	36mg	50%**

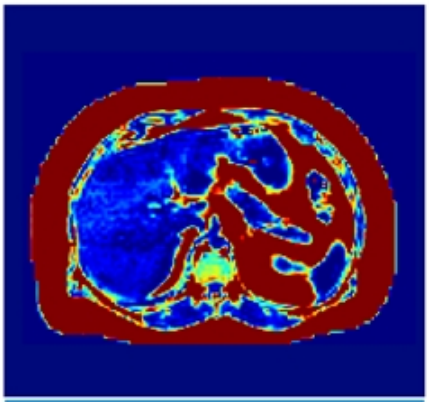
89bio

MRI Analysis Set; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo

BIO89-100 Showed Substantial Reduction in Liver Fat and Liver Volume After 12 Weeks of Treatment (Subject at 27mg QW)

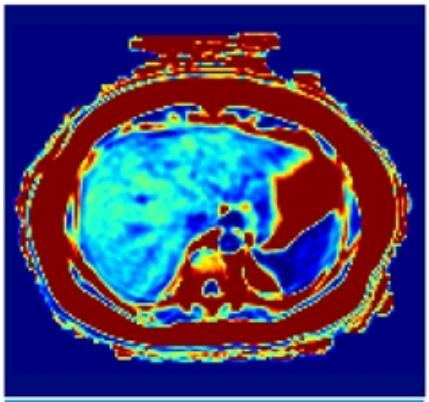


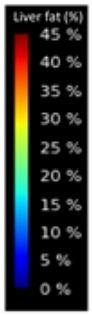


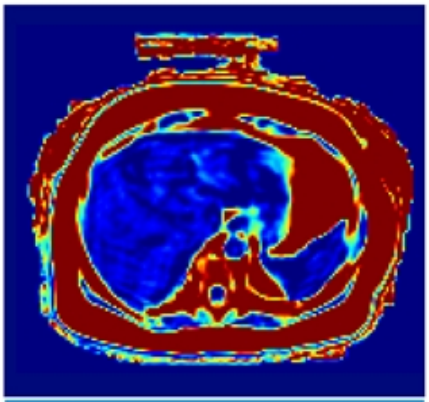


Parameter	Baseline	Week 13	% Change
Liver fat	41.1%	5.1%	-87.6%
Liver volume (L)	2.2	1.4	-35.4%

BIO89-100 Showed Substantial Reduction in Liver Fat and Liver Volume After 12 Weeks of Treatment (Subject at 18mg Q2W)

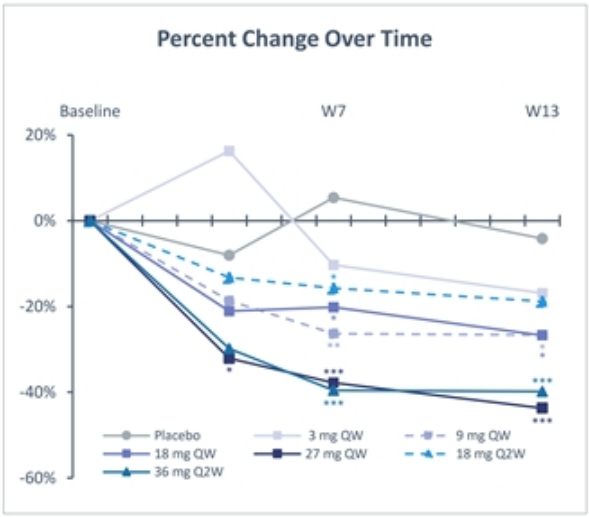


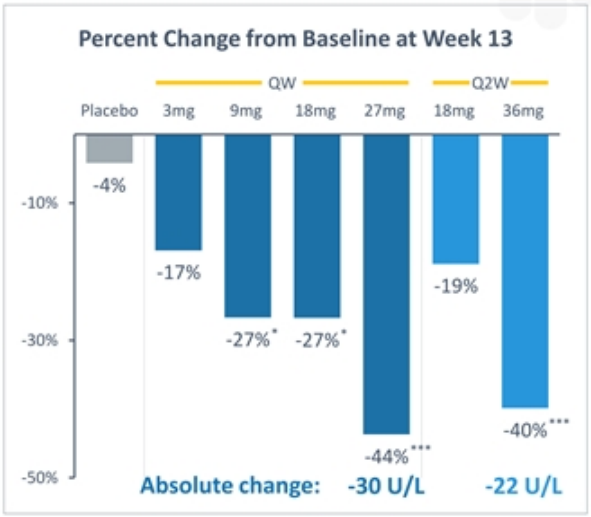




Parameter	Baseline	Week 13	% Change
Liver fat	16.8%	3.5%	-79.2%
Liver volume (L)	1.2	0.9	-27.7%

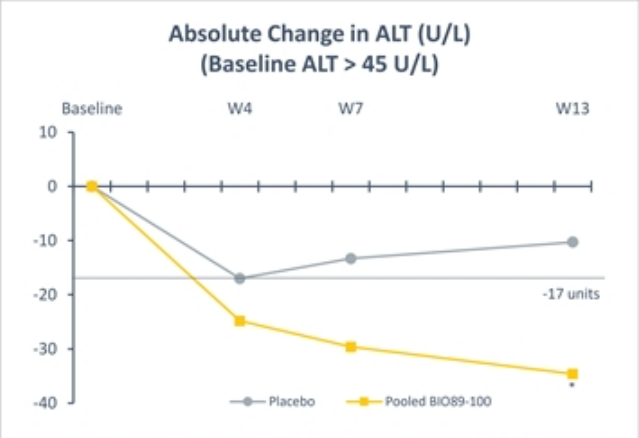
BIO89-100 Significantly Reduces ALT



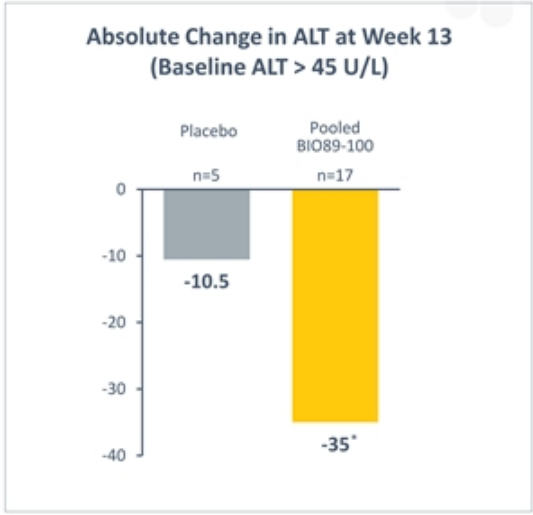


PD Analysis Set; Pre-planned sensitivity analysis; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo

BIO89-100 has Clinically Meaningful Impact on Subjects with High ALT

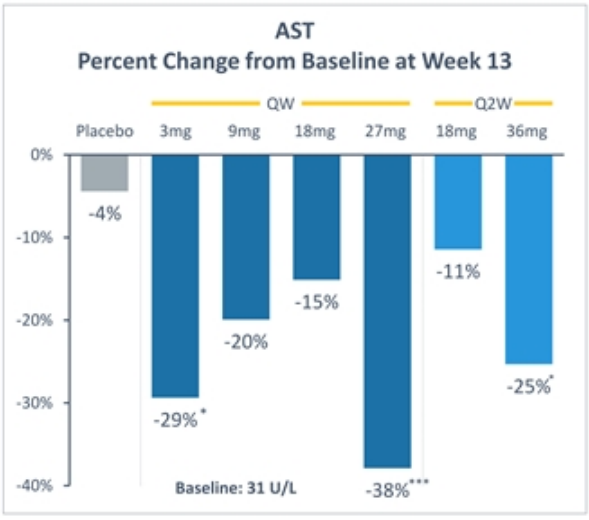


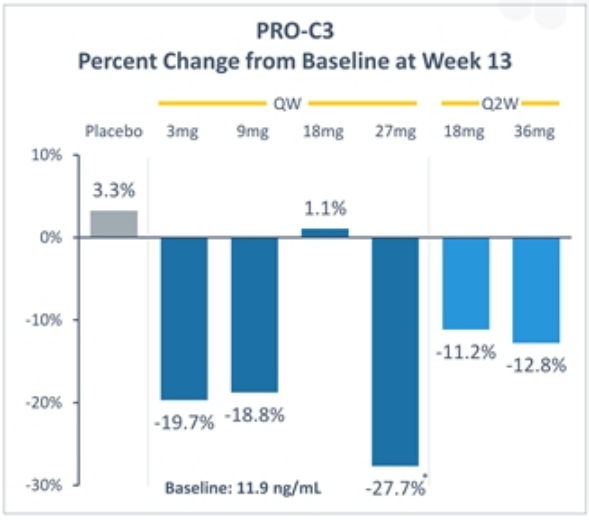
Change in ALT of ≥17 U/L has been correlated with improvement in fibrosis



89bio PD Analysis Set in baseline ALT > 45 U/L (placebo n=6, pooled BIO89-100 n=22); Pre-planned sensitivity analysis; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo

BIO89-100 Significantly Improves Other Important Liver Biomarkers Despite Low Baseline Values

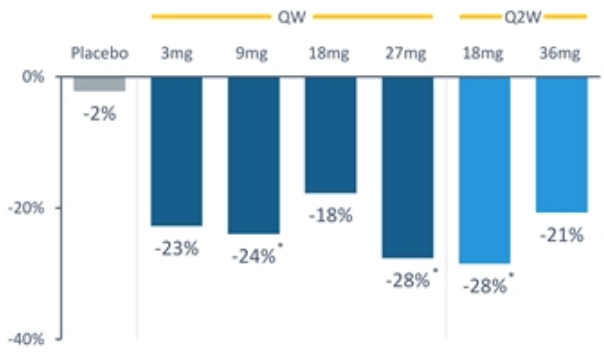




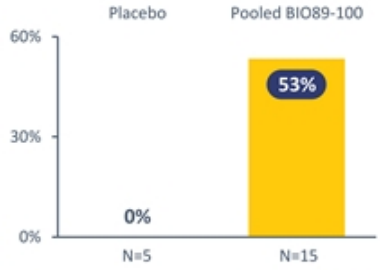
PD Analysis Set; Pre-planned sensitivity analysis; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo

BIO89-100 Significantly Reduces Triglycerides with Greater Benefit Observed in Subjects with High Triglycerides

Percentage Change from Baseline at Week 13 (All Subjects)



TG Normalization# Rate at week 13 (Subgroup with Baseline TG ≥200 mg/dL)



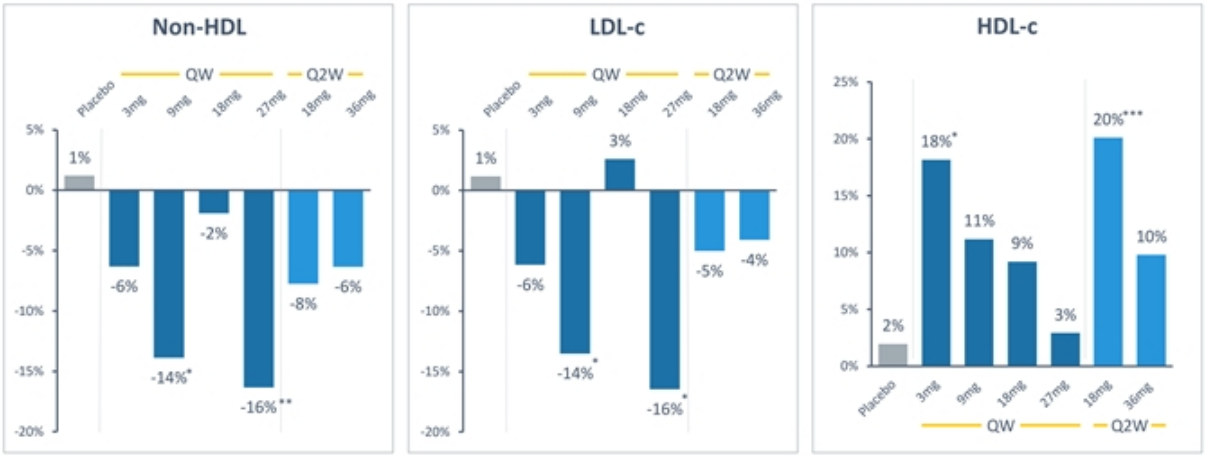
Decrease from baseline in BIO89-100 treated subgroup with baseline TG ≥200 mg/dL

- **TG: 33%-49%**
- **Non-HDL: 8%-29%**

PD Analysis Set; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo; # TG <150 mg/dL

BIO89-100 Significantly Improves Key Lipid Markers

Percentage Change from Baseline At Week 13



PD Analysis Set; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo

BIO89-100 Effect on Glycemic Control

Change From Baseline At Week 13

	Placebo	3mg QW	9mg QW	18mg QW	27mg QW	18mg Q2W	36mg Q2W
Adiponectin Percentage Change	-4.3%	37.7%*	25.5%*	29.1%*	60.9%***	23.1%*	24.1%
Insulin[&] Percentage Change	10.0%	-8.5%	-9.4%	-22.5%	-6.9%	-39.7%	-34.5%
HbA1c (%) Absolute Change	<0.1	0.6	0.1	0.1	-0.3	-0.1	0.5

No meaningful changes in weight were observed, except in the 27 mg QW cohort that saw a significant percentage reduction in weight relative to placebo

PD Analysis Set; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo [&]Week7 (last measurement)

Safety Overview

Treatment Emergent Adverse Event (TEAE)	Placebo (n=18)	3mg QW (n=7)	9mg QW (n=12)	18mg QW (n=11)	27mg QW (n=10)	18mg Q2W (n=14)	36mg Q2W (n=9)
TEAE Leading to Death	0	0	0	0	0	0	0
TEAE Leading to Discontinuation	0	0	0	0	1[a]	1[b]	0
Serious Adverse Event COVID 19 [Not Drug Related]	0	0	0	0	0	1	1

[a] skin rash; [b] hyperglycemia [Not Drug Related]

Safety Analysis Set; one placebo subject received one dose of BIO89-100 3mg and is summarized in 3mg QW group

Treatment Emergent Adverse Event in ≥ 10% of Pooled BIO89-100 Group

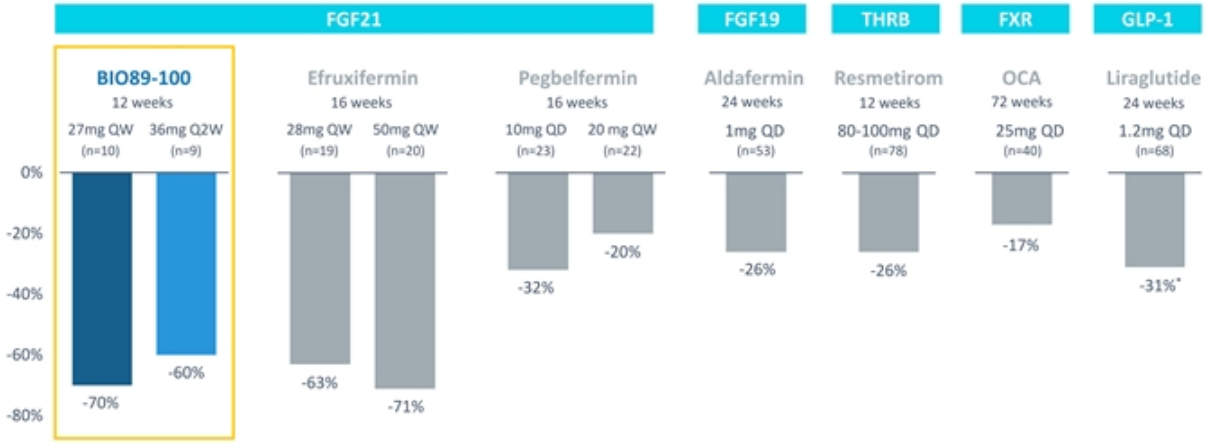
Preferred Term n (%)	Placebo (n=18)	Pooled BIO89-100 (n=63)	3mg QW (n=7)	9mg QW (n=12)	18mg QW (n=11)	27mg QW (n=10)	18mg Q2W (n=14)	36mg Q2W (n=9)
Increased Appetite	0	15.9%	4	2	0	2	2	0
Diarrhea	22.2%	12.7%	1	2	0	2	1	2
Headache	5.6%	11.1%	1	0	0	2	2	2

- GI adverse events were similar to placebo; 7.9% of subjects reported nausea in pooled BIO89-100 vs. 16.7% in placebo
- No hypersensitivity AE reported; few mild injection site reaction events reported
- No tremor reported; no adverse effects on blood pressure or heart rate
- Only treatment related AE reported in ≥10% of pooled BIO89-100 group was mild increased appetite

Safety Analysis Set; one placebo subject received one dose of BIO89-100 3mg and is summarized in 3mg QW group

BIO89-100 Has a Favorable Clinical Profile Relative to Leading Classes in Development for NASH

Relative Reduction in Liver Fat versus Placebo



Note: All data regarding third-party studies on this slide are based on third-party trials, some of which are in different stages of development. Conclusions on this slide are not based in head-to-head results. Efficacy shown here may change in future clinical trials
*Not placebo-controlled

BIO89-100 – Demonstrating the Promise of FGF21 in NASH

- ✓ SIGNIFICANT LIVER FAT REDUCTION
- ✓ IMPRESSIVE RESPONDER RATES AT HIGH THRESHOLD (≥50% FAT REDUCTION)
- ✓ LARGE, CLINICALLY MEANINGFUL CHANGES IN ALT
- ✓ ROBUST LIPID CHANGES – TRIGLYCERIDES, NON-HDL, LDL
- ✓ FAVORABLE SAFETY AND TOLERABILITY PROFILE WITH LIMITED GI EVENTS
- ✓ UNIQUE DOSING REGIMEN – FIRST EVERY TWO-WEEK FGF21 ANALOG

89bio

Powerful Science.
Meaningful Medicines.
Changing Lives.