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): March 22, 2023

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 7.01 Regulation FD Disclosure.

On March 22, 2023, 89bio, Inc. (the "Company") issued a press release announcing positive topline data from its Phase 2b trial (ENLIVEN) of pegozafermin (previously BIO89-100) in patients with nonalcoholic steatohepatitis (NASH). The Company will host a conference call and webcast today, Wednesday, March 22, 2023 at 8:00 am, Eastern Time, to discuss the data results.

A copy of the press release is furnished and the presentation that will be referenced during the conference call is filed as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K and are incorporated by reference herein. The exhibit furnished under Item 7.01 of this Current Report on Form 8-K 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, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits*.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated March 22, 2023
99.2	Slide Presentation, dated March 22, 2023
104	The cover page from the Company's Current Report on Form 8-K formatted in Inline XBRL

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: March 22, 2023

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

89bio's Phase 2b ENLIVEN Trial of Pegozafermin in Nonalcoholic Steatohepatitis (NASH) Achieved High Statistical Significance on Both Primary Histology Endpoints with Weekly (QW) and Every-Two-Week (Q2W) Dosing at 24 Weeks

- 44mg Q2W dose had a placebo-adjusted effect size of 20% on at least one-stage fibrosis improvement without worsening of NASH (p=0.008) and 24% on NASH resolution without worsening of fibrosis (p=0.0005)—

- 30mg QW dose had a placebo-adjusted effect size of 19% on at least one-stage fibrosis improvement without worsening of NASH (p=0.008) and 21% on NASH resolution without worsening of fibrosis (p=0.0009)—

- 44mg Q2W and 30mg QW doses had at least one-stage fibrosis improvement without worsening of NASH at 3.5 times placebo rate and NASH resolution without worsening of fibrosis at 12 to 14 times placebo rate—

- Every-two-week dose data reinforces pegozafermin's potential to be a differentiated treatment ideally suited for a chronic, asymptomatic disease like NASH -

– Positive data from this rigorous trial supports advancement to Phase 3 –

– Conference call and webcast today at 5:00 a.m. PDT/8:00 a.m. EDT –

SAN FRANCISCO, March 22, 2023 – 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 positive topline data from the Phase 2b ENLIVEN trial evaluating treatment with pegozafermin in patients with nonalcoholic steatohepatitis (NASH). In the study, both the 44mg every-two-week (Q2W) and 30mg weekly (QW) doses met, with high statistical significance, both the primary histology endpoints per the U.S. Food and Drug Administration (FDA) guidance on endpoints and statistical analysis.

The 44mg Q2W and the 30mg QW dose groups both demonstrated at least one-stage fibrosis improvement without worsening of NASH (27% and 26%, respectively) at 3.5 times the placebo rate (7%) and NASH resolution without worsening of fibrosis (26% and 23%, respectively), between 12 to 14 times the placebo rate (2%). The ENLIVEN study biopsies were scored independently by three expert blinded pathologists to minimize individual reader bias and inter-reader variability.

"I was pleased to see the impressive results on the critical histology endpoints and non-invasive tests in the ENLIVEN trial. I was especially encouraged by the significant improvement in fibrosis relative to placebo, as fibrosis is a key driver of NASH disease progression which can lead to cirrhosis and other negative clinical outcomes," said Arun J. Sanyal, MBBS, M.D., Professor, Departments of Medicine, Physiology, and Molecular Pathology, Virginia Commonwealth University. "These data are all the more significant given the rigor of the study methodology, including how the biopsies were read to reduce the impact of reader bias and variability. The ENLIVEN study followed a stringent analytical plan consistent with FDA guidance, and the low placebo response rate provides high confidence that this trial showed the true potential treatment effect of pegozafermin."

Table 1. Histological Outcome Measures* at Week 24

	Placebo (n=61)	15mg QW (n=14)	30mg QW (n=66)	44mg Q2W (n=51)
At least one-stage fibrosis improvement without worsening of NASH[1]	7%	22%	26%	27%
p-value		p=0.1	p=0.008	p=0.008
NASH resolution without worsening of fibrosis[2]	2%	37%	23%	26%
p-value		p<0.0001	p=0.0009	p=0.0005

* Multiple imputation analysis via Cochran-Mantel-Haenszel (CMH) test stratified by Type 2 Diabetes Mellitus status (yes vs. no) and fibrosis stage (F2 vs. F3)

1 Improvement in liver fibrosis by ≥1 stage and no worsening of steatohepatitis defined as no increase in NAFLD Activity Score (NAS) for ballooning, inflammation, or steatosis (FDA draft guidance).

2 Resolution of steatohepatitis is defined as absent fatty liver disease or isolated or simple steatosis without steatohepatitis and a NAS score of 0-1 for inflammation, 0 for ballooning and any value for steatosis (FDA draft guidance).

Results were consistent and achieved statistical significance for the 44mg Q2W and 30mg QW dose groups using multiple imputation analysis (as shown in Table 1), completers analysis (patients who had baseline and end of treatment biopsies at week 24), and intention-to-treat (ITT) analysis (Phase 3 analysis plan). Using the completers analysis methodology on the fibrosis endpoint, the placebo-adjusted effect size for the 44mg Q2W and 30mg QW dose groups was 20% and 19%, respectively (p=0.008 and p=0.009, respectively), and on the NASH resolution endpoint, the placebo-adjusted effect size for the 44mg Q2W and 30mg QW dose groups was 24% and 21%, respectively (p=0.0004 and p=0.0009, respectively). Results were also statistically significant for both doses on both primary histology endpoints using an ITT analysis that imputes patients with missing biopsies as non-responders.

“The treatment effect and highly statistically significant results observed across the two FDA approvable histology endpoints is very encouraging and clearly support advancement into Phase 3 development,” said Rohit Loomba, M.D., MHSc, Director, NAFLD Research Center, University of California San Diego, and lead investigator of ENLIVEN. “These data are amongst one of the most consistent data sets for drugs in clinical development for NASH with a parallel improvement in both MRI-PDFF and ALT, and bodes well for the likelihood of success in the upcoming Phase 3 program. Given NASH is a chronic and often asymptomatic disease, I am excited to see the strong efficacy and tolerability results observed with every-two-week dosing as this would provide clinicians and patients multiple advantages.”

Meaningful changes were observed compared to baseline in liver fat and other key non-invasive tests (“NITs”) of liver inflammation and fibrosis. Improvements were also observed in HbA1c and across important lipid markers that are important factors for an effective treatment for NASH.

Table 2. Liver Non-Invasive Tests (NITs) Results [marker of]

	Placebo (n= 61)	30mg QW (n= 66)	44 mg Q2W (n= 51)
Mean Change from Baseline[1]			
MRI-PDFF [liver fat content][2]	-14%	-52%***	-54%***
ALT [liver damage]	-5%	-42%***	-32%***
VCTE kPA [liver stiffness]	0.7	-3.0**	-2.4**
Pro-C3 [collagen deposition]	6%	-18%***	-17%***
Responder Analysis [1]			
cT1 Responders[3] [liver inflammation/fibrosis]	14%	61%***	38%*

*** p<0.001, **p<0.01, *p<0.05 versus placebo.

1 Results for the 15mg QW dose on the NITs in table are (all are shown as changes from baseline except cT1 which is responder analysis): MRI-PDFF -33%; ALT -38%; VCTE kPA -1.6; Pro-C3 -5%; cT1 40%

2 MRI-PDFF Analysis set in subjects with >10% liver fat (n=125)

3 A patient is designated a cT1 responder with ≥80 msec reduction in hepatic fibro-inflammation as compared to baseline. cT1 analysis was performed at sites where available.

The ENLIVEN study also included 14 biopsy-confirmed NASH patients with compensated cirrhosis (F4 patients) who were not part of the primary analysis but continued in the study, 12 of which underwent a follow-up biopsy at week 24. In descriptive analysis of these data, five out of 11 pegozafermin-treated patients experienced at least one-stage improvement in liver fibrosis with no worsening of NASH by week 24 compared with zero out of one patient on placebo. An additional four pegozafermin-treated patients experienced at least one-stage improvement in liver fibrosis.

Pegozafermin continued to demonstrate a favorable safety and tolerability profile consistent with prior studies. Across dose groups, the most frequently reported treatment-related adverse events (AEs) were Grade 1 or 2 gastrointestinal events (diarrhea, nausea and increased appetite) most of which were mild to moderate in nature. Rates of treatment-related AEs observed were less frequent with the Q2W dosing regimen. A total of five patients treated with pegozafermin were discontinued due to treatment-related AEs all of which were Grade 2 compared with none for placebo. A single drug-related serious adverse event of uncomplicated pancreatitis was experienced by a patient in the 44mg Q2W dose group after a single dose of pegozafermin which resolved in a short time period.

“Our vision has been to develop a therapy that addresses the liver and cardiometabolic manifestations of this complex liver disease and do so in a well-tolerated and convenient way for seamless integration into patient lives,” said Hank Mansbach, Chief Medical Officer of 89bio. “These data demonstrate that we are on our way to making this vision a reality and highlight pegozafermin’s potentially differentiated profile based on its efficacy and tolerability results to date and convenient dosing interval. We are pleased to see that every-two-week dosing produced remarkably similar results to weekly dosing, which is expected to provide us optionality as we work with the FDA to advance pegozafermin into Phase 3 development.”

Today’s Conference Call Information

89bio will host a conference call and webcast at 5:00 a.m. PDT / 8:00 a.m. EDT today, March 22, 2023. Analysts and investors can participate in the conference call by dialing +1 (877) 407-0784 for domestic callers and +1 (1-201-689-8560) for international callers, using the conference ID 13737204. The webcast can be accessed live here and on the Events & Presentations page in the Investors section of the 89bio website, www.89bio.com. The webcast will be archived on 89bio’s website for at least 30 days after the conference call.

About ENLIVEN

ENLIVEN is a multicenter, randomized, double-blind, placebo-controlled Phase 2b trial designed to evaluate the safety and efficacy of weekly or every-two-week dosing of pegozafermin for the treatment of patients with fibrosis stage F2—F3 NASH and NAS ≥ 4 for 48 weeks. In the study, 219 patients were randomized and dosed with pegozafermin 44mg Q2W, 30mg QW, 15mg QW, or placebo; 27 patients were prospectively excluded from the primary analysis population based on fibrosis stage or NAS score resulting in 192 patients in the full analysis set.

Primary outcomes measured were proportion of participants with resolution of NASH without worsening of fibrosis and proportion of participants with ≥1 stage decrease in fibrosis stage with no worsening of NASH at 24 weeks. Secondary measures included change from baseline in liver fat, liver enzymes, noninvasive markers of liver fibrosis, glycemic control, lipoproteins, and body weight as well as safety and tolerability measures. Study patients are being treated in a blinded extension phase for 24 weeks for a total treatment period of 48 weeks, with some placebo patients re-randomized to receive pegozafermin in the extension phase.

In the ENLIVEN study, biopsies were scored independently by three pathologists on the NAS components and fibrosis using the NASH-CRN criteria. Pathologists were blinded to the clinical trial participant, treatment, and study timepoint. There was protocol-specific training before and during the study to improve concordance between readers. The scores from each reader were then compared by an algorithm. If all three agreed on the score, that was recorded as the final score. If there was disagreement, the mode was selected and if that was not available the median or consensus call score was recorded. On average, full agreement or mode determined the final score for more than 95% of the biopsies.

About pegozafermin

Pegozafermin is a specifically engineered glycoPEGylated analog of fibroblast growth factor 21 (FGF21) being developed for the treatment of non-alcoholic steatohepatitis (NASH) and severe hypertriglyceridemia (SHTG). FGF21 is an endogenous hormone that modulates important drivers of lipid metabolism and NASH including triglyceride reduction, glycemic control, steatosis, inflammation and fibrosis. Pegozafermin was specifically engineered using a unique glycoPEGylated technology to extend the half-life while maintaining potency.

About 89bio

89bio is a clinical-stage biopharmaceutical company dedicated to the development and commercialization of innovative therapies for the treatment of liver and cardiometabolic diseases. The company's lead product candidate, pegozafermin, is currently being developed for the treatment of NASH and SHTG. 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, efficacy and clinical benefits of pegozafermin, the safety and tolerability profile of pegozafermin, pegozafermin as a potentially differentiated treatment for NASH, 89bio's clinical development plans for pegozafermin, including commencement of a Phase 3 trial based on results from the Phase 2b ENLIVEN trial, the potential dosing regimen of pegozafermin, if approved, and the relationship between the results from the positive data from Phase 2b ENLIVEN trial and results of future clinical studies. 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 clinical benefit and safety of pegozafermin; expectations regarding the initiation of the first Phase 3 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; 89bio's substantial dependence on the success of it lead product candidate; competition from competing products; expectations regarding FDA approval and feedback; 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 Annual Report on Form 10-K for the year ended December 31, 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.

# # #

Investor Contact:
Ryan Martins
Chief Financial Officer
investors@89bio.com

PJ Kelleher
LifeSci Advisors, LLC
+1-617-430-7579
pkelleher@lifesciadvisors.com

Media Contact:

Sheryl Seapy
Real Chemistry
sseapy@realchemistry.com

Exhibit 99.2

89bio

Pegozafermin Phase 2b (ENLIVEN) Topline Results in Nonalcoholic Steatohepatitis (NASH)

Nasdaq: ETNB

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, or intentions relating to product candidates, potential market opportunities, patient acceptance of pegozafermin, estimates of market size, the potential clinical benefit, effect on the histology and safety and tolerability profile of pegozafermin (formerly BIO89-100), the clinical potential of pegozafermin, potential indications for pegozafermin, the anticipated dosing regimen for pegozafermin, if approved, the timing of regulatory meetings or discussions, 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 under the caption "Risk Factors" and elsewhere in such report and in other subsequent disclosure documents filed with the U.S. Securities and Exchange Commission.

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 risks and 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 or obligation 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.

Pegozafermin – A Potentially Differentiated and Foundational NASH Drug

Statistically Significant Results on Fibrosis Improvement and NASH Resolution

- Fibrosis improvement – 3.5x and NASH resolution – 12-14x placebo rate

Significant Results with Weekly and Every-Two-Week Dosing on Both Endpoints

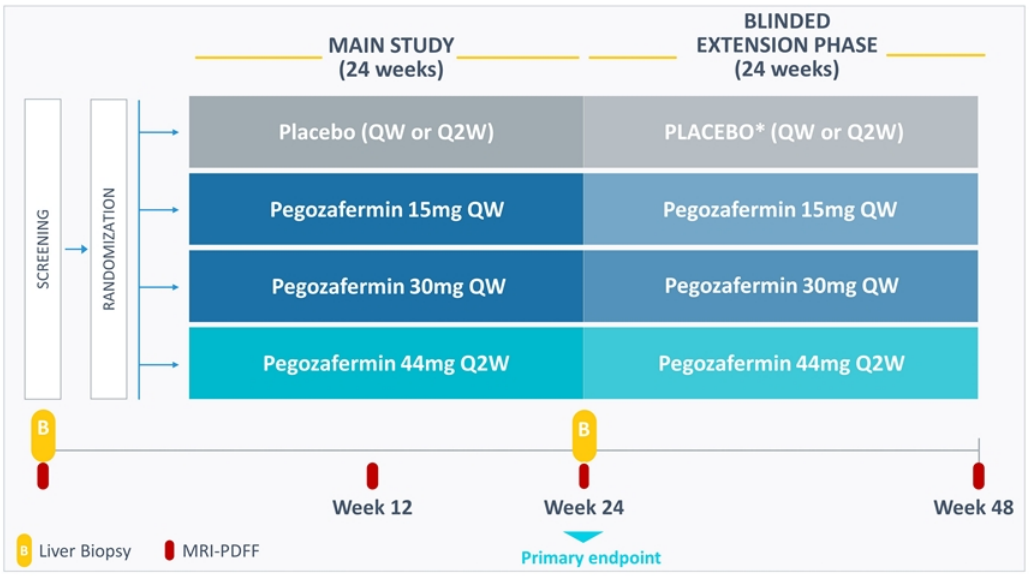
- Only drug in the category pursuing this optionality

Favorable Safety and Tolerability Profile

Rigorous Trial Increases Our Confidence in Phase 3

- FDA guidance on endpoints and analysis; Rigorous biopsy reading methods; Large study

ENLIVEN Trial Design



PRIMARY ANALYSIS POPULATION

- F2-F3 NASH; NAS ≥4

PRIMARY ENDPOINTS

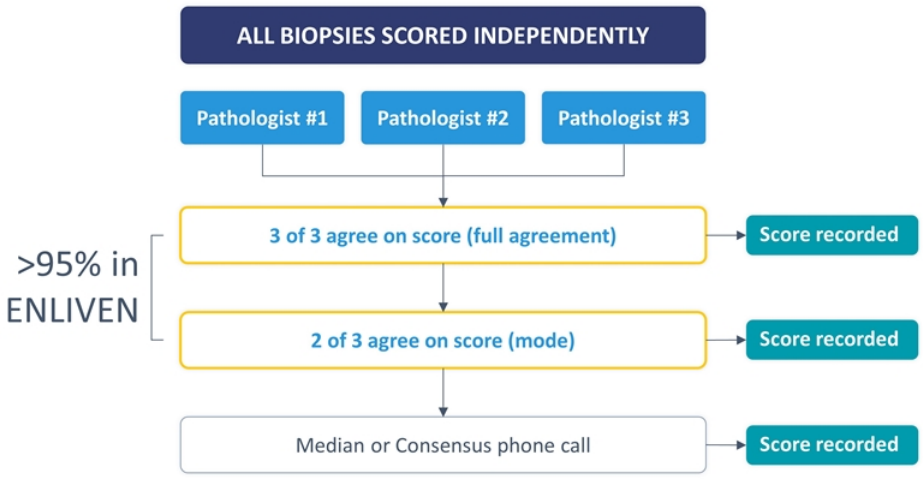
- ≥1-stage fibrosis improvement with no worsening of NASH[1]
- NASH resolution with no worsening of fibrosis[2]

KEY SECONDARY EFFICACY ENDPOINTS

- ≥2-point change in NAS with no worsening of fibrosis
- Non-invasive liver markers (liver fat, liver injury, fibrosis markers)

1 Improvement in liver fibrosis by ≥1 stage and no worsening of steatohepatitis defined as no increase in NAS for ballooning, inflammation, or steatosis (FDA draft guidance).
2 Resolution of steatohepatitis is defined as absent fatty liver disease or isolated or simple steatosis without steatohepatitis and a NAS score of 0-1 for inflammation, 0 for ballooning and any value for steatosis (FDA draft guidance).
*Some placebo patients were re-randomized in the extension phase to receive pegozafermin.
NAS, NAFLD Activity Score; MRI-PDFF, Magnetic resonance imaging-estimated proton density fat fraction; QW: Every week; Q2W: Every 2 weeks

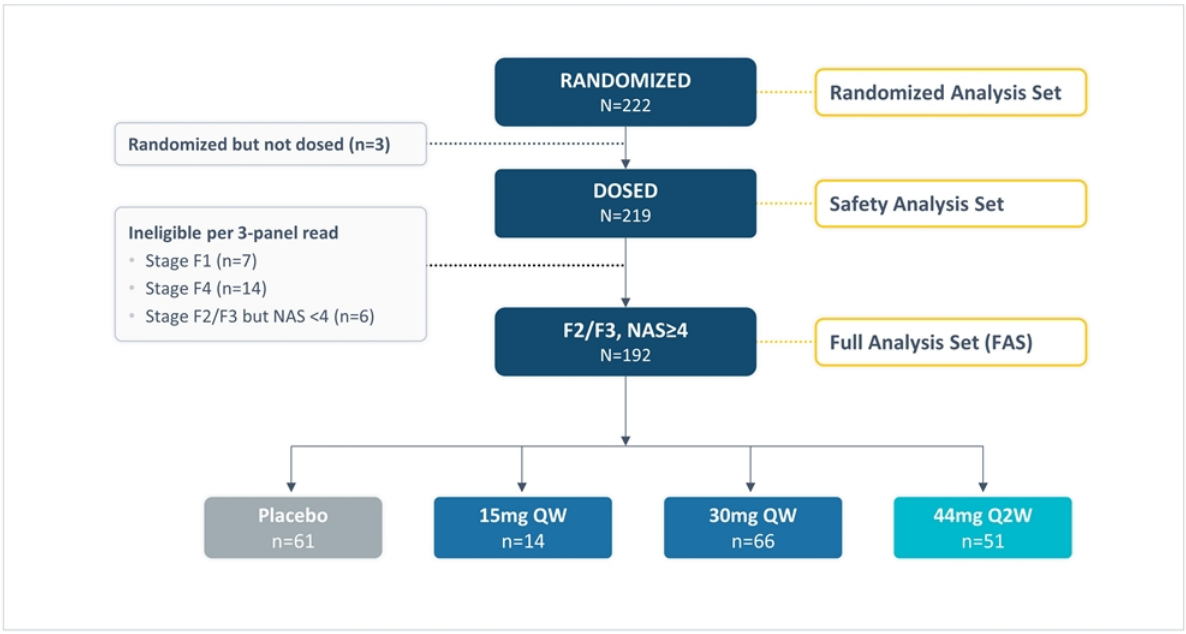
Rigorous Biopsy Reading Method Designed to Identify Drug Effect



- All biopsies scored independently by three pathologists (on 4 components of NASH-CRN criteria)
- Pathologists underwent protocol-specific harmonization training before and during trial
- Pathologists were blinded to subject, treatment and sequence

Designed to reduce impact of individual reader bias and inter-reader variability

Patient Disposition and Analysis Sets



Analysis Sets were prospectively defined
Completer Analysis Set = FAS subjects with biopsies at both baseline and Week 24 (n=164).
MRI-PDFF Analysis Set = all subjects in FAS with baseline and at least one post-baseline MRI-PDFF assessment (n=181).

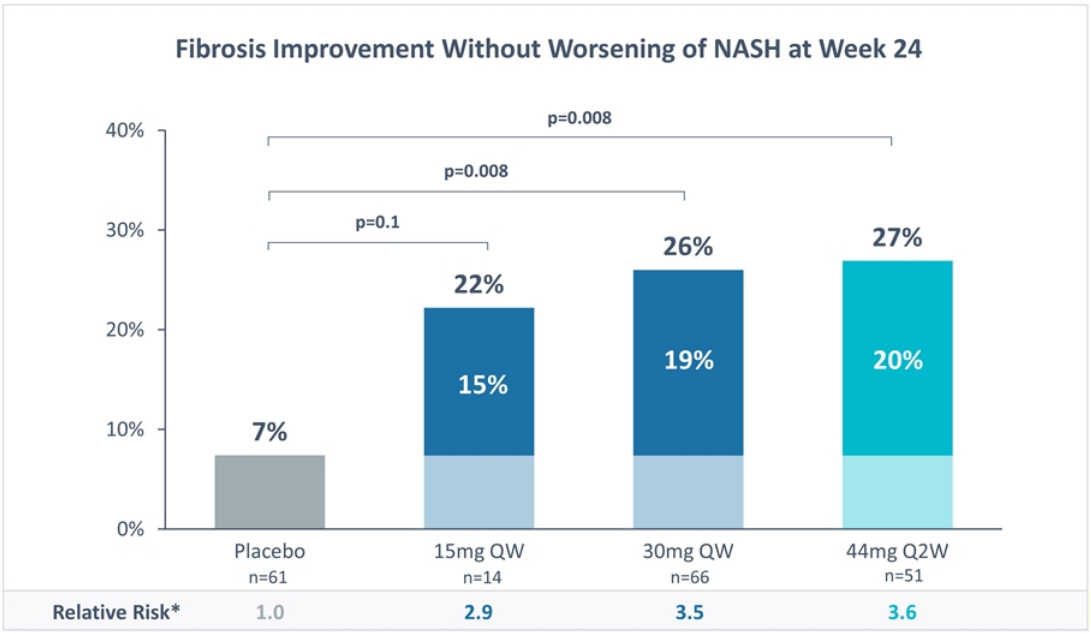
Baseline Characteristics Well Balanced Across Dose Groups

Parameter Mean or %	Placebo (n=71)	15mg QW (n=21)	30mg QW (n=73)	44mg Q2W (n=57)	Total (n=222)
Age (years)	56	55	55	55	**56**
Female	55%	43%	69%	65%	**61%**
BMI (kg/m^2)	38	38	35	36	**37**
Type 2 Diabetes	69%	86%	62%	61%	**66%**
Fibrosis Stage (% F3)	66%	43%	64%	53%	**60%**
NAFLD Activity Score	5.0	4.8	5.3	5.2	**5.1**
Liver Fat Content (MRI-PDFF)	16.7%	15.8%	16.7%	15.8%	**16.4%**
Liver Stiffness (VCTE, kPa)	14.1	11.2	12.5	13.2	**13.0**
PRO-C3 (ng/mL)	50	62	54	52	**53**
ALT (U/L)	50	61	60	56	**56**
AST (U/L)	41	48	47	42	**44**
HbA1c, overall population (%)	6.6	7.0	6.6	6.7	**6.7**
Triglycerides (mg/dL)	170	186	175	165	**172**

89bio

Source: Randomized Analysis Set.
ALT, alanine aminotransferase; AST, aspartate aminotransferase; BMI, body mass index; NAFLD, nonalcoholic fatty liver disease; PRO-C3, N-terminal type III collagen propeptide; VCTE, Vibration-controlled transient elastography.

Pegozafermin Demonstrated Statistical Significance on Fibrosis Improvement with Weekly and Every-Two-Week Dosing



Relative risk is calculated by dividing drug response by placebo response

89bio

* Relative risk presented is calculated by dividing the drug response by placebo response. Relative risk calculated using statistical methods show similar results.
Source: Full Analysis Set; multiple imputation analysis via Cochran-Mantel-Haenszel (CMH) test stratified by type 2 diabetes mellitus (T2DM) status (yes vs. no) and fibrosis stage (F2 vs. F3).

Pre-Specified Additional Analyses Confirm Robustness of Primary Efficacy Results

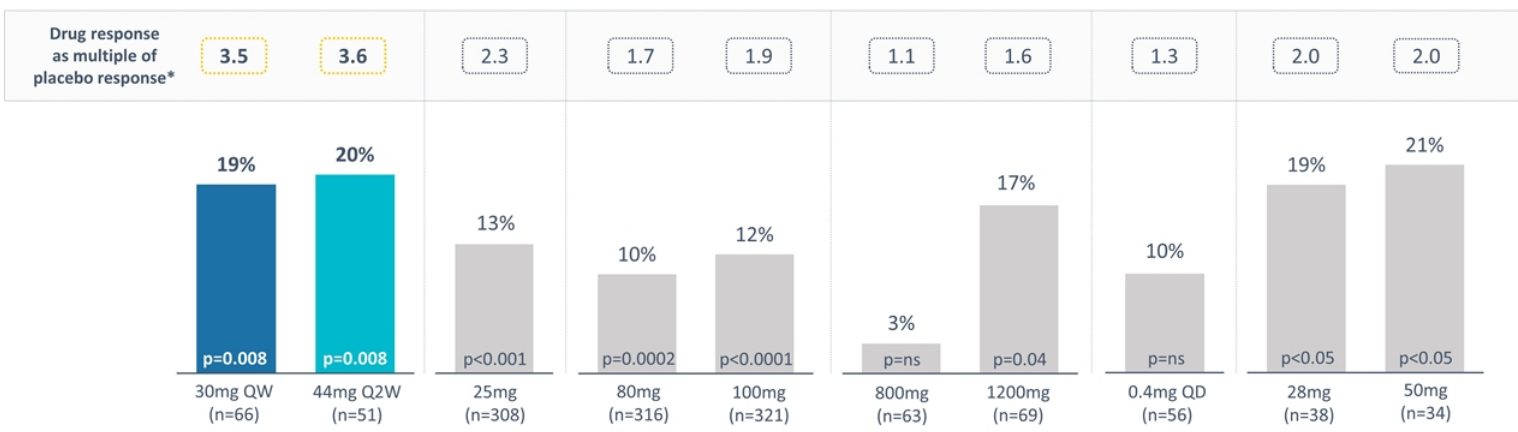
Fibrosis Improvement Without Worsening of NASH at Week 24

	30mg QW	44mg Q2W
Completer Analysis Set (n=164)		
Effect Size (placebo-adjusted)	19%	20%
p-value	0.009	0.008
Intent-to-treat (ITT; missing data = non-responder); (n=192)		
Effect Size (placebo-adjusted)	15%	16%
p-value	0.019	0.015

Source: FAS for ITT and Completer Analysis Set

Clinical Data in Pre-Cirrhotic Patients

≥1 Stage Fibrosis Improvement with No Worsening of NASH (placebo-adjusted)



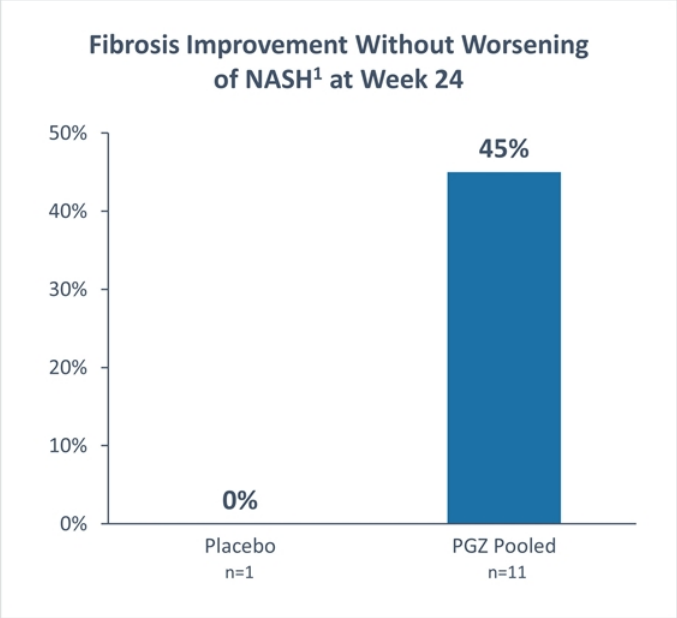
*Drug response as multiple of placebo response is calculated by dividing drug response by placebo response

[1] Results same for Completer Analysis Set

[2] ≥1 stage fibrosis improvement with no worsening of NAS

Note: These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted.

Descriptive Analysis Data of Cirrhotic (F4) Patients from ENLIVEN



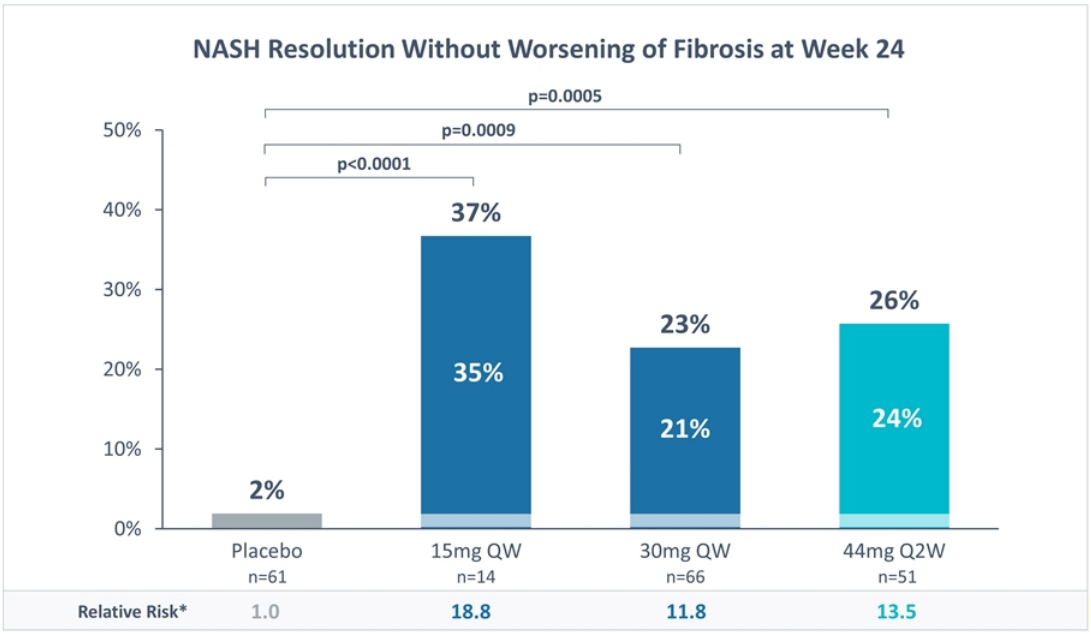
12/14 F4 patients enrolled in ENLIVEN had follow-up biopsies at week 24

- 5/11 patients had fibrosis improvement without worsening of NASH[1]
- An additional 4 patients had fibrosis improvement only (9/11 total treated patients)

89bio

[1]Improvement in liver fibrosis by ≥1 stage and no worsening of steatohepatitis defined as no increase in NAS for ballooning, inflammation, or steatosis.

Pegozafermin Demonstrated Statistical Significance on NASH Resolution at All Doses



	Placebo	15mg QW	30mg QW	44mg Q2W
Relative Risk*	1.0	**18.8**	**11.8**	**13.5**

Relative risk is calculated by dividing drug response by placebo response

89bio

* Relative risk presented is calculated by dividing the drug response by placebo response. Relative risk calculated using statistical methods show similar results.
Source: Full Analysis Set; multiple imputation analysis via Cochran-Mantel-Haenszel (CMH) test stratified by T2DM status (yes vs. no) and fibrosis stage (F2 vs. F3).

Pre-Specified Additional Analyses Confirm Robustness of Primary Efficacy Results

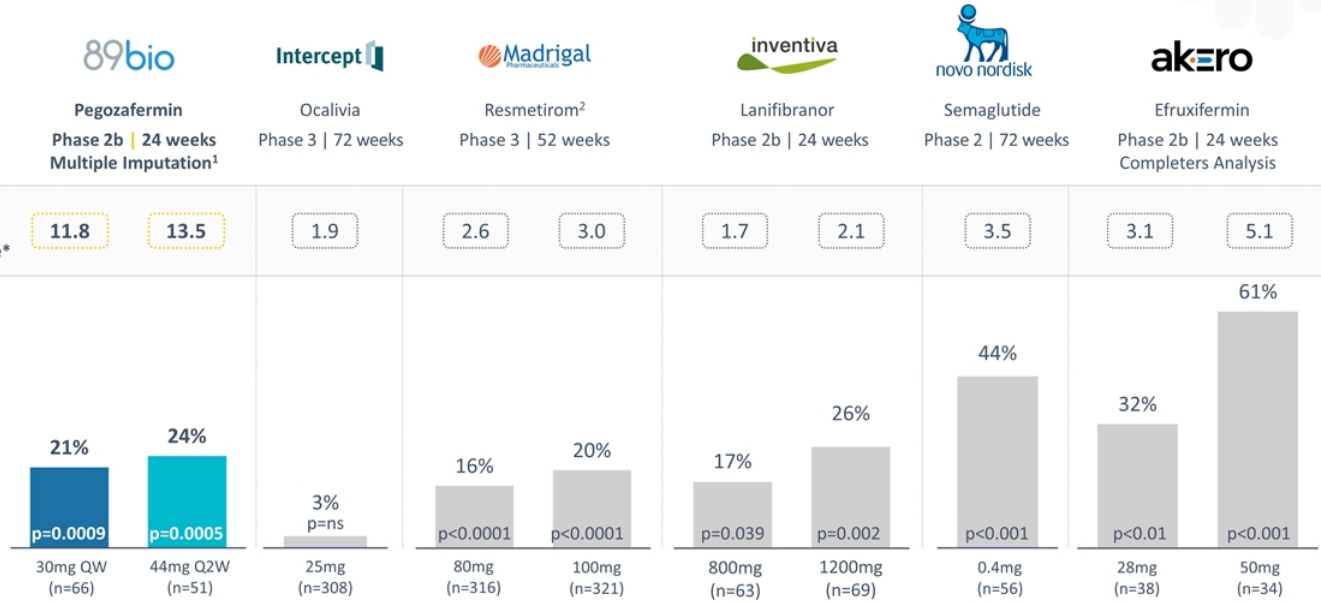
NASH Resolution Without Worsening of Fibrosis at Week 24

	30mg QW	44mg Q2W
Completer Analysis Set (n=164)		
Effect Size (placebo-adjusted)	21%	24%
p-value	0.0009	0.0004
ITT (missing data = non-responder); (n=192)		
Effect Size (placebo-adjusted)	17%	20%
p-value	0.0019	0.0009

Source: FAS for ITT and Completer Analysis Set

Clinical Data in Pre-Cirrhotic Patients

NASH Resolution with No Worsening of Fibrosis



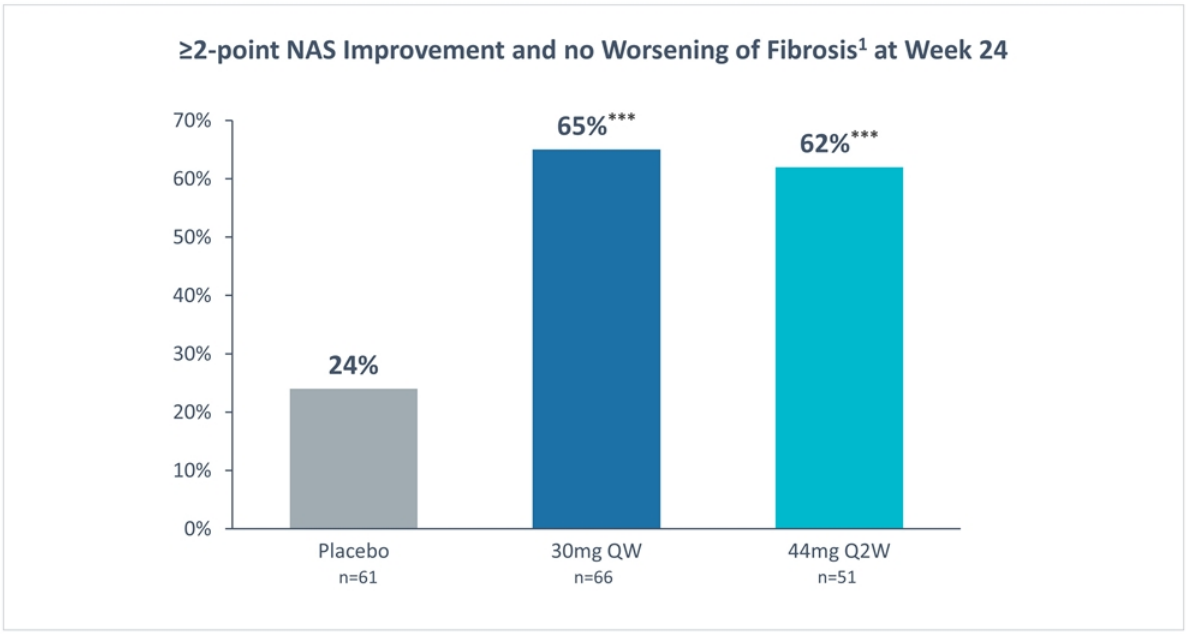
* Drug response as multiple of placebo response is calculated by dividing drug response by placebo response

[1] Results same for Completer Analysis Set

[2] NASH resolution with ≥2 point reduction in NAS and no worsening of fibrosis

Note: These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted.

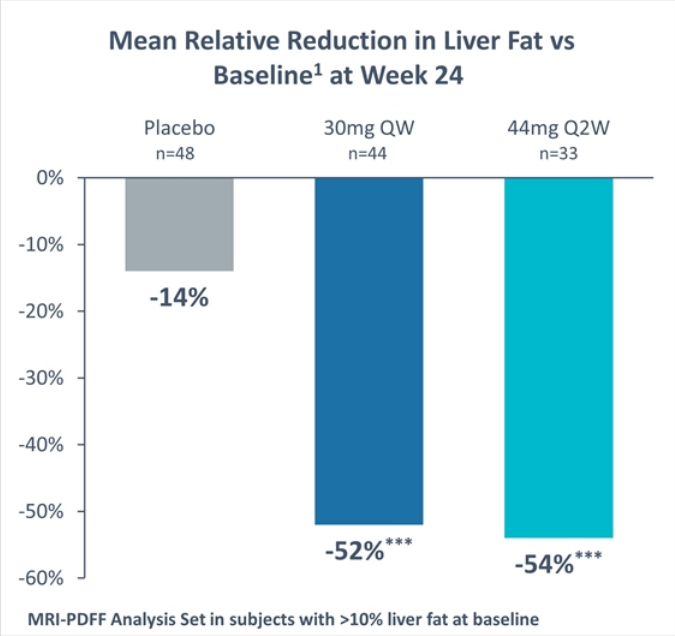
Pegozafermin Demonstrated Statistical Significance on ≥2-point NAS Improvement



Results for the 15mg QW dose: 37%

[1] Full Analysis Set. Analysis via Cochran-Mantel-Haenszel (CMH) test stratified by T2DM status (yes vs. no) and fibrosis stage (F2 vs. F3)
***p<0.001 versus placebo.

Pegozafermin Demonstrated Robust Liver Fat Reduction with High Responder Rates by MRI-PDFF at Week 24



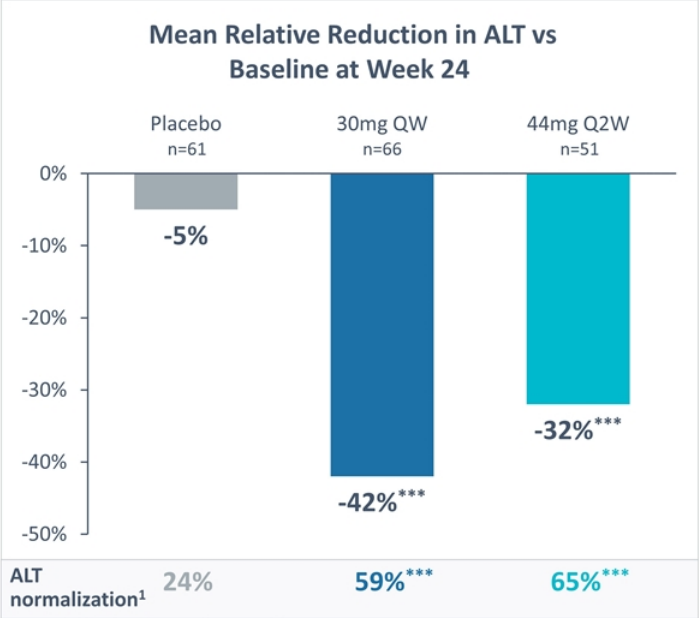
Proportion of Patients Achieving ≥50% Reductions in Liver Fat[2] at Week 24

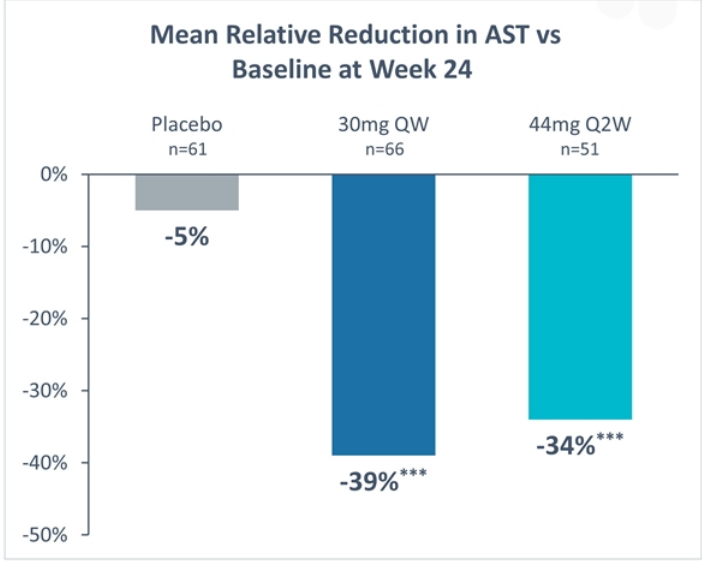
Placebo (n=48)	30mg QW (n=44)	44mg Q2W (n=33)
13%	66%***	67%***

Results for the 15mg QW dose: -33% (n=12; p=ns)

[1]Analysis via mixed model repeated measure (MMRM). [2]Analysis via Cochran-Mantel-Haenszel (CMH) test stratified by T2DM status (yes vs. no) and fibrosis stage (F2 vs. F3).
***p<0.001 versus placebo

Pegozafermin Demonstrated Significant Improvements in Markers of Liver Injury (ALT and AST)





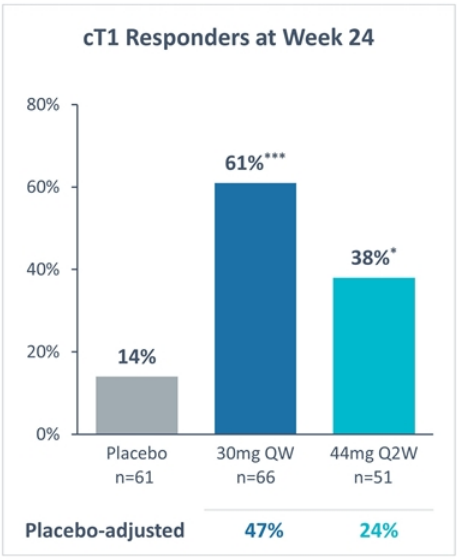
ALT Results for the 15mg QW dose: -38% (n=14; p<0.01)

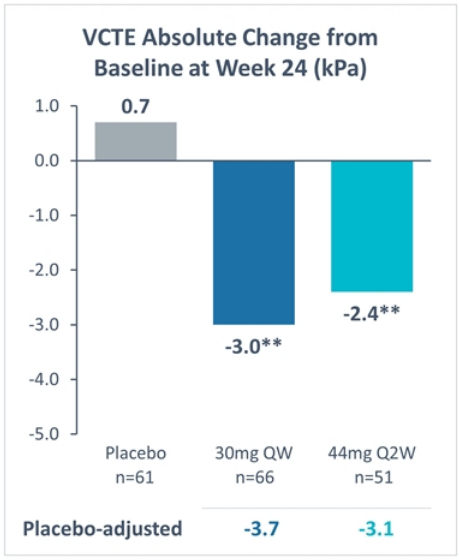
[1]ALT normalization defined as patients with ALT ≥30 U/L at baseline (n=133) with end-of-study ALT <30 U/L.

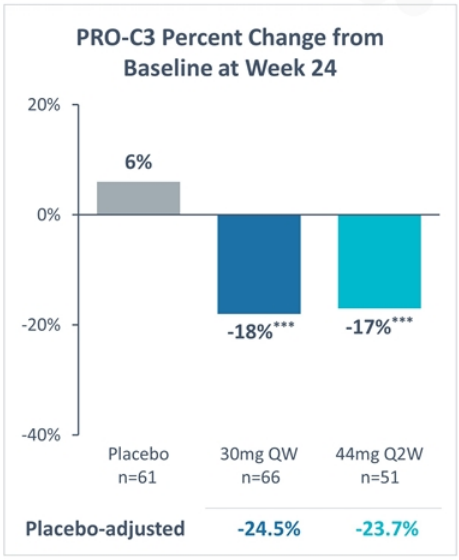
89bio

Source: Full Analysis Set: Analysis via mixed model with repeated measure (MMRM). Data presented as LS Means.
***p<0.001 versus placebo.

Pegozafermin Demonstrated Significant Reductions in Non-Invasive Markers (NITs) of Hepatic Inflammation and Fibrosis





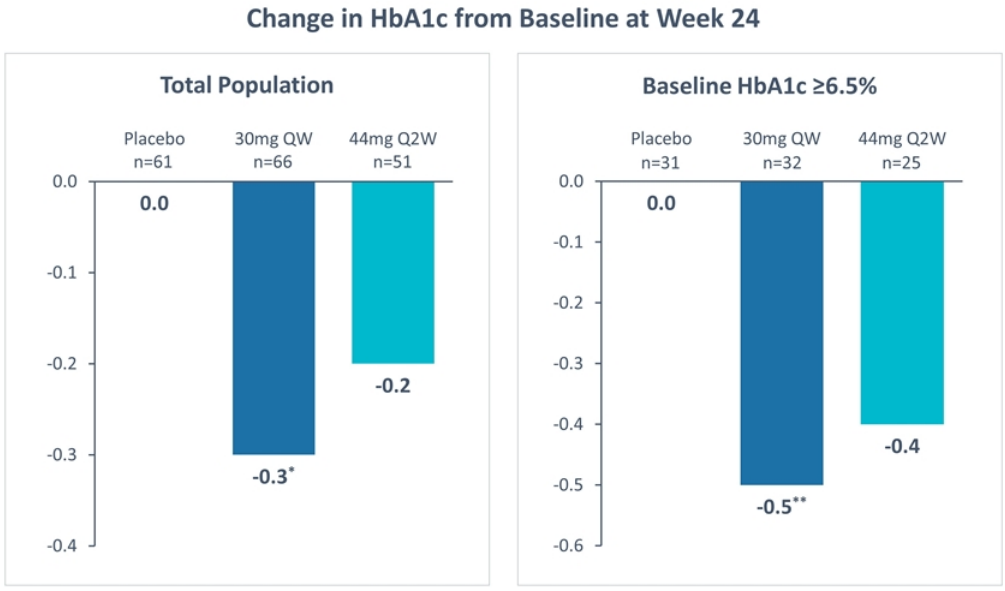


Results for the 15mg QW dose: cT1 40% (n=10; p=ns); VCTE -1.6 kPa (n=14; p=ns); PRO-C3 -5% (n=14; p=ns).

Source: Full Analysis Set for FibroScan and PRO-C3 assessments and MRI-PDFF analysis set for cT1, Analysis via MMRM for cT1 and PRO-C3, ANCOVA for VCTE. A patient is designated a cT1 responder with ≥80 msec reduction as compared to baseline. cT1 analysis was performed at sites where available.
*p<0.05, **p<0.01, ***p<0.001 versus placebo.

89bio

Pegozafermin Demonstrated Meaningful Reductions in HbA1c

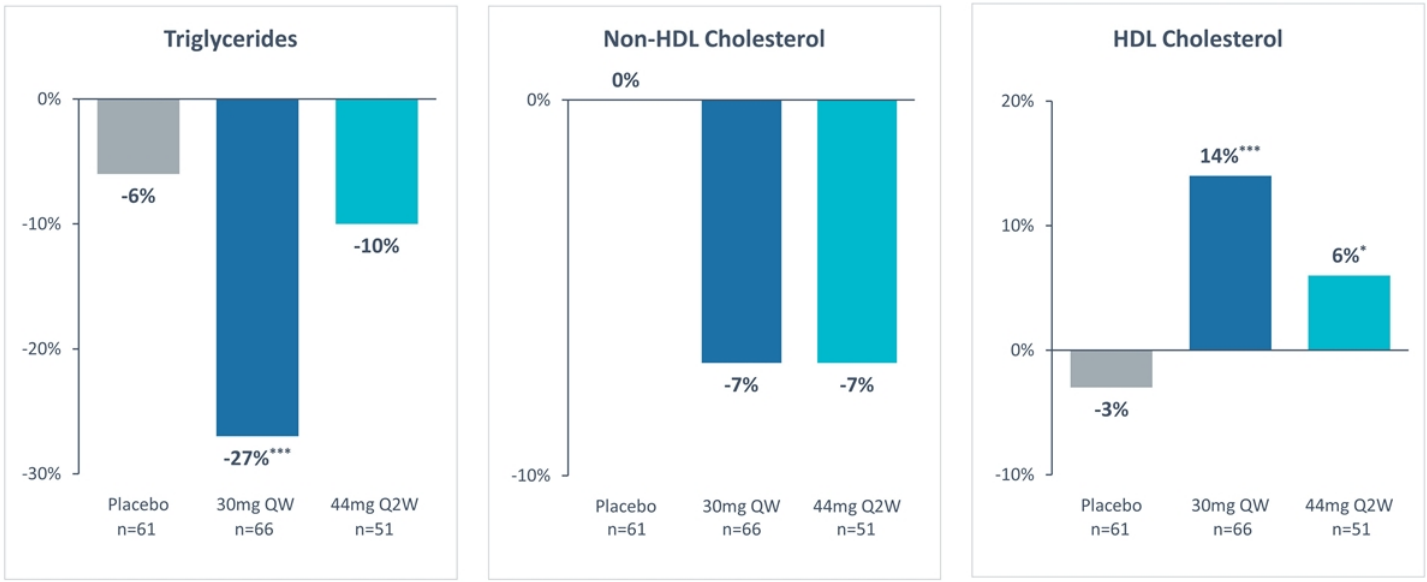


Source: Full Analysis Set for either overall population or FAS with baseline HbA1c ≥6.5%. Analysis via MMRM.

*p<0.05, **p<0.01 versus placebo.

Pegozafermin Demonstrated Meaningful Changes in Serum Lipids

Percent Change in Serum Lipids from Baseline at Week 24



89bio

Source: Full Analysis Set. Analysis via van Eltren Test for triglycerides (reported as median) and mixed model with repeated measure (MMRM). Subjects with missing week 24 triglycerides are excluded from the non-parametric analysis. Non-HDL-cholesterol and HDL Cholesterol (reported as LS means) with changes from baseline (absolute or %) as dependent variables.
*p<0.05, **p<0.01, ***p<0.001 versus placebo.

Pegozafermin Was Well Tolerated Across Doses

Low incidence of treatment-related TEAEs

Drug-related TEAEs in ≥10% of patients

Preferred Term	Placebo (n=69)	15mg QW (n=21)	30mg QW (n=72)	44mg Q2W (n=57)
Diarrhea	3%	24%	17%	9%
Nausea	1%	14%	21%	18%
Injection site erythema	3%	14%	14%	5%
Injection site rash	1%	0	10%	4%
Increased appetite	0	10%	13%	5%

Most TEAEs were grade 1 or 2. No tremor reported.

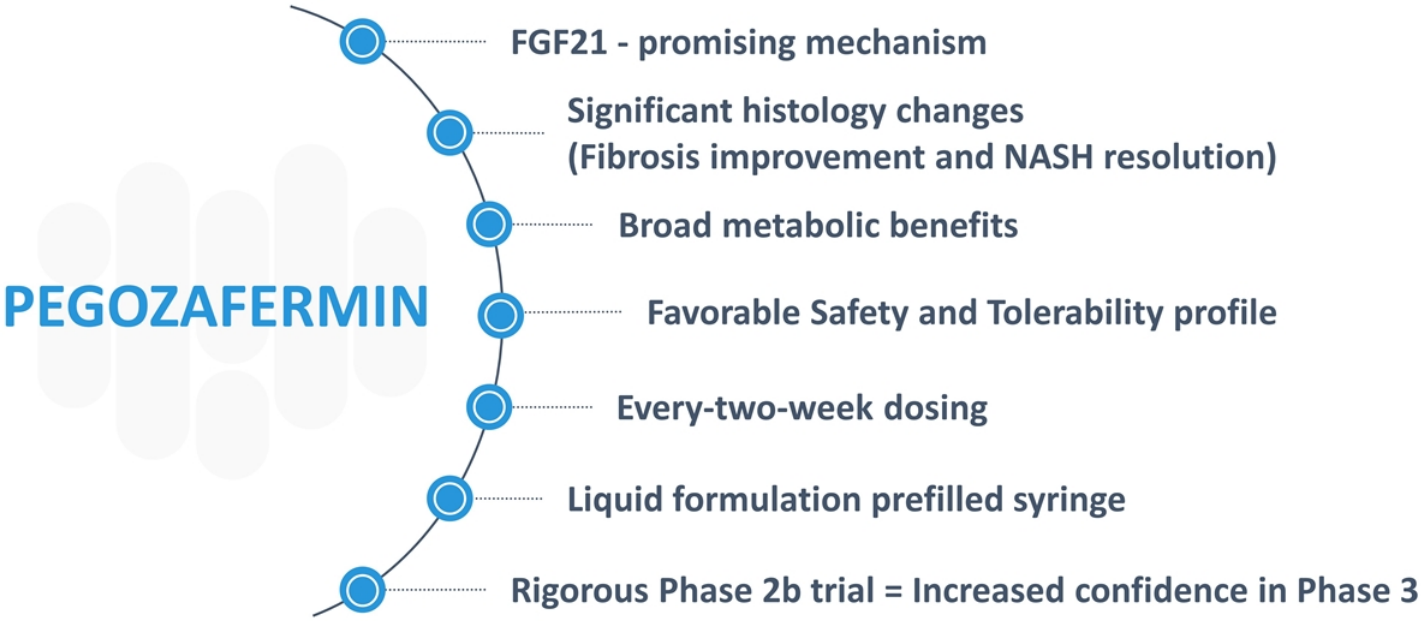
	Placebo	15mg QW	30mg QW	44mg Q2W
Drug-related AEs leading to discontinuation	0	5%[a]	6%[b]	2%[c]
Drug-related Serious Adverse Event (SAE)	0	0	0	2%[c]

Related discontinuations: [a] Diarrhea [15 mg QW] ; [b] Diarrhea [30 mg QW]; Nausea [30 mg QW]; Diarrhea [30 mg QW]; ISR erythema [30 mg QW]; [c] Pancreatitis [44 mg Q2W].
Unrelated discontinuations: Angina [placebo]; Colon CA [30 mg QW]; COVID-19 [30 mg QW].

89bio

Source: Safety Analysis Set. AE table cutoff ≥10% of patients for placebo, 30mg QW and 44mg Q2W doses.

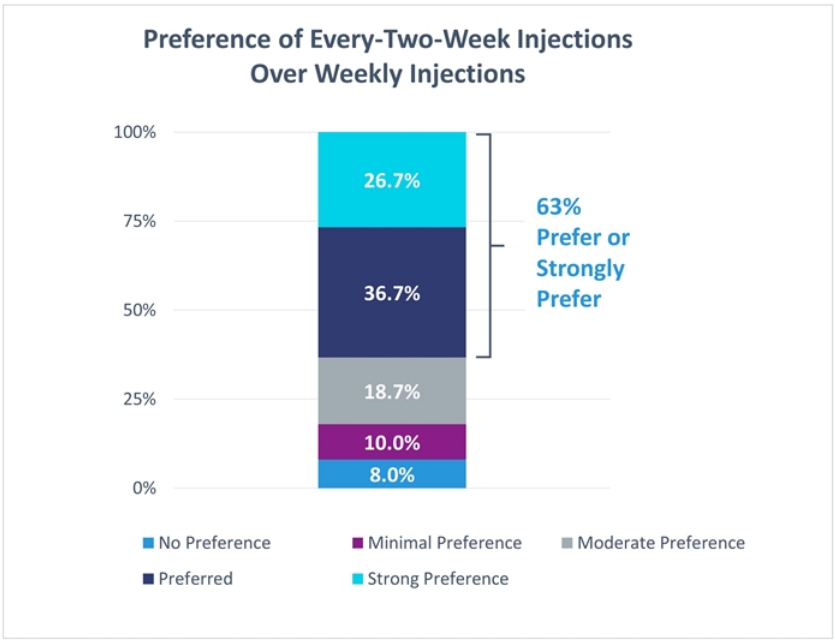
Pegozafermin – A Potentially Differentiated and Foundational NASH Therapy



89bio

APPENDIX

Over 60% of T2D Patients Prefer or Strongly Prefer Every-Two-Week Injections



- Every-two-week dosing provides opportunity for physicians to optimize therapy to patient preference
- Compliance is important in treatment for chronic, asymptomatic diseases

89bio

Source: primary market research with 150 people with type 2 diabetes, 2019.