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): January 24, 2022

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 8.01 Other Events.

On January 24, 2022, the Company issued a press release announcing the topline results from an expansion cohort of the Phase 1b/2a trial of pegozafermin for the treatment of nonalcoholic steatohepatitis. A copy of the press release is furnished herewith as Exhibit 99.1 and incorporated herein by reference.

Also on January 24, 2022, the Company made available an updated corporate presentation on the Company's website. A copy of the corporate presentation is filed herewith as Exhibit 99.2 and incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information furnished pursuant to this Item 8.01, including Exhibit 99.1, 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 by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits.*

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated January 24, 2022
99.2	Corporate Presentation, dated January 24, 2022
104	Cover page interactive data file (embedded within the inline XBRL document)

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: January 24, 2022

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

89bio Reports Positive Topline Results from an Expansion Cohort of the Phase 1b/2a Trial of Pegozafermin (BIO89-100) for the Treatment of NASH

- *63% of patients achieved 2-point or greater improvement in NAS without worsening of fibrosis; clinically meaningful improvements on registration enabling endpoints of NASH resolution (32%) and fibrosis improvement (26%)*

- *Robust changes on multiple non-invasive liver tests, markers of cardiovascular health and glycemic control support pegozafermin's potential as a compelling treatment option for NASH*

- *Phase 2b ENLIVEN trial ongoing in NASH patients with results expected in first half 2023*

- *Conference call and webcast today at 1:30 p.m. PST/4:30 p.m. EST*

SAN FRANCISCO, January 24, 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 announced positive topline results from an open-label expansion cohort of 20 patients (Cohort 7) in the Phase 1b/2a proof-of-concept study evaluating pegozafermin (formerly BIO89-100) for the treatment of NASH.

"The totality of the pegozafermin data is promising with clinically meaningful changes on histology endpoints, impressive changes on all non-invasive assessments looking at total liver health, as well as significant changes versus baseline in cardiovascular markers and glycemic control," said Rohit Loomba MD, MHSc, Director of the NAFLD Research Center, University of California San Diego and primary investigator of the study. "NASH is a complex disease and addressing overall liver health together with treating the underlying drivers of the disease is important in considering therapeutic options for our patients."

In this single-arm cohort, biopsy-confirmed, fibrosis stage F2 and F3 NASH patients were treated once weekly for 20 weeks with 27 mg of pegozafermin. At baseline, 65% of patients were fibrosis stage F3. Of the 20 patients enrolled, 19 received an end-of-treatment biopsy and the results from these 19 patients were as follows:

Table: Histology results

2-point or greater improvement in NAS without worsening of fibrosis[1] *(primary endpoint)*	63%
2-point or greater improvement in NAS[1]	74%
NASH resolution without worsening of fibrosis	32%
One-stage improvement of fibrosis without worsening of NASH	26%
NASH resolution or fibrosis improvement	47%

NAS = NAFLD Activity Score

1 A 2-point improvement in NAS score required a 1-point improvement in either ballooning or inflammation

Results also showed clinically meaningful and significant changes across key non-invasive tests (NITs) associated with fibrosis, risk of fibrosis or NASH resolution.

Table: Non-invasive tests (NITs) [marker of]

	Mean change from baseline at Week 20	Responder rates by clinically relevant thresholds
MRI-PDFF [liver fat content][1]	-64%***	100%/78% [³ 30%/³ 50%]
ALT (Alanine aminotransferase) [liver damage][2]	-46%***	71%[3] [³ 17 U/L]
FAST Score [risk for advanced fibrosis][4]	-76%***	88% [£ 0.35]
VCTE [liver stiffness][5]	-31%***	72% [> 20% decrease]
Pro-C3 [collagen deposition][6]	-20%***	63% [> 15% decrease]

*** p<0.001

1 Changes from baseline ³ 30% and ³ 50% have been correlated with NASH improvement

2 ALT changes ³ 17 U/L have been correlated with histological improvement

3 In patients with elevated ALT as defined by ³30 U/L in women and ³40 U/L in men (n=14)

4 FAST score is a composite of imaging and blood markers and measured on 0-1 scale, a score £ 0.35 predicts Fibrosis Stage F0/F1 and NAS <4

5 VCTE is a Fibroscan assessment, >20% reduction has been correlated with fibrosis improvement

6 Pro-C3 is a blood-based measurement, >15% reduction has been correlated with fibrosis improvement

“NASH is a multi-faceted disease and challenging to appropriately diagnose and manage. NITs of liver health and associated measures such as liver fat content, lipids, glycemic control and body weight are critically important for the successful management of patients with NASH,” said Stephen Harrison, M.D., medical director of Pinnacle Clinical Research. “The NITs 89bio utilized in this study provide clinically meaningful information because they assess the whole liver and thus are likely to be good indicators of disease improvement.”

In addition to significant improvement in liver health, treatment with pegozafermin also had significant positive effects on glycemic control, lipids, and body weight.

Table: Cardio-metabolic endpoints

	Mean change from baseline at Week 20
HbA1c absolute change[1]	-0.9%**
Triglycerides[2]	-32%***
LDL-C	-13%*
HDL-C	+23%***
Body Weight	-4%***

*p<0.05; **p<0.01; ***p<0.001

1 In patients with HbA1c ³ 6.5% at baseline (n=10); patients were all on concomitant diabetes medications

2 In patients with elevated triglycerides at baseline (n=11); reduction was -26% across total population

In 83 patients treated with pegozafermin across the full Phase 1b/2a study, pegozafermin continues to be generally well tolerated with a favorable safety profile. There have been no drug-related serious adverse events, only one treatment-related discontinuation, no tremors and no hypersensitivity reactions have been observed. In the open-label histology cohort the most commonly reported treatment-related adverse events were nausea, diarrhea, vomiting and injection site reactions, most of which were graded as mild.

“We are very pleased with the full data from our Phase 1b/2a study showing promising efficacy and safety and the encouraging histology results in this cohort further support pegozafermin as a promising drug for the treatment of NASH,” said Hank Mansbach, Chief Medical Officer of 89bio. “We are looking

forward to seeing results from our ongoing Phase 2b ENLIVEN trial, which will evaluate pegozafermin in greater than 200 patients with NASH with follow-up biopsy after 24 weeks of treatment. These results also bode well for our ongoing Phase 2 ENTRIGUE trial in severe hypertriglyceridemia (SHTG) patients with data expected in the first half of 2022."

Today's Conference Call Information

89bio will host a conference call and webcast at 1:30 p.m. PST / 4:30 p.m. EST today, January 24, 2022. Analysts and investors can participate in the conference call by dialing (877) 705-6003 for domestic callers and +1 (201) 493-6725 for international callers, using the conference ID 13726359. The webcast can be accessed live on the Events & Presentations page in the Investors section of the 89bio website, www.89bio.com. The webcast will be archived on the company's website for at least 30 days after the conference call.

About pegozafermin

Pegozafermin is a potentially best-in-class fibroblast growth factor 21 (FGF21) analog and an ideal candidate for the treatment of non-alcoholic steatohepatitis (NASH) and severe hypertriglyceridemia (SHTG). FGF21 is an endogenous hormone that modulates important drivers of NASH including glycemic control, steatosis, inflammation and fibrosis. Pegozafermin was specifically engineered using a unique glycoPEGylated technology to extend the half-life while maintaining potency. Pegozafermin combines efficacy, best-in-class dosing convenience, and favorable safety and tolerability. Recent Phase 1b/2a data with pegozafermin in biopsy-confirmed NASH patients demonstrated clinically meaningful changes on histology endpoints and non-invasive measures of total liver health, in patients with NASH as well as many of the underlying metabolic comorbidities commonly associated with NASH. Pegozafermin is currently being evaluated in the Phase 2b ENLIVEN trial in NASH and the Phase 2 ENTRIGUE trial for the treatment of SHTG.

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, pegozafermin, is a specifically engineered glycoPEGylated analog of FGF21. Pegozafermin 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. 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 for the treatment of NASH, the efficacy and safey of pegozafermin, pegozafermin's potential as a compelling treatment option for NASH, the timing for data from the Phase 2b ENLIVEN trial and Phase 2 ENTRIGUE trial and the relationship between the results from the expansion cohort and the ongoing Phase 2 ENTRIGUE trial. 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: positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; and other risks and uncertainties identified in 89bio's Annual Report on Form 10-K for the year ended December 31, 2020, its Quarterly Reports on Form 10-Q 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

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Pegozafermin (formerly BIO89-100) Phase 1b/2a NASH Histology Cohort Topline Results

Nasdaq: ETNB

January 24, 2022

Disclaimer

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, plans or intentions relating to product candidates, the potential clinical benefit, effect on histology and safety and tolerability profile of pegozafermin (formerly BIO89-100), the clinical potential of pegozafermin, potential indications for pegozafermin, the association of clinical data with potential clinical benefit in other indications, the anticipated timing, design, endpoints, and conduct of our ongoing clinical trials for pegozafermin, the timing of anticipated milestones, 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.

Pegozafermin – Growing Evidence of Strong Profile in Non-Alcoholic Steatohepatitis (NASH)

✓ **Previously reported data from the phase 1b/2a study results showed:**

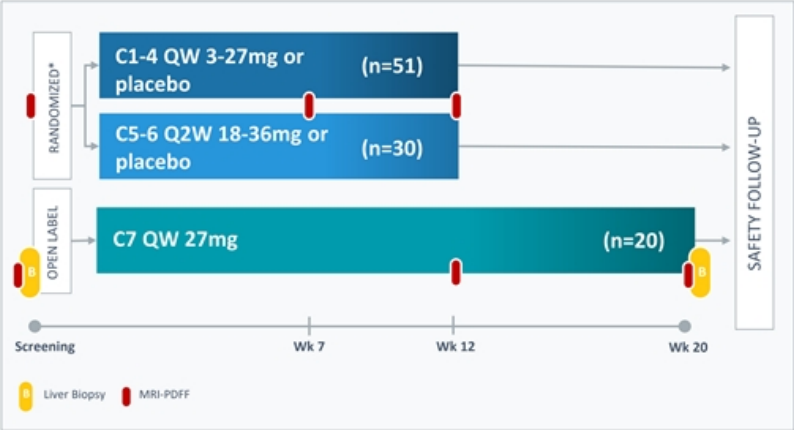
- Significant effect on liver and cardio-metabolic parameters
- Low incidence of treatment-related adverse events (AEs)
- Potential for every two-week dosing

✓ **Robust data from histology cohort (cohort 7) consistent with previous findings and validate pegozafermin's effect on histology**

- Meaningful changes on key histology endpoints – NAS >2pt., NASH Resolution, & Fibrosis
- Significant changes on non-invasive tests (NITs), glycemic control (HbA1c), lipid markers and body weight
- Favorable safety and tolerability profile

Results from phase 2b ENLIVEN study in >200 NASH F2/F3 patients expected in 1st half 2023

Phase 1b/2a NASH Trial Design – Randomized and Open-Label Cohorts



Cohort 7: 19/20 (95%) patients completed treatment and had end-of-treatment biopsies; 1 patient discontinued treatment due to withdrawal of consent

Biopsies were centrally read at baseline and end of treatment by a single pathologist

MRI dataset: 18 patients with Week 20 MRI; PD data: 19 subjects with Week 20 data

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*Randomized, double-blind, placebo-controlled

C7: Interim data based on Jan 3, 2022 data cut

RANDOMIZED* COHORTS 1-6

KEY INCLUSION CRITERIA

- Biopsy confirmed or phenotypic NASH
- PDFF≥10%

KEY ENDPOINTS

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

OPEN-LABEL COHORT 7

KEY INCLUSION CRITERIA

- F2-F3 NASH; NAS ≥4
- MRI-PDFF ≥8%

KEY ENDPOINTS

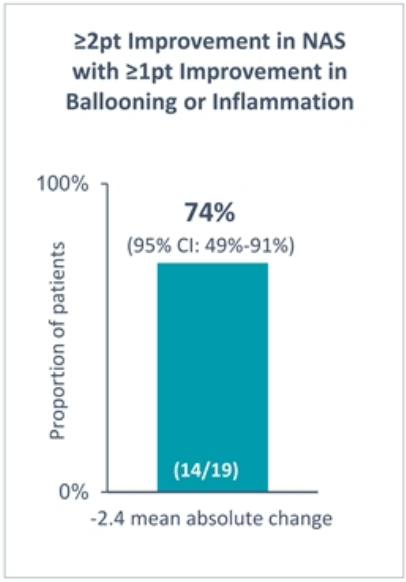
- ≥2 point improvement in NAS
- NASH Resolution
- Fibrosis Improvement
- Safety/tolerability

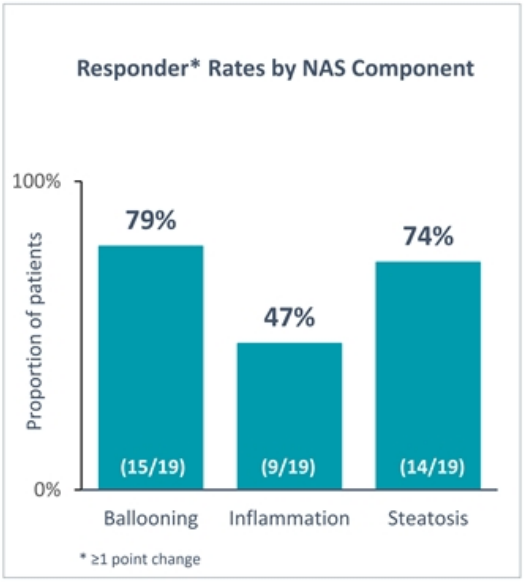
Baseline Characteristics

Parameter Mean or %	Cohort 7 (n=20)	Cohorts 1-6 (n=81)
Age (years)	58.4	51.9
Female	75.0%	61.7%
Weight (kg)	104.6	93.6
BMI (kg/m^2)	37.0	34.6
Type 2 Diabetes	85.0%	45.7%
% F2 / % F3	35% / 65%	NA
NAS	5.3	NA
MRI-PDFF (%)	21.1	21.3
ALT (U/L)	47.1	41.5
AST (U/L)	36.1	31.0
Pro-C3 (ng/mL)	19.3	11.9
VCTE (kPA)	14.3	7.3
Triglycerides (mg/dL)	170.0	174.3

NA: Not applicable

Pegozafermin Robustly Improved NAFLD Activity Score (NAS) and All Components of NAS

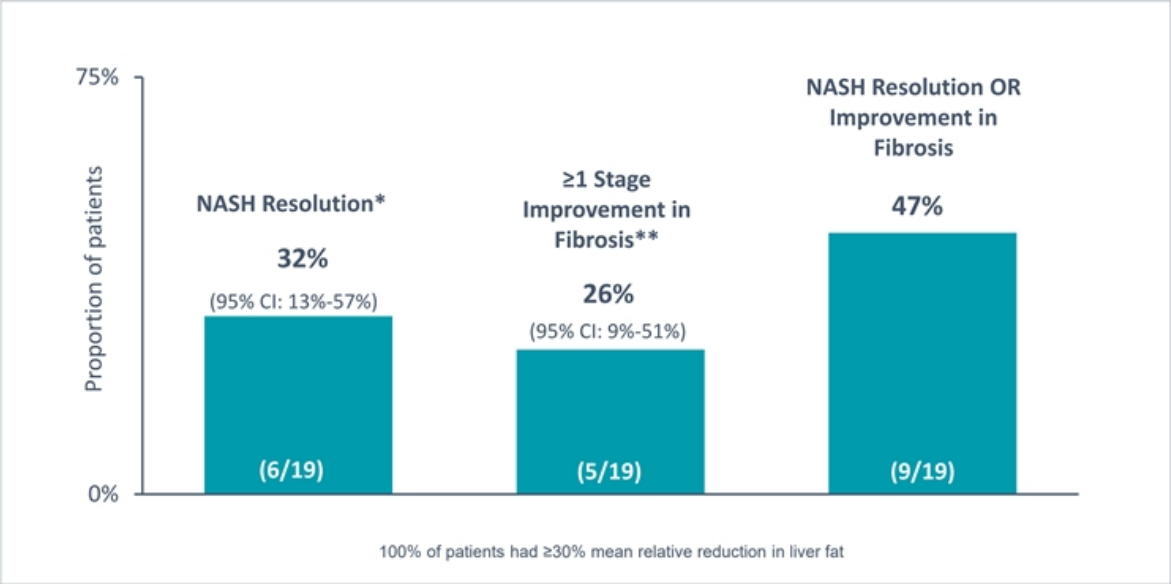




- **63%** of patients had ≥2point improvement in NAS and no worsening of fibrosis* (primary endpoint)
- **100%** of patients had improvement or no change in ballooning and inflammation

* with ≥1 point improvement in ballooning or inflammation

Pegozafermin Demonstrated Clinically Meaningful Changes on Key Histological Efficacy Endpoints



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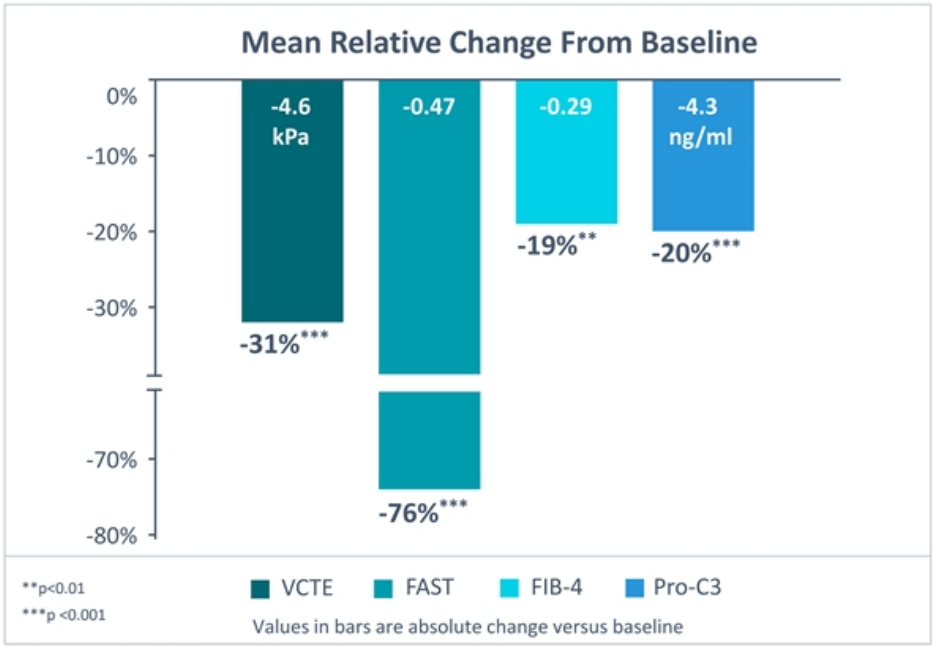
*and no worsening of fibrosis **and no worsening of NASH

Pegozafermin Substantially Improved Scores Across Non-Invasive Tests (NITs) Correlated with Advanced Fibrosis



NIT DESCRIPTIONS

- VCTE: FibroScan® liver stiffness measure
- FAST score: FibroScan (VCTE and CAP) plus AST; 0-1 scale
- FIB-4 score: Composite serum marker/age measure
- Pro-C3: Collagen deposition serum biomarker

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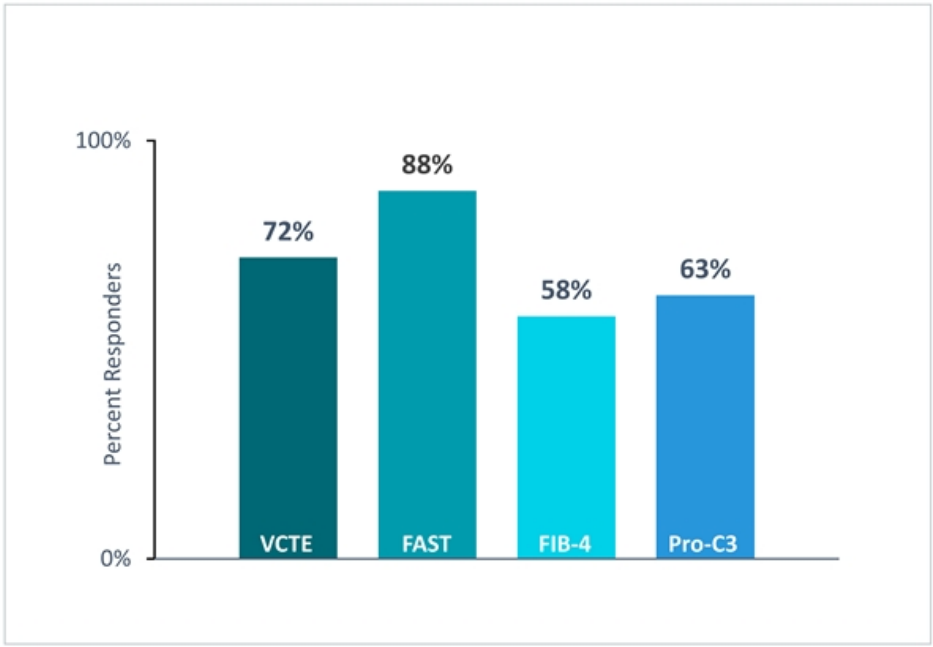
p value for change from baseline based on MMRM analysis
VCTE and FAST exclude one outlier with poor quality measurement

Pegozafermin had High Percentages of Responders Based on Clinically Relevant Thresholds for NITs



CLINICALLY RELEVANT THRESHOLDS

- VCTE: >20% reduction correlates with fibrosis improvement
- FAST score: Score ≤ 0.35 predicts Fibrosis Stage F0/F1 and NAS <4
- FIB-4 score: Score <1.3 predicts Fibrosis Stage F0/F1
- Pro-C3: >15% reduction correlates with fibrosis improvement

Tapper EB, *Am J Gastroenterol*, 2016
Newsome PN, *Lancet Gastroenterol Hepatol*, 2020
Kanwal F, *Gastroenterology*, 2021
Luo Y, *Scientific Reports*, 2018

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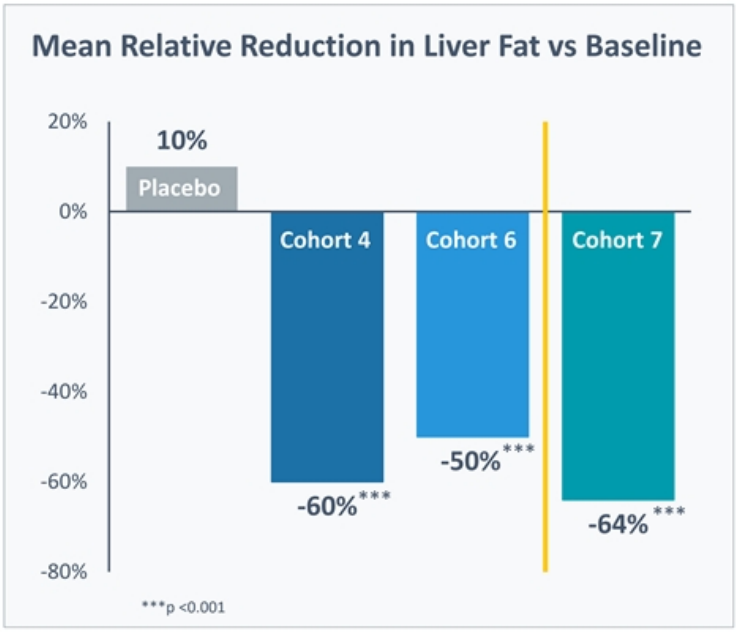
VCTE and FAST data exclude one outlier with poor quality measurement

Pegozafermin: Robust Liver Fat Reduction with High Responder Rates Consistent with Prior Cohorts



	≥30% Relative Reduction in Liver Fat	≥50% Relative Reduction in Liver Fat
Cohort 7	100%	78%
Cohort 4	86%	71%
Cohort 6	88%	50%

Cohort 7: 27mg QW data at 20 weeks, Cohort 4: 27mg QW data at 13 weeks, Cohort 6: 36mg Q2W at 13 weeks

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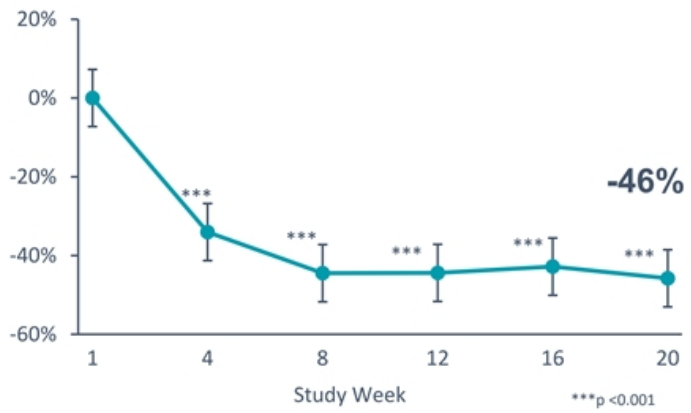
C7: MRI Analysis Set; p value for change from baseline based on MMRM analysis; Data from week 20
C4 and C6: MRI Analysis Set; MMRM LS Mean; p value vs placebo; Data from week 13

Loomba R, *Hepatology*, 2020
Harrison SA, *Hepatology Communications*, 2021

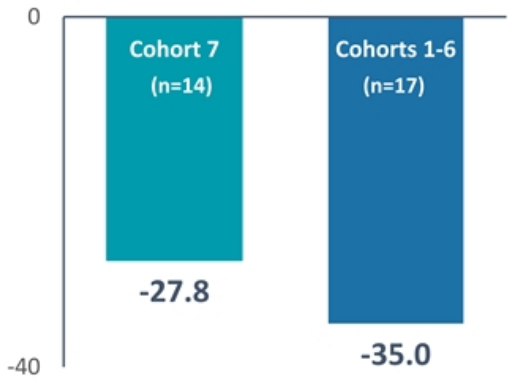
Pegozafermin: Clinically Significant Reduction in ALT Consistent with Prior Cohorts

ALT – Mean Change vs Baseline
(All Patients- Cohort 7)



Comparable changes were observed with AST

ALT – Absolute Change vs Baseline (U/L)
Patients with elevated ALT at baseline



% patients with ≥17 U/L reduction

71% **71%**

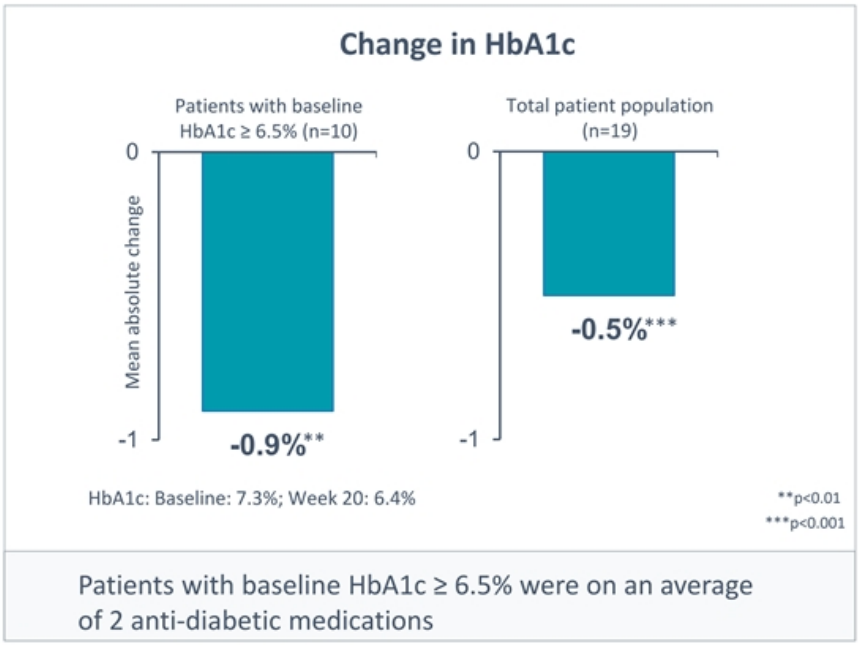
Loomba R, *Hepatology*, 2020

C7: elevated ALT ≥30 U/L for women and ≥40 U/L for men; Week 20

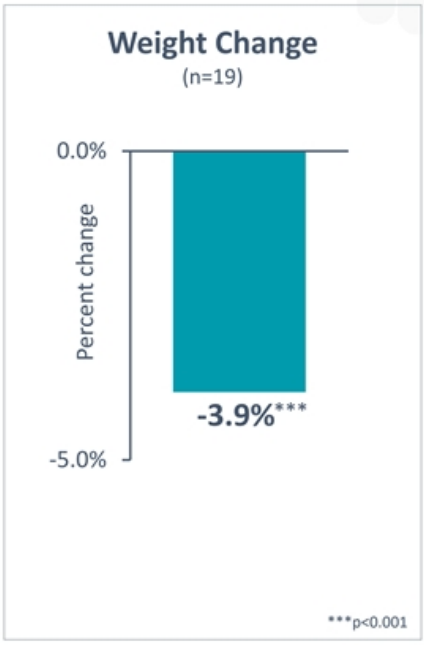
C1-6: PD Analysis Set in baseline ALT > 45 U/L; Pre planned sensitivity analysis; MMRM LS Mean at Week 13

89bio p value for change from baseline based on MMRM analysis

Pegozafermin Demonstrated Clinically Meaningful Improvement on HbA1c and Notable Body Weight Reduction

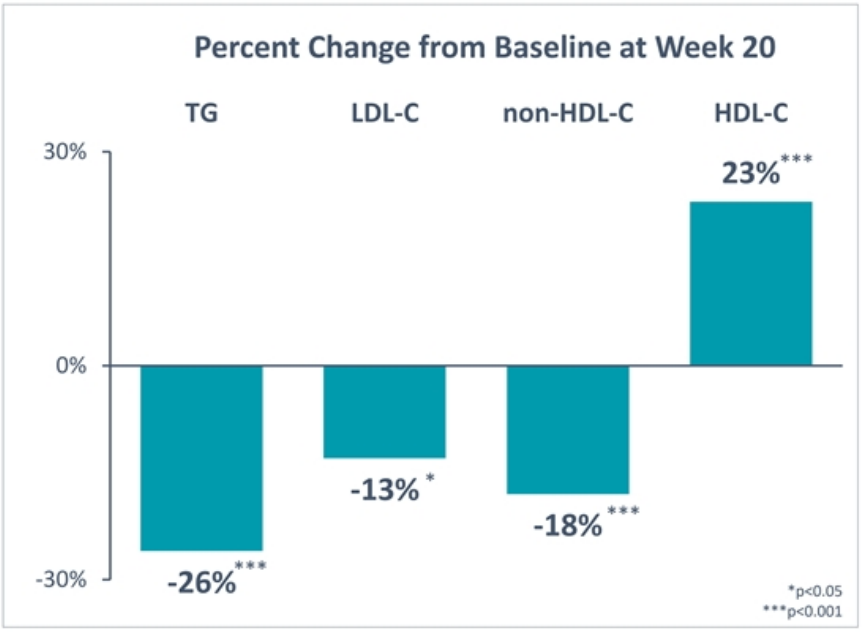


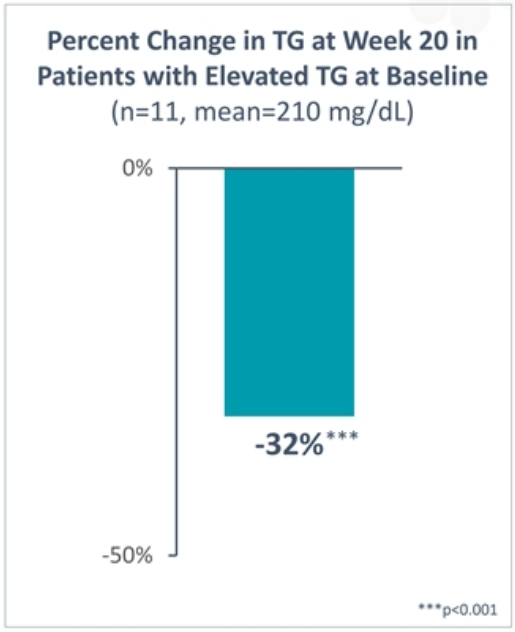
Patients with baseline HbA1c ≥ 6.5% were on an average of 2 anti-diabetic medications



p value for change from baseline based on MMRM analysis

Pegozafermin Demonstrated Clinically Meaningful Improvements in Lipid Parameters

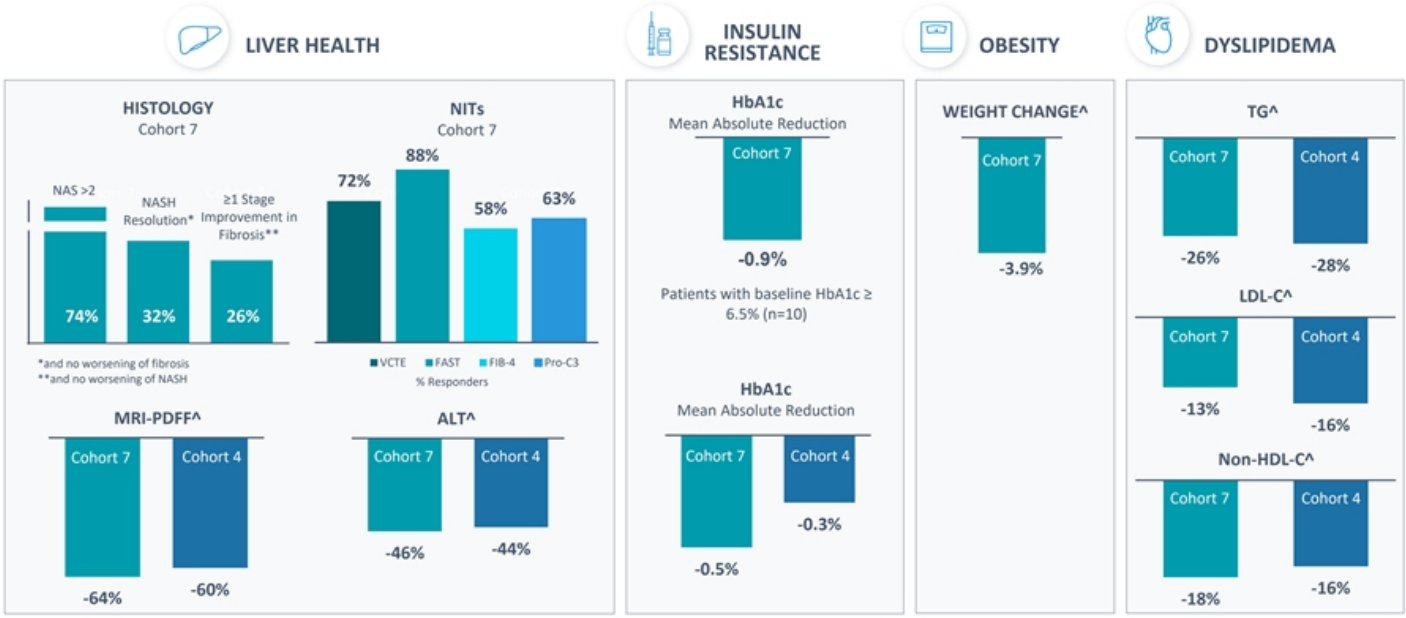




89bio p value for change from baseline based on MMRM analysis

Elevated TG: TG ≥ 150 mg/dL

Pegozafermin Improves Many Markers of Liver Health and Co-Morbidities Associated with NASH



^Mean reduction from baseline
Cohort 7: 27mg QW data at 20 weeks, Cohort 4: 27mg QW data at 13 weeks

Pegozafermin Was Well Tolerated Across Doses

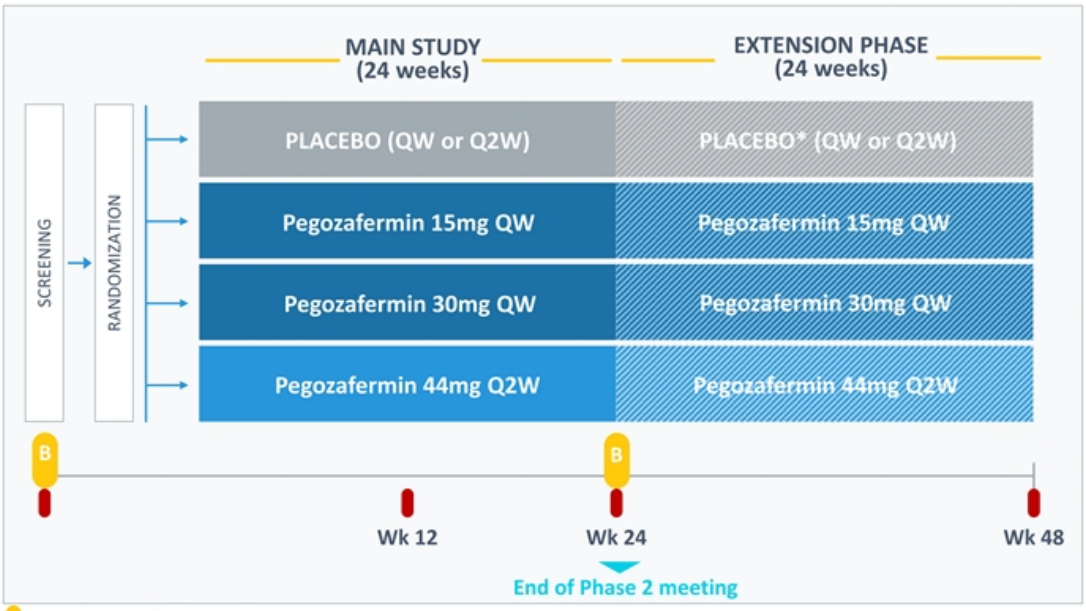
Low Incidence of Treatment-Related AEs in ≥ 10% of Pooled Pegozafermin Group

Preferred Term n (%)	Placebo (n=18)	Cohort 1 3mg QW (n=7)	Cohort 2 9mg QW (n=12)	Cohort 3 18mg QW (n=11)	Cohort 4 27mg QW (n=10)	Cohort 5 18mg Q2W (n=14)	Cohort 6 36mg Q2W (n=9)	Cohort 7 27mg QW (n=20)	Pooled pegoza (n=83)
Increased Appetite	0%	57%	17%	0%	20%	14%	0%	5%	13%
Diarrhea	11%	0%	8%	0%	20%	7%	22%	25%	13%
Nausea	11%	0%	0%	9%	0%	14%	0%	35%	12%

- Pegozafermin shows favorable safety and tolerability profile with no treatment related serious adverse events
- No tremors or hypersensitivity AEs reported; few mild injection site reaction events reported
- In cohort 7, other treatment related AEs observed in ≥10% of patients were vomiting (10%), injection site bruising (10%), injection site erythema (10%) and decreased appetite (10%); no events grade 3+ reported

C1-6: Safety Analysis Set; one placebo subject received one dose of pegozafermin 3mg and is summarized in 3mg QW group

Next Step: Phase 2b (ENLIVEN) NASH Trial Design



B Liver Biopsy MRI-PDFF

KEY INCLUSION CRITERIA

- F2-F3 NASH; NAS ≥4

PRIMARY ENDPOINTS

- Fibrosis Improvement
- NASH Resolution

SAMPLE SIZE

- N= 216 patients

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* Some placebo patients will be re-randomized in the extension phase to receive pegozafermin

Cohort 7 Results Confirm and Extend the Growing Evidence of Pegozafermin's Potential in NASH

- ✓ **Robust effects across key histology endpoints**
- ✓ **Impressive results in non-invasive clinically relevant measures of overall liver health**
- ✓ **Significant changes in glycemic control, lipids and body weight address key underlying drivers of NASH**
- ✓ **Favorable safety and tolerability profile**

Phase 1b/2a Study Results Provide High Level of Confidence in Pegozafermin's Benefits in Severe Hypertriglyceridemia (SHTG)

KEY PARAMETERS OF INTEREST IN SHTG	PEGOZAFERMIN RESULTS
Triglyceride reduction (TG) (primary endpoint)	✓
LDL-c reduction	✓
Non-HDL-c reduction	✓
Liver fat reduction	✓
Glycemic control (HbA1c)	✓

ENTRIGUE Study

- 8-week study of multiple doses of pegozafermin in patients with baseline TG ≥500 mg/dL
- Primary endpoint is % change in TG from baseline; Key secondary endpoints include other lipid and metabolic parameters and liver fat (MRI-PDFF)
- Results expected 1H22

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Professor of Medicine, Director of Hepatology
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Investment Highlights

Pegozafermin has potential to be a leading drug for liver and cardio-metabolic disorders

- Validated with compelling profile: strong efficacy including histology in NASH, favorable safety/tolerability, and potential best-in-class dosing

Pursuing two promising large indications with competitively differentiated profile

- NASH: Potential backbone treatment addressing multiple facets of NASH
- SHTG: Potential to treat TGs and metabolic dysregulation with quicker path to market

Program status/milestones

- SHTG: Phase 2 ENTRIGUE trial topline data in 1H22
- NASH: Phase 2b ENLIVEN trial topline data in 1H23

Strong capital position - $150.7M* in pro-forma cash (DEC 31, 2021)

* Includes $20M in debt

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Q&A