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): June 10, 2021

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 June 10, 2021 89bio, Inc. (the "Company") made available an updated corporate presentation on the Company's website. A copy of the corporate presentation is furnished herewith as Exhibit 99.1 and incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 8.01, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (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 of 1933, as amended, 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	Corporate Presentation, dated June 10, 2021

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.

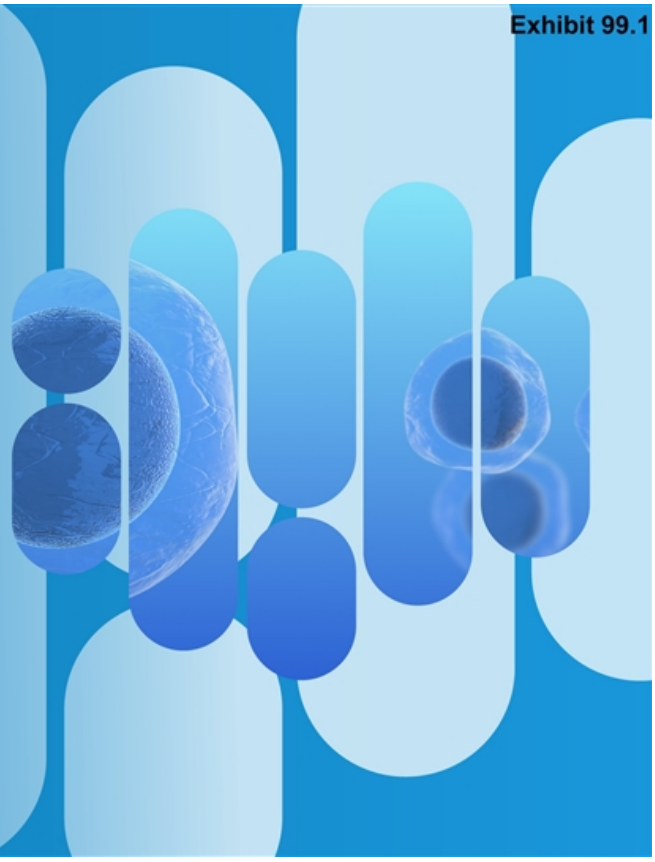
Date: June 10, 2021

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

Exhibit 99.1

89bio

Powerful Science
Meaningful Medicines
Changing Lives



Nasdaq: ETNB

June 2021

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, endpoints and conduct of our planned and ongoing 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.

89bio - Investment Highlights

BIO89-100 HAS POTENTIAL TO BE A LEADING DRUG FOR LIVER AND CARDIO-METABOLIC DISORDERS

- Highly differentiated FGF21 using GlycoPEGylation technology to optimize efficacy and dosing
- Validated with compelling profile: strong efficacy, 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

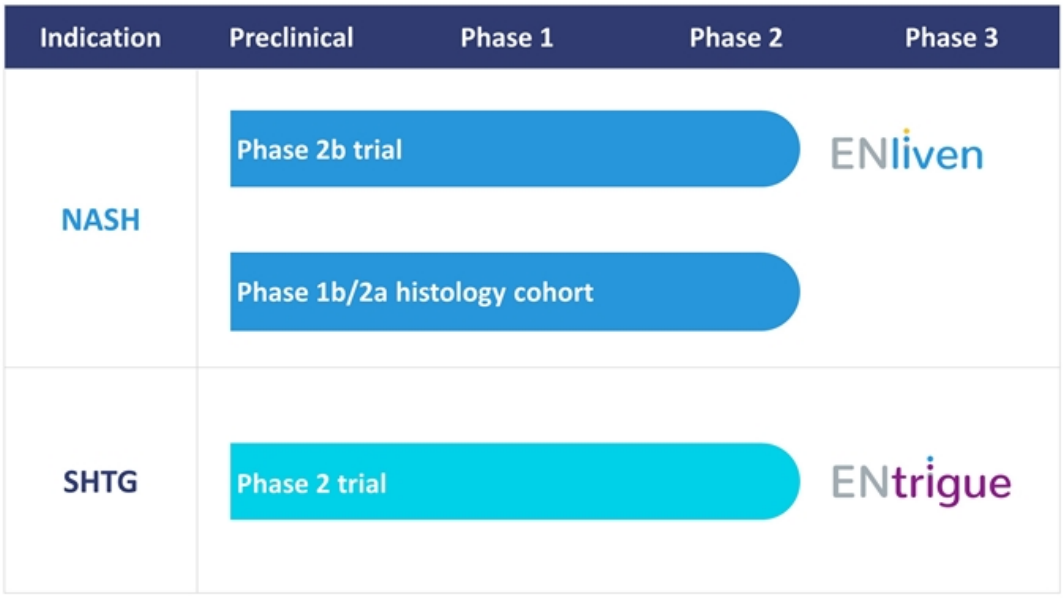
PROGRAM STATUS/MILESTONES

- NASH: Phase 2b ENLIVEN trial ongoing; Topline data from paired-biopsy, open-label histology cohort by YE21
- SHTG: Topline data from Phase 2 ENTRIGUE trial in 1H22

STRONG CAPITAL POSITION - $189.6M IN CASH, CASH EQUIVALENTS, AND SHORT-TERM INVESTMENTS (MAR 31, 2021)

ESTABLISHED MANUFACTURING EXPERTISE AND IP PROTECTION INTO 2038 AND BEYOND

Advancing BIO89-100 in Clinical Development



89bio

Opportunity in NASH

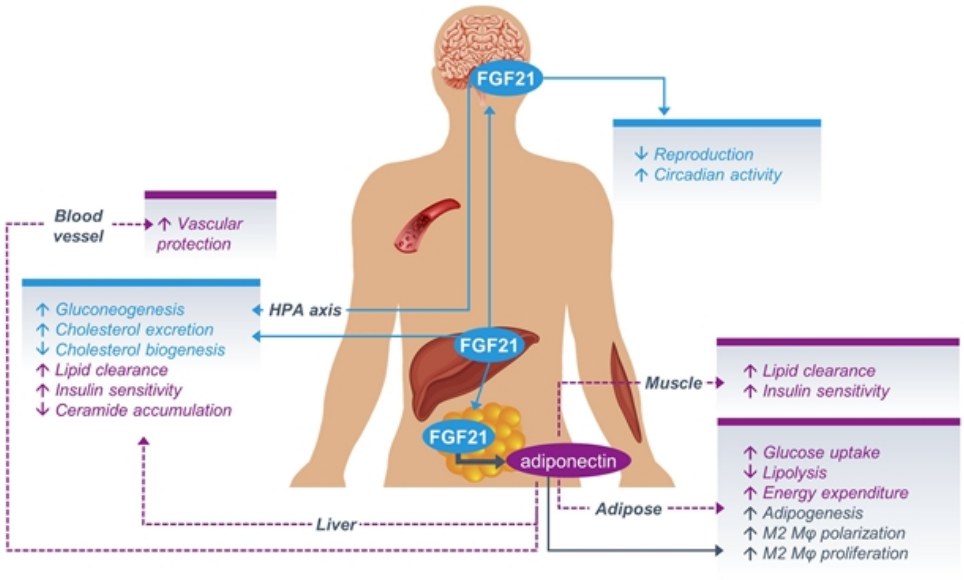
NASH is a Serious Liver Condition With Significant Co-Morbidities

Metabolic Dysregulation → Excess Liver Fat Accumulation → Progressive Disease

- No treatments currently available
- 16.5 million cases projected to grow to 27 million cases by 2030
- Expected to become the leading cause of liver transplant

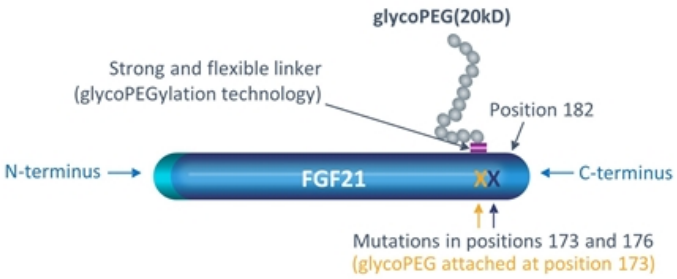
Co-morbidity	Prevalence in NASH population
Hypertriglyceridemia	83%
Obesity	82%
Hyperlipidemia / Dyslipidemia	72%
Metabolic syndrome	71%
Type 2 diabetes	44%

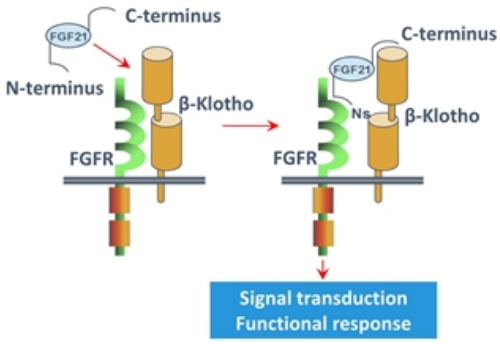
FGF21 Has Potential To Be Mainstay of Therapy In NASH



- Endogenous metabolic hormone that regulates energy expenditure and glucose and lipid metabolism
- Reduces liver fat by action within liver and from periphery
- Impacts liver fibrosis via metabolic pathway and upregulation of adiponectin
- Native FGF21 has a short half-life of < 2 hours

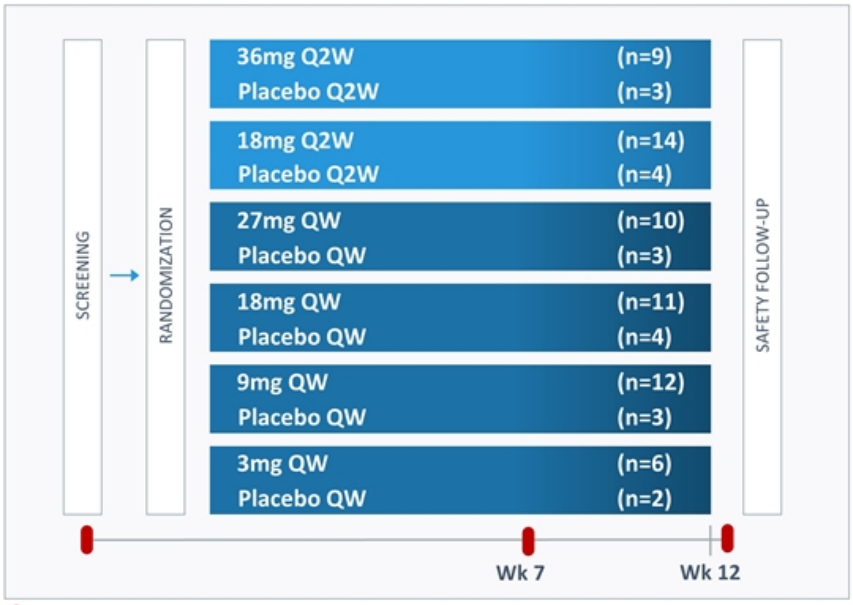
BIO89-100 Is An FGF21 Optimally Engineered To Balance Potential for Efficacy and Long Dosing Interval





- Proprietary glycoPEGylation technology with site-specific mutations
- Increases half-life of native FGF21 (< 2 hours) to 55-100 hours based on single ascending dose study
- Low nanomolar potency against FGF receptors 1c, 2c, 3c, similar to native FGF21
- No activity against FGF receptor 4 which is the primary target of FGF19, and which can lead to increased LDL levels

Phase 1b/2a NASH Trial Design



MRI-PDFF

- Placebo (n=19) combined across cohorts for analysis
- Randomized, pharmacodynamic (PD) and safety analysis set n=81; Study completers n=71
- MRI analysis set n=75 (patients with post-baseline MRI)

KEY INCLUSION CRITERIA

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

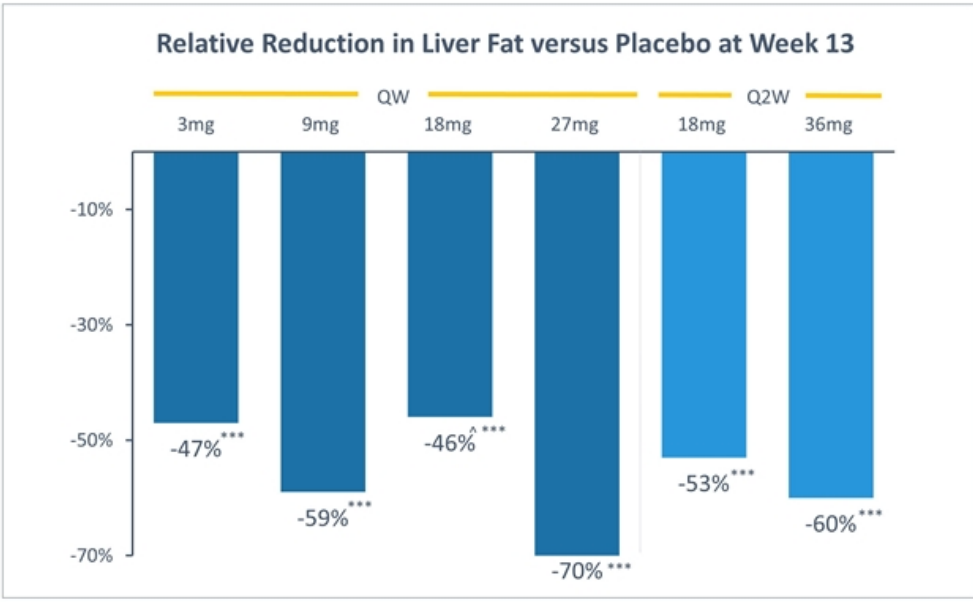
*Patients with biopsy-proven F1-3

#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

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



MRI Analysis Set; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo; placebo relative increase of 10% from baseline

^ 60% relative reduction in liver fat vs. placebo when final 2 patients from this dose group were excluded in a post-hoc analysis. These 2 patients came from 2 separate newly activated sites which came online just before the study closed enrollment in the midst of the COVID pandemic

Significant Numbers of Patients Achieved Clinically Meaningful Responder Rates on BIO89-100

	≥30% Relative Reduction in Liver Fat	≥50% Relative Reduction in Liver Fat
Placebo	0%	0%
3mg QW	60%**	20%
9mg QW	82%***	54%***
18mg QW^	60%**	50%**
27mg QW	86%***	71%***
18mg Q2W	69%**	39%**
36mg Q2W	88%***	50%**

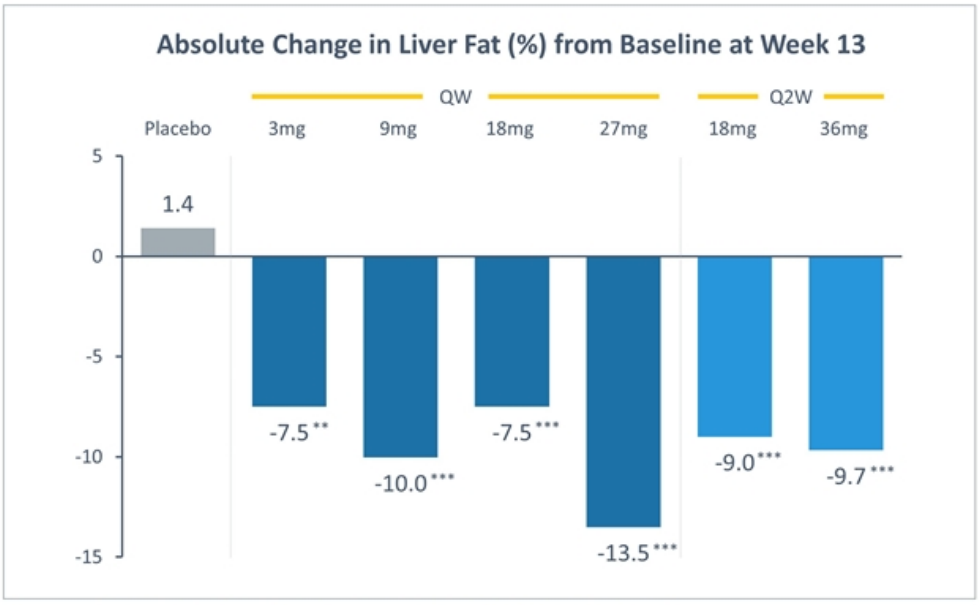
- Up to **43%** of patients normalized their liver fat (<5%)
- ≥30% relative reduction in liver fat has been correlated with NASH resolution and fibrosis improvement
- 71% of patients on 27 mg QW dose had ≥70% relative reduction in liver fat

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

^ 75% and 63% patients achieved a ≥30% and a ≥50% reduction in liver fat vs. baseline when final 2 patients from this dose group were excluded in a post-hoc analysis. These 2 patients came from 2 separate newly activated sites which came online just before the study closed enrollment in the midst of the COVID pandemic

89bio

BIO89-100 Significantly Reduced Liver Fat Across All Dose Groups



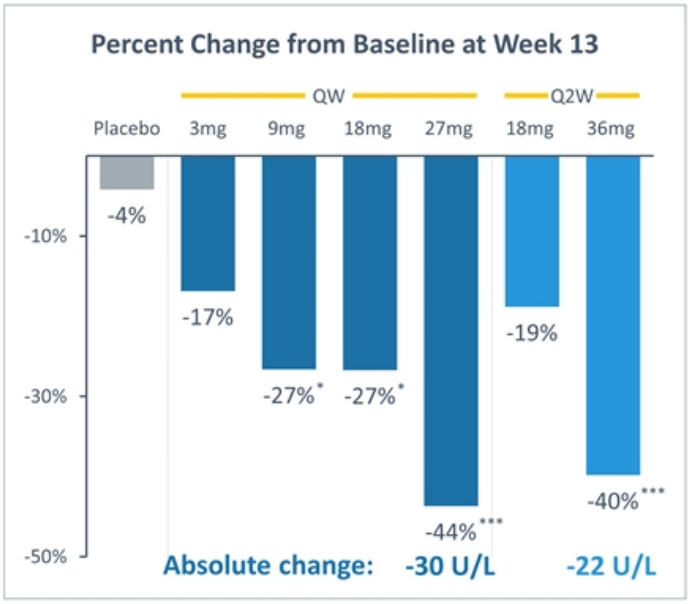
- Baseline characteristics were similar between NASH and PNASH patients
- Reductions in absolute percentage of liver fat from baseline, % responders on MRI-PDFF and BIO89-100's effect on reducing ALT and TGs were also similar across NASH and PNASH patients

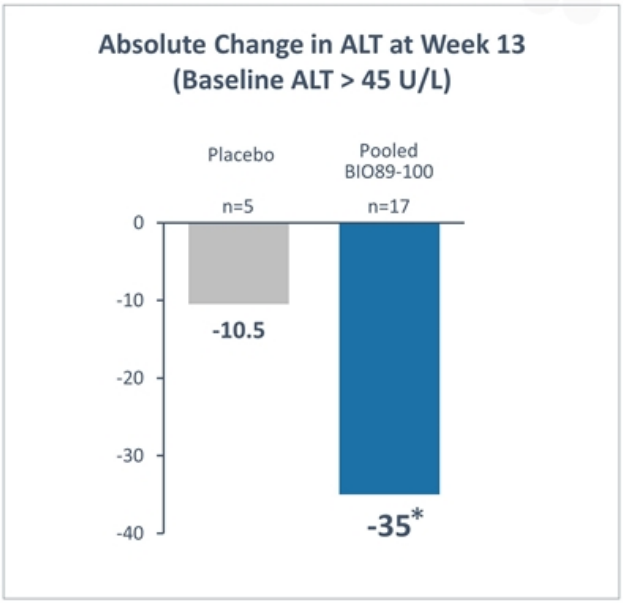
MRI Analysis Set; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo

^ 10% absolute reduction in liver fat from baseline when final 2 patients from this dose group were excluded in a post-hoc analysis. These 2 patients came from 2 separate newly activated sites which came online just before the study closed enrollment in the midst of the COVID pandemic

89bio

BIO89-100 Significantly Reduced ALT with Greater Reduction Observed in Patients with Elevated Baseline ALT



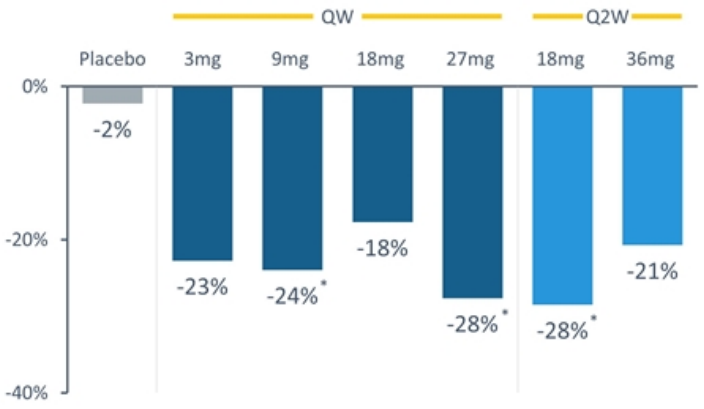


Change in ALT of ≥17 U/L has been correlated with improvement in fibrosis

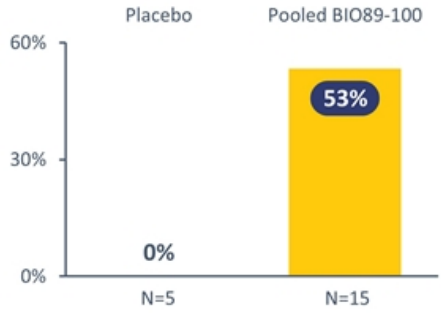
PD Analysis Set in baseline ALT > 45 U/L (placebo n=6, pooled BIO89-100 n=22); Pre-planned sensitivity analysis; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo

BIO89-100 Significantly Reduced Triglycerides with Greater Benefit Observed in Patients with High Triglycerides

Percentage Change from Baseline at Week 13 (All Patients)



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



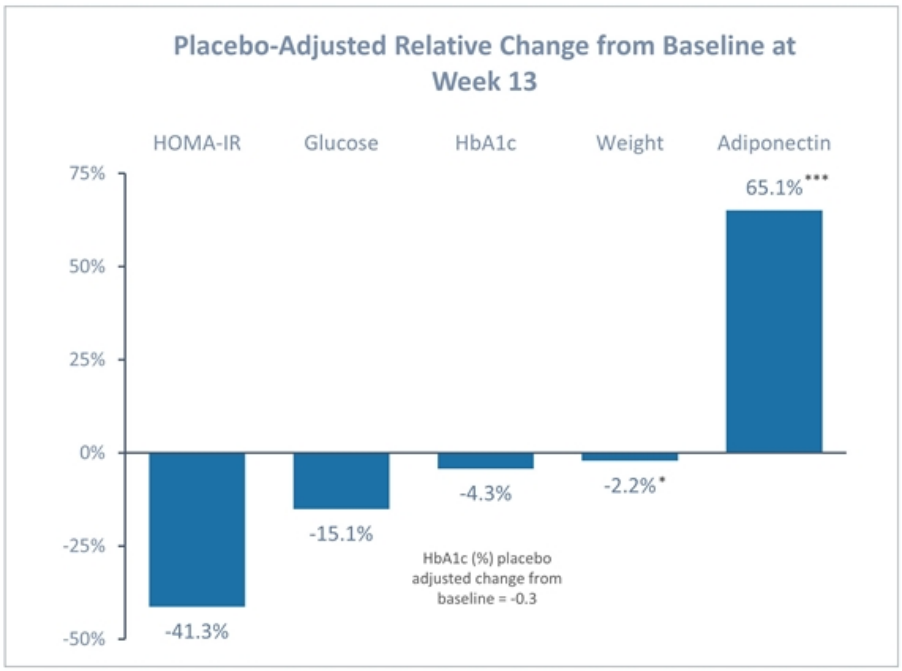
Decrease from baseline in BIO89-100 treated subgroup with baseline TG ≥200 mg/dL

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

89bio

PD Analysis Set; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo; # TG <150 mg/dL
TG at baseline (Total population): Pooled BIO89-100 (174.4 mg/dL) and Placebo (174.0 mg/dL)
TG at baseline (Subgroup with Baseline ≥ 200 mg/dL): Pooled BIO89-100 (288.1 mg/dL) and Placebo (228.0 mg/dL)

BIO89-100 (27 mg QW) Improved Metabolic Markers



PD Analysis Set; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo.
Placebo HOMA-IR: -0.1%; Glucose: +7.9%; HbA1c +0.61%; Weight: +1.4% Adiponectin: -4.3%

BIO89-100 Demonstrated a Favorable Safety Profile

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 patient received one dose of BIO89-100 3mg and is summarized in 3mg QW group

BIO89-100 Was Well Tolerated Across Doses

Low Incidence of Treatment-Related Emergent AEs in ≥ 10% of Pooled BIO89-100 Group

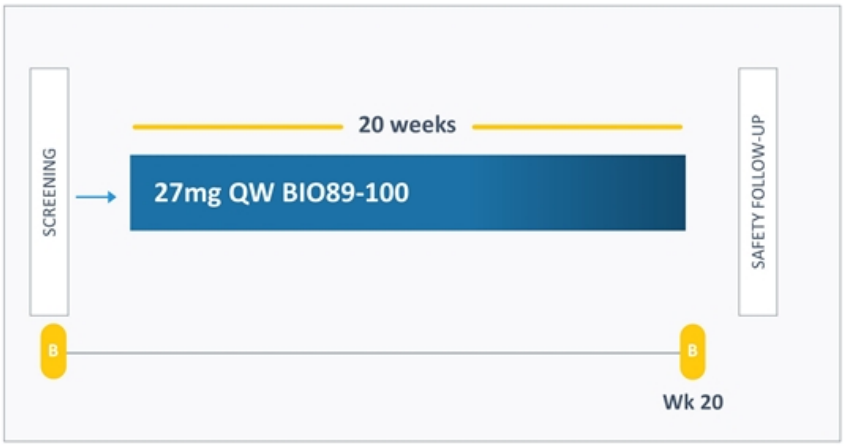
Preferred Term n (%)	Placebo (n=18)	Pooled BIO89-100 (n=63)	3mg QW (n=7)	9mg QW (n=12)	18mg QW (n=11)	27mg QW (n=10)	18mg Q2W (n=14)	36mg Q2W (n=9)
Increased Appetite	0.0%	15.9%	4	2	0	2	2	0

- GI related AEs were similar to placebo
  - Diarrhea: 9.5% vs. 11.1% (Pooled BIO89-100 vs. Placebo)
  - Nausea: 4.8% vs. 11.1% (Pooled BIO89-100 vs. Placebo)
  - Vomiting: 0.0% vs. 0.0% (Pooled BIO89-100 vs. Placebo)
- No hypersensitivity AE reported; few mild injection site reaction events reported
- No tremor reported; no adverse effects on blood pressure or heart rate

89bio

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

Phase 1b/2a NASH Open-label Histology Cohort Trial Design



B Liver Biopsy

KEY INCLUSION CRITERIA

- F2-F3* NASH; NAS ≥4
- MRI-PDFF ≥8%

PRIMARY ENDPOINT

- ≥2 improvement in NAS
- Safety/tolerability

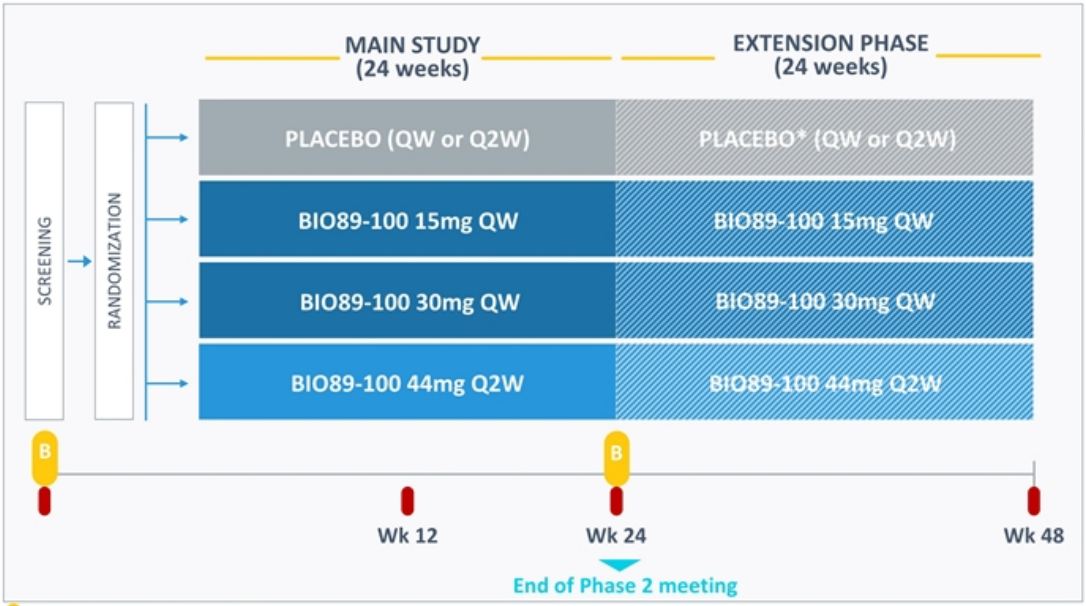
KEY SECONDARY ENDPOINTS

- Fibrosis Improvement
- NASH Resolution
- Liver fat (MRI-PDFF)
- Non-invasive tests

89bio

* Limited number of high-risk F1

Phase 2b (ENLIVEN) NASH Trial Design



B Liver Biopsy MRI-PDFF

89bio

* Some placebo patients will be re-randomized in the extension phase to receive BIO89-100

KEY INCLUSION CRITERIA

- F2-F3 NASH; NAS ≥4
- MRI-PDFF ≥8%

PRIMARY ENDPOINTS

- Fibrosis Improvement
- NASH Resolution

OTHER ENDPOINTS

- Other histological endpoints
- NITs – Pro-C3, ELF, FIB-4
- cT1
- Lipid and metabolic assessments
- Liver fat (MRI-PDFF)
- Safety

Comparative Profile of FGF21 Analogs

	BIO89-100	Efruxifermin	Pegbelfermin
Structure	• GlycoPEGylated FGF21	• Fc-fused FGF21	• PEGylated FGF21 (with non-native amino acid substitution)
Efficacy	• Significant effect on liver parameters • Robust impact on broad metabolic parameters • EFX demonstrated positive data in F4 patients		• Lower effects across all liver and metabolic parameters
Tolerability	• Well-tolerated at all doses • Placebo-like GI profile • No tremors	• High frequency and withdrawals from GI events in all 3 clinical studies • Tremors observed in MAD and Phase 2a studies	• Similar to BIO89-100
Dosing Frequency	• Weekly and Every Two-Weeks	• Weekly	• Daily or Weekly
Phase 2b Drug Product	• Liquid	• Frozen	• Liquid
Development Timelines	• Phase 2b (F2/F3) initiated in 2Q21	• Phase 2b (F2/F3) initiated in 1Q21	• Phase 2b (F3 and F4) complete - results pending

Note: All data regarding third-party studies on this slide are based third-party studies, which are in different stages of development, and not our own. Conclusions on this slide are not based on head-to-head results. Response rates are not guaranteed to maintain the same levels in future clinical studies.

89bio

Opportunity in SHTG

SHTG Market Is Large with Significant Unmet Need

LARGE PATIENT POPULATION

- Estimated **up to 4 million** patients
- Characterized by severely elevated **TG levels (≥ 500 mg/dL);** TGs are a type of non-cholesterol fat

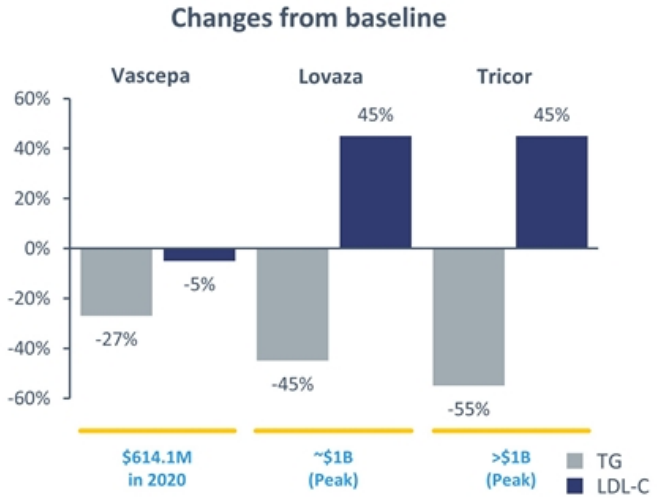
WITH HIGH UNMET NEED AND MULTIPLE CO-MORBIDITIES

- **Up to 50%*** of treated patients are refractory to current standard of care
- **56% of patients** have hepatic fat
- **Up to 70%** of patients have other dyslipidemias or Type 2 Diabetes

Primary research with physicians confirms unmet need and co-morbidities as above

* 50% is based on registrational trials of Vascepa and Epanova (at 4mg/day dose) approved in SHTG

Current Therapies Reached Blockbuster Status Despite Falling Short on Safety and Effect on Co-Morbidities



	FISH OILS		FIBRATES
	Vascepa (EPA)	Lovaza (EPA+DHA)	Tricor
Reduce Hepatic Fat	–	–	–
Improve LDL-C	–	Worsens LDL	Worsens LDL
ALT	–	Warnings, Monitoring Required	
Glycemic Control	–	–	–
Tolerability/ Safety	May prolong bleeding time		Myopathy, Creatinine increases, DDI

– Unchanged or Inconclusive

- US approval endpoint: % change in TGs from baseline; no clinical outcomes study required
- Ph 3 trials precedent*: Single 12-wk trials with ~200-300 pts

Unlike other therapies, BIO89-100 addresses the broad metabolic issues in these patients

89bio

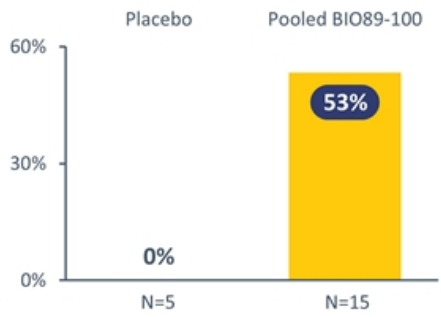
* Conclusions on this slide are not based on head-to-head results

BIO89-100 Significantly Reduced Triglycerides with Greater Benefit Observed in Patients with High Triglycerides

Percentage Change from Baseline at Week 13 (All Patients)

% change from baseline at week 13 (27mg QW dose)	
Hepatic fat	-60%
LDL-C	-16%
HbA1c (absolute change)	-0.3

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



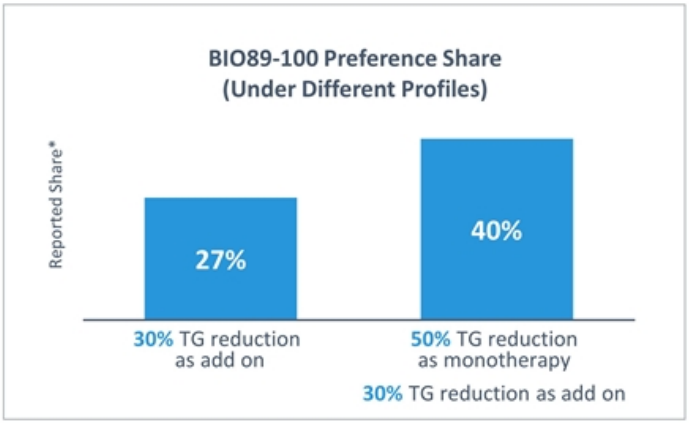
Decrease from baseline in BIO89-100 treated subgroup with baseline TG ≥200 mg/dL

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

89bio

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

Physicians Research Showed Strong Interest in the Broad Metabolic Profile of BIO89-100 for Their SHTG Patients



BIO89-100 Preference Share If Other Metabolic Benefits Observed

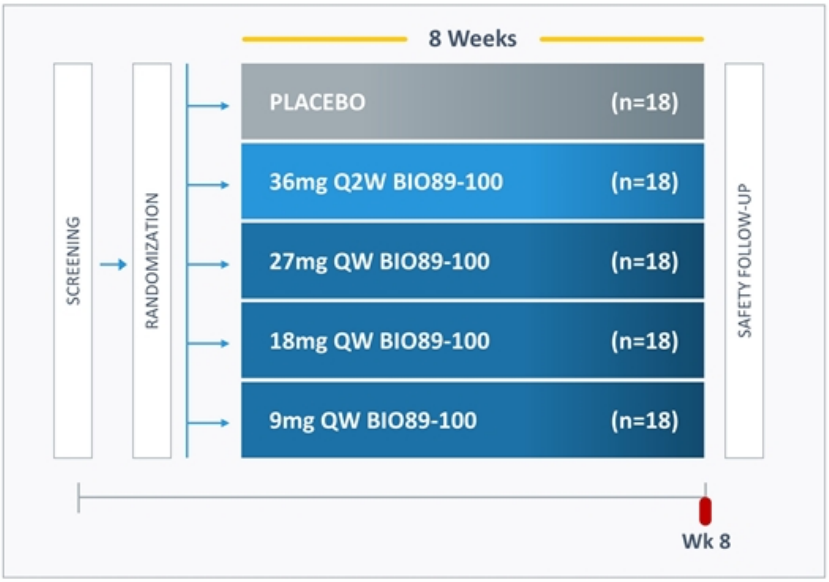
Parameter	Meaningful Chg. in Parameter	Share* for Meaningful Change + TG Reduction
Liver fat reduction	38%	**50% - 76%**
ALT normalization	40%	**48% - 74%**
LDL-C reduction	19%	**47% - 73%**

Analyst Consensus Estimate for SHTG Peak US Sales of ~$1.3B for BIO89-100

89bio

Source: 89bio Physician Quantitative Study with 150 US cardiologists, endocrinologists, and primary care physicians who treat patients with SHTG, July 2020– July 2020
*Reported shares are unadjusted and not weighted. Increases in shares are not additive. Reported shares generally overestimate actual use.

ENTRIGUE – Phase 2 SHTG Trial Design



% Chg in TGs from baseline

KEY INCLUSION CRITERIA

- TG ≥500 mg/dL and ≤2,000 mg/dL
- Background therapy of statins and/or prescription fish oil OR not on any background therapy

PRIMARY ENDPOINT

- % Change in TGs from baseline

KEY SECONDARY ENDPOINTS

- Other lipids and metabolic parameters
- Liver fat (MRI-PDFF)

89bio

* Based on Vascepa and Epanova programs

ENTRIGUE – Phase 2 SHTG Fibrate Cohort Trial Design

% Chg in TGs from baseline

KEY INCLUSION CRITERIA

- TG ≥500 mg/dL and ≤2,000 mg/dL
- Background therapy of fibrates

PRIMARY ENDPOINT

- % Change in TGs from baseline

KEY SECONDARY ENDPOINTS

- Other lipids and metabolic parameters
- Liver fat (MRI-PDFF)

Financial Position Summary

Cash, cash equivalents and short-term investments

$189.6 million (as of March 31, 2021)

Achievements and Milestones

ACHIEVEMENTS (~3 Years)

- ✓ Significant progress in the clinic: SAD, Phase 1b/2a in NASH, Phase 2 in SHTG, additional cohorts ongoing in NASH/SHTG
- ✓ Completed key preclinical studies including long-term tox
- ✓ Manufacture product at CMO
- ✓ Liquid formulation
- ✓ IP through 2038
- ✓ Strong balance sheet

PROGRAM STATUS/MILESTONES

- Phase 2b (ENLIVEN) NASH trial – Ongoing
- NASH histology results – YE21
- Topline results from Phase 2 (ENTRIGUE) SHTG trial – 1H22

89bio - Investment Highlights

BIO89-100 HAS POTENTIAL TO BE A LEADING DRUG FOR LIVER AND CARDIO-METABOLIC DISORDERS

- Highly differentiated FGF21 using GlycoPEGylation technology to optimize efficacy and dosing
- Validated with compelling profile: strong efficacy, 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

- NASH: Phase 2b ENLIVEN trial ongoing; Topline data from paired-biopsy, open-label histology cohort by YE21
- SHTG: Topline data from Phase 2 ENTRIGUE trial in 1H22

STRONG CAPITAL POSITION - $189.6M IN CASH, CASH EQUIVALENTS, AND SHORT-TERM INVESTMENTS (MAR 31, 2021)

ESTABLISHED MANUFACTURING EXPERTISE AND IP PROTECTION INTO 2038 AND BEYOND

89bio

Appendix

Experienced Management Team Positions 89bio for Success

Rohan Palekar
CEO

CEO, CCO experience

Commercial, strategy, and R&D experience

Otsuka AVANIR MEDIVATION J&J 89bio

Hank Mansbach, MD
CMO

20+ years biopharma and R&D leadership in clinical development and medical affairs

ultragenyx MEDIVATION VALEANT gsk

Ram Waisbourd
COO & CBO

20 years of operations, BD, and strategy experience

teva XTLbio

Ryan Martins
CFO

CFO, Strategy/IR, finance, sell-side experience

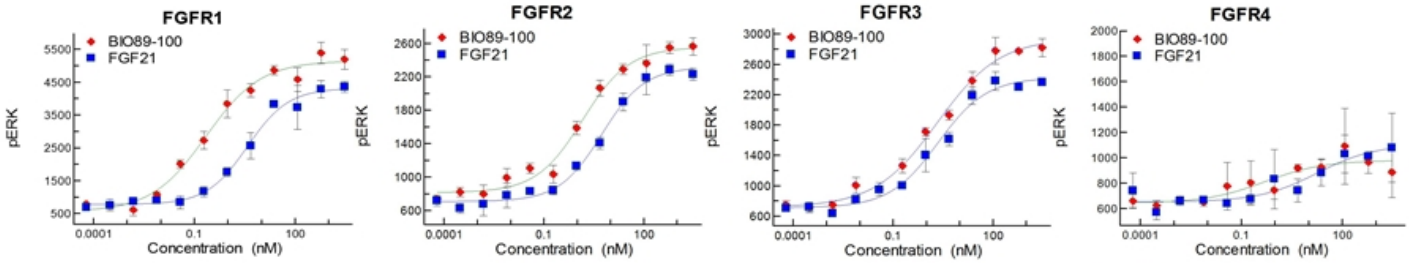
REVOLUTION MEDICINES ultragenyx pharmaceutical Jefferies CHIRON LEHMAN BROTHERS LAZARD BARCLAYS

Quoc Le-Nguyen
CTO & Head of Quality

20+ years biopharma and leadership in technical operations, product supply, and quality

Aduro NOVARTIS BIOMARIN BAYER

BIO89-100 Exhibits Highly Potent FGF Receptor Agonism



- BIO89-100 has the potential to reproduce the beneficial metabolic effects of native FGF21

RECEPTOR	FGF21	BIO89-100
	EC_{50} (nM)	EC_{50} (nM)
	Mean ± S.D.	Mean ± S.D.
KLB	nd	nd
KLB/FGFR1	4.5 ± 1.0	0.3 ± 0.07
KLB/FGFR2	4.5 ± 0.9	1.1 ± 0.4
KLB/FGFR3	1.8 ± 0.3	1.2 ± 0.4
KLB/FGFR4	nd	nd

nd – not determined; rhFGF19 EC_{50} at FGFR4 = 1.7 ± 0.4

89bio

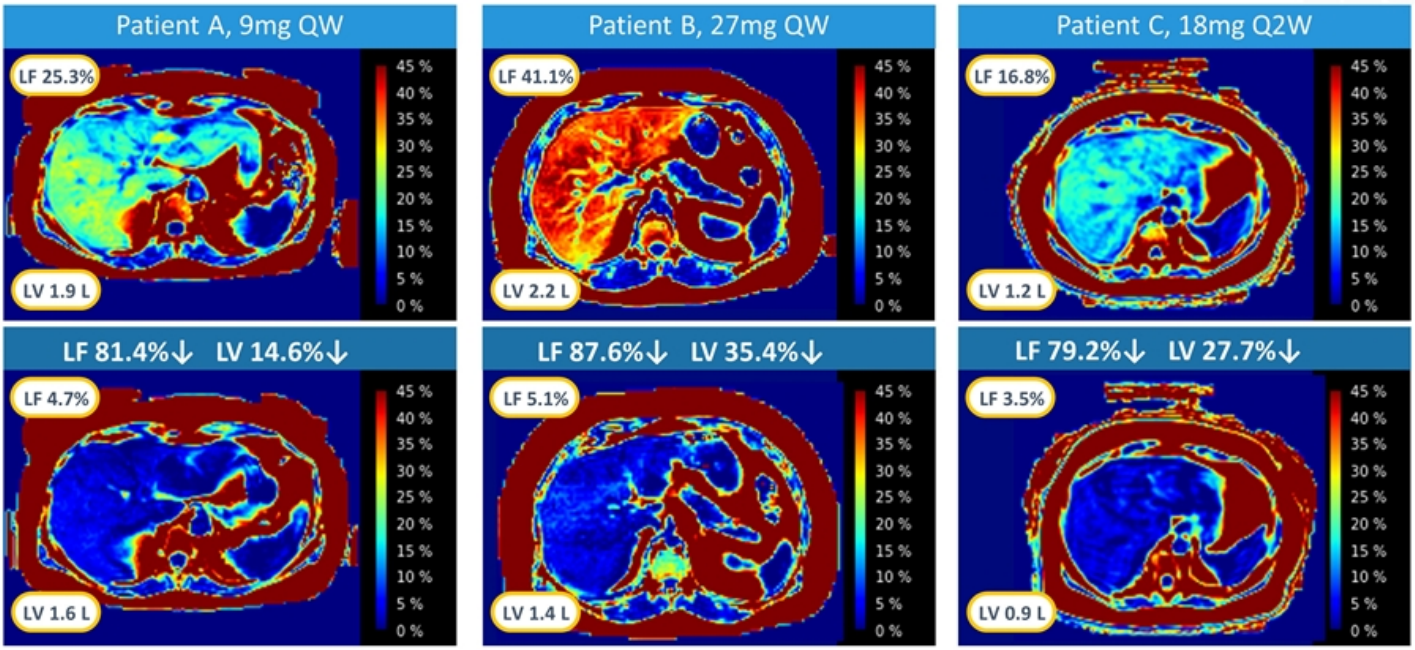
* Receptor agonism measured in L6 cells expressing β-klotho and either FGF Receptor 1c, 2c, 3c, or 4 via pERK functional assay
** Figures represent data from a single experiment; Table represents mean data from multiple experiments

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

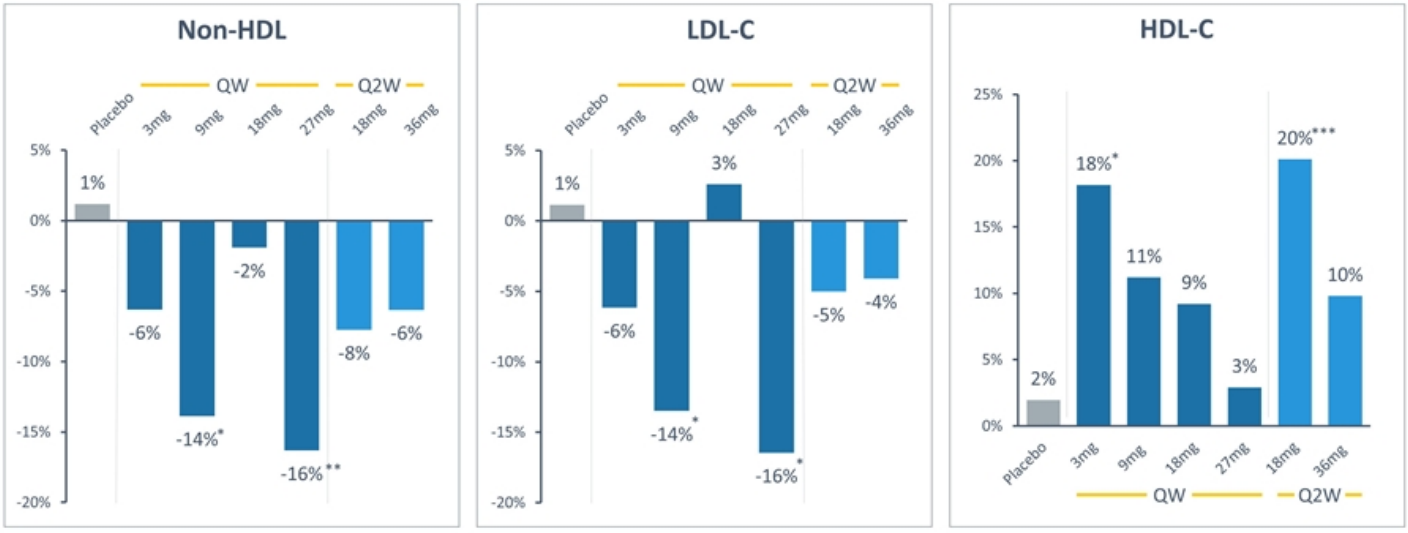
Baseline characteristics were similar between NASH (n=15) and PNASH (n=66) patients

Substantial Reduction in Liver Fat and Liver Volume Across Dose Groups



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 % Change	-4.3%	37.7%*	25.5%*	29.1%*	60.9%***	23.1%*	24.1%
Insulin& % 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)

Similar Baseline Characteristics in Patients with Biopsy-Proven NASH or PNASH

Parameter Mean or %	NASH (N=15)	PNASH (N=66)	Overall (N=81)
Age (years)	50.6	52.2	51.9
Male	20%	42.2%	38.3%
Weight (kg)	99.3	92.3	93.6
BMI (kg/m2)	35.4	34.4	34.6
Type 2 Diabetes	26.7%	50%	45.7%
ALT (U/L)	42.9	41.1	41.5
ALT > ULN (45 U/L)	26.7%	36.4%	34.6%
AST (U/L)	34.9	30.0	31.0

BIO89-100 has Overall Efficacy Comparable to EFX and Superior to Pegbelfermin

	BIO89-100 (12 weeks)		EFRUXIFERMIN (16 weeks*)		PEGBELFERMIN (16 weeks)	
	All Doses	27mg QW	28mg QW	50mg QW	10mg QD	20mg QW
KEY EFFICACY PARAMETERS						
MRI-PDFF						
Relative reduction in fat vs. placebo (%)	47-70	70	63	71	32	20
≥30% Responder (%)	60-88	86	84	85	56	54
ALT % Chg. vs. Baseline	-17 to -44%	-44%	~-40%	~-50%	-33%	-22%
PRO-C3 % Chg. vs. Baseline	-1.1 to -28%	-28%	-34%	-27%	-30%	-19%
Adiponectin % Chg. vs. Baseline	+23 to +61%	+61%	+69%	+88%	+15%	+15%

- Emerging histology data with Efruxifermin appears superior to Aldafermin. BIO89-100 non-invasive data was similar to that of Efruxifermin

89bio

* MRI-PDFF data is at 12 weeks
Note: All data regarding third-party studies on this slide are based third-party studies, which are in different stages of development, and not our own. Conclusions on this slide are not based on head-to-head results. Response rates are not guaranteed to maintain the same levels in future clinical studies.

BIO89-100 has Better Tolerability Profile Compared to EFX

	BIO89-100 (12 weeks)		EFRUXIFERMIN* (16 weeks)		PEGBELFERMIN (16 weeks)	
	Pooled	27 mg QW	28mg QW	50mg QW	20mg QW	10mg QD
SELECTED AEs	**Treatment Related AEs**		**Treatment Related AEs ≥10%**		**Most Frequent AEs**	
Diarrhea	9.5%	20%	26%	53%	21%	12%
Nausea	4.8%	0%	32%	21%	16%	13%
Vomiting	0.0%	0%	26%	11%	Present but % not reported	
Frequent Bowel Movement	3.2%	10%	16%	11%	0%	20%
Increased Appetite	15.9%	20%	21%	21%	Not reported	
Other	Drug Related D/C: Skin rash (1)		Drug Related D/C: Tremor (1); Acute pancreatitis (1); Nausea and/or vomiting (3)			

*doses expected in Ph2b ; "other" category from all doses

Note: All data regarding third-party studies on this slide are based third-party studies, which are in different stages of development, and not our own. Conclusions on this slide are not based on head-to-head results. Response rates are not guaranteed to maintain the same levels in future clinical studies.

FGF21 – Highly Differentiated Mechanism versus Leading Therapeutics in Development for NASH

		FGF21	FXR	PPAR*	THR-β	GLP-1
Robust efficacy with respect to liver pathologies	Liver fat reduction	✓	✓		✓	✓
	Fibrosis improvement	✓	✓	✓	?	
Ability to address underlying co-morbidities	Triglyceride reduction	✓		✓	✓	
	LDL-C improvement	✓	Worsens LDL		✓	
	HDL-C improvement	✓		✓		
	Glycemic control	✓		✓		✓
Well tolerated at effective dose	Limited Side Effects	✓ GI effect**	Pruritis LDL ↑	Weight Gain Edema	Drug-drug interaction	✓ GI effect
	Dosing frequency	Injectable QD/QW/Q2W	Oral	Oral	Oral	Injectable QD

✓ Effective ? Indeterminate ✓ Modest Effect Unknown or Unchanged

* Based on pan-PPAR ** for certain agents

Note: Table representative of data published and/or presented on the mid/late-stage clinical programs targeting these mechanisms.
Third party company data taken from publications/publicly available presentations.