

**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): October 5, 2020**

**89bio, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-39122**  
(Commission  
File Number)

**36-4946844**  
(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 October 5, 2020, 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**

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Corporate Presentation, dated October 5, 2020</a>

**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.

Date: October 5, 2020

**89bio, Inc.**

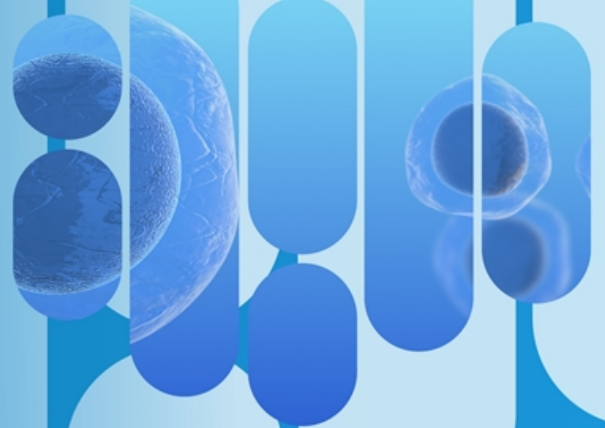
By: /s/ Rohan Palekar  
Rohan Palekar  
Chief Executive Officer

89bio

Powerful Science  
Meaningful Medicines  
Changing Lives

Nasdaq: **ETNB**

October 2020





# Disclaimer



## Cautionary Note Regarding Forward-Looking Statements

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

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

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

# 89bio - Investment Highlights



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

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- Validated in NASH demonstrating strong efficacy results, favorable safety/tolerability profile, and potential best-in-class dosing

## **BIO89-100 DELIVERS ON THE PROMISE OF FGF21**

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- FGF21 is a highly differentiated approach and potential backbone of treatment in NASH

## **PURSUING TWO PROMISING LARGE INDICATIONS**

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- NASH: Compelling benefit-risk profile in a differentiated class
- SHTG: Potential for quicker path to market with competitive differentiation (first FGF21 to market based on registrational trials planned in 2022)

## **MAJOR ANTICIPATED MILESTONES**

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- NASH: Initiation of a Phase 2b trial as part of a potential Phase 2b/3 trial in 1H21
- SHTG: Topline data from Phase 2 trial in 2H21

## **ESTABLISHED MANUFACTURING EXPERTISE AND IP PROTECTION INTO 2038 AND BEYOND**

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89bio

Opportunity in NASH



# BIO89-100: A Compelling Drug Candidate for NASH



## ROBUST EFFICACY RESULTS

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- Statistically significant reductions in liver fat and in key liver markers (ALT)
- Majority of patients achieved a  $\geq 30\%$  (up to 88%) or a  $\geq 50\%$  (up to 71%) reduction in liver fat

## FAVORABLE SAFETY/TOLERABILITY PROFILE

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- Very low frequency of GI adverse events and overall profile comparable to placebo
- Expected to drive physician adoption and patient compliance in this chronic, generally asymptomatic patient population

## POTENTIAL BEST IN CLASS DOSING REGIMEN

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- First FGF21 analog to show benefit in NASH with two-week dosing

## KEY UPCOMING MILESTONES

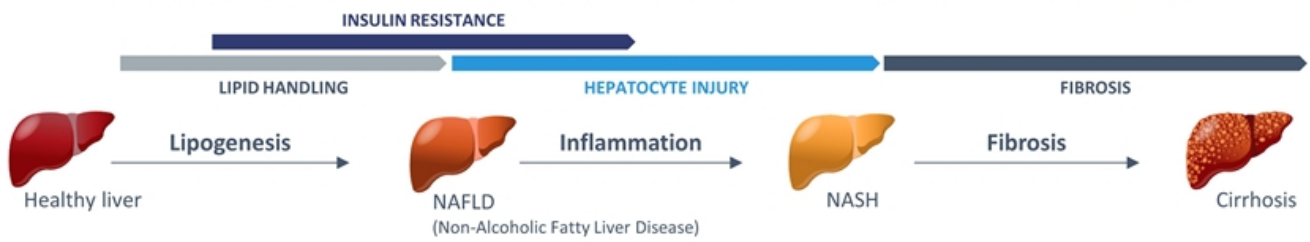
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- Initiation of a Phase 2b trial as part of a potential Phase 2b/3 trial: 1H21

# NASH is a Serious Liver Condition With Significant Co-Morbidities



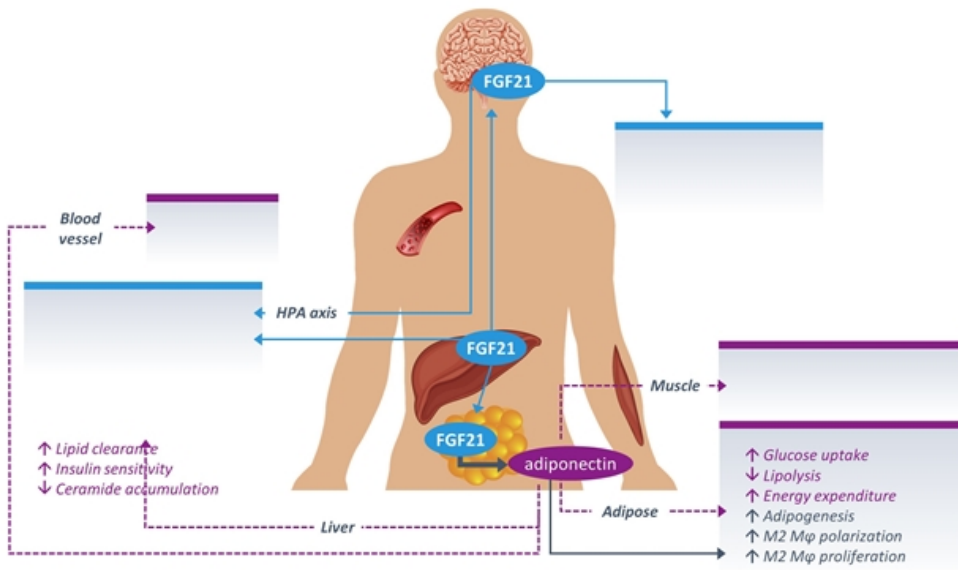
Metabolic Dysregulation → Excess Liver Fat Accumulation → Progressive Disease



- 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

# FGF21 – Validated and Highly Differentiated Mechanism for NASH

	FGF21	FGF19	FXR	PPAR*	THR-β	GLP-1	
Efficacy with respect to liver pathologies	Liver fat reduction	✓	✓	✓	✓	✓	
	Fibrosis improvement	✓	✓	✓	✓	?	
	Triglyceride reduction	✓	✓		✓	✓	
Ability to address underlying co-morbidities	LDL-C improvement	✓	Worsens LDL	Worsens LDL		✓	
	HDL-C improvement	✓			✓		
	Glycemic control	✓			✓	✓	
Well tolerated at effective dose	Limited Side Effects	✓ GI effect**	LDL ↑	Pruritis LDL ↑	Weight Gain Edema	Drug-drug interaction	✓ GI effect
	Route of administration/ Dosing frequency	Injectable QD/QW/Q2W	Injectable QD	Oral QD	Oral QD	Oral QD	Injectable QD

✓ Effective      ? Indeterminate      ✓ Modest Effect      Unknown or Unchanged

\* Based on pan-PPAR \*\* for some FGF21 analogs

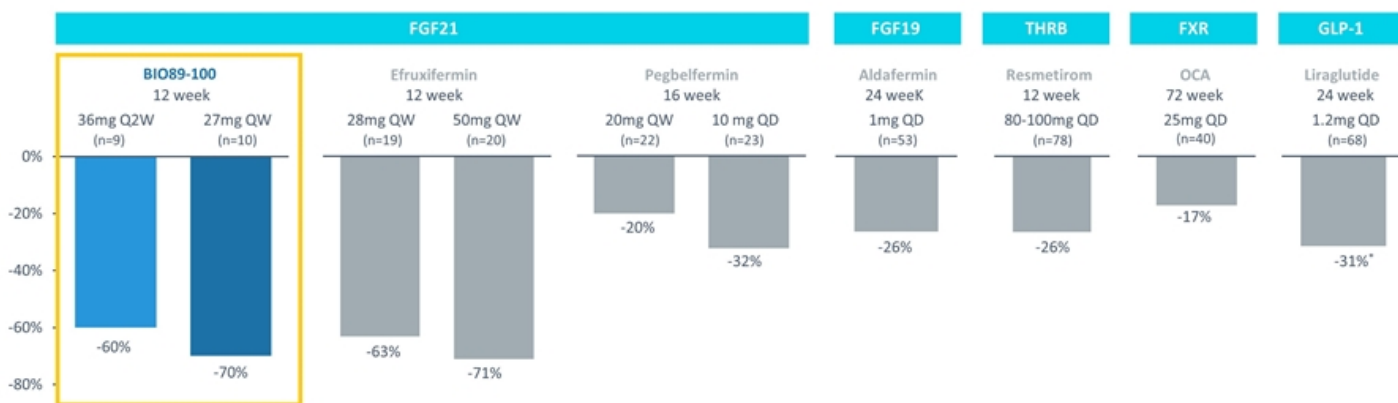
Note: Table representative of data published and/or presented on the mid/late stage clinical programs targeting these mechanisms. Conclusions on this slide are not based on head to head results. Third party company data taken from publications/publicly available presentations.





# FGF21 – Highly Promising Mechanism for NASH

## RELATIVE CHANGE IN LIVER FAT FROM PLACEBO (% REDUCTION)



- Reductions in liver fat as demonstrated through decreases in MRI-PDFF have been shown to correlate with histology benefits especially in the case of proportion of patients achieving a  $\geq 30\%$  reduction in liver fat from baseline

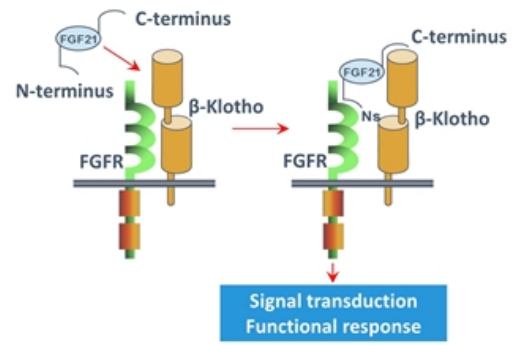
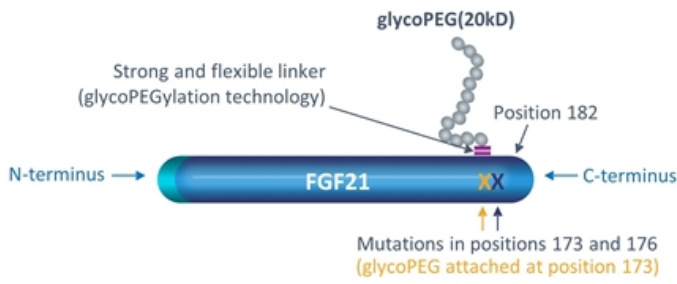


\* Not placebo controlled; \*\*No worsening of NAS (NAFLD Activity Score)

Note: All data regarding third-party studies on this slide are based on third-party trials, some of which are in different stages of development. Conclusions on this slide are not based in head-to-head results. Efficacy shown here may change in future clinical trials; Graphs are representative of data published and/or presented on the mid/late stage clinical programs targeting these mechanisms



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



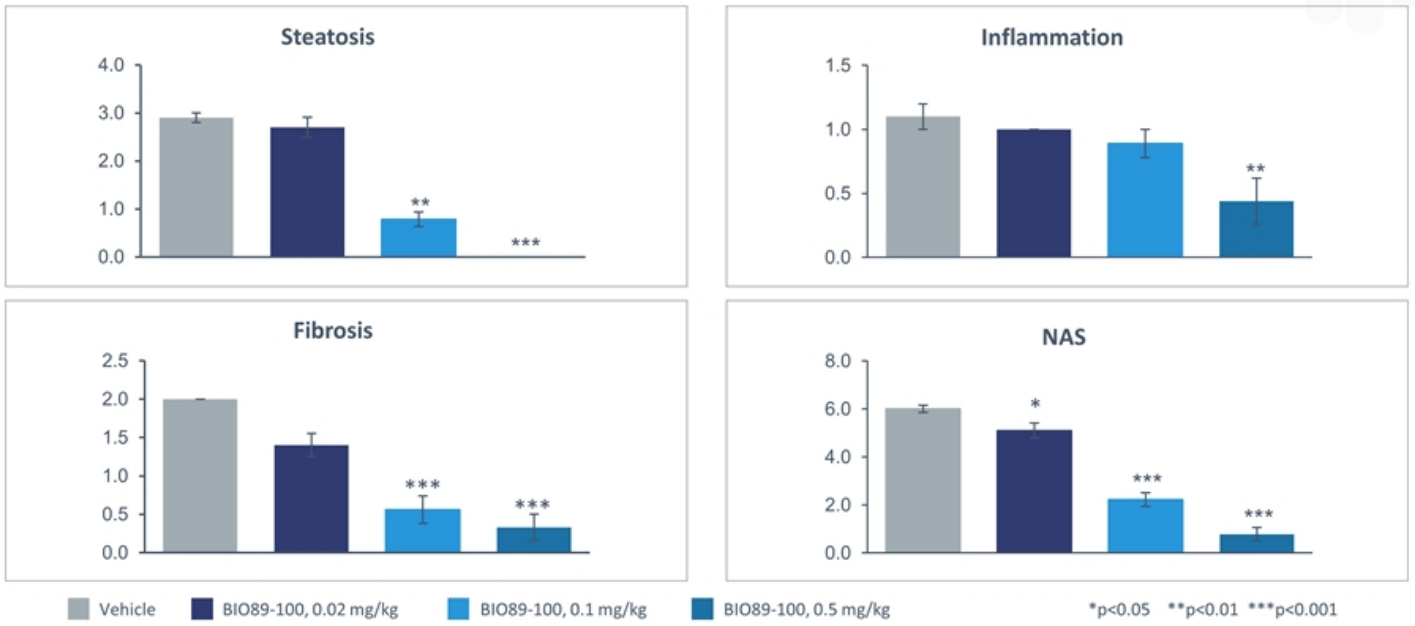
- FGF21 is an endogenous metabolic hormone that regulates energy expenditure and glucose and lipid metabolism
- Proprietary glycoPEGylation technology with site-specific mutations
- Long half-life of 55-100 hours vs. native FGF21 half-life of < 2 hours based on single ascending dose study
- Low nanomolar potency against FGF receptors 1c, 2c, 3c, similar to native FGF21; no activity against receptor 4 that can lead to increased LDL levels

# Extensive Pre-clinical and Early Clinical Data With BIO89-100



		Reduced Hepatocyte Injury	Reduced Liver Steatosis, Inflammation & Fibrosis	Improved Lipid Handling*	Improved Insulin Sensitivity	Body Weight Reduction
PRECLINICAL STUDIES	DIN mouse model (10 weeks)	✓	✓	✓	✓	✓
	DIN mouse model (19 weeks)	✓	✓	✓	✓	✓
	Diabetic obese cynomolgus monkey study (8 weeks; weekly dosing)	✓	Not evaluated	✓	✓	✓
	Diabetic obese cynomolgus monkey study (4 weeks; weekly & 2-week dosing)	✓	Not evaluated	✓	✓	✓
HUMAN	Single Ascending Dose Study in healthy volunteers	BIO89-100 was safe, well tolerated, showed significant improvements in key lipid parameters, and had a half-life of 55-100 hours with dose proportional PK				

# Reduction In Steatosis, Inflammation, Fibrosis and NAFLD Activity Score With BIO89-100 In DIN Model



Note: Obeticholic acid, 25 mg/kg tested as active control – did not separate from control in this study  
 Scoring system: Steatosis (0-3), Inflammation (0-3), Fibrosis (0-4), NAS (0-13) - all were assessed at week 19; mean scores

# Phase 1b/2a Results: Promising Benefit-Risk Profile with Convenient Dosing



## ROBUST EFFICACY RESULTS

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

## FAVORABLE SAFETY RESULTS & TOLERABILITY

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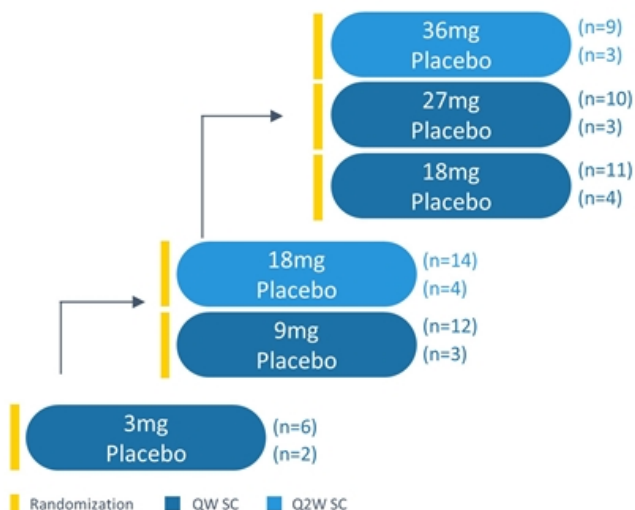
- Well tolerated at all doses with low incidence of adverse events that occurred in  $\geq 10\%$  of subjects
- Very low frequency of gastrointestinal events and similar profile to placebo
- No hypersensitivity or tremor observed; no adverse effects on heart rate or blood pressure

## POTENTIAL BEST-IN-CLASS DOSING REGIMEN

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- Strong efficacy and favorable tolerability seen with weekly and two-week dosing

# BIO89-100-002: Trial Design



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

## KEY INCLUSION CRITERIA

- NASH\* or phenotypic NASH (PNASH)<sup>#</sup>
  - PDFF ≥ 10%
- \*Subjects with biopsy-proven F1-3  
<sup>#</sup>Central obesity plus T2DM or evidence of liver injury

## KEY TRIAL ENDPOINTS

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

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

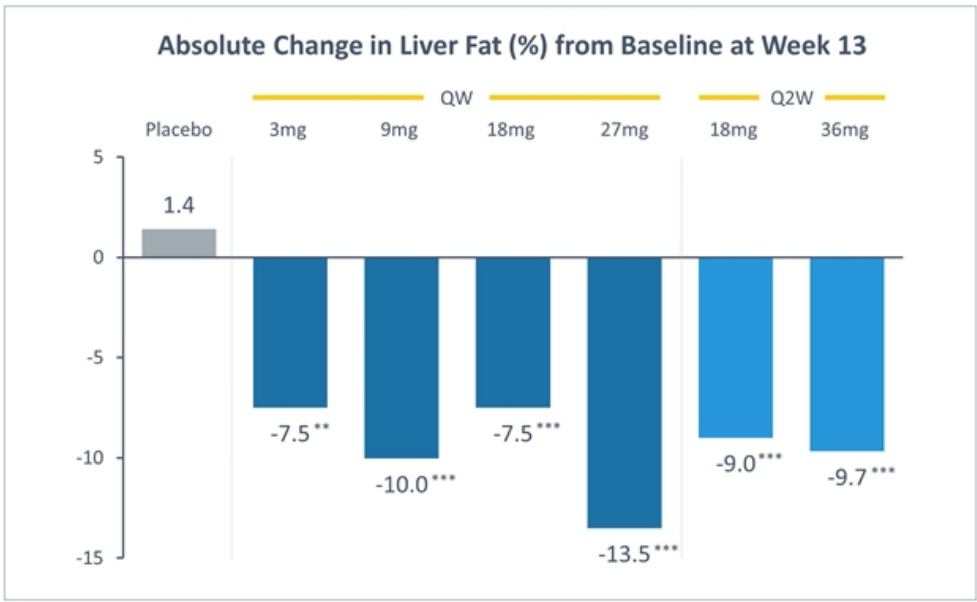
## Baseline Characteristics



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

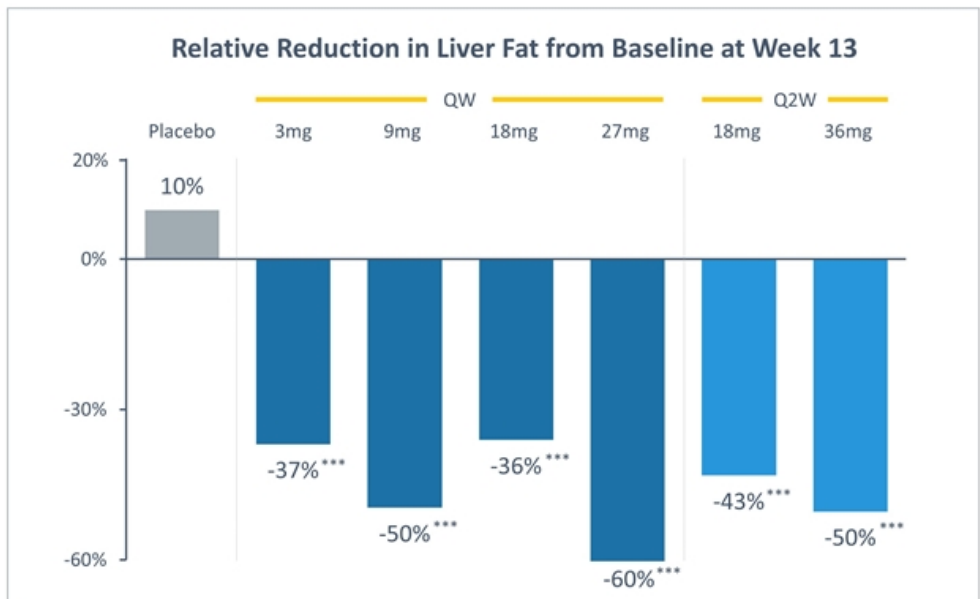
Baseline characteristics were similar between NASH (n=15) and PNASH (n=66) subjects

# BIO89-100 Significantly Reduces Liver Fat Across All Dose Groups



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

# BIO89-100 Reduces Liver Fat in Significant Percentage of Subjects



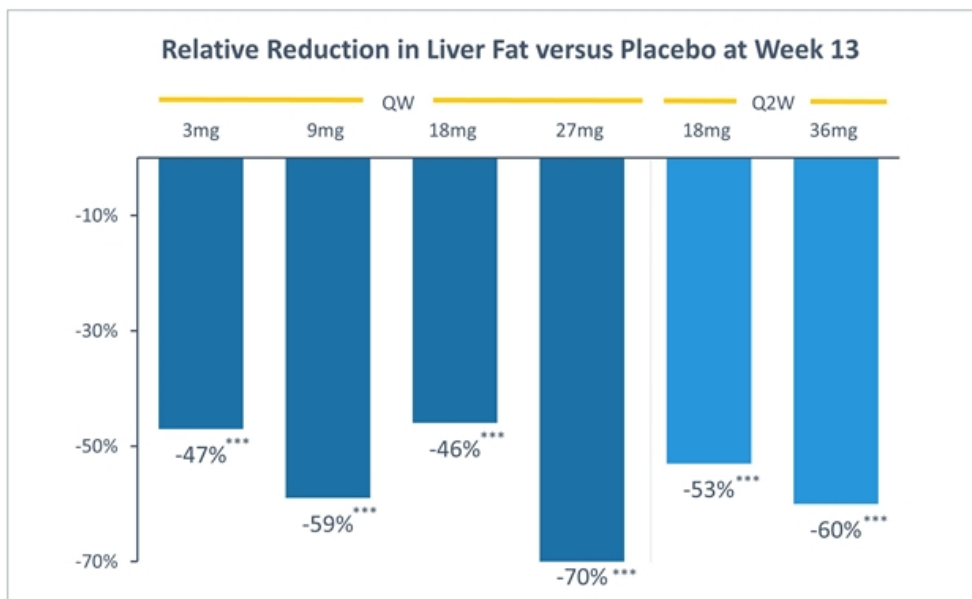
Proportion of Subjects with  $\geq 30\%$  Relative Reduction in Liver Fat

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

- $\geq 30\%$  relative reduction in liver fat has been correlated with NASH resolution and fibrosis improvement



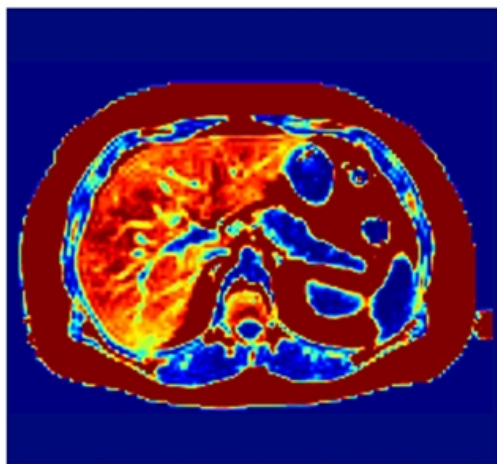
# Majority of Subjects on BIO89-100 Achieved $\geq 50\%$ Reduction in Liver Fat



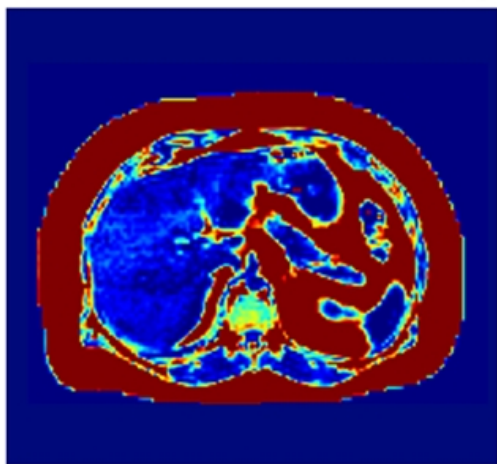
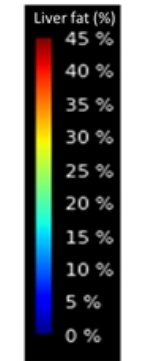
Proportion of Subjects with  $\geq 50\%$  Relative Reduction in Liver Fat

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

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

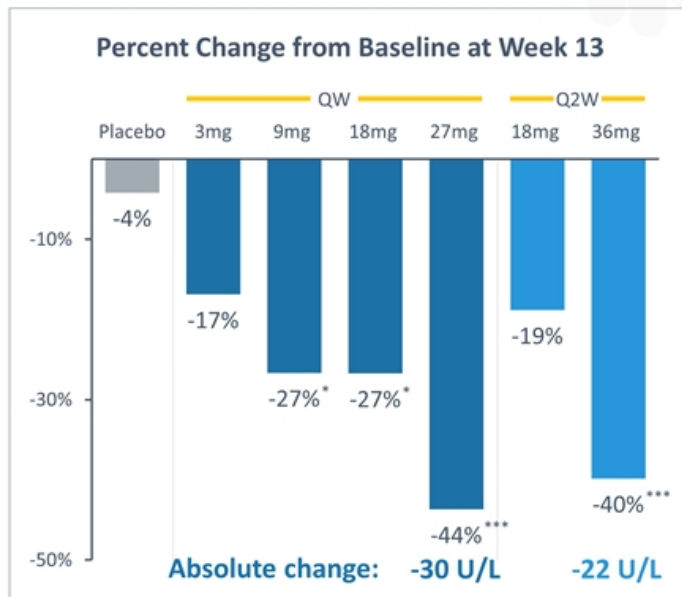
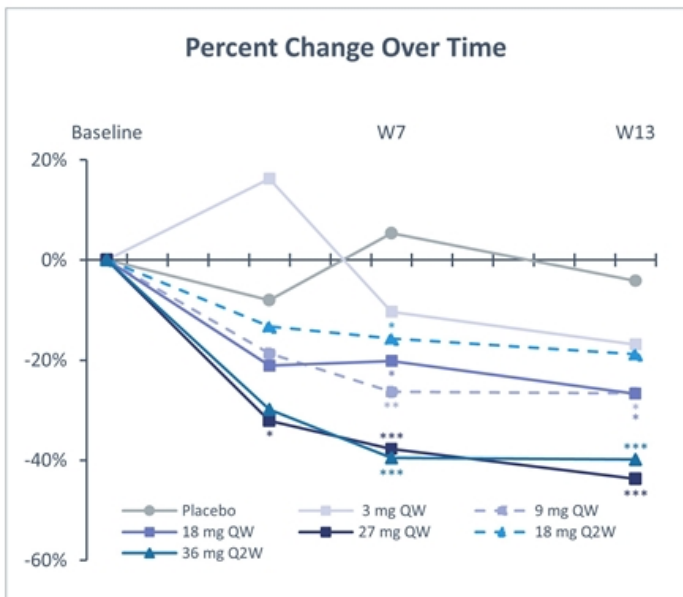


Parameter	Baseline
Liver fat	41.1%
Liver volume (L)	2.2

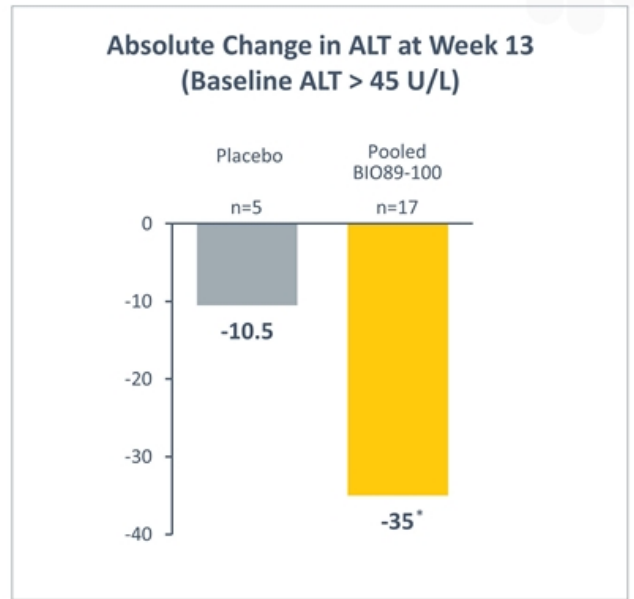
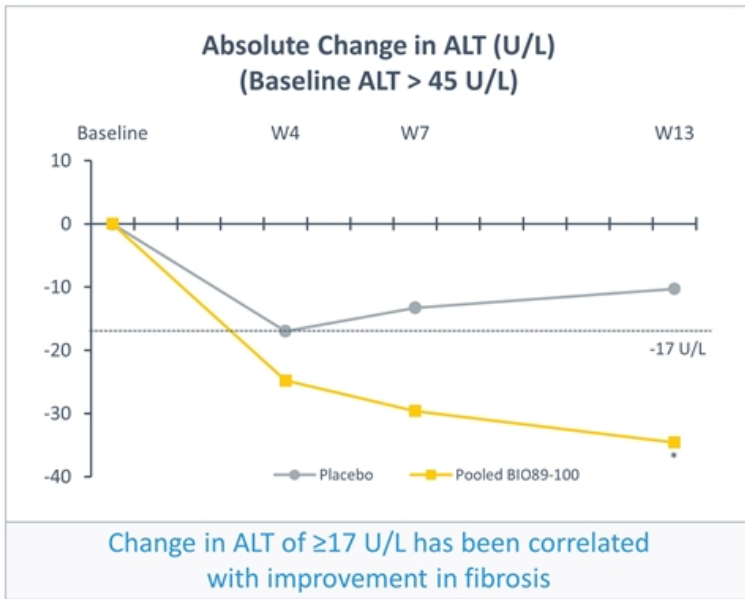


Week 13	% Change
5.1%	-87.6%
1.4	-35.4%

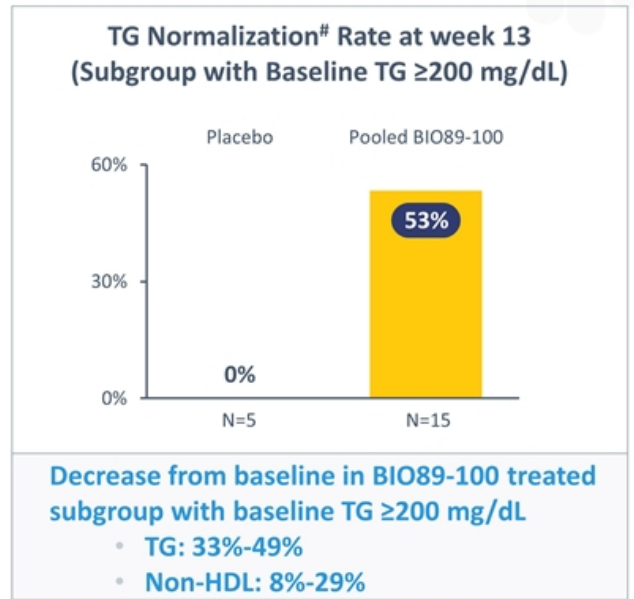
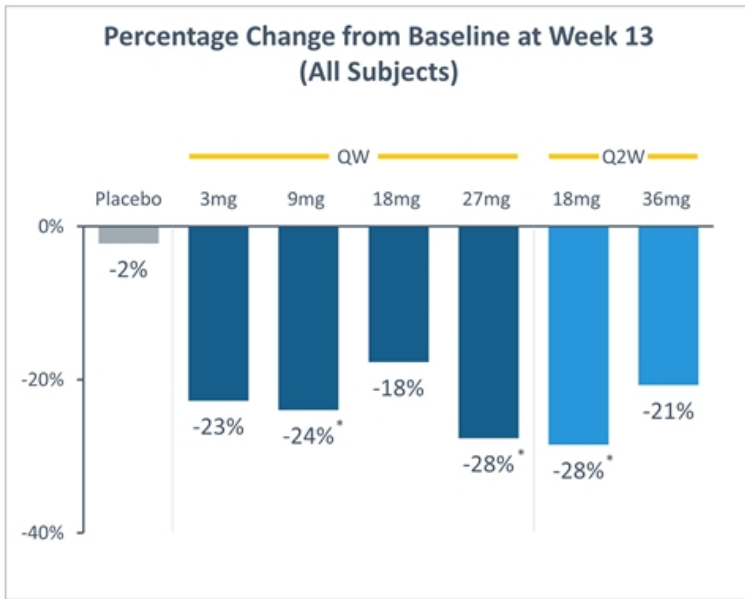
# BIO89-100 Significantly Reduces ALT



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



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



# Safety Overview



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

<sup>a</sup> skin rash; <sup>b</sup> hyperglycemia [Not Drug Related]

## Treatment-Related Emergent AEs in $\geq 10\%$ 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
  - 9.5% of subjects reported diarrhea in pooled BIO89-100 vs. 11.1% in placebo
  - 4.8% of subjects reported nausea in pooled BIO89-100 vs. 11.1% in placebo
  - 0.0% of subjects reported vomiting in pooled BIO89-100 vs. 0.0% in placebo
- No hypersensitivity AE reported; few mild injection site reaction events reported
- No tremor reported; no adverse effects on blood pressure or heart rate

# Comparative Data Among FGF21 Analogs: Efficacy



	BIO89-100 (12 weeks)		EFRUXIFERMIN (16 weeks*)		PEGBELFERMIN (16 weeks)	
	All Doses	27mg QW	28mg QW	50mg QW	10mg QD	20mg QW
<b>KEY EFFICACY PARAMETERS</b>						
<b>MRI-PDFF</b>						
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%
TG % Chg. vs. Baseline	-18 to -28%	-28%	-37%	-45%	-5%	-5%
Adiponectin % Chg. vs. Baseline	+23 to -61%	+61%	+69%	+88%	+15%	+15%

\* 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.

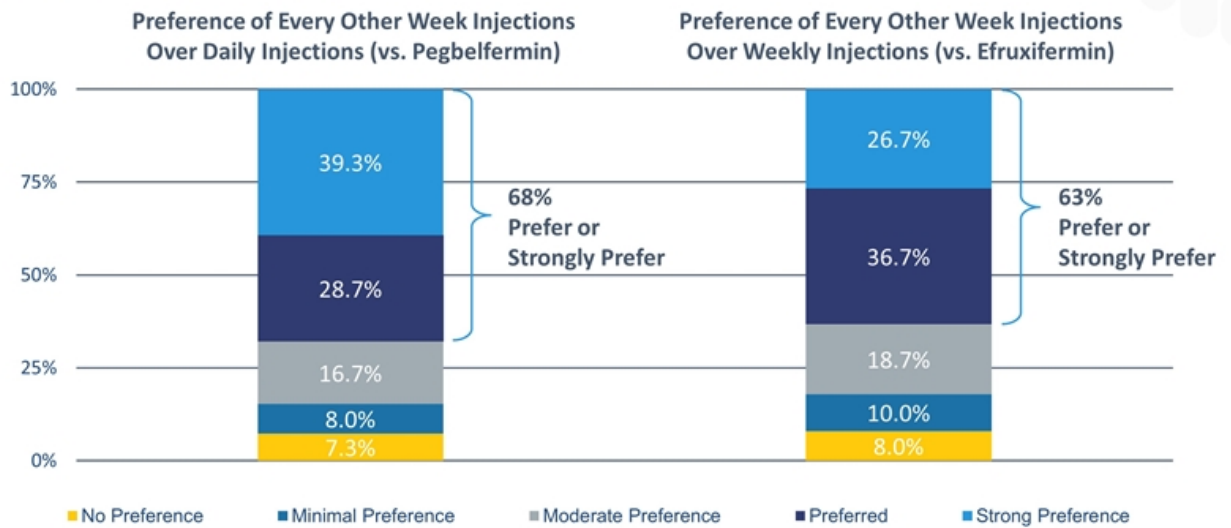


# Comparative Data Among FGF21 Analogs: Safety (Selected AEs)/Dosing

	BIO89-100 (12 weeks)	EFRUXIFERMIN (16 weeks)		PEGBELFERMIN (16 weeks)	
	Pooled BIO89-100	28mg QW	50mg QW	20mg QW	10mg QD
SELECTED AE's	Treatment Related AEs	Treatment Related AEs ≥10%		Most Frequent AEs	
Diarrhea	9.5%	26%	53%	21%	12%
Nausea	4.8%	32%	21%	16%	13%
Vomiting	0.0%	26%	11%	Present but not reported	
Frequent Bowel Movement	3.2%	16%	11%		20%
Increased Appetite	15.9%	21%			
Other	ISR (Erythema): 5% ISR (Pruritis): 3% Discontinuation: Skin rash – 1 patient	ISR (Erythema): 12% ISR: 10% Discontinuation: Tremor – 1 patient, Acute pancreatitis – 1 patient		ISR (Bruising): 8%	
Dosing	GlycoPEGylated; QW or Q2W	Fusion Protein; QW		Pegylated; QD or QW	

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.

# Dosing Preference Study: >60% of T2D Patients Prefer Or Strongly Prefer Every Other Week Injections



Study conducted in obese Type 2 diabetics (n=150); dosing preferences for treatment of chronic liver condition Q's 20 & 22: Please rate your level of preference of "dosing frequency" over "dosing frequency" for long-term use

- In our SHTG market research conducted with cardiologists, endocrinologists and PCPs, going from a weekly to every two-week sub-Q injectable increases market share by 30% (share goes up by 8.0% from a base of 27%). This assumes an equivalent efficacy profile

89bio

Opportunity in SHTG



# BIO89-100: A Compelling Drug Candidate for SHTG



## SIGNIFICANT MARKET OPPORTUNITY

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- Estimated up to 4M patients
- Approved drugs have limitations and do not provide broad metabolic benefits

## BIO89-100 IS A HIGHLY DIFFERENTIATED MOLECULE

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- Statistically significant reductions in TGs across multiple doses in NASH trial
- Greater reductions in patients with high TGs at baseline ( $\geq 200$  mg/dL)
- Statistically significant changes in liver fat, ALT, LDL and HbA1c with high dose

## POTENTIALLY QUICKER TO MARKET OPPORTUNITY

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- Established regulatory path for approval
- Smaller, quicker registrational trials (expected to be in registrational trials in 2022)

## KEY UPCOMING MILESTONES

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- Phase 2 trial topline data: 2H21

# SHTG Market Is Large with Significant Unmet Need



LARGE PATIENT  
POPULATION

Estimated **up to 4 million** patients



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

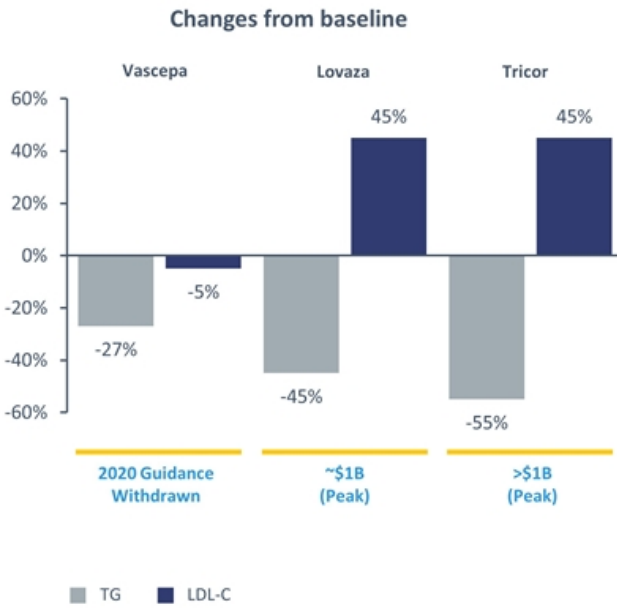
**PRIMARY RESEARCH WITH PHYSICIANS CONFIRMS  
UNMET NEED AND CO-MORBIDITIES**

- **53%** of patients don't achieve triglycerides <500 mg/dL with first line drug therapy
- **51%** of patients are suspected to have fatty liver disease
- **45%** of patients have glycemic control issues



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

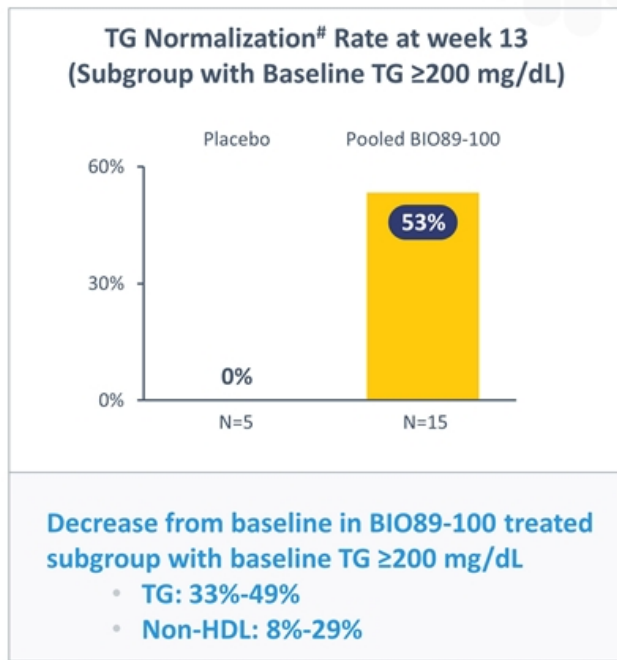
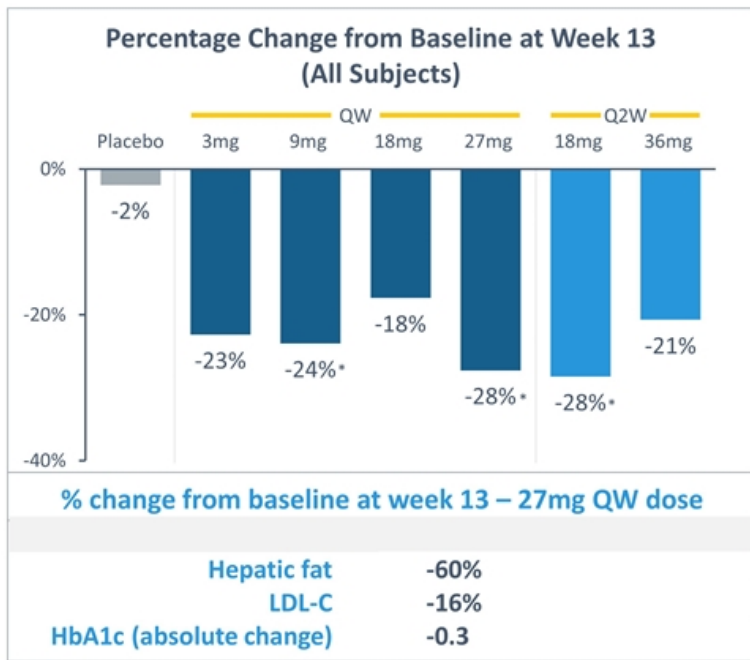
# Current Therapies Reach Blockbuster Status Despite Falling Short on Safety and Effect on Co-Morbidities



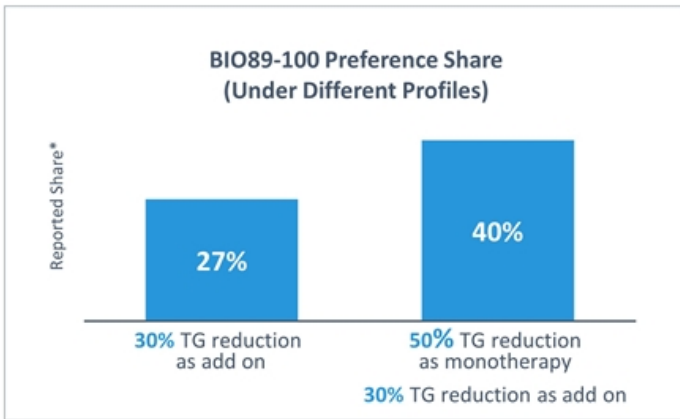
	FISH OILS		FIBRATES
	Vascepa (EPA)	Lovaza (EPA+DHA)	Tricor
Reduce Hepatic Fat	-	-	-
Improve LDL-C	-	Worsens LDL	Worsens LDL
ALT	-	Warnings, Monitoring Required	
Glycemic Control	-	-	-
Tolerability/Safety		May prolong bleeding time	Myopathy, Creatinine increases, DDI

■ Unchanged or Inconclusive

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



# Physicians Research Shows 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**



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.



# SHTG May Represent a Quicker and Less Expensive Path To Market



- 1 US approval endpoint: TG reduction from baseline; no clinical outcome study required
- 2 Phase 3 trials precedent\*: Single 12-week trials with ~200 - 300 patients

## BIO89-100 Ongoing and Anticipated Development Plan

STUDY	DESIGN
Phase 2 Trial	<ul style="list-style-type: none"><li>• Adults with TG <math>\geq</math> 500; N = ~90</li><li>• Weekly and every two-week dosing for a period of 8 weeks</li><li>• Primary endpoint: Reduction from baseline in TG</li><li>• Secondary endpoints: Other lipids and liver fat (MRI-PDFF)</li><li>• Timing: Topline data in 2H21</li></ul>
Registrational Trial**	<ul style="list-style-type: none"><li>• Patients with TG <math>\geq</math> 500 mg/dL; Endpoint = % reduction of TG from baseline</li><li>• Potential initiation in 2022</li></ul>



**Cash, cash equivalents  
and short-term investments**

**\$73.9 million (as of June 30, 2020)**

**89bio received an aggregate of approx.  
\$157.3 million in estimated net proceeds  
in 3Q20 from underwritten public offerings  
of common stock**

**Debt facility for a tranching secured term  
loan of up to \$15.0 million (no drawdown)**

# Achievements and Milestones



## ACHIEVEMENTS (~2 Years)

- ✓ Completed 2 clinical trials and POC in NASH
- ✓ Third clinical trial in SHTG initiated
- ✓ Completed preclinical package including long-term tox
- ✓ Manufacture product at CMO
- ✓ New IP through 2038
- ✓ Strong balance sheet



## CURRENT FOCUS

- Alignment with agency and preparation for next NASH trial
- Execution of SHTG Phase 2 trial
- Scale-up of manufacturing
- Finalize liquid formulation development for use in Phase 2b NASH trial



## MILESTONES

- Initiation of a Phase 2b NASH trial as part of a potential Phase 2b/3 trial – 1H21
- SHTG Phase 2 topline results – 2H21
- Initiation of SHTG registrational trials (pending positive Phase 2 data) – 2022

# 89bio - Investment Highlights



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

- Validated in NASH demonstrating strong efficacy results, favorable safety/tolerability profile, and potential best-in-class dosing

## **BIO89-100 DELIVERS ON THE PROMISE OF FGF21**

- FGF21 is a highly differentiated approach and potential backbone of treatment in NASH

## **PURSUING TWO PROMISING LARGE INDICATIONS**

- NASH: Compelling benefit-risk profile in a differentiated class
- SHTG: Potential for quicker path to market with competitive differentiation (first FGF21 to market based on registrational trials planned in 2022)

## **MAJOR ANTICIPATED MILESTONES**

- NASH: Initiation of a Phase 2b trial as part of a potential Phase 2b/3 trial in 1H21
- SHTG: Topline data from Phase 2 trial in 2H21

## **ESTABLISHED MANUFACTURING EXPERTISE AND IP PROTECTION INTO 2038 AND BEYOND**



## Management Team



**Rohan Palekar**  
CEO

- CEO, CCO experience
- Avanir, Medivation, J&J
- Commercial, strategy, and R&D experience



**Hank Mansbach, MD**  
CMO

- 20+ years biopharma and R&D leadership in clinical development and medical affairs
- Ultragenyx, Medivation, Valeant, GSK



**Ram Waisbourd**  
COO and CBO

- 20 years of operations, BD, and strategy experience
- VP of strategy and transformation, Teva R&D
- VP of business development, XTL bio



**Ryan Martins**  
CFO

- CFO, Strategy/IR, finance, sell-side experience
- Revolution Medicines, Ultragenyx, Chiron, Jefferies, Lazard, Barclays/Lehman Brothers



**Quoc Le-Nguyen**  
CTO and Head of Quality

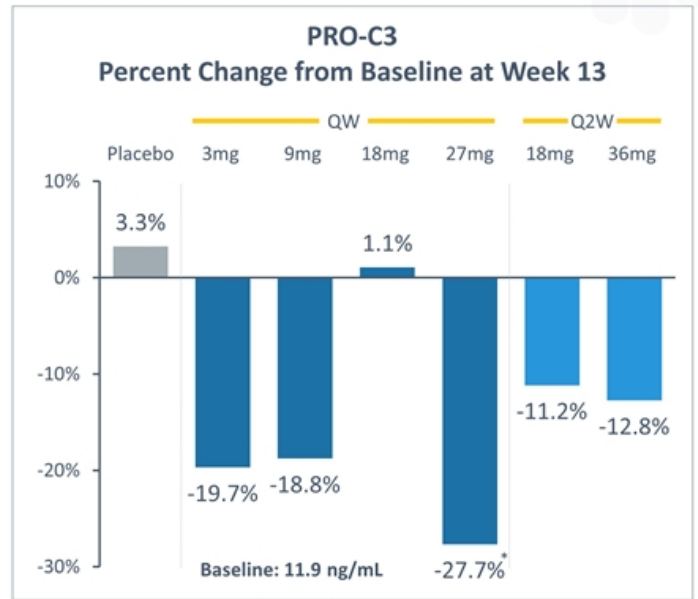
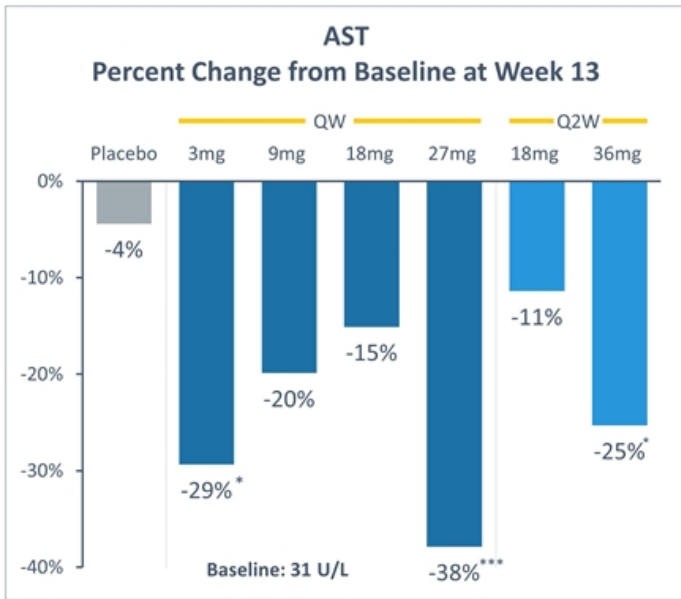
- 20+ years biopharma and leadership in technical operations, product supply, and quality
- Aduro, Bayer, Novartis, Chiron, BioMarin

89bio

Appendix



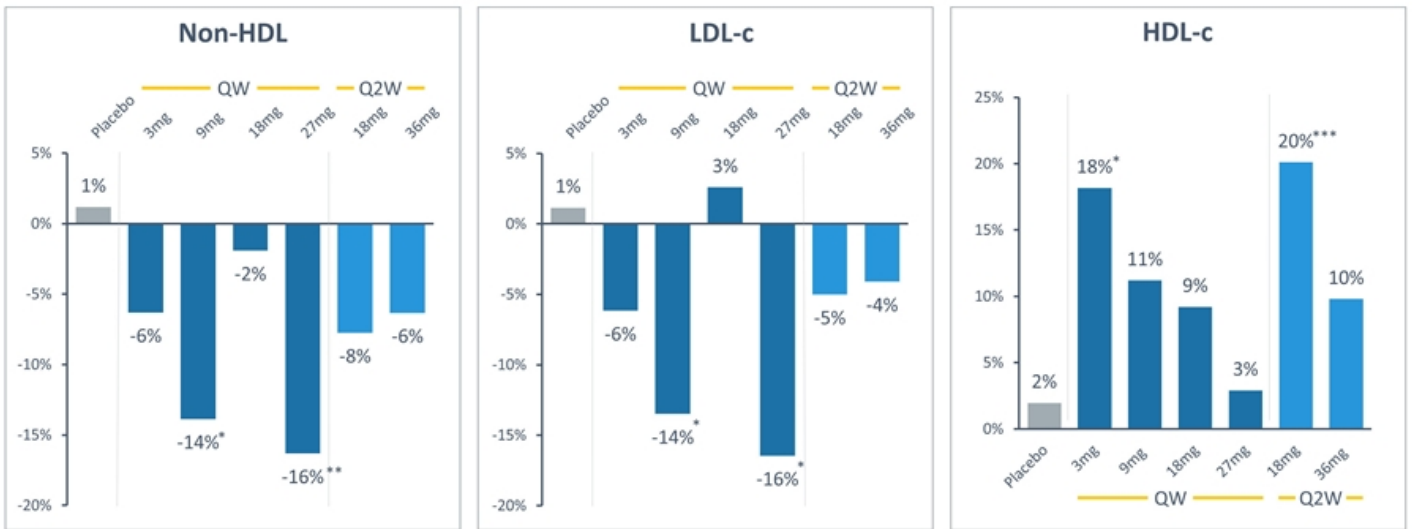
# BIO89-100 Significantly Improves Other Important Liver Biomarkers Despite Low Baseline Values



# BIO89-100 Significantly Improves Key Lipid Markers



Percentage Change from Baseline At Week 13





# 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
<b>Adiponectin</b> % Change	-4.3%	37.7%*	25.5%*	29.1%*	60.9%***	23.1%*	24.1%
<b>Insulin<sup>§</sup></b> % Change	10.0%	-8.5%	-9.4%	-22.5%	-6.9%	-39.7%	-34.5%
<b>HbA1c (%)</b> 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