# 89bio

# Powerful Science Meaningful Medicines Changing Lives

Nasdaq: ETNB

March 2021

#### Disclaimer

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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.

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# 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; Highly differentiated FGF21 (GlycoPEGylation technology)
- FGF21 is a unique approach and a 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 Phase 2b trial in 1H21; Topline data from paired-biopsy, open-label histology cohort by YE21
- SHTG: Topline data from Phase 2 trial in 2H21

STRONG CAPITAL POSITION - \$219.2M IN CASH, CASH EQUIVALENTS, AND SHORT-TERM INVESTMENTS (SEP 30, 2020)

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

# Advancing BIO89-100 in Clinical Development

Indication	Preclinical	Phase 1	Phase 2	Phase 3	Next Milestones
NASH	Phase 2b trial				Initiate the Phase 2b trial in 1H21 Report topline data from
	Phase 1b/2a his	stology cohort			the paired-biopsy, open- label histology cohort by YE21
SHTG	Phase 2 trial				Report topline data from the Phase 2 trial in 2H21

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# **Opportunity in NASH**





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

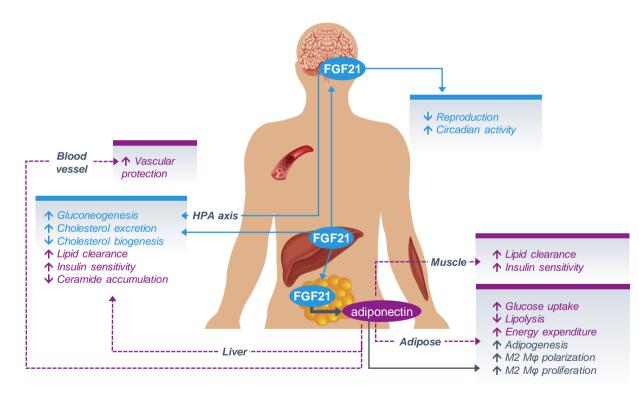
Metabolic Dysregulation  $\rightarrow$  Excess Liver Fat Accumulation  $\rightarrow$  Progressive Disease



- 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

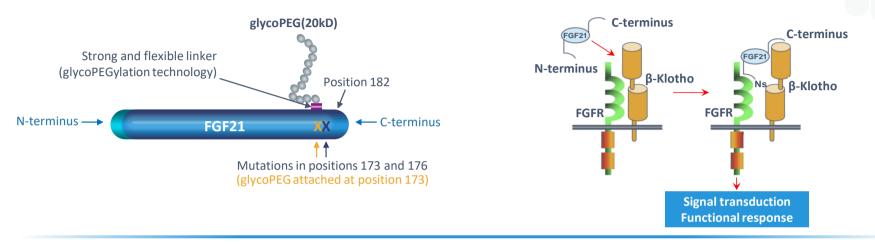
Co-morbidity	Prevalence in NASH population
Hypertriglyceridemia	83%
Obesity	82%
Hyperlipidemia / Dyslipidemia	72%
Metabolic syndrome	71%
Type 2 diabetes	44%

## FGF21 Has Potential To Be Mainstay of Therapy In NASH



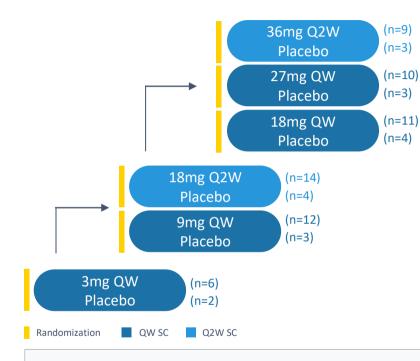
- Endogenous metabolic hormone that regulates energy expenditure and glucose and lipid metabolism
- Reduces liver fat by action within liver and from periphery
- Impacts liver fibrosis via metabolic pathway and upregulation of adiponectin
- Native FGF21 has a short halflife of < 2 hours</li>

# 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
- Increases half-life of native FGF21 (< 2 hours) to 55-100 hours based on single ascending dose study</li>
- Low nanomolar potency against FGF receptors 1c, 2c, 3c, similar to native FGF21
- No activity against FGF receptor 4 that can lead to increased LDL levels

# Phase 1b/2a NASH Trial Design



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

#### **KEY INCLUSION CRITERIA**

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

\*Subjects with biopsy-proven F1-3 #Central obesity plus T2DM or evidence of liver injury

#### **KEY TRIAL ENDPOINTS**

- Safety, PK
- Relative changes in liver fat
- Serum lipids, liver and metabolic markers
- Randomized, pharmacodynamic (PD) and safety analysis set n=81; Study completers n=71
- MRI analysis set n=75 (subjects with post-baseline MRI)

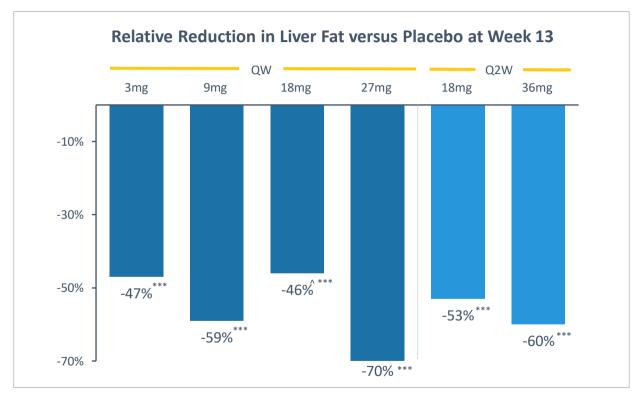
#### **Baseline Characteristics**

Parameter Mean or %	Placebo (n=19)	Pooled BIO89-100 (n=62)	3mg QW (n=6)	9mg QW (n=12)	18mg QW (n=11)	27mg QW (n=10)	18mg Q2W (n=14)	36mg Q2W (n=9)
Age (years)	52.6	51.7	56.1	49.5	51.5	52.0	51.2	52.5
Male/Female	36.8%	38.7%	16.7%	50%	27.3%	20%	28.6%	88.9%
Weight (kg)	93.6	93.6	87.9	87.2	87.1	94.0	101.5	101.1
BMI (kg/m²)	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



#### Majority of Subjects 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

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^ 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 Achieve Clinically Meaningful Responder Rates on BIO89-100

	≥30% Relative Reduction	≥50% Relative Reduction
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 subjects
 normalized their liver fat
 (<5%)</li>

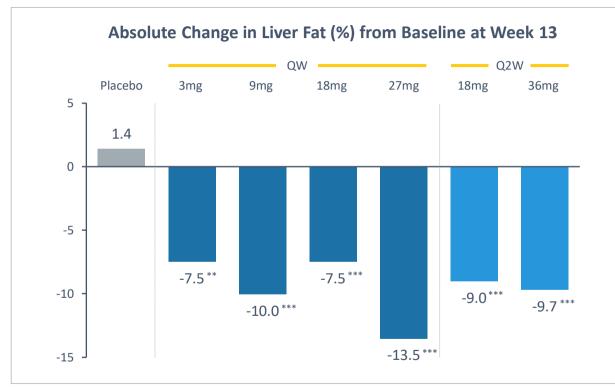
- ≥30% relative reduction in liver fat has been correlated with NASH resolution and fibrosis improvement
- 71% of subjects on 27 mg QW dose had ≥70% relative reduction in liver fat

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

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



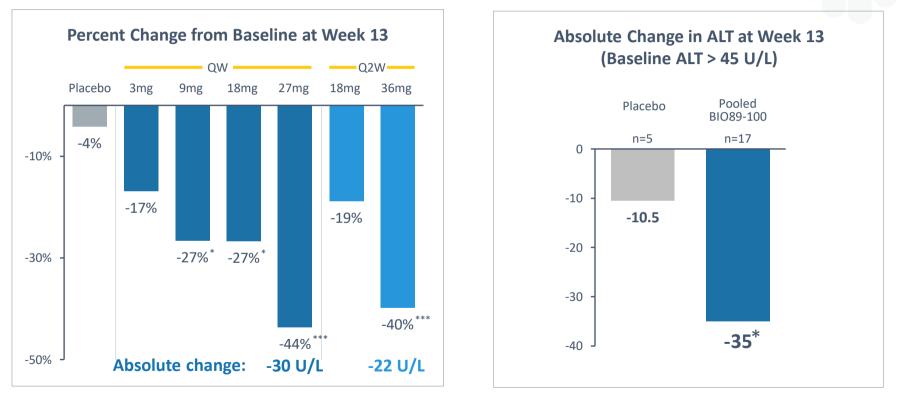
- Baseline characteristics were similar between NASH and PNASH subjects
- Reductions in absolute percentage of liver fat from baseline, % responders on MRI-PDFF and BIO89-100's effect on reducing ALT and TGs were also similar across NASH and PNASH patients

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

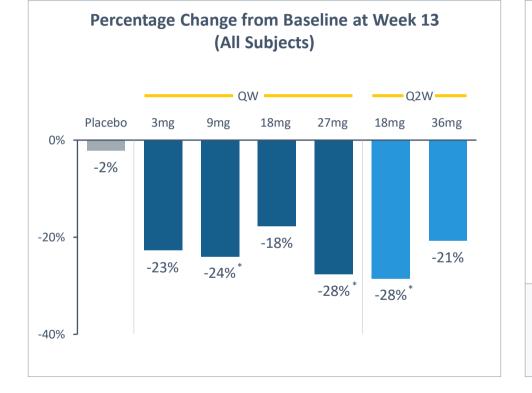
# BIO89-100 Significantly Reduces ALT with Greater Reduction in Patients with Elevated Baseline ALT



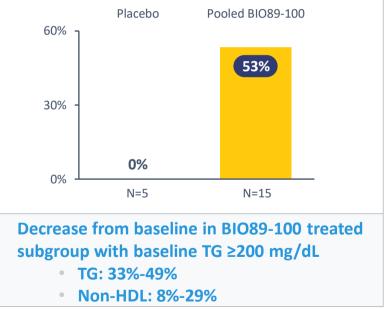
Change in ALT of  $\geq$ 17 U/L has been correlated with improvement in fibrosis

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



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

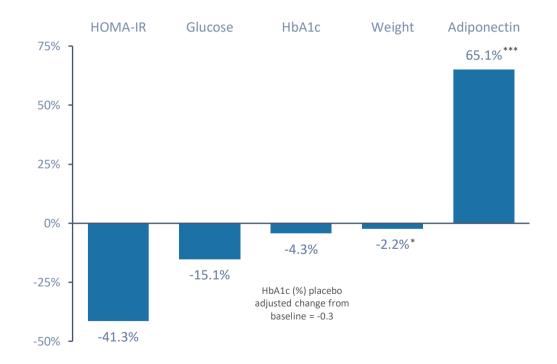


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PD Analysis Set; MMRM LS Mean; \* p<0.05; \*\* p<0.01; \*\*\* p<0.001 versus placebo; "TG <150 mg/dL TG at baseline (Total population): Pooled BIO89-100 (174.4 mg/dL) and Placebo (174.0 mg/dL) TG at baseline (Subgroup with Baseline  $\geq$  200 mg/dL):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

#### Improvements in Metabolic Markers With BIO89-100 27mg QW

Placebo-Adjusted Relative Change from Baseline at Week 13



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%

## 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 ≥ 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 Profile of FGF21 Analogs**

	BIO89-100	Efruxifermin	Pegbelfermin
Structure	<ul> <li>GlycoPEGylated FGF21</li> </ul>	<ul> <li>Fc-fused FGF21</li> </ul>	<ul> <li>PEGylated FGF21 (with non- native amino acid substitution)</li> </ul>
Efficacy	<ul><li>Significant effect on liver param</li><li>Robust impact on broad metable</li></ul>		<ul> <li>Lower effects across all liver and metabolic parameters</li> </ul>
Tolerability	<ul><li>Well-tolerated at all doses</li><li>Placebo-like GI profile</li><li>No tremors</li></ul>	<ul> <li>High frequency and withdrawals from GI events in all 3 clinical studies</li> <li>Tremors observed in MAD and Phase 2a studies</li> </ul>	• Similar to BIO89-100
Dosing Frequency	• Weekly and Every Two-Weeks	• Weekly	Daily or Weekly
Commercial Drug Product	• Liquid	<ul> <li>Lyophilized</li> <li>(Phase 2b in frozen)</li> </ul>	• Liquid
Development Timelines	• Phase 2b starts in 1H2021	• Phase 2b initiated in 1H2021	<ul> <li>Phase 2b (F3 and F4) complete - results pending</li> </ul>



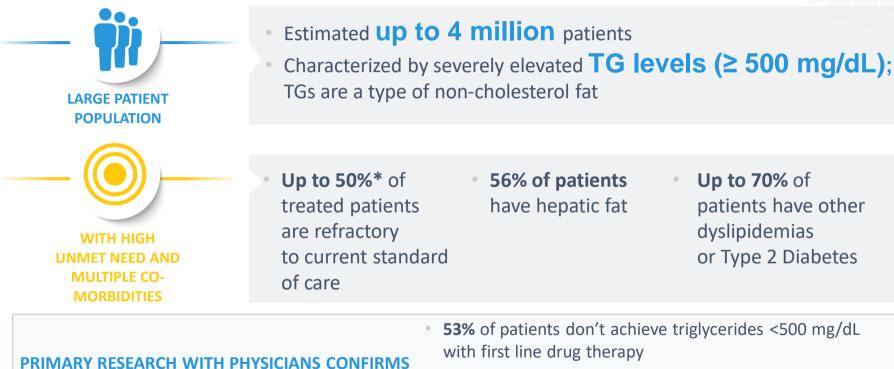
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# Opportunity in SHTG





# SHTG Market Is Large with Significant Unmet Need

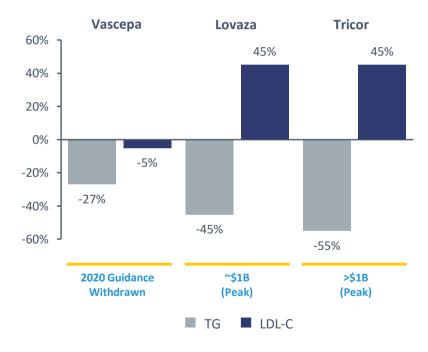


- **51%** of patients are suspected to have fatty liver disease
- **45%** of patients have glycemic control issues

**UNMET NEED AND CO-MORBIDITIES** 

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

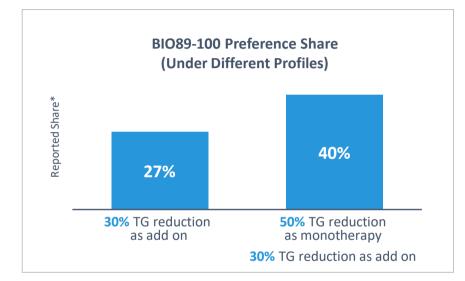
**Changes from baseline** 



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

Unchanged or Inconclusive

## 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

Meaningful Chg. in Parameter	Share* for Meaningful Change + TG Reduction
38%	50% - 76%
40%	48% - 74%
19%	47% - 73%
	in Parameter 38% 40%

#### 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
- 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> <li>Adults with TG ≥ 500; N = ~90 (patients could be on background medications)</li> <li>Weekly (9mg, 18mg, 27mg) and every two-week (36 mg) dosing for 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> <li>Patients with TG ≥ 500 mg/dL; Endpoint = % reduction of TG from baseline</li> <li>Potential initiation in 2022</li> </ul>

## **Financial Position Summary**

# Cash, cash equivalents and short-term investments

\$219.2 million (as of September 30, 2020)

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

# **Experienced Management Team Positions 89bio for Success**











Rohan Palekar CEO

CEO, CCO experience

Commercial, strategy, and R&D experience

Hank Mansbach, MD

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

20 years of operations, BD, and strategy experience Ryan Martins CFO

CFO, Strategy/IR, finance, sell-side experience Quoc Le-Nguyen CTO & Head of Quality

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

Otsuka AVANIR MEDIVATION





teva

**XTL**bio







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

## **Achievements and Milestones**

# ACHIEVEMENTS (~2.5 Years)

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

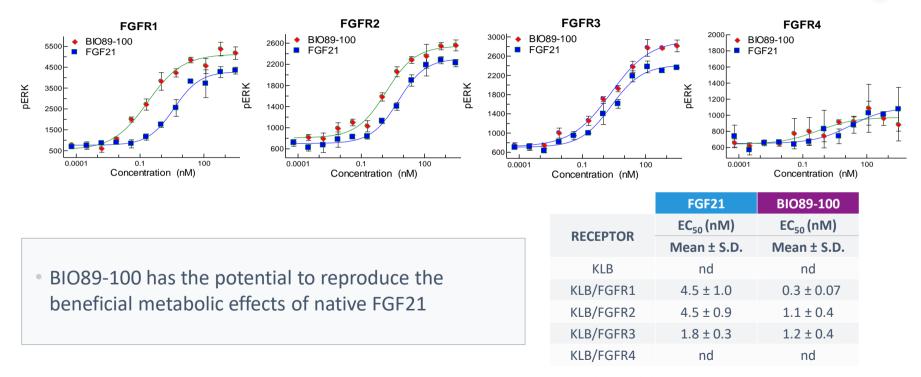


- Initiation of Phase 2b NASH trial 1H21
- NASH histology results YE21
- SHTG Phase 2 results 2H21
- Initiation of SHTG registrational trials (pending positive Phase 2 data) – 2022

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# Appendix

#### BIO89-100 Exhibits Highly Potent FGF Receptor Agonism

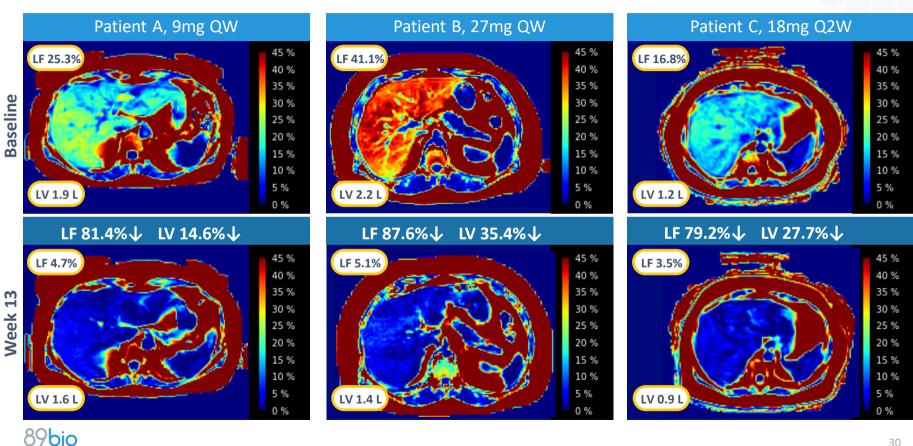


nd – not determined; rhFGF19 EC<sub>50</sub> at FGFR4 =  $1.7 \pm 0.4$ 

\* Receptor agonism measured in L6 cells expressing β-klotho and either FGF Receptor 1c, 2c, 3c, or 4 via pERK functional assay

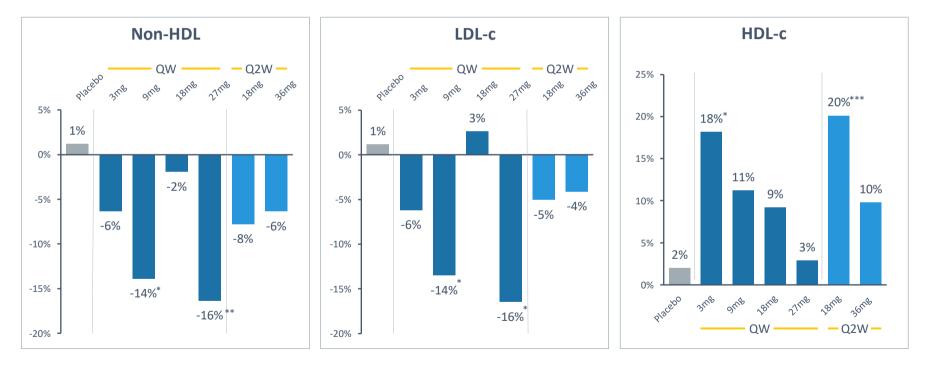
\*\* Figures represent data from a single experiment; Table represents mean data from multiple experiments

## 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



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#### 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%*	<b>25.5%</b> *	<b>29.1</b> % <sup>*</sup>	60.9%***	<b>23.</b> 1% <sup>*</sup>	24.1%
Insulin <sup>&amp;</sup> % 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



# Similar Baseline Characteristics in Subjects with Biopsy-Proven NASH or PNASH

Parameter	NASH	PNASH	Overall
Mean or %	(N=15)	(N=66)	(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)			IFERMIN veeks*)	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%

\* 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

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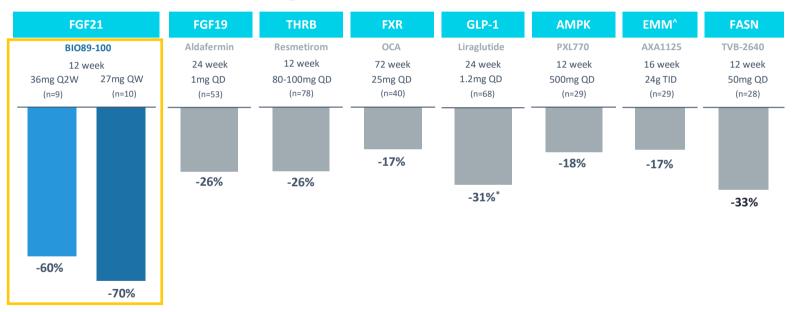
# FGF21 – Highly Differentiated Mechanism versus Leading Therapeutics in Development for NASH

		FGF21	FGF19	FXR	PPAR*	THR-β	GLP-1
Robust efficacy with respect to liver pathologies	Liver fat reduction	~	<b>~</b>	<ul> <li>Image: A second s</li></ul>		~	~
	Fibrosis improvement	~	~	~	~	?	
	Triglyceride reduction	~	~		~	~	
Ability to address underlying co- morbidities	LDL-C improvement	~	Worsens LDL	Worsens LDL		~	
	HDL-C improvement	~			<ul> <li>Image: A second s</li></ul>		
	Glycemic control	~			~		~
Well tolerated at effective dose	Limited Side Effects	GI effect**	LDL 个	Pruritis LDL 个	Weight Gain Edema	Drug-drug interaction	GI effect
	Dosing frequency	Injectable QD/QW/Q2W	Injectable QD	Oral	Oral	Oral	Injectable QD
		<ul> <li>Effective</li> </ul>	? Indeterminate V Modest Effect			Unknowr	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.

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



#### **Relative Change In Liver Fat From PLACEBO (% Reduction)**

\* Not placebo controlled; \*\*No worsening of NAS (NAFLD Activity Score); ^EMM=Endogenous Metabolic Modulators.

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