

**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): April 13, 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 April 13, 2020, the Company issued a press release announcing that it closed enrollment in its Phase 1b/2a trial for nonalcoholic steatohepatitis with 98% of patients enrolled and has delayed initiation of its severe hypertriglyceridemia trial due to the ongoing COVID-19 pandemic. The press release also reported new preclinical data confirming BIO89-100's mechanism of action via potent FGF receptor agonism. A copy of the press release is furnished herewith as Exhibit 99.1 and incorporated herein by reference.

On April 13, 2020, the Company also made available an updated corporate presentation on the Company's website. A copy of the corporate presentation is furnished herewith as Exhibit 99.2 and incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 8.01, including Exhibits 99.1 and 99.2, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated April 13, 2020
99.2	Corporate Presentation, dated April 13, 2020

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: April 13, 2020

89bio, Inc.

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



89bio Announces Closing of Enrollment in its Phase 1b/2a NASH Trial and Reports New Preclinical Data Confirming BIO89-100's Mechanism of Action Via Potent FGF Receptor Agonism

- Closed enrollment in its Phase 1b/2a NASH trial with 98% of patients enrolled and delays initiation of its SHTG trial due to the COVID-19 pandemic; Reaffirms guidance for NASH trial topline data in 2H20 -

- BIO89-100 demonstrated low nanomolar potency against FGF receptors 1c, 2c and 3c similar to recombinant human FGF21 (rhFGF21) -

San Francisco, California, April 13, 2020 — 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 that it closed enrollment in its Phase 1b/2a trial for nonalcoholic steatohepatitis (NASH) with 98% of patients enrolled and has delayed initiation of its severe hypertriglyceridemia (SHTG) trial due to the ongoing COVID-19 pandemic. 89bio also reported new preclinical data confirming BIO89-100's mechanism of action via potent FGF receptor agonism.

"I am extremely proud that our team was able to close enrollment in our Phase 1b/2a NASH trial with 98% of patients enrolled, despite the challenging environment related to the ongoing COVID-19 pandemic. We are monitoring the situation and will adjust plans if needed to minimize any trial disruption due to COVID-19. We continue to expect topline data in the second half of 2020," said Rohan Palekar, Chief Executive Officer of 89bio. "In addition, we will delay initiation of our Phase 2 trial of BIO89-100 in SHTG until conditions improve to allow us to execute the trial safely and efficiently. In the interim, we plan to complete all preparatory work to enable enrollment as soon as conditions enable it. We plan to follow the guidelines put forth by the U.S. Centers for Disease Control and Prevention, as well as national, state and local governments and make the proactive decisions necessary to protect the health and safety of all of our stakeholders."

The Phase 1b/2a proof-of-concept trial in NASH is a multicenter, randomized, double-blind, placebo-controlled, multiple ascending dose-ranging trial in patients with NASH or patients with NAFLD and a high risk of NASH. In this trial, 81 patients were randomized to receive weekly or every other week subcutaneous dosing of BIO89-100 or placebo for 12 weeks. The trial is designed to assess the safety, tolerability and PK properties of BIO89-100 as well as absolute change from baseline in hepatic fat fraction measured by magnetic resonance imaging – proton density fat fraction (MRI-PDFF). MRI-PDFF will be assessed at week 7 and at end of the trial along with other key biomarkers that will be evaluated more frequently. 89bio is working closely with its contract research organization partners and clinical sites to mitigate any potential impact of the COVID-19 pandemic on the trial. Topline data is still expected in the second half of 2020 and the Company plans to initiate the Phase 2b trial in the first half of 2021.

89bio is delaying the initiation of its Phase 2 trial of BIO89-100 for the treatment of SHTG, which was planned for the first half of 2020. The Company plans to complete all activities to be operationally prepared to enroll the trial once the external environment is conducive to executing the trial safely and effectively.

The Company has adequate clinical supplies for the ongoing NASH trial and the planned SHTG trial.

New BIO89-100 Preclinical Data

“Our new preclinical data demonstrates that BIO89-100 has similar activity to rhFGF21 at FGF receptors 1c, 2c and 3c, suggesting that BIO89-100 could reproduce the beneficial metabolic benefits of the native hormone, which may translate into clinical benefits for patients with NASH and SHTG,” said Dr. Hank Mansbach, Chief Medical Officer of 89bio.

Activation of the FGF receptors 1c, 2c and 3c, together with the co-receptor β -klotho, are critical to the signaling of FGF21 and are believed to be responsible for the beneficial metabolic effects observed. In an in vitro study of receptor agonism, BIO89-100 was shown to have activity at very low nanomolar concentrations in cells co-expressing β -klotho and each of FGF receptors 1c, 2c or 3c. The EC50 (concentration at which one half of the maximal FGF receptor agonist effect is observed) for BIO89-100 was similar across FGF receptors 1c, 2c and 3c and comparable or superior to that of rhFGF21 in this functional assay. An EC50 could not be calculated for rhFGF21 or BIO89-100 at FGF receptor R4.

Investors are encouraged to review the Company’s updated Corporate Presentation slide deck that provides an overview of the Company’s business and is available under the “Investors” tab of the Company’s website at www.89bio.com, or by request to the Company.

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, BIO89-100, is being developed for the treatment of NASH. The company also intends to develop BIO89-100 for the treatment of SHTG. BIO89-100 is a specifically engineered glycoPEGylated analog of FGF21 that is currently in a proof of concept Phase 1b/2a clinical trial in patients with NASH or NAFLD and a high risk of NASH. 89bio is headquartered in San Francisco with operations in Herzliya, Israel. Visit 89bio.com for more information.

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, 89bio’s expectations regarding plans for its clinical programs and clinical trials, the association of preclinical data with potential clinical benefit and timing of anticipated milestones. 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 U.S. Securities and Exchange Commission (SEC)), many of which are beyond 89bio’s control and subject to change. Actual results could be materially different. Risks and uncertainties include: expectations regarding the

completion and outcome of 89bio's Phase 1b/2a proof of concept clinical trial evaluating BIO89-100 in patients with NASH or patients with NAFLD and a high risk of NASH; expectations regarding the timing, completion and outcome of 89bio's proof of concept Phase 2 clinical trial evaluating BIO89-100 in patients with SHTG; the unpredictable relationship between preclinical study results and clinical study results; the effect of the COVID-19 pandemic on 89bio's clinical trials and business operations; and other risks and uncertainties identified in 89bio's Annual Report on Form 10-K for the year ended December 31, 2019, filed March 18, 2020 with the SEC 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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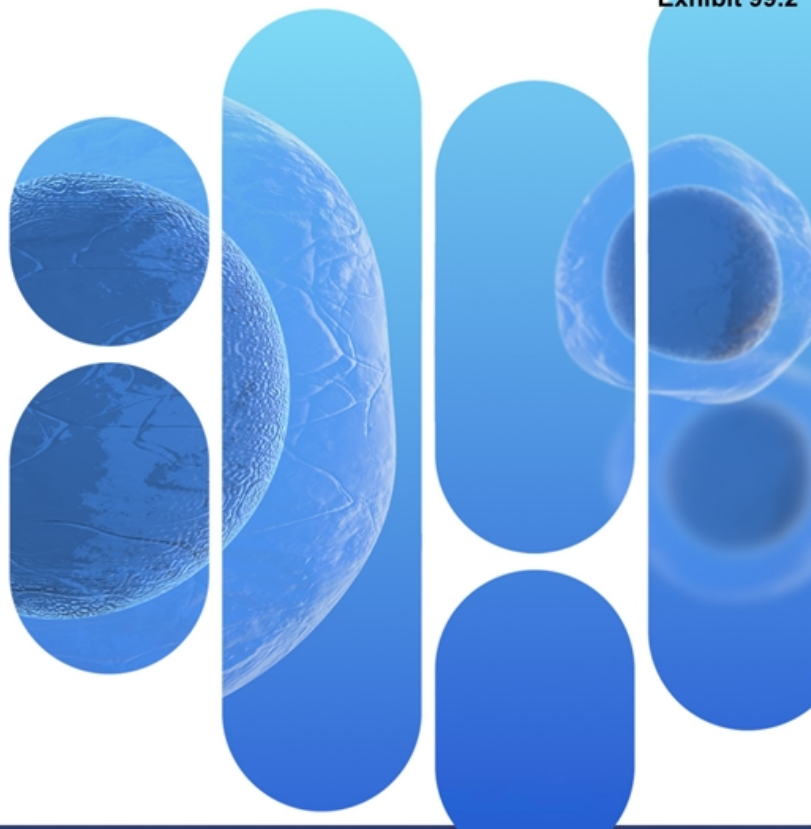
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89bio

**Developing a
Differentiated FGF21
for NASH and SHTG**

NASDAQ: ETNB

April 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. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this presentation including those described more fully our most recent Form 10-K under the caption "Risk Factors" and elsewhere in such report.

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. 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 in our most recent Form 10-K under the caption "Risk Factors" and elsewhere in such report.

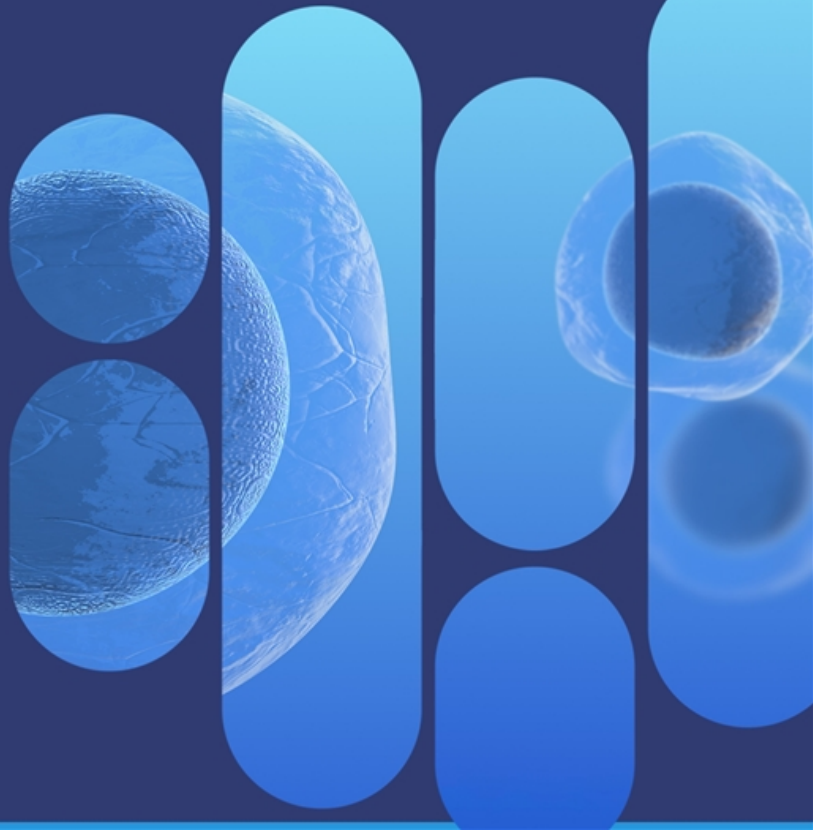
89bio – Investment Highlights

Significant Commercial Opportunities	<ul style="list-style-type: none">• Targeting large and growing unmet need in Non-Alcoholic Steatohepatitis (NASH) and Severe Hypertriglyceridemia (SHTG)
Potentially Differentiated Asset Targeting Clinically Validated Mechanism in NASH	<ul style="list-style-type: none">• BIO89-100 is a glycoPEGylated analog of FGF21 with compelling early human data• FGF21 has the potential to become mainstay of NASH therapy – addresses key liver pathologies and underlying metabolic dysregulation
Potentially Differentiated Therapy for SHTG	<ul style="list-style-type: none">• Robust reduction in triglyceride levels seen in animal and human studies• Established development and regulatory path offering a potentially quicker path to market for BIO89-100
Anticipated Near-term Catalysts	<ul style="list-style-type: none">• Two trials with BIO89-100: (i) ongoing Phase 1b/2a trial in NASH (enrollment complete and topline data anticipated in 2H20); (ii) planned Phase 2 trial in SHTG (initiation in 1H20 delayed due to the COVID-19 pandemic)• Potential to transition to Phase 2b trial in NASH in 1H21
Established Manufacturing Expertise; Long IP Protection	<ul style="list-style-type: none">• Established manufacturing process in place for near-term clinical supplies• Issued composition of matter patent expected to expire in 2038

89bio



**OPPORTUNITY IN
NASH**



BIO89-100 is A Compelling Drug Candidate in NASH

NASH IS A SERIOUS LIVER CONDITION

- Large market size with significant economic burden and no FDA-approved treatment options
- Complicated disease with significant co-morbidities

FGF21 HAS THE POTENTIAL TO BE MAINSTAY OF THERAPY GIVEN ITS BROAD-BASED EFFECTS

- Addresses steatosis and fibrosis and underlying metabolic issues

BIO89-100 HAS THE POTENTIAL TO BE A DIFFERENTIATED FGF21 ANALOG

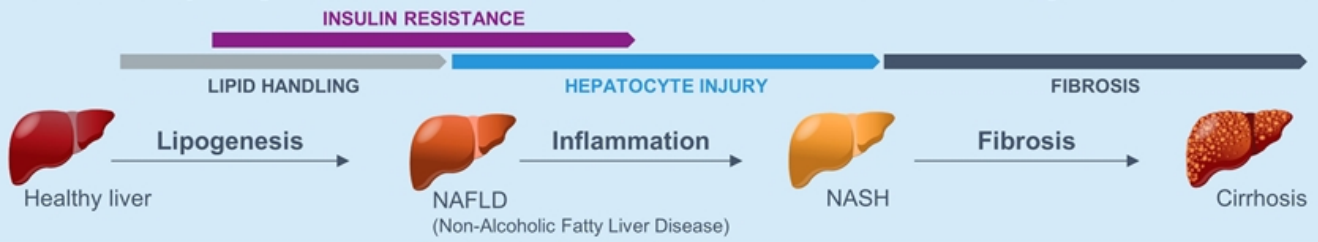
- Proprietary glycoPEGylation technology may offer robust biologic effects, favorable tolerability profile and a longer dosing interval

ROBUST CLINICAL AND PRECLINICAL DATA WITH AN UPCOMING ANTICIPATED EFFICACY READOUT

- Phase 1a trial showed favorable tolerability, PK and PD markers building on strong preclinical package
- Phase 1b/2a trial in NASH has closed enrollment with 98% patients enrolled (81/83 patients) due to impact of the COVID-19 pandemic; topline data expected in 2H20

NASH is A Serious Liver Condition With No FDA Approved Treatments

Metabolic Dysregulation → Excess Liver Fat Accumulation → Progressive Disease



- **16.5 million** projected to grow to **27 million** by 2030
 - Expected to become the leading cause of liver transplant in 2020
- **Significant economic burden – \$223 billion** expected lifetime economic burden of patients in US (2017)

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

NASH Therapeutics - Market Dynamics

1 Key Attributes for Successful NASH Therapies

- Robust efficacy with respect to liver pathologies
- Ability to address underlying co-morbidities
- Well tolerated

2 Potential for Multiple Winners

- Similarities to multi-billion diabetes and dyslipidemia markets
- Potent injectables have the potential to be a preferred treatment option for some patient populations (e.g. GLP-1 agonists achieved ~\$9 billion in sales in 2018*)

FGF21 product candidates have the potential to deliver on key attributes for successful NASH therapies

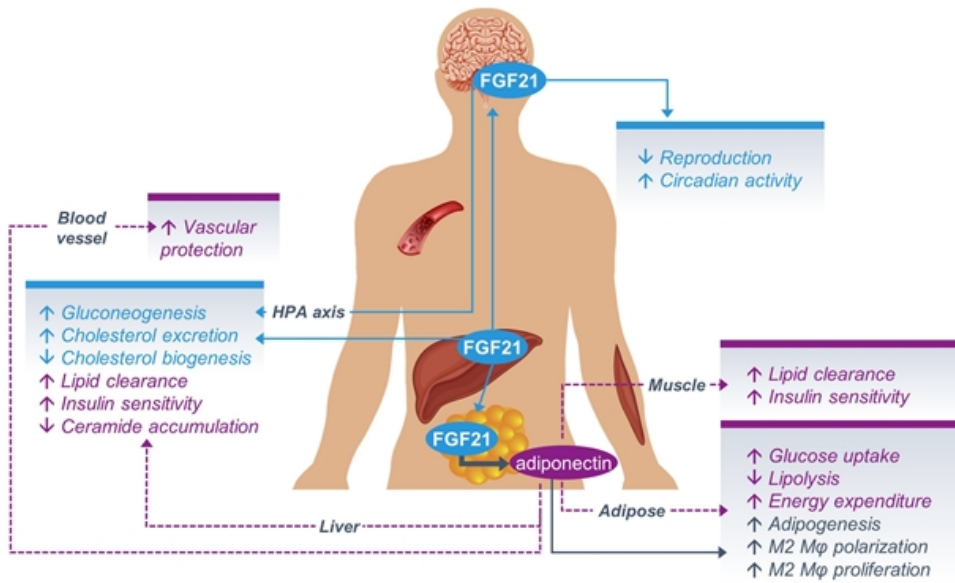
		FGF CLASS					
		FGF21	FGF19	FXR	PPAR*	THR-β	GLP-1
Robust efficacy with respect to liver pathologies	Liver fat reduction	✓	✓	✓		✓	?
	Fibrosis improvement	✓	✓	✓	?	?	
	Triglyceride reduction	✓	✓		✓	✓	
Ability to address underlying co-morbidities	LDL-C improvement	✓	Worsens LDL	Worsens LDL	✓	✓	
	HDL-C improvement	✓			✓		
	Glucose reduction	✓			✓		✓
Well tolerated at effective dose	Limited Side Effects	✓	LDL ↑	Pruritis LDL ↑	Risk of renal toxicity; Hepatitis	Drug-drug interaction	✓ GI effect

✓ Effective
 ? Indeterminate
 ✓ Modest Effect
 Unknown or Unchanged

* Based on PPARα/δ and PPARδ

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.

FGF21 Has Potential To Be Mainstay of Therapy in NASH

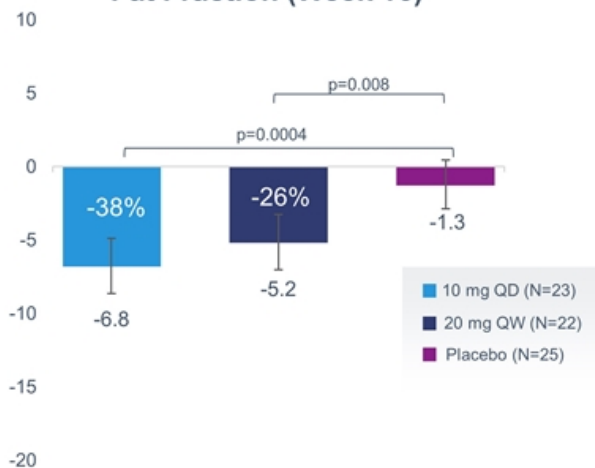


- Endogenous metabolic hormone that regulates energy expenditure and glucose and lipid metabolism
- Activates FGF receptors 1c, 2c, 3c, not believed to activate receptor 4 (leads to increased LDL)
- Signaling requires co-activation of beta-klotho receptor
- Native FGF21 has a short half-life of < 2 hrs

FGF21 – Clinically Validated in NASH

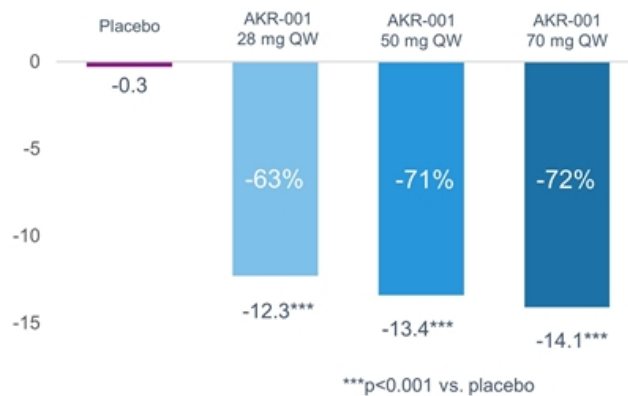
Results from Pegbelfermin's (BMS) and AKR-001's (Akeru) Phase 2a Studies

Pegbelfermin Absolute Change in % Liver Fat Fraction (Week 16)



- Reduction in serum Pro-C3; effect also demonstrated on MRE
- Well tolerated; most common AEs were GI AEs
- Half-life (T1/2) was 19–24 hour

AKR-001 Absolute Reduction in % Liver Fat (Mean Change from Baseline to Week 12)



- Relative reduction in liver fat >70% at two high doses tested
- Statistically significant reductions in ALT across all doses
- Safety/tolerability not reported as study remains blinded

FGF19 – Additional Validation of FGF Class

Recent Topline Results from Cohort 4 of aldafermin (NGM282) Phase 2 Study

- 22% of aldafermin (1mg QD) vs. 0% placebo patients achieved composite endpoint of fibrosis improvement and NASH resolution - statistically significant at week 24
- 39% reduction in absolute liver fat content at 24 weeks by MRI-PDFF in aldafermin patients; 38% of patients (versus 18% of placebo) had fibrosis improvement ≥ 1 stage with no worsening of NASH at week 24
- Mean increase of 45 mg/dL in LDL-C after 2 weeks

FGF19/FGF21 - SIMILARITIES

- Same family of non-heparin binding FGF hormones
- Believed to regulate energy metabolism and lipid metabolism in similar manner
- Activate FGF receptors 1c, 2c and 3c

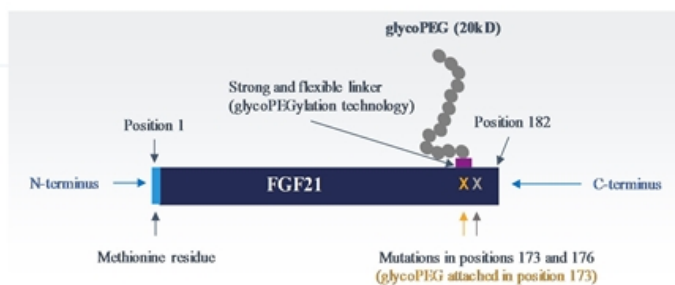
FGF19 LIMITATIONS

- Significant increases in LDL due to activation of FGFR4 vs. LDL decreases seen with FGF21 analogs
- aldafermin is a once-daily subcutaneous injection

BIO89-100 Is A Long Acting glycoPEGylated FGF21 Analog

TECHNOLOGY TO IMPROVE CLINICAL PROFILE

- Site-specific glycoPEGylation technology designed to prevent degradation, extend half-life, minimize potential for aggregation and retain potency
- Incorporated by Teva for approved product: Lonquex®



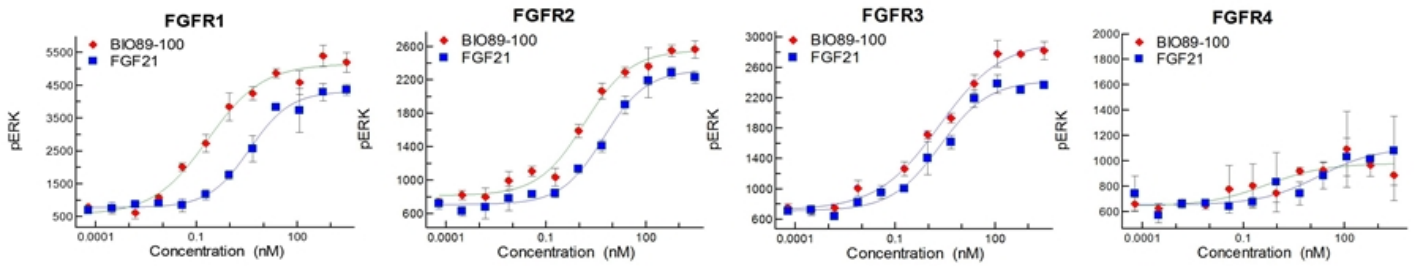
TARGETED MUTATIONS TO KEEP C-TERMINUS INTACT

- Two mutations via substitutions with natural amino acid sequences inserted at positions 173 and 176, near FAP enzyme cleavage site at C-terminus (critical for β -klotho binding)
- Single linear 20 kDa glycoPEG moiety attached at position 173

LONG HALF-LIFE (55-100 HOURS) MAY SUPPORT WEEKLY OR EVERY 2-WEEK DOSING

- Half-life of 55-100 hours which is significantly longer than Pegbelfermin (19-24 hours)

Preclinical Data Confirms BIO89-100's Mechanism of Action Via Potent FGF Receptor Agonism



- BIO89-100 demonstrated low nanomolar potency against FGF Receptors 1c, 2c and 3c but not 4c similar to recombinant human FGF21
- BIO89-100 has the potential to reproduce the beneficial metabolic effects of native FGF21 which may translate into clinical benefits for patients with NASH and SHTG

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

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

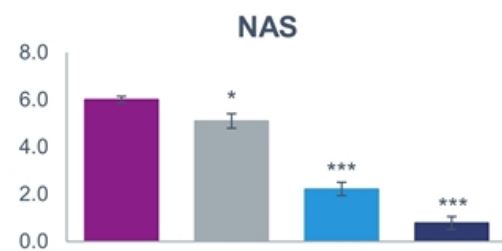
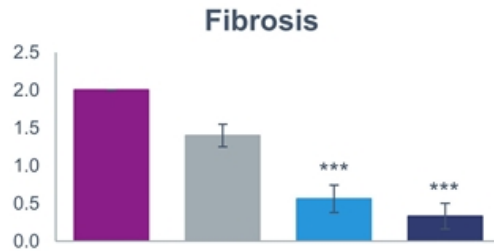
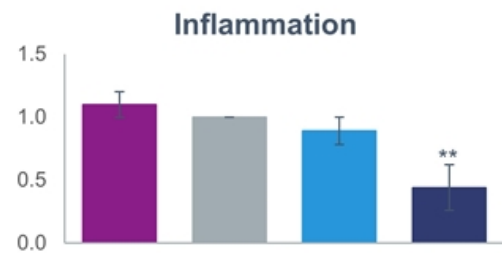
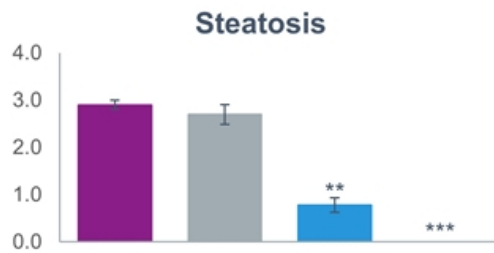
Strong Preclinical Data with BIO89-100

Preclinical Pharmacology Study with BIO89-100	Reduced Hepatocyte Injury	Reduced Liver Steatosis, Inflammation & Fibrosis	Improved Lipid Handling*	Improved Insulin Sensitivity	Body Weight Reduction
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	✓	✓	✓

✓ Statistically significant benefit observed

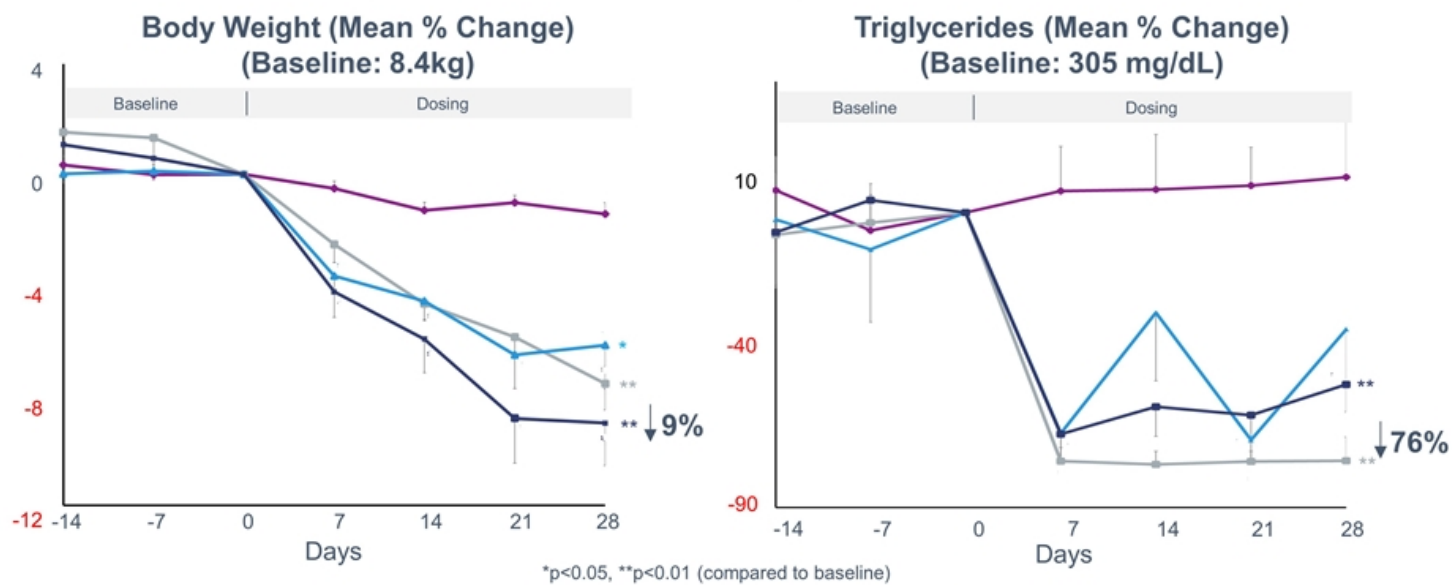
* Improved TG and cholesterol

Reduction in Steatosis, Inflammation, Fibrosis and NAFLD Activity Score with BIO89-100 in DIN Model



■ Vehicle
 ■ BIO89-100, 0.02 mg/kg
 ■ BIO89-100, 0.1 mg/kg
 ■ BIO89-100, 0.5 mg/kg
 *p<0.05 **p<0.01 ***p<0.001

Significant Reduction in Body Weight and Triglycerides in Diabetic Obese Monkeys With Once Every 2 Weeks Dosing



—●— Vehicle weekly
 —●— BIO89-100, 1.0 mg/kg, weekly
 —●— BIO89-100, 1.0 mg/kg once every 2 weeks
 —●— BIO89-100, 2.0 mg/kg once every 2 weeks

BIO89-100 Demonstrated a Favorable Clinical Profile in Phase 1a Study

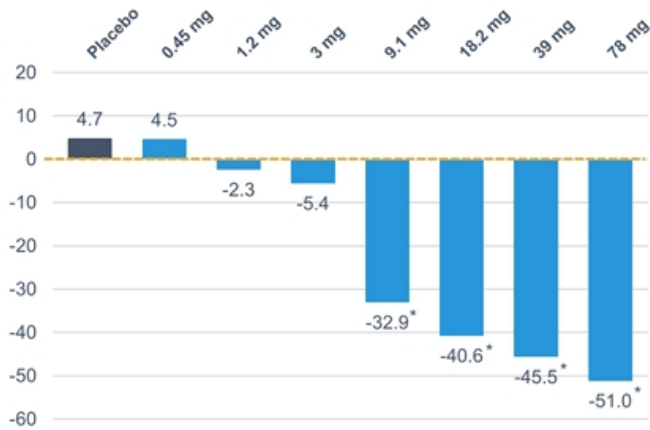
- Well tolerated
 - Most commonly observed treatment related AEs (in ≥ 2 subjects) were injection site reaction and headache, all of which were reported as mild
- PK was dose proportional; half-life of 55–100 hours
- Significant improvements in key lipid parameters at 8 and 15 days after single dose (baseline values were in normal range)*
 - Triglycerides reduction up to 51%
 - LDL-C reduction up to 37%
 - HDL-C increase up to 36%
- Supports weekly and once every 2-week dosing regimen

Trial Design:

Double-blind, placebo-controlled Single Ascending Dose (SAD); 58 healthy volunteers; 7 dose cohorts

Robust and Durable Improvement in Triglycerides Following a Single Dose of BIO89-100

Mean Percentage Change at Day 8 from Baseline in Triglycerides (%)

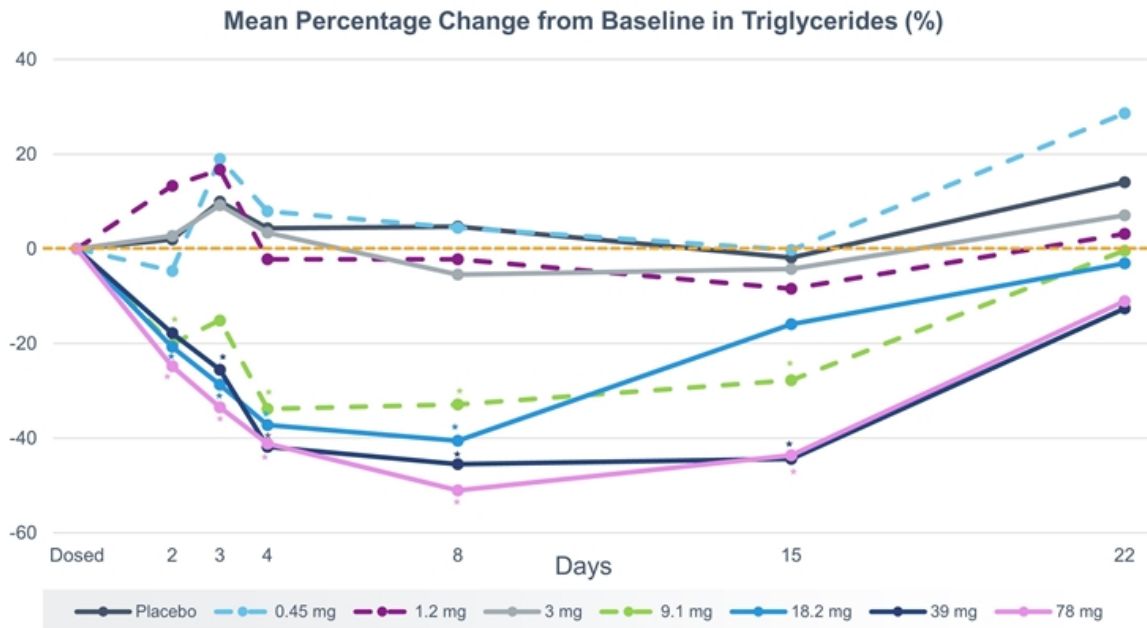


Mean Percentage Change at Day 15 from Baseline in Triglycerides (%)

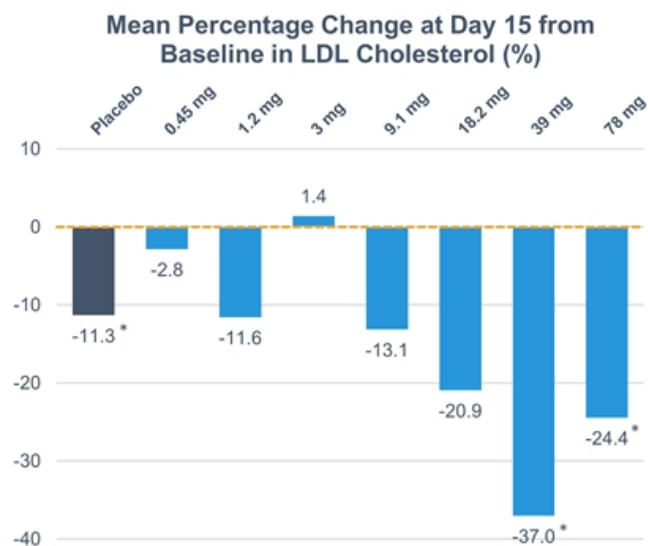
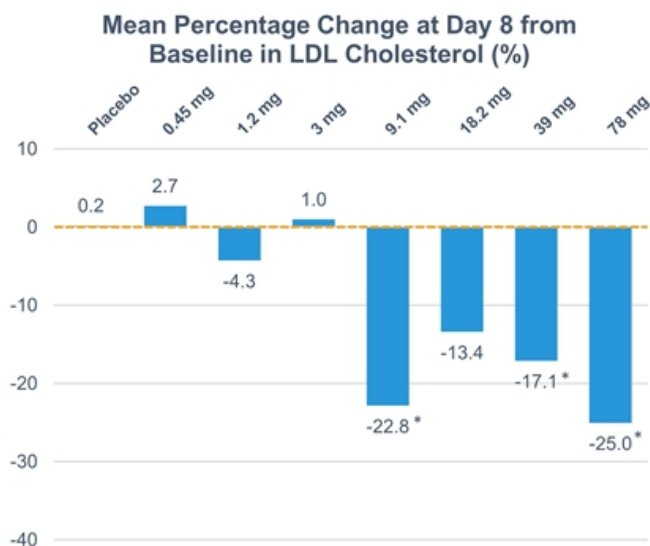


Dose (mg)	Placebo	0.45mg	1.2mg	3mg	9.1mg	18.2mg	39mg	78mg
N	15	6	6	6	7	6	6	6
Baseline	99.3	83.2	76.5	78.2	95.9	84.5	124.5	101.5

Rapid and Durable Improvement in Triglycerides Following a Single Dose of BIO89-100

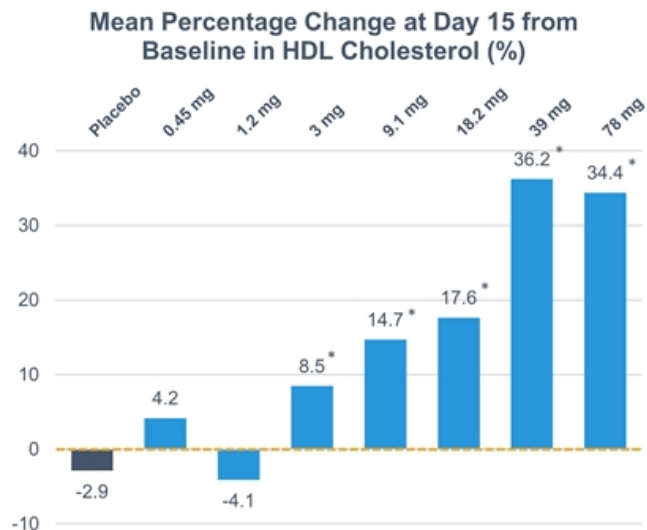
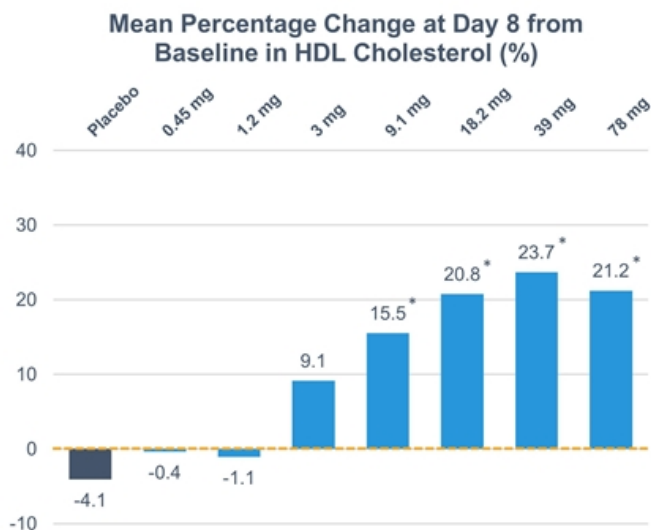


Robust and Durable Improvement in LDL Cholesterol Following a Single Dose of BIO89-100



Dose (mg)	Placebo	0.45mg	1.2mg	3mg	9.1mg	18.2mg	39mg	78mg
N	15	6	6	6	7	6	6	6
Baseline	129.6	97.8	122	123.3	120.3	122.8	138.8	130.3

Robust and Durable Changes in HDL Cholesterol Following a Single Dose of BIO89-100



Dose (mg)	Placebo	0.45 mg	1.2 mg	3 mg	9.1 mg	18.2 mg	39 mg	78 mg
N	15	6	6	6	7	6	6	6
Baseline	50.8	44.5	50	48.5	51	44.8	44.2	42.7

FGF21 Class - Pegbelfermin and AKR-001

PEGBELFERMIN (BMS)

- Pegylated molecule with moderate half-life of 19-24 hours—dosed daily and weekly
 - Mutations with non-native amino acid substitutions
- Efficacy was lower when dosed weekly versus daily across key lipid measures in Phase 1 and 2a trials

% Change vs. baseline (Day 15)*	Phase 1b study	
	10mg QD	21mg QW
TRIG	-35%	-25%
LDL-C	-25%	-20%
HDL-C	-8%	-9%

- Changes in TG and LDL-C in Phase 2a study in weekly dosing arm were 5% and 1% respectively

AKR-001 (AKERO)

- Fusion Protein molecule with extended half-life (3–4 days)
- Stat. sig. reductions in liver fat observed at all dose levels at week 12; safety remains blinded
 - Dosed weekly in ongoing Phase 2a study in NASH- 28mg, 50mg and 70 mg
- Tolerability issues seen at high doses in Phase 1 study in diabetic patients
 - At 140mg QW (n=9), 4 withdrawals due to GI/ CNS side effects; 4 patients with tremors
- Initiation of Phase 2b study projected in 1H21

FGF21 class has potential to become mainstay of therapy and hence multi-billion-dollar market. Multiple drugs with different clinical profiles within the same class could all be hugely successful, similar to other therapeutic areas (e.g. GLP-1, anti-TNF, Interferon-beta)

BIO89-100: Phase 1b/2a Study

- Design: Randomized, double-blind, placebo-controlled
- Population: NASH or NAFLD patients with high risk of NASH*
- Dosing: Weekly or every 2 weeks regimen; six dosing cohorts: 3mg QW to 36mg Q2W
- Duration: 12 weeks
- Size/Power: n=81** patients enrolled; powered to show statistical difference on MRI-PDFF
- US Study: Ongoing; Results expected in 2H20

FDA has concurred with overall trial design including study population, dose selection and study treatment duration

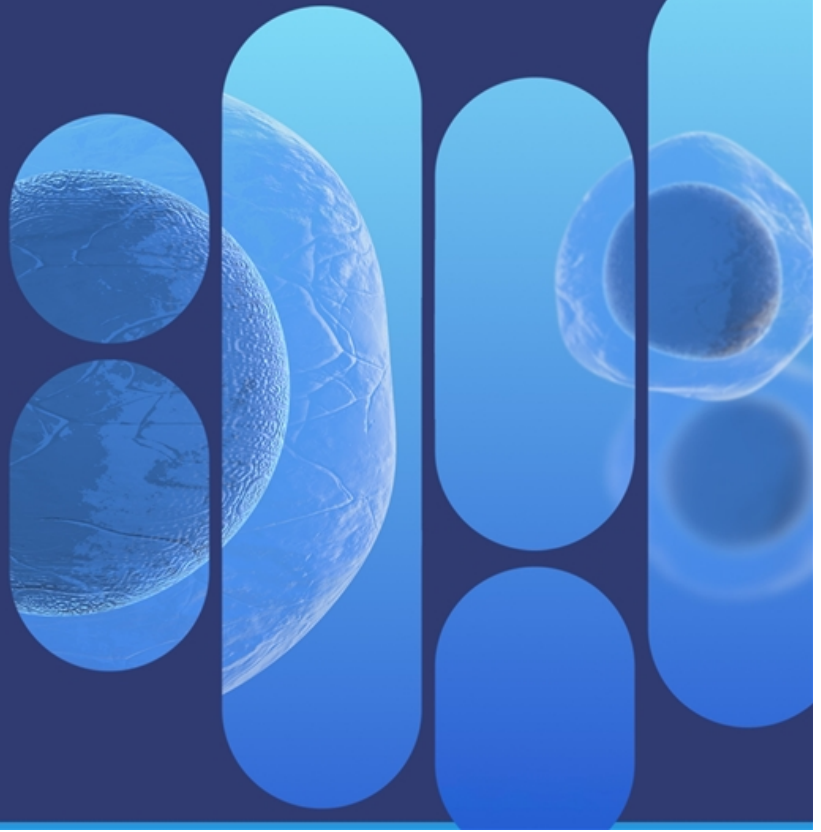
Trial Endpoints:

- Safety, PK
- MRI-PDFF - (Week 7 and end of study)
- Serum Lipids
- Key NASH biomarkers including:
 - ALT
 - Pro-C3
 - ELF
 - Inflammatory markers

89bio



**OPPORTUNITY IN
SHTG**



BIO89-100: A Compelling Drug Candidate For SHTG

SIGNIFICANT COMMERCIAL OPPORTUNITY

- Large patient population who are unable to achieve treatment goals with existing therapies
- Increased interest in lowering TGs to reduce residual CV risk

FGF21 IS A HIGHLY PROMISING MECHANISM OF ACTION FOR TREATMENT OF SHTG

- Removes lipids from circulation, increases lipid catabolism and has the potential to address multiple co-morbidities (dyslipidemia, diabetes)

BIO89-100 OFFERS A POTENT AND DIFFERENTIATED PROFILE RELATIVE TO EXISTING THERAPIES

- Showed significant reduction in triglycerides in preclinical and clinical studies (up to 78% in monkey study and up to 51% after a single human dose)
- Potential for use as monotherapy or in combination with existing drugs or those in development

ESTABLISHED REGULATORY PATH; POTENTIAL FOR RELATIVELY SMALLER AND FASTER TRIALS

- Potential to be faster to market than NASH

SHTG Market Opportunity

Large Patient Population...

Estimated **up to 4 million** patients in the US with **TG \geq 500 mg/dL**

...With Large Unmet Need

up to 50%* of treated patients are **refractory to current standard of care**

Diagnosis and treatment rates are expected to increase in the future

Increasing awareness of the importance of treating elevated TGs

- Residual CV risk despite effective LDL treatments with statins
- Outcome study (REDUCE-IT) demonstrated that reducing TG can significantly lower CV events

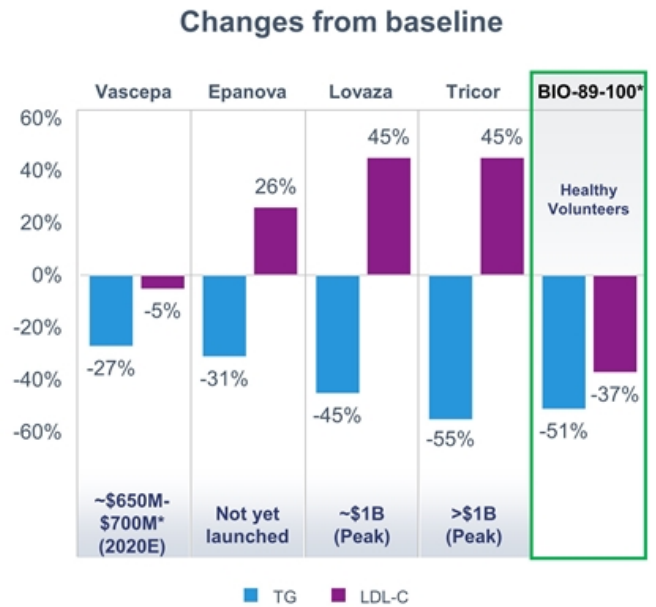
SHTG Therapeutics – Key Attributes

Key Attributes for Successful SHTG Therapies

- Robust TG reduction
- Address multiple co-morbidities of patients (dyslipidemia and insulin resistance)
- Need to have favorable benefit/risk profile
- Support compliance with effective dosing

BIO89-100 has the potential to deliver on key attributes for successful SHTG therapy

	FISH OILS			FIBRATES	FGF21 Analogs
	Vascepa (EPA)	Epanova (EPA+DHA)	Lovaza (EPA+DHA)	Tricor	
LDL-C Improvement	-	Worsens LDL	Worsens LDL	Worsens LDL	✓
HDL-C Improvement	-	-	-	-	✓
Effect on other metabolic co-morbidities (liver fat, glycemic control)	-	-	-	-	✓
Tolerability/Safety	May prolong bleeding time			Myopathy LDL and LFT increases DDI	✓ GI effect
Dosing convenience	4 capsules / Day with food	2-4 capsules / day	4 capsules / Day with food	1 tablet/day	Infrequent SC injection – compliance benefit



✓ Effective - Unchanged or Inconclusive

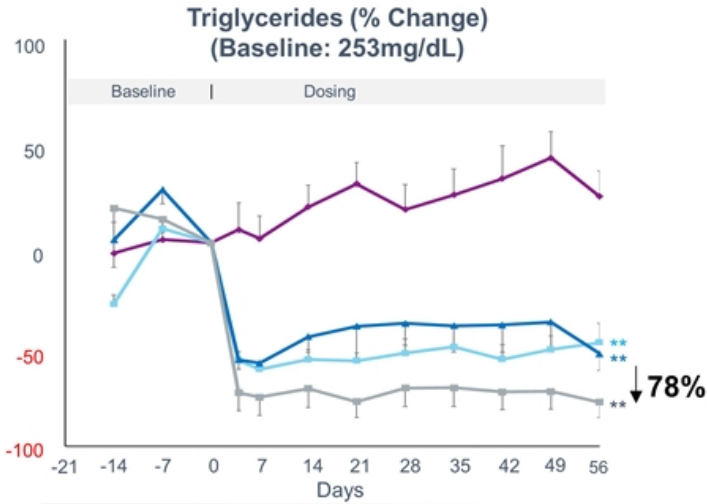


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* Conclusions on this slide are not based on head-to-head results

* Maximal data from Phase 1 SAD study

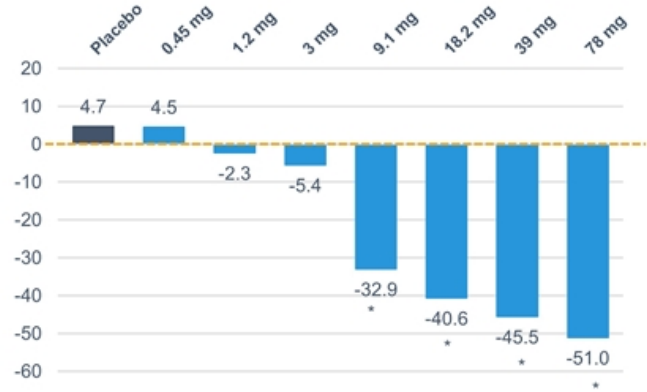
Potent and Durable Reduction in Triglycerides Observed with BIO89-100



Data from study in obese diabetic monkeys

- Vehicle weekly
- BIO89-100, 0.1 mg/kg weekly
- BIO89-100, 0.3 mg/kg weekly
- BIO89-100, 1.0 mg/kg weekly

Mean Percentage Change at Day 8 from Baseline in Triglycerides (%)



Data from study in SAD in healthy volunteers

Dose (mg)	Placebo	0.45mg	1.2mg	3mg	9.1mg	18.2mg	39mg	78mg
N	15	6	6	6	7	6	6	6
Baseline	99.3	83.2	76.5	78.2	95.9	84.5	124.5	101.5

* 95% CI exclude 0% change from baseline

SHTG Clinical and Regulatory Path is Defined and May Represent a Quicker Path to Market

- 1 US approval in SHTG has been granted based on demonstration of TG reduction from baseline; clinical outcome study was not required for certain third-party approvals
- 2 Phase 3 studies for Vascepa and Epanova were single, 12-week trials with 75–100 patients per treatment arm

BIO89-100 Anticipated Development Plan*

Study	Design
Phase 2 Study*	<ul style="list-style-type: none">• Adults with TG \geq 500 on no background TG lowering therapy or on stable dose of statin and/or prescription fish oil; N = ~90• Multiple doses vs placebo• Primary endpoint: Reduction from baseline in TG• Secondary endpoints: Other lipids, hsCRP, glucose, body weight, safety, PK• Study duration: Topline data would be expected approximately a year or so after dosing our first patient
Registrational Trial*	<ul style="list-style-type: none">• Patients with TG \geq 500mg/dL; Endpoint = % reduction of TG from baseline

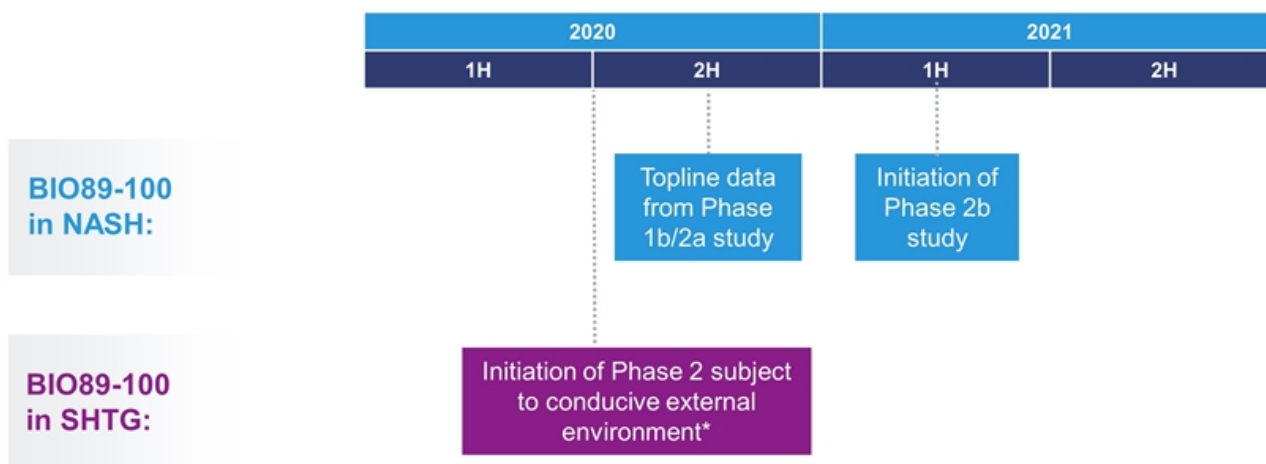
* Phase 2 study initiation delayed due to the COVID-19 pandemic; Study designs and development plan to be confirmed with regulatory feedback

Financial Position Summary

- **Completed successful upsized IPO on November 13, 2019**
 - Raised gross proceeds of \$97.6 million
 - Priced within range at \$16.00/share

- **Cash Position**
 - \$93.3 million (as of March 31, 2020);
 - On April 7, 2020, 89bio entered into a debt facility with Silicon Valley Bank for a tranching secured term loan of up to \$15.0 million

Recent and Upcoming Anticipated Clinical Milestones



* Delayed due to the COVID-19 pandemic; Study designs and development plan to be confirmed with regulatory feedback

Management Team

Rohan Palekar, CEO		<ul style="list-style-type: none">• CEO, CCO experience• Avanir, Medivation, J&J• Commercial, strategy, and R&D experience
Hank Mansbach, MD CMO		<ul style="list-style-type: none">• 20+ years biopharma and R&D leadership in clinical development and medical affairs• Ultragenyx, Medivation, Valeant, GSK
Ram Waisbourd COO and CBO		<ul style="list-style-type: none">• 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		<ul style="list-style-type: none">• CFO, Strategy/IR, finance, sell-side experience• Revolution Medicines, Ultragenyx, Chiron, Jefferies, Lazard, Barclays/Lehman Brothers
Quoc Le-Nguyen CTO & Head of Quality		<ul style="list-style-type: none">• 20+ years biopharma and leadership in technical operations, product supply, and quality• Aduro, Bayer, Novartis, Chiron, BioMarin

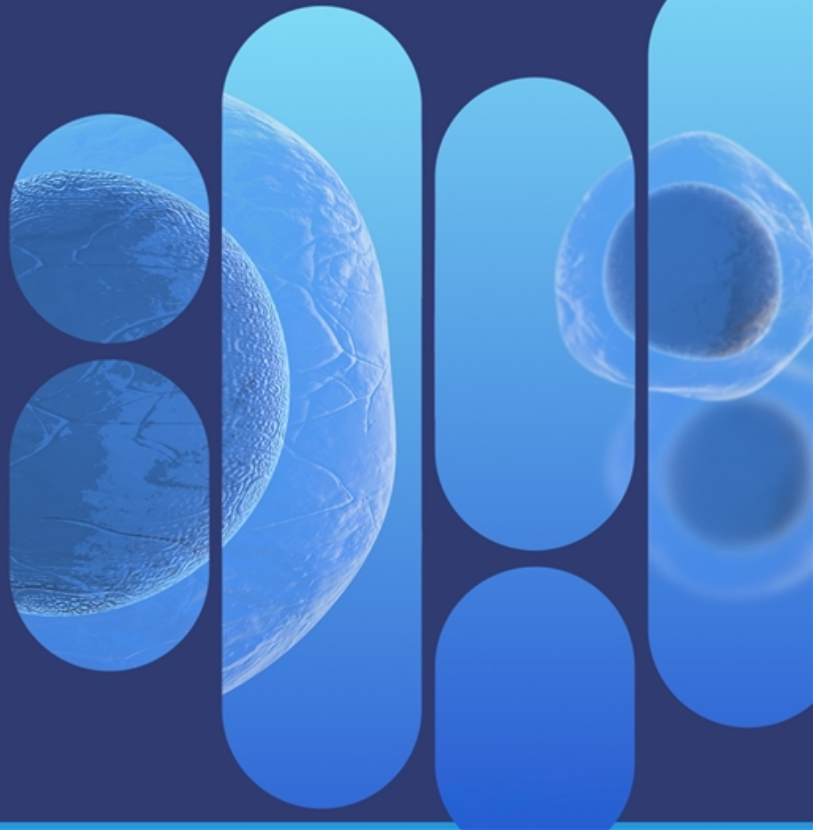
89bio – Investment Highlights

Significant Commercial Opportunities	<ul style="list-style-type: none">• Targeting large and growing unmet need in Non-Alcoholic Steatohepatitis (NASH) and Severe Hypertriglyceridemia (SHTG)
Potentially Differentiated Asset Targeting Clinically Validated Mechanism in NASH	<ul style="list-style-type: none">• BIO89-100 is a glycoPEGylated analog of FGF21 with compelling early human data• FGF21 has the potential to become mainstay of NASH therapy – addresses key liver pathologies and underlying metabolic dysregulation
Potentially Differentiated Therapy for SHTG	<ul style="list-style-type: none">• Robust reduction in triglyceride levels seen in animal and human studies• Established development and regulatory path offering a potentially quicker path to market for BIO89-100
Anticipated Near-term Catalysts	<ul style="list-style-type: none">• Two trials with BIO89-100: (i) ongoing Phase 1b/2a trial in NASH (enrollment complete and topline data anticipated in 2H20); (ii) planned Phase 2 trial in SHTG (initiation in 1H20 delayed due to the COVID-19 pandemic)• Potential to transition to Phase 2b trial in NASH in 1H21
Established Manufacturing Expertise; Long IP Protection	<ul style="list-style-type: none">• Established manufacturing process in place for near-term clinical supplies• Issued composition of matter patent expected to expire in 2038

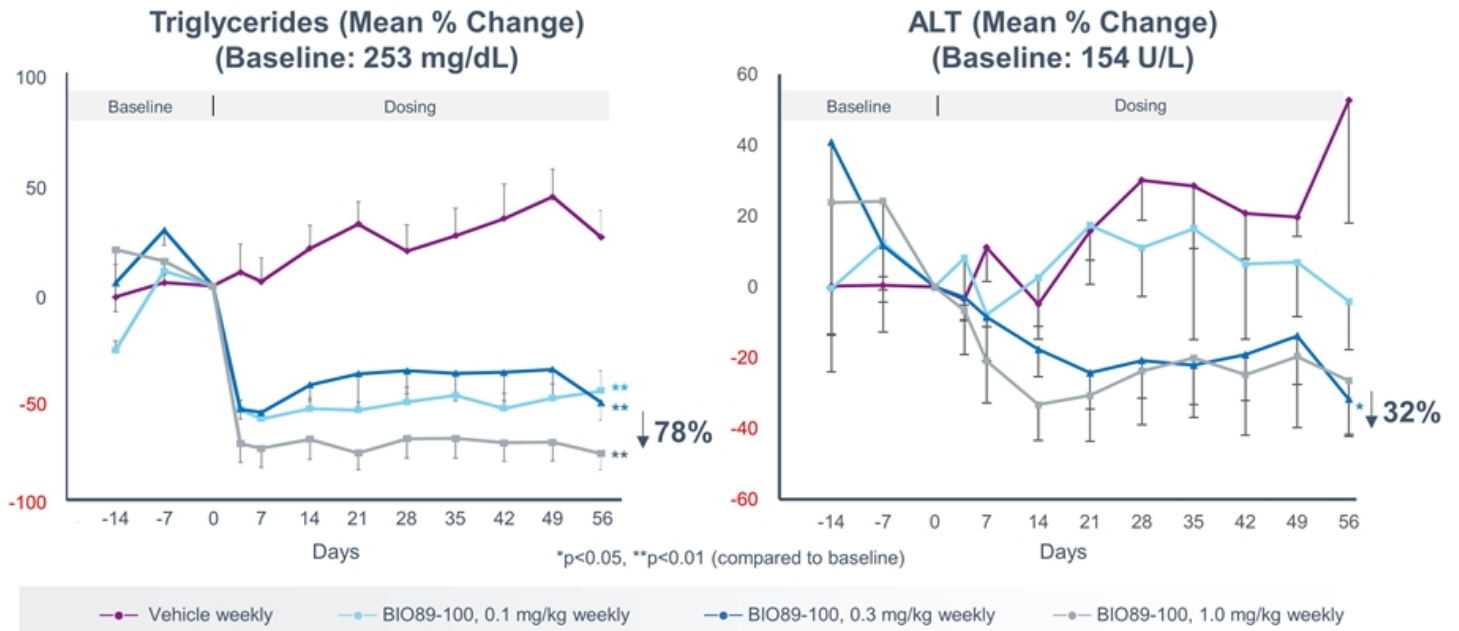
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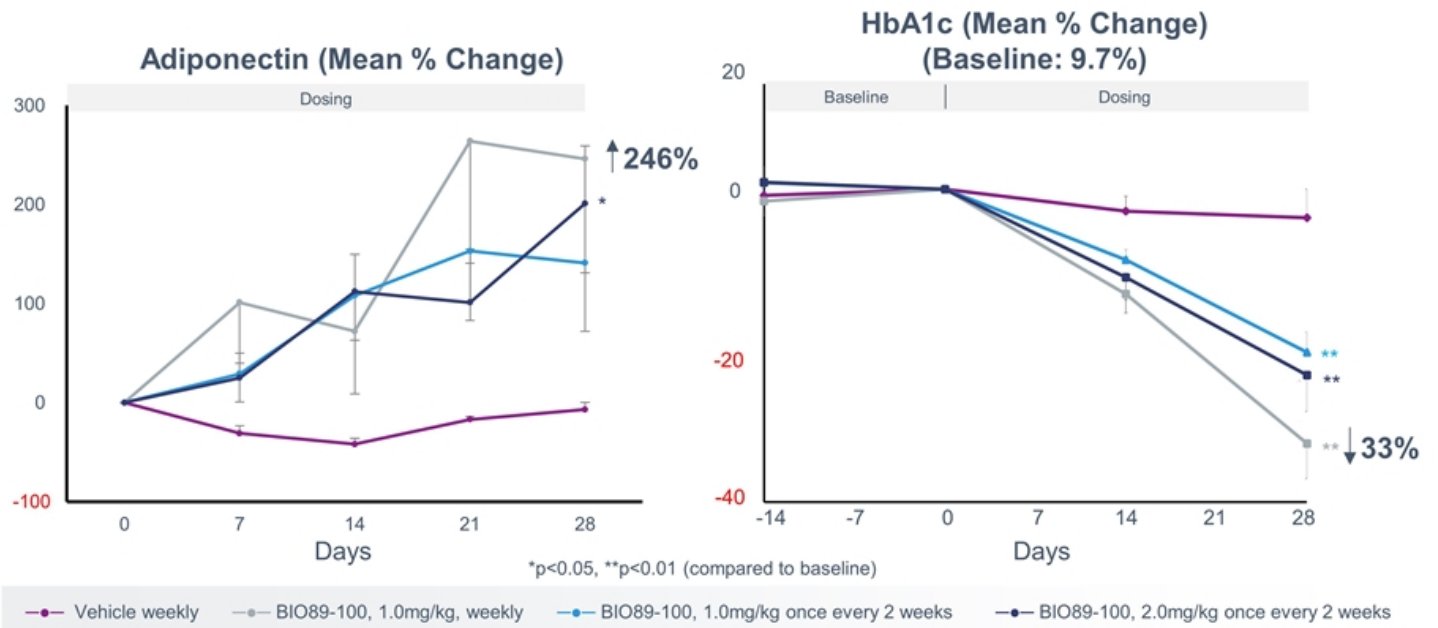
APPENDIX



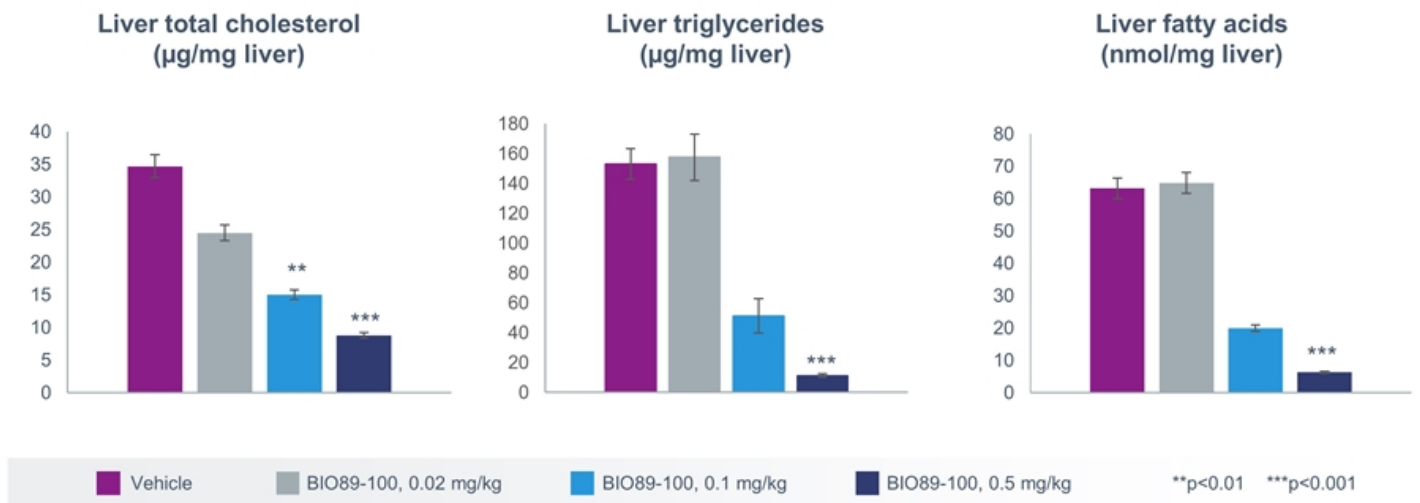
Significant Reduction in Triglycerides and ALT with BIO89-100 in 8-Week Diabetic Obese Monkey Study



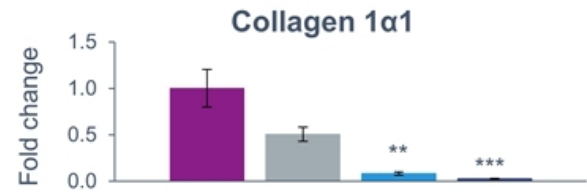
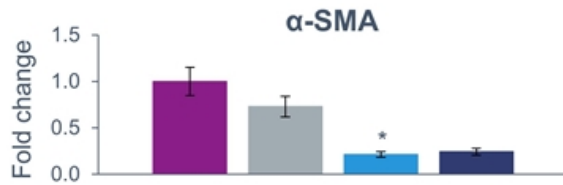
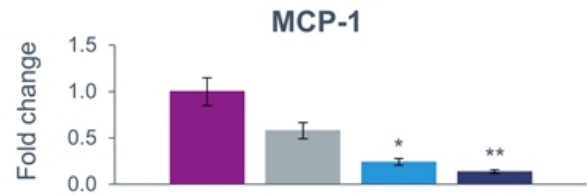
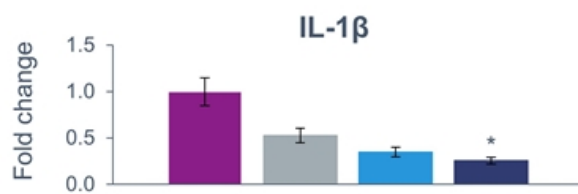
Significant Changes in Adiponectin and HbA1c in Diabetic Obese Monkeys With Once Every 2 Weeks Dosing



Reduction in Liver Cholesterol, Triglycerides and Fatty Acids with BIO89-100 in DIN Model

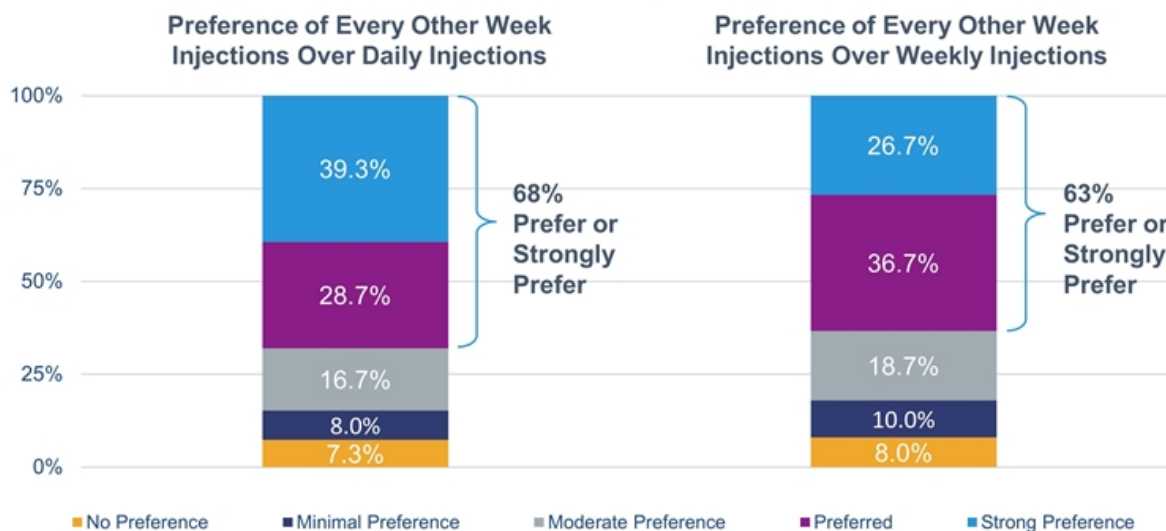


Improvement in Inflammatory and Fibrotic Markers with BIO89-100 in DIN Model



Vehicle BIO89-100, 0.02 mg/kg BIO89-100, 0.1 mg/kg BIO89-100, 0.5 mg/kg *p<0.05, **p<0.01, ***p<0.001

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