

**GSBR-1290** Phase 2 Program

November 13, 2024





# **Forward looking statements**

This presentation contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including, without limitation, statements concerning the Company's future plans and prospects, any expectations regarding the safety, efficacy, tolerability and CMC and scalability of GSBR-1290 and other candidates under development, the ability of GSBR-1290 to treat obesity, T2DM, or related indications, the planned initiation and study design of the Company's ACCESS and ACCESS II clinical studies of GSBR-1290 in patients with obesity, or overweight with a weight-related comorbidity and the timing thereof; the selection of a development candidate for the Company's amylin receptor agonist program; the timing and design of the Company's amylin receptor agonist program and its potential as a promising approach to obesity treatment; the timing and design of the Company's GIPR and GLP-1R/GIPR and other oral small molecule programs; the ability of the Company to expand to additional indications; and the planned timing of the Company's anticipated milestones and data results. In addition, when or if used in this presentation, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to the Company may identify forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Although the Company believes the expectations reflected in such forward-looking statements are reasonable, the Company can give no assurance that such expectations will prove to be correct. Readers are cautioned that actual results, levels of activity, safety, performance or events and circumstances could differ materially from those expressed or implied in the Company's forward-looking statements due to a variety of risks and uncertainties, which include, without limitation, risks and uncertainties related to the preliminary nature of the results due to length of the study and sample size and results from earlier clinical studies not necessarily being predictive of future results, potential delays in the commencement, enrollment and completion of the Company's planned clinical studies, the Company's ability to advance GSBR-1290, LTSE-2578, ANPA-0073 and its other therapeutic candidates, obtain regulatory approval of and ultimately commercialize the Company's therapeutic candidates, competitive products or approaches limiting the commercial value of the Company's product candidates, the timing and results of preclinical and clinical studies, the Company's ability to fund development activities and achieve development goals, the Company's reliance on third parties, including clinical research organizations, manufacturers, suppliers and collaborators, over which it may not always have full control, the impact of any global pandemics, inflation, supply chain issues, rising interest rates, future bank failures and other macroeconomic factors on the Company's business, its ability to protect its intellectual property and other risks and uncertainties described in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 8, 2024, Quarterly Report on Form 10-Q for the guarter ended June 30, 2024 filed with the SEC on August 8, 2024, and future reports the Company may file with the SEC from time to time. All forwardlooking statements contained in this presentation speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.



# Agenda

#### **Opening Remarks and Overview**

#### GSBR-1290 Phase 2 ACCESS Program

- Overview
- ACCESS & ACCESS II Study Designs

#### **Building a Leading Oral Small Molecule Portfolio**

- GSBR-1290 backbone
- Combination therapy approach
- Amylin program

Q&A

**Raymond Stevens, Ph.D.** *Chief Executive Officer* 

Blai Coll, M.D., Ph.D. Chief Medical Officer

Raymond Stevens, Ph.D., CEO

Raymond Stevens, Ph.D., CEO Blai Coll, M.D., Ph.D., CMO Jun Yoon, Chief Financial Officer

# Mission: Bring Small Molecule Innovation to Areas of Great Unmet Need



GLP-1R<sup>1</sup> Agonist PEPTIDE

#### **MEDICINES ACCESSIBLE FOR ALL**

#### **Oral Small Molecule Opportunities**

- Broader accessibility
- Oral formulation provides more patient options
- Potential for long-term weight loss maintenance
- Large-scale manufacturing; lower cost of goods
- Potential fixed dose combination advantages



#### GLP-1R Agonist SMALL MOLECULE



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# **GSBR-1290 Key Characteristics Demonstrate Potential Best-in-Class Profile**





## GSBR-1290 Obesity Data to Date: Potential Best-in-Class Oral GLP-1R Agonist







# **GSBR-1290** Phase 2 ACCESS Program



## **GSBR-1290** Phase 2 ACCESS Program – Two Studies to Accelerate Development

Late-stage Phase 2 program with two separate studies designed to accelerate timeline to Phase 3 while providing the potential for best-in-class efficacy with higher doses

# ACCESS

# ACCESSI

- "Low and Slow" titration to optimize tolerability Low 5mg starting dose with 4-week titration intervals- an established titration schedule to minimize GI-related adverse events
- Designed to confirm competitive efficacy 36-week study with ≥ 16 weeks on target dose to demonstrate longer-term efficacy profile
- Dose-range finding Evaluating 45 mg, 90 mg, and 120 mg to confirm efficacy

 Favorable safety profile and proportional exposure enable us to study higher doses
Supported by large safety margin (≥ 150 fold at 120

mg) and dose proportional exposure between 60 mg and 120 mg

 Separate study to evaluate higher doses for further weight-loss differentiation Assessment of 180 mg and 240 mg will help establish the maximum tolerated dose for Phase 3





A Phase 2b, Randomized, Double-blind, Placebo-controlled, Dose-range Finding Study of the Efficacy and Safety of Multiple Doses of GSBR-1290 in Participants Living with Obesity (Body Mass Index ≥ 30 kg/m2), or Overweight (Body Mass Index ≥ 27 kg/m2) with at Least One Weight-related Comorbidity



## **GSBR-1290 ACCESS Study Design**

Study details

N = 220 Randomized 3:1 (GSBR-1290: placebo)

Participants with:

Body mass index (BMI)  $\ge$  30 kg/m<sup>2</sup>

or

• BMI ≥ 27 kg/m2 with ≥ 1 weight-related comorbidity

	Titration phase (every 4 weeks)					Maintenance phase (at target dose)
	5 mg	15 mg	30 mg			45 mg
	5 mg	15 mg	30 mg	60 mg		90 mg
	5 mg	15 mg	30 mg	60 mg	90 mg	120 mg
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#### **Primary endpoint**

 % change in body weight at week 36 compared to baseline (active vs. placebo)

#### Key secondary/exploratory endpoints

- Safety and tolerability profile of a monthly titration scheme
- Pharmacokinetics of GSBR-1290

# ACCESSI

A Phase 2, Randomized, Double-blind, Placebo-controlled Study of the Safety, Tolerability, and Efficacy of Increasing Optimal Doses of GSBR-1290 in Participants Living with Obesity (Body Mass Index ≥ 30 kg/m2) or Overweight (Body Mass Index ≥ 27 kg/m2) with at Least One Weight-related Comorbidity



# **GSBR-1290 ACCESS II Study Design**



#### **Primary endpoint**

• Safety and tolerability of GSBR-1290

#### Key secondary/exploratory endpoints

- Pharmacokinetics of GSBR-1290
- % change in body weight at week 36 compared to baseline (active vs. placebo)

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# **GSBR-1290:** Backbone of a Metabolic Franchise



# Where Does GSBR-1290 Fit in the GLP-1R Agonist Landscape?

STRUCTURE



**Metabolic Franchise Strategy – Combinations and Potential Indication Expansion** 





## **Robust Portfolio of Oral Non-Peptide Small Molecules for Obesity**

#### **GSBR-1290**

- Oral small molecule; once-daily dosing
- Monotherapy backbone for chronic maintenance with potential best-in-class efficacy and safety
- Potential fixed-dose combination with other oral non-peptides

#### Amylin

- Oral small molecule; once-daily dosing
- Potential for tolerability advantages
- Lean muscle mass preservation potential
- Potential fixed-dose combination with other oral non-peptides

Phase 2 program underway Top-line data expected in Q4 2025 Development Candidate selection expected in Q4 2024

#### **GSBR-1290 + Amylin Combination**

Potential for more significant weight loss and tolerability optimization Label expansion & additional indications



# **Robust Portfolio and Multiple Potential Catalysts in 2024 – 2026**

~\$915.3 M cash<sup>1</sup> as of September 30, 2024

**Anticipated Milestones – Entire Small Molecule Portfolio** 



Single-ascending dose/Multiple-ascending dose (SAD/MAD) 2.

3. Idiopathic pulmonary fibrosis (IPF)



# Q&A

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