



PreveCeutical Medical Inc.  
CSE:PREV | OTC:PRVCF | FSE:18H



Q1 - 2026

# Investor Presentation

# Our Mission

BioGene commits to  
**Delivering the Future of Genetic Medicines**  
with Precision Delivery, opening the door to alternative  
patient-friendly routes of LNP administration through  
innovative products and platforms that target key  
tissues of interest in obesity and diabetes...and beyond!

# Our Vision

Our vision is to deliver safe, effective, patient-friendly **curative** therapies for metabolic disorders that restore normal metabolic function involved in glucose regulation and fat metabolism.

# Board of Directors



**Stephen Van Deventer**

Stephen is the **Chairman, CEO and President** of BioGene Therapeutics and **PreveCeutical Medical**, with extensive experience in capital markets with a focus on life sciences. Stephen has started and raised millions in the capital markets space.



**Deepak Sampath, PhD**

Deepak will serve as an Independent Director for BioGene. He is the Senior VP, Head of Research at **Ultragenyx**, with previous experience at **Pfizer** and **Genetech**, along with over 100 publications, 20 issued patents and numerous IND, NDA, BLA filings and drug approvals for the treatment of cancer



**Steve Glover**

Steve joins BioGene as a Board Member, bringing multifaceted experience in Fortune 100 and start-up environments. He sits as Chairman and CEO of Nasdaq-listed **ZyVersa Therapeutics** and was former Chairman of **Ambrx**, which was acquired for \$2B.



**Patroski J. Lawson, MSP**

Linnéa has been appointed **Director of Science** at BioGene Therapeutics and sits on the board at **PreveCeutical Medical**. Linnéa is an accomplished biophysicist with years of experience with expertise in pharmacology, oncology, cell biology and gene editing.

# Senior Management



**Stephen Van Deventer**  
Stephen is the **Chairman, CEO and President** of BioGene Therapeutics and **PreveCeutical Medical**, with extensive experience in capital markets with a focus on life sciences. Stephen has started and raised millions in the capital markets space.



**Alex McAuly, CPA**  
Alex serves as the **Chief Financial Officer** for BioGene. He is a Chartered Professional Accountant of Canada with vast experience in running publically traded companies through his astute knowledge of accounting principles in North America and Europe.



**Harry Parekh, PhD**  
Harry is welcomed to the BioGene team as **Chief Science Officer & Scientific Founder of BioGene**. Harry is currently a Director of Research and Research Group Leader at the **University of Queensland, Australia**. He also serves as **CRO & Scientific Founder** for PreveCeutical Medical.



**Francis Tavares, PhD**  
Francis serves as **Chief Technology Officer** of BioGene Therapeutics. He has extensive experience in the preclinical development of small inhibitors in various target classes. He is founder of and CEO of **ChemoGenics BioPharma**.



**Kamal Albarazanji**  
Kamal joins BioGene Therapeutics as the **Senior Director of Metabolic Research**. He is a prolific researcher with a wealth of experience in in vivo pharmacology, target validation, and translational research with numerous patents and peer-reviewed manuscripts.

# Corporate Advisory Board



**Steve Glover**

Steve acts the chairman of our **Corporate Advisory Board**, bringing operational expertise spanning commercialization, integrated product development, and governance having overseen over 25 product launches in multiple therapeutic areas



**Stephen Van Deventer**

Stephen serves on the **Corporate Advisory Board**. He brings over 30 years of experience to the role as a Founder and CEO of several companies in the companies in the therapeutics and life sciences sector.



**Deepak Sampath, PhD**

Deepak will serve on BioGene's **Corporate Advisory Board**. He has been instrumental in establishing strategic partnerships with academic institutions and industry leaders, a skill that will help moving our science into therapeutic breakthroughs.



**Brian Gallagher, Jr.**

Brian will sit on the **Corporate Advisory Board** bringing critical investment experience within the life sciences sector raising capital through various channels including the **Michigan Biomedical Venture Fund, Slate Bio and Trek Ventures.**



**Kathy Rokita**

Kathy is joining the **Corporate Advisory Board** and currently is a Managing Director at **CBIZ** and has provided consulting services for physician groups and healthcare organizations for over 30 years. She has had successful exits, most notably as a Principal at Somerset CPAs.

# Scientific Advisory Board



**Deepak Sampath, PhD**

Deepak serves as chairman of BioGene's **Scientific Advisory Board**. He has extensive experience in small molecules, protein biologics, nucleic acids and gene therapies and has driven numerous programs from early research and discovery to clinical trials and regulatory approval.



**Prof. Mirela Delibegović**

As a member of BioGene's **Scientific Advisory Board**, Mirela brings a wealth of knowledge in metabolic physiology with a focus on diabetes, obesity and CVD. Prof Mirela holds the prestigious **Regius Chair of Physiology at The University of Aberdeen, UK.**



**Barry Ticho, MD, PhD**

Barry will serve on BioGene's **Scientific Advisory Board**. Barry holds several prestigious roles as Founder and Board Member at **Verve Therapeutics, Cardior Pharmaceuticals, Sania Therapeutics and Stoke Therapeutics.**



**Francis Tavares, PhD**

Francis sits on the **Scientific Advisory Board** bringing experience proposing and championing over 15 metabolic targets in several classes in preclinical drug discovery areas encompassing inflammation, cancer, diabetes and immunology



**Kamal Albarazanji**

Kamal is joining the **Scientific Advisory Board**. His career spans notable roles at **SmithKline Beecham** (now **GSK**) where he contributed to groundbreaking work in renin inhibitors for hypertension, insulin sensitizer like Avandia, and neuropeptide programs for obesity.

# BIOGENE AUSTRALIA

BioGene has established a wholly-owned subsidiary in Brisbane, Queensland, Australia.

Bolster R&D activities and provide significant cash-back on R&D from the Australian government.

BioGene is eligible to receive **43.5%** cash back from Australian Federal Government on all R&D, clinical trial and operational costs.

Brisbane hosts a series of globally-renowned research, manufacturing and clinical trial facilities.



Queensland Government  
Royal Brisbane and Women's Hospital  
Metro North Health



Queensland Government  
Children's Health Queensland  
[biogenetherapeutics.com](http://biogenetherapeutics.com)



Metro South Health

# Problem



## OBESITY

1

Cases have tripled in the past decade leading to elevated risk of mortality: heart disease, stroke and dementia.

## DIABETES

2

1 in 10 adults are diagnosed with diabetes. Childhood rates of diabetes & obesity are on a steep upward trajectory.

## DRUG SIDE EFFECTS

3

Debilitating and even life-threatening side effects have emerged with current marketed weight-loss treatments.

# Obesity Rates

## Obesity Cases Triple in a Decade

- The World Obesity Federation (WOF) predicts the economic impact of obesity will reach **>US\$4 trillion annually by 2035**.
- WOF report predicts that by 2035, **HALF** of the world's population (**>>4 billion people!**), will be classified as "obese".
- Childhood obesity cases are anticipated to impact **>200 million boys and >170 million girls** by 2035.

[www.mordorintelligence.com/industry-reports/weight-loss-diabetes-drug-market](http://www.mordorintelligence.com/industry-reports/weight-loss-diabetes-drug-market)

# Diabetes rates

## 1-in-10 Adults are Diabetic with Child Cases Rapidly Rising

- Leads to **>4 million** adult deaths a year.
- **Over 570 million** adults aged between 20 and 79 years are **currently** living with diabetes.
- Projections indicate **>640 million** cases by 2030, increasing by **over 20% to >780 million by 2045**.
- Childhood rates of continue to rise at alarming rates!

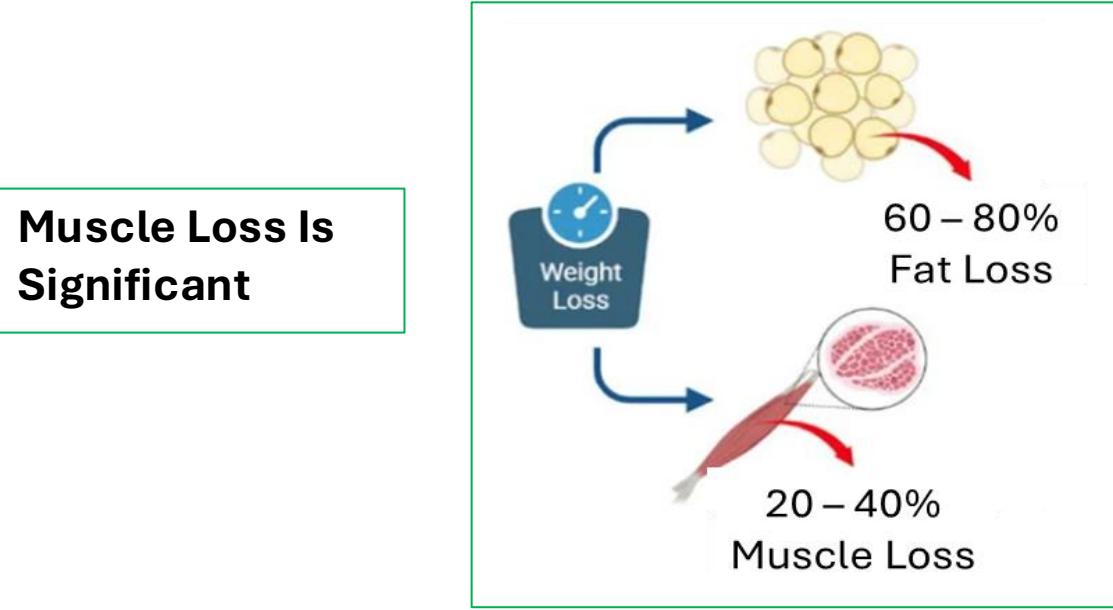
<https://www.mordorintelligence.com/industry-reports/weight-loss-diabetes-drug-market> <https://www.cnbc.com/2023/04/28/obesity-drugs-to-be-worth-200-billion-in-next-10-years-barclays-says.html>

Barclays capital markets projects a **US\$200 billion** weight-loss market by *circa.* 2030

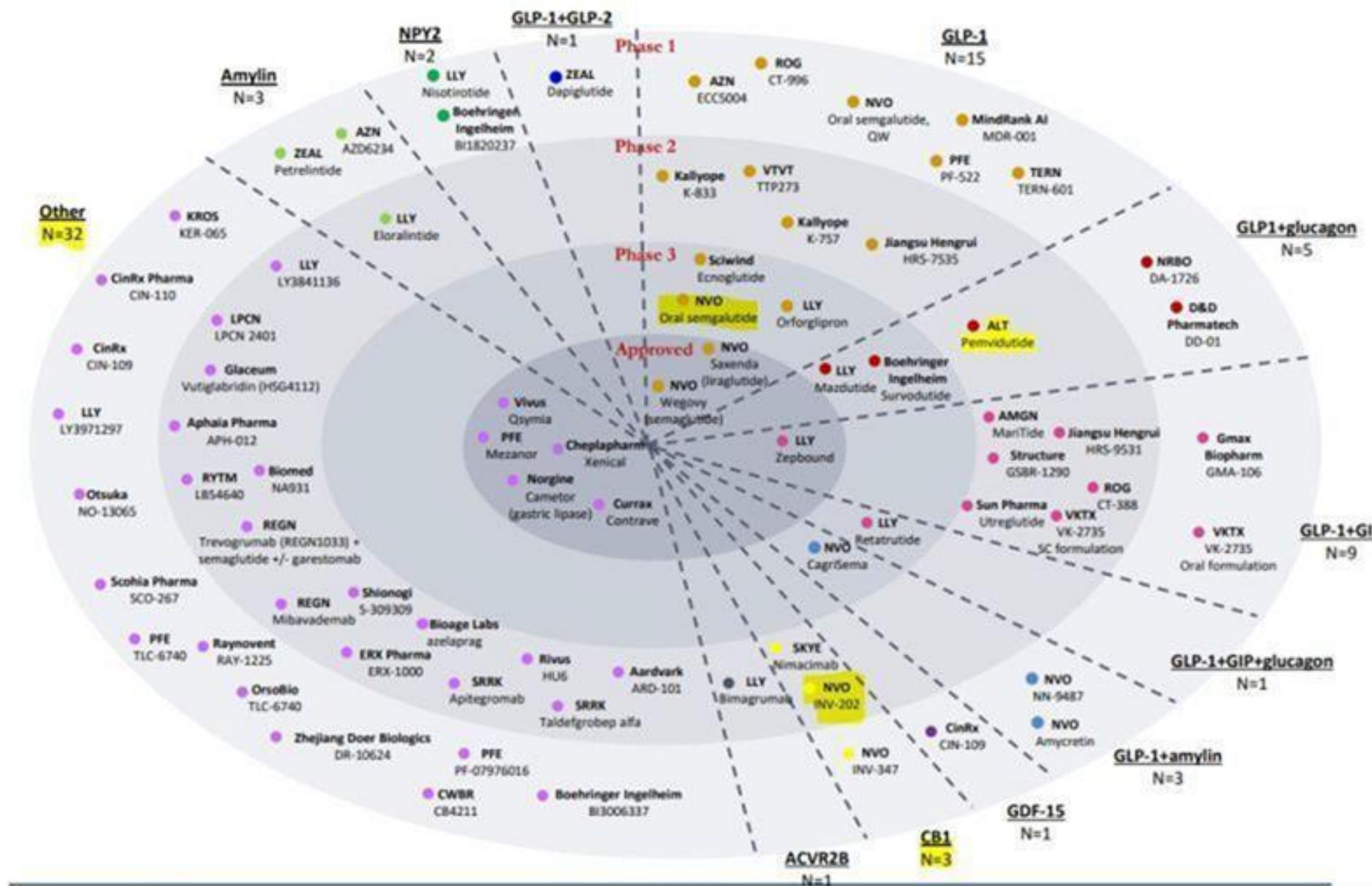
# GLP1 agonist have changed the obesity treatment paradigm but significant unmet medical needs remain

## Present with an array of issues:

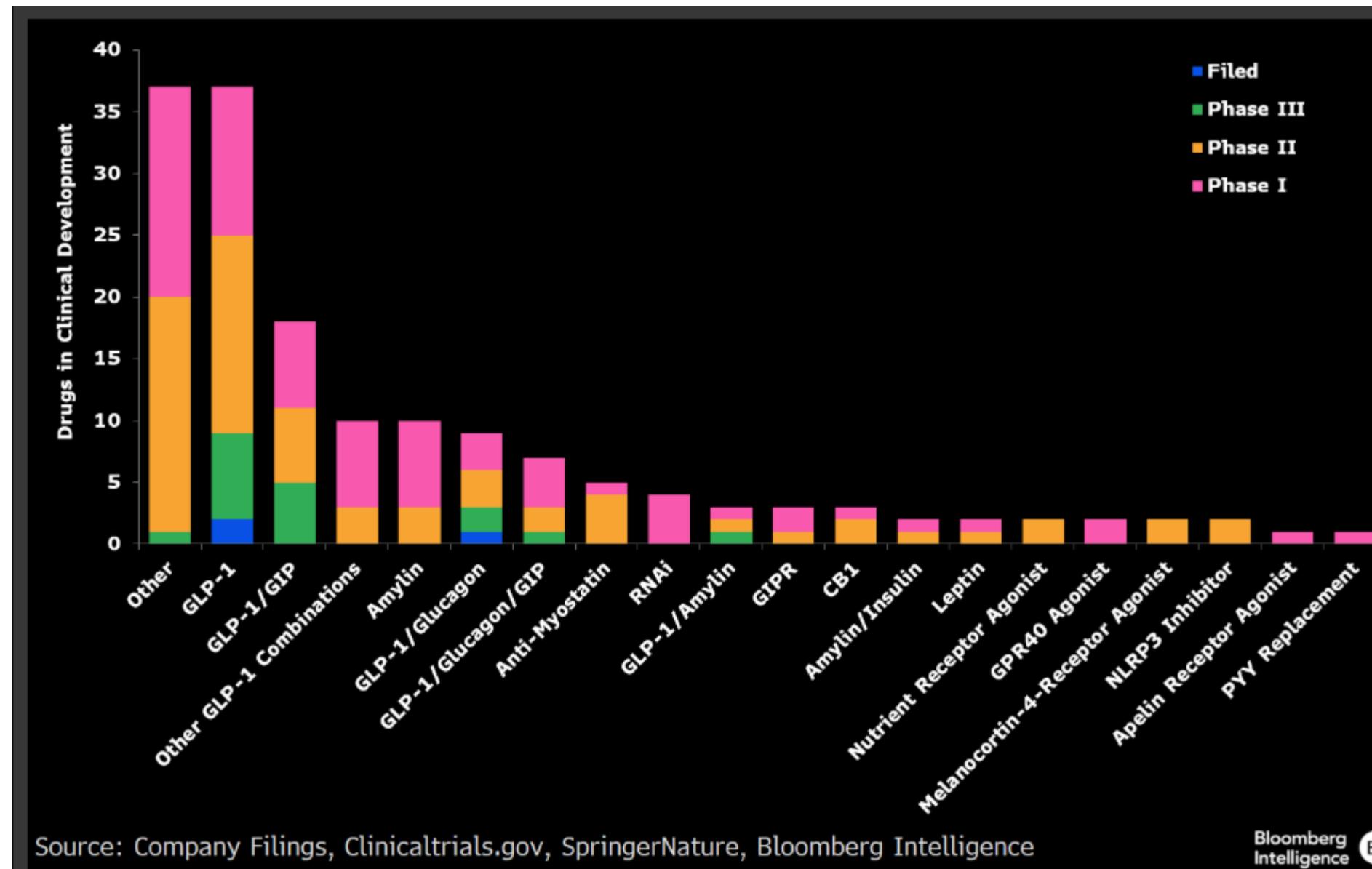
- Severe sometimes **life-threatening side effects**
  - **40% of patients stop treatment** by one year
- **20-40% muscle loss**
- Patients build **tolerance** over time
- **Don't restore metabolic functions**
  - Rapid rebound in weight gain after discontinuation due to side effects
  - Injections are painful, **inconvenient**
  - Oral route – real world challenges w.r.t dosing and bioavailability due to poor diet of target population



# The Obesity Landscape is Rapidly Evolving into Next Generation Therapies



# Landscape of Nucleic Acid Therapeutics for Obesity Treatment



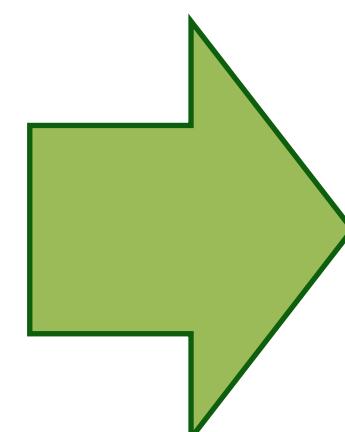
## siRNA Companies

### **Alnylam Pharmaceuticals (NASDAQ: ALNY)**

- **Program:** ALN-APP (targeting amyloid precursor protein in the CNS) and other metabolic disease candidates
- **Technology:** Proprietary siRNA platform, with success in multiple therapeutic areas
- **Status:** Early-stage development for obesity and metabolic disorders

### **Novo Nordisk (NYSE: NVO)**

- **Program:** Acquired Dicerna Pharmaceuticals (siRNA platform) in 2021 for \$3.3B
- **Technology:** Developing RNAi-based therapies for metabolic diseases, including obesity
- **Status:** Early R&D, potential combination with GLP-1 therapies (e.g., Wegovy)



### **Arrowhead Pharmaceuticals (NASDAQ: ARWR)**

- **Program:** Investigating siRNA for metabolic and cardiometabolic diseases
- **Technology:** TRiM™ (Targeted RNAi Molecule) platform
- **Status:** Focused on liver-centric pathways; potential obesity applications

### **Silence Therapeutics (NASDAQ: SLN)**

- **Program:** Developing siRNA therapies for metabolic and cardiovascular diseases
- **Technology:** Proprietary mRNA-targeting siRNA platform
- **Status:** Partnered with AstraZeneca for metabolic disease research

### **Eli Lilly (NYSE: LLY)**

- **Program:** Has siRNA obesity programs in preclinical development
- **Technology:** Acquired RNAi assets to expand beyond incretin-based obesity treatments
- **Status:** Exploring siRNA approaches alongside its established GLP-1 portfolio

# BioGene's A-to-Z solution

Dual gene therapy siRNAs targeting obesity and diabetes -> **restore metabolic function with reduced side effects, increased compliance and cost-effectiveness**

## **SOL-GEL PLATFORM**

A versatile platform revolutionizing Nose-to-Brain delivery of therapeutics with global patents pending

## **BIORESPONSIVE LNP PLATFORM**

Bioresponsive self-assembling lipid nanoparticle (bLNP) platform technology effectively delivering and releasing genetic cargo

\*US Patent GRANTED\*

## **Smart-siRNA's**

Metabolically-stabilised and multiple exon targeting siRNA's specifically against PTP1B, validated

## **DUAL GENE THERAPY**

Smart-siRNAs targeting PTP1B delivered using our bLNP platform directly N2B with Sol-Gel, in an easy-to-use nasal spray format

# SOL-GEL Nose-To-Brain Platform Delivery



## Direct Nose-to-Brain Delivery

Desired patient outcomes are achieved by consistent and sustained delivery to whole brain, dose after dose.



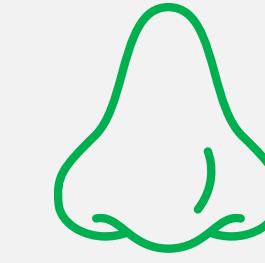
## Challenges with Oral Delivery Route

Rapid breakdown by enzymes in the gut. Increasing incidence of GI distress from oral dosing of medication complicated by poor diet.



## The Blood-Brain-Barrier

BBB remains a universal hurdle for drugs intended for the brain when administered via conventional routes (oral, injection), which we altogether circumvent.



## Olfactory Pathway Targeting with Sol-Gel

An ideal and proven pathway for rapid, direct and sustained brain delivery of therapeutic cargo, via our patient-friendly nasal spray Sol-Gel platform.

**Sol-Gel delivery altogether circumvents the BBB – not a hurdle for BioGene!**

# What is the Sol-Gel Platform?

A *solution* that is engineered to rapidly *gel* upon contact with mucosa...

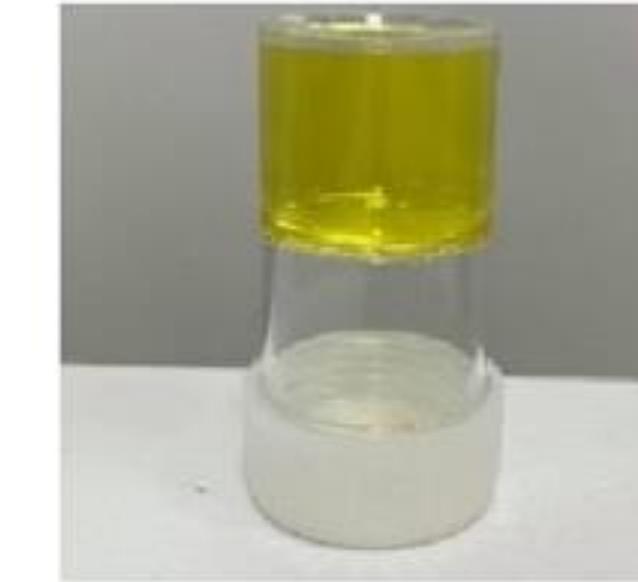
- Targeted spray delivery and retention on mucosa
- Controlled and sustained release (nanomicellar-formulation) to and through mucosa

## Room temperature

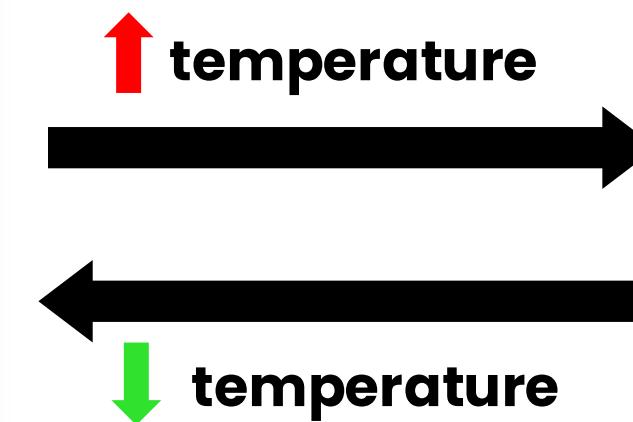


Solution state permits spraying via devices and extensive/uniform tissue coverage

## Body Temperature



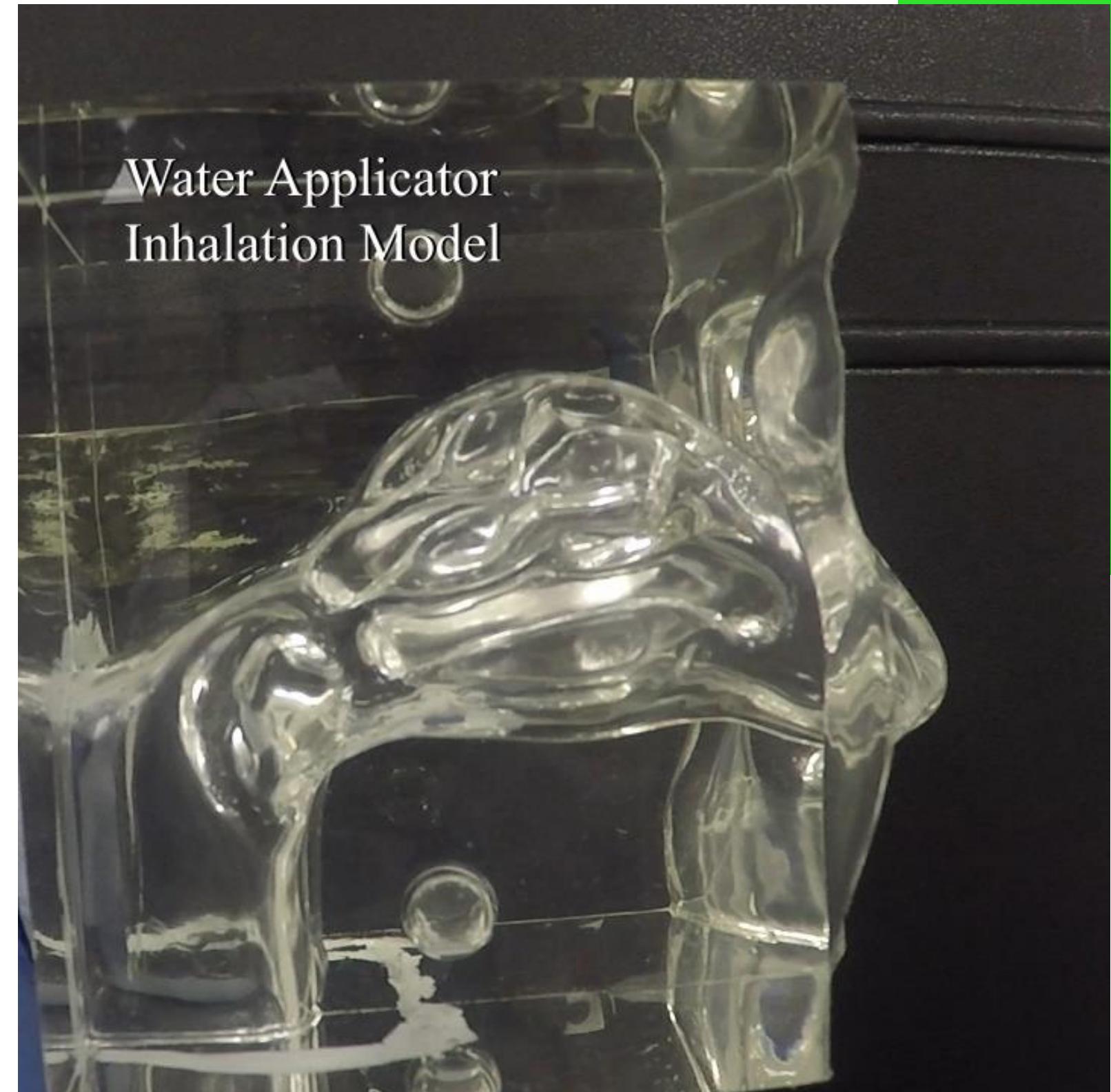
Mucoadhesive functional gel promotes sustained & controlled delivery



# Conventional nasal spray delivery intranasally

Nasal sprays deliver formulation throughout the nasal cavity, and are rapidly cleared...

- Anterior & posterior leakage
- Rapid ciliary clearance
- Poor retention
- Unpredictable transmucosal delivery to trigeminal nerves



# Sol-Gel Platform Technology & Device

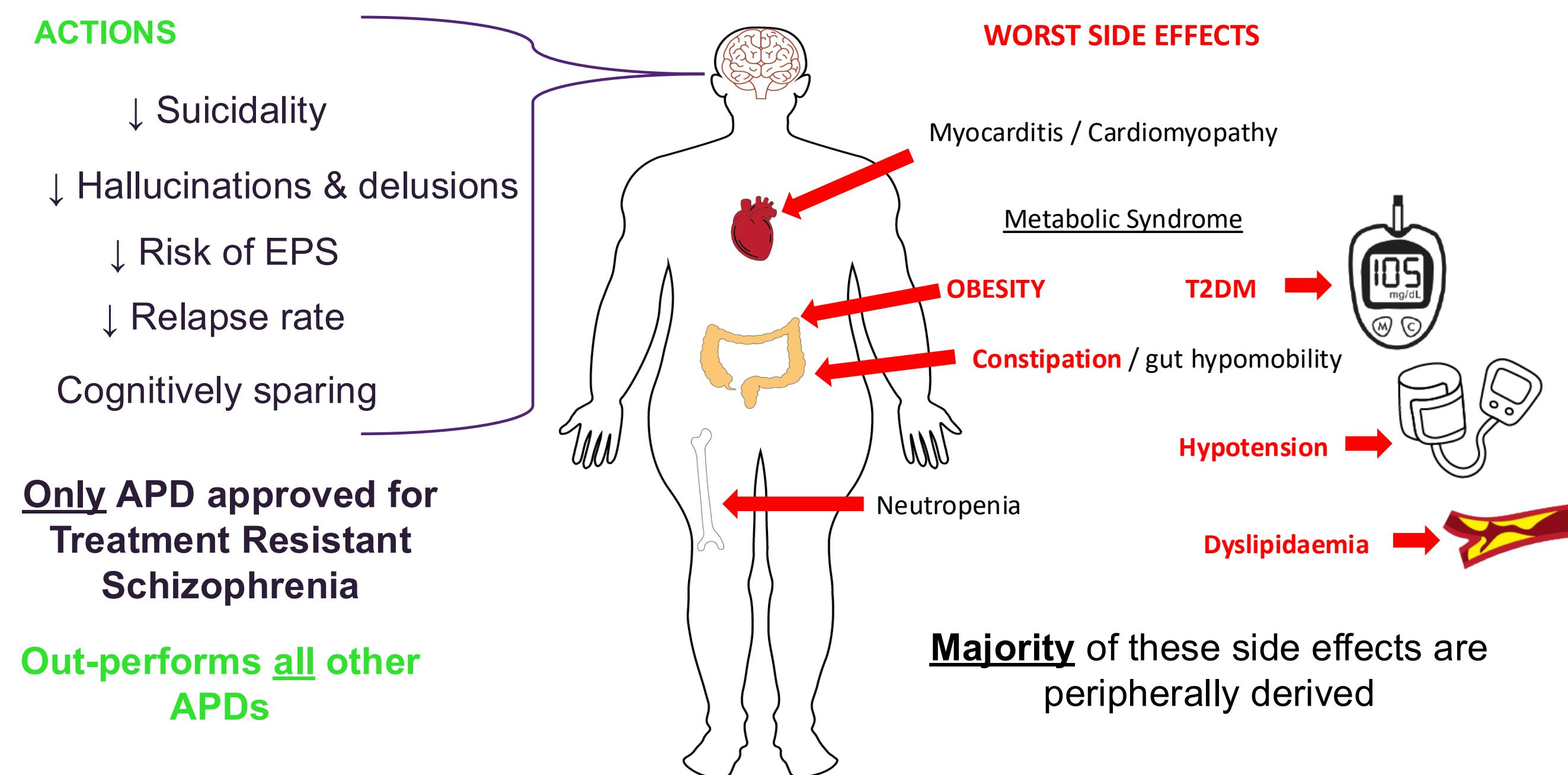
Olfactory mucosa targeting, rapid sol-to-gel transition, muco-retention and sustained delivery

- Exclusive olfactory targeting
- Direct, rapid nose-to-brain delivery
- Mucoadhesive sol-gel provides for sustained & controlled delivery
- Patient-friendly water or buffer vehicle - no alcohols or oils



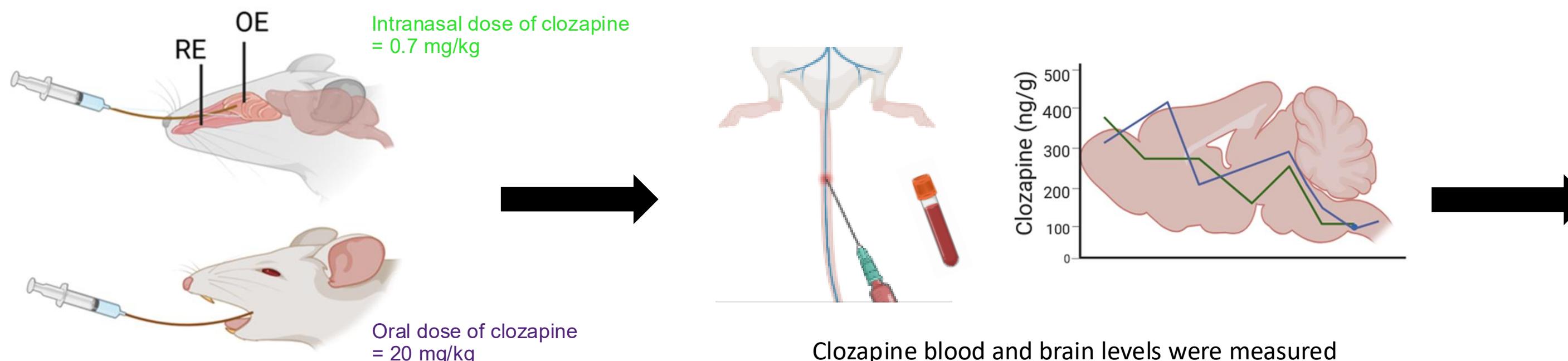
# PoC study using N2B sol-gel for treatment refractive psychosis...

## Clozapine: Peripheral Side Effects



# PoC study confirms N2B sol-gel **brain-biased delivery** for treatment refractive psychosis...

- Clozapine is exemplary in alleviating positive & negative ve symptoms of psychosis, but is plagued with serious, debilitating peripheral side effects, limiting it's use to treatment refractive schizophrenia
- A preclinical study was conducted comparing oral vs intranasal sol-gel delivery of clozapine in rodents trained in conditioned avoidance response – an industry standard 'read out' of anti-psychotic effect



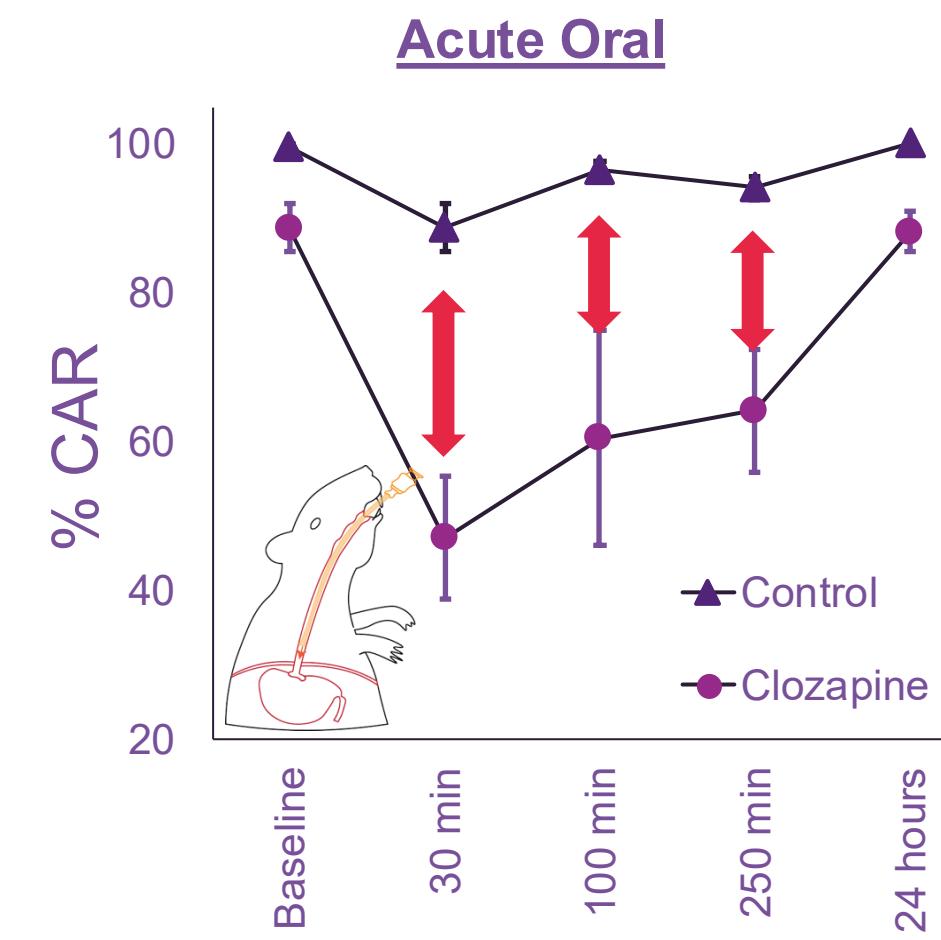
A clozapine sol-gel formulation delivered intranasally to the olfactory epithelium (top) was compared with oral delivery (bottom)

**Blood levels were ≈10-fold greater when the same animals were dosed orally vs intranasally**

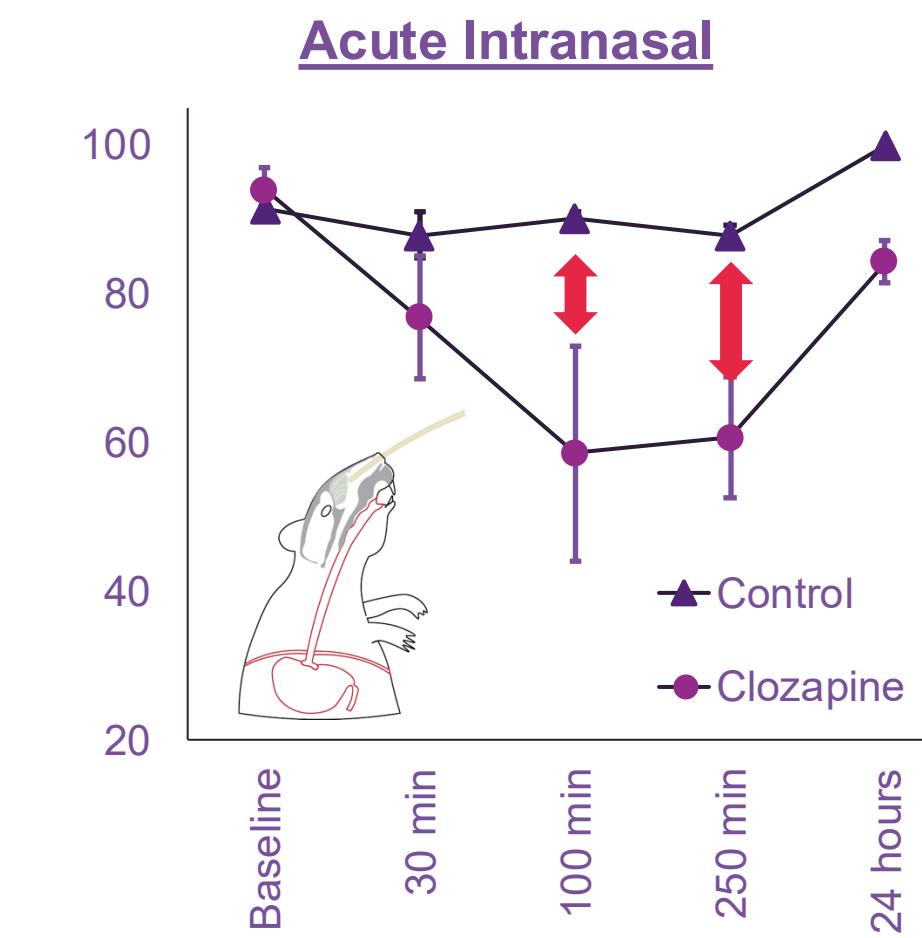
**But what about efficacy...?**

# PoC study confirms N2B sol-gel is efficacious for treatment refractive psychosis...

Clozapine anti-psychotic drug action - daily dosing for 7 days (acute study)



Oral = 20 mg/kg



IN = 0.7 mg/kg

This is  
28-fold  
lower than  
the oral  
dose!!!

Confirmed sustained efficacy after CHRONIC dosing to TWO months - Human trials planned...

# BioGene's Solution for Next Generation Diabetes and Obesity Therapeutics

Dual gene therapy siRNAs targeting obesity and diabetes -> **restore metabolic function with reduced side effects, increased compliance and cost-effectiveness**

## **SOL-GEL PLATFORM**

A versatile platform revolutionizing Nose-to-Brain delivery of therapeutics with global patents pending



## **BIORESPONSIVE LNP PLATFORM**

Bioresponsive self-assembling lipid nanoparticle (bLNP) platform technology effectively delivering and releasing genetic cargo

\*US Patent GRANTED\*



## **Smart-siRNA's**

Metabolically-stabilised and multiple exon targeting siRNA's specifically against PTP1B, validated

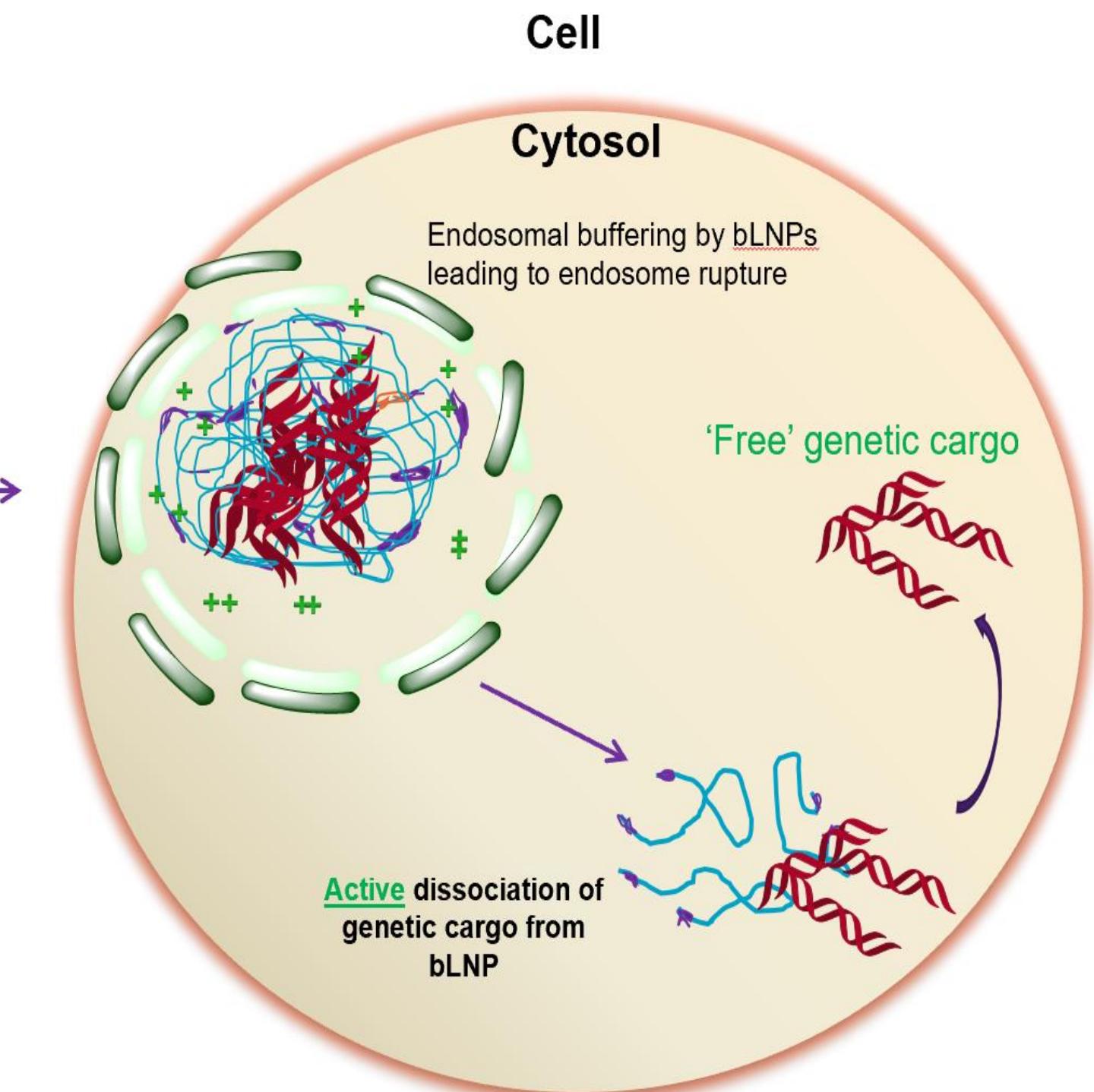
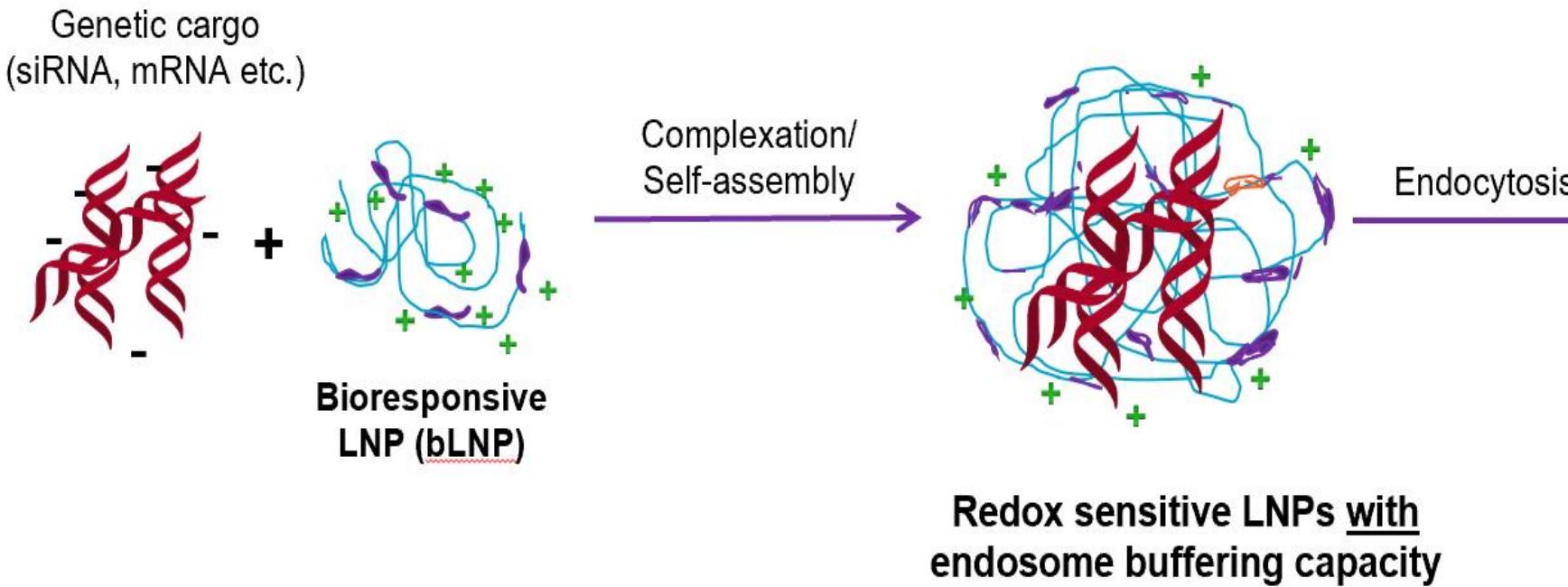


## **DUAL GENE THERAPY**

Smart-siRNAs targeting PTP1B delivered using our bLNP platform directly N2B with Sol-Gel, in an easy-to-use nasal spray format

# Non-Viral Vector Platform - BioGene's Bioresponsive LNPs (bLNP)

- Next generation – non-viral **bioresponsive vector**
- US Patent # 11,566,044 granted, 31st March 2023



Comprehensive release of **all** genetic cargo from their carrier...

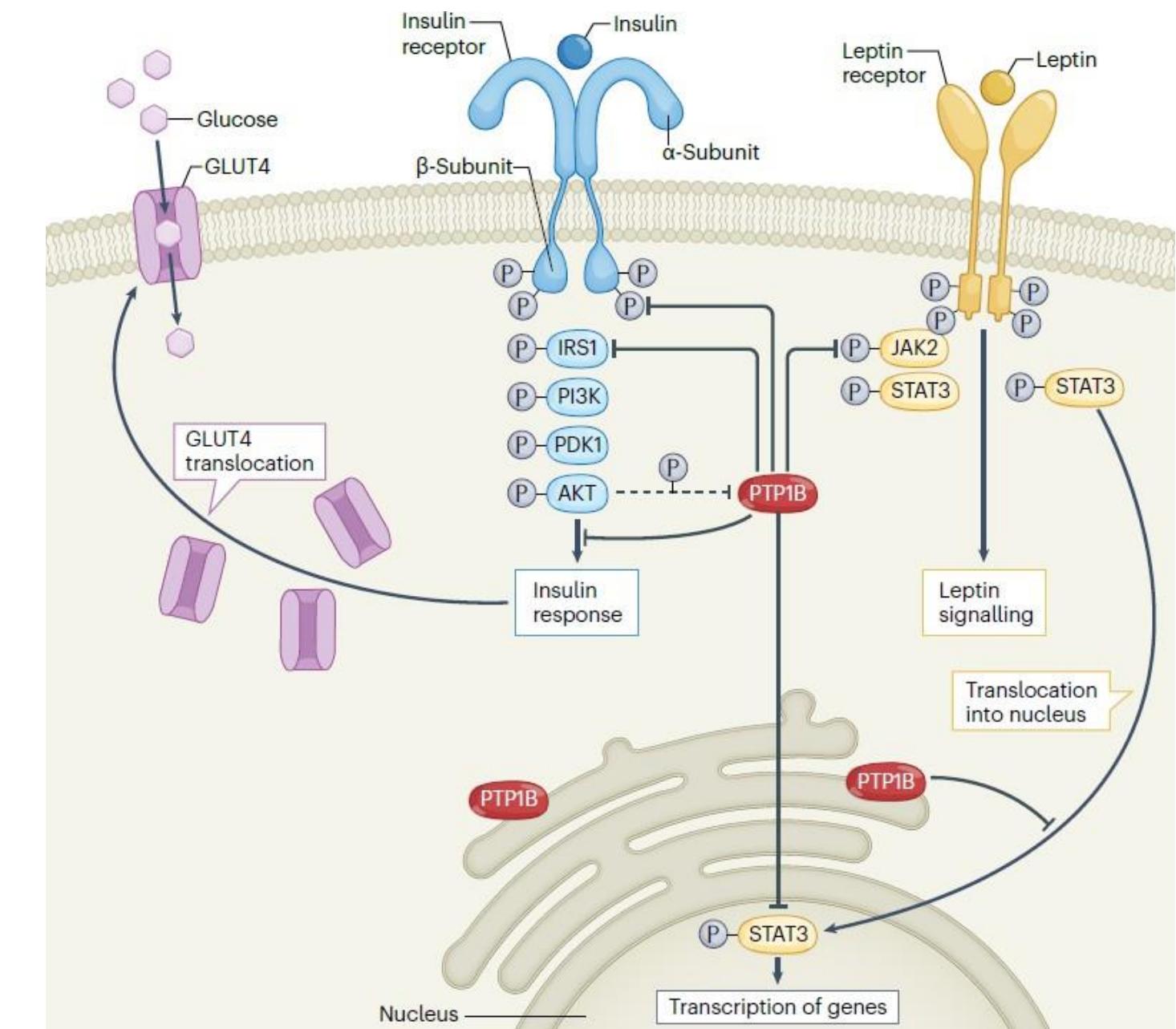
Significant implications for precision medicine in **mainstream** disease re: dosing, pricing and patient accessibility...

# PTP1B Validation in Diabetes (insulin resistance) & Obesity (leptin signaling)

PTP1B directly dephosphorylates the Insulin Receptor while indirectly acting on the leptin receptor to regulate satiety through Jak2/Stat3.

**Dual therapy approach:** our bLNPs specifically targeting PTP1B has been uniquely designed with lipids with both anti-inflammatory and direct PTP1B inhibition properties.

50% reduction in PTP1B deemed adequate to restore metabolic homeostasis.

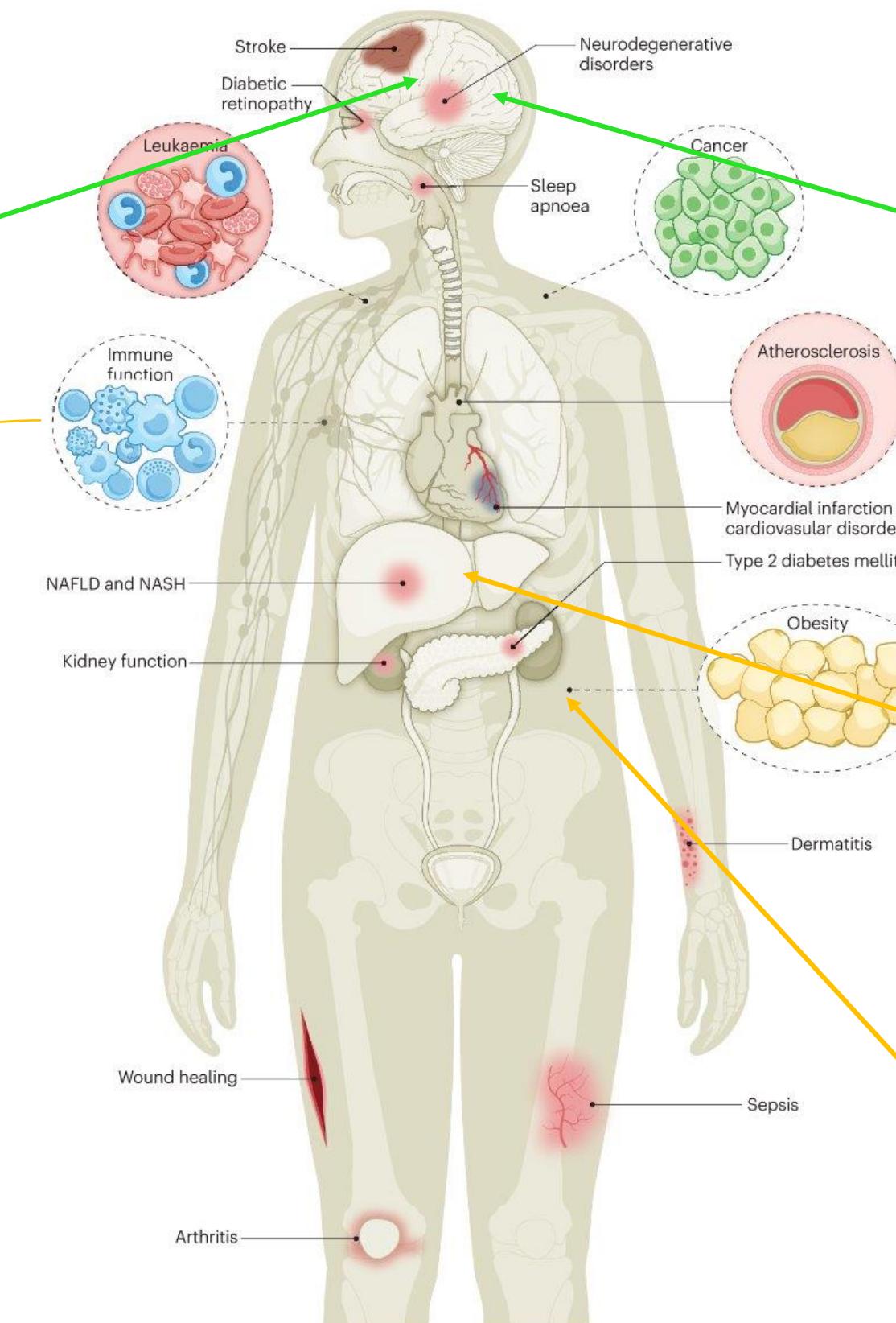


# PTP1B ↓ in the CNS only, restores both insulin & leptin sensitivity\*

CNS

## Neuron-specific PTP1B -/- leads to

- Decrease in body weight & fat mass
- Increased activity and energy expenditure
- Increased leptin secretion
- Improved glucose homeostasis.



PERIPHERY

## PTP1B -/- in skeletal muscle leads to

- Body weight effect similar to WT
- **Improved glucose insulin sensitivity**

## PTP1B -/- in leptin-receptor expressing neurons leads to

- **Leptin hypersensitivity**
- Decrease in body weight & fat mass
- Decreased body weight & fat mass gain upon HFD-feeding

## PTP1B -/- in liver leads to

- No effect on body weight.
- **Decreased gluconeogenesis and plasma lipid levels**
- **Protective against HFD-induced inflammation and ER-stress.**

## PTP1B -/- in adipose leads to

- Potential to inc. body weight, enlarge adipocytes and impair insulin sensitivity.

# Central (brain) PTP1B targeting exhibits the most profound global effects on both energy balance & glucose homeostasis\*

- Global neuronal deletion of PTP1B **dramatically reduces obesity and enhances leptin + insulin sensitivity**<sup>%</sup>
- Various areas of the brain involved in energy balance (**hypothalamus, hindbrain, and limbic (reward) centres**) control key metabolic processes including:
  - feeding (satiety);
  - body weight gain/loss;
  - energy expenditure;
  - core temperature regulation;
  - peripheral insulin sensitivity;
  - liver metabolism

## What about PTP1B effects on muscle?

- **PTP1B inhibition elicits non-cachectic (non-muscle) fat-specific weight loss, a common side effect of marketed GLP1RAs<sup>^</sup>**

\*Data derived from phenotypes in genetic constitutive knockdowns in mice - lab of Prof Mirela Delibegović FRSE, The University of Aberdeen, UK (see slide 27)

<sup>%</sup>[https://link.springer.com/chapter/10.1007/978-1-4614-7855-3\\_4](https://link.springer.com/chapter/10.1007/978-1-4614-7855-3_4) ;

<sup>^</sup><https://onlinelibrary.wiley.com/doi/pdf/10.1038/oby.2009.444>;

# Targeting PTP1B in peripheral tissue vs CNS – key differences

Studies correlating lowered PTP1B levels to metabolic impact in liver, muscle and adipose tissue highlight:

## For the Periphery

- **In liver** – this improves insulin signalling & responsiveness, reduces gluconeogenesis & lipogenesis, alleviates ER stressors **without impacting weight loss**
- **In muscle** - boosts insulin-stimulated glucose uptake and elevates whole-body glucose tolerance
- **In adipose tissue** - **increased adipocyte expansion and lipogenesis, without improving systemic glucose control**

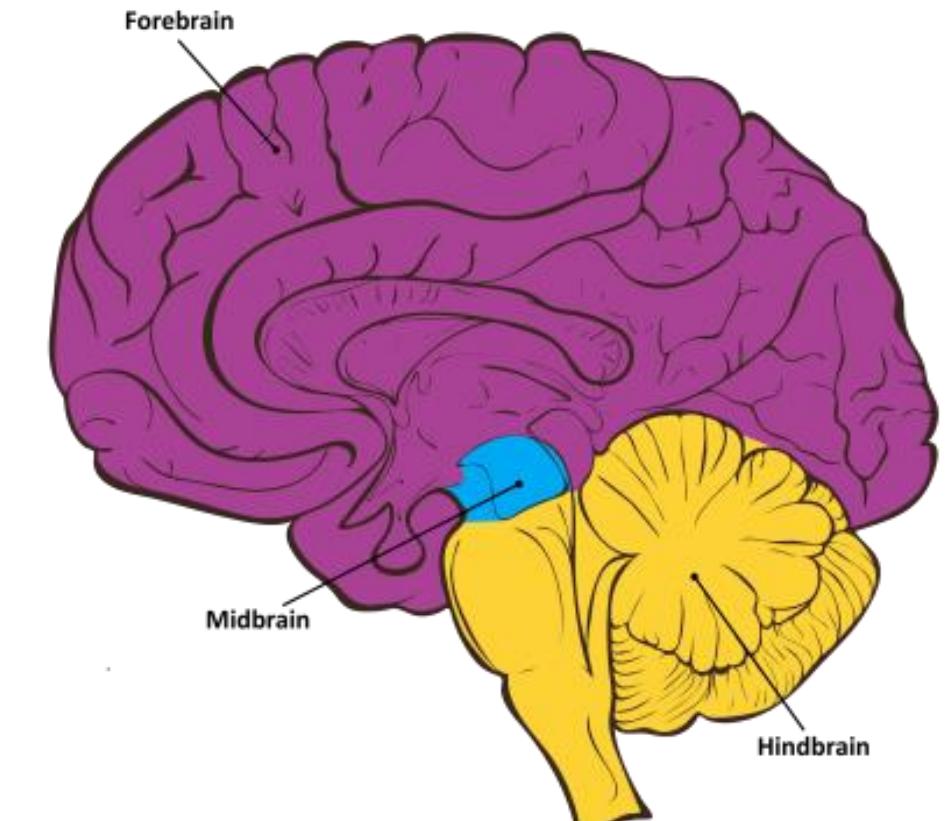
## For the CNS – global neuronal KO of PTP1B in all brain regions (**forebrain**, **mid-brain** & **hindbrain**) leads to:

- **Marked protection from high fat diet-induced obesity\***
- **Leanness due to ↓ food intake and ↑ energy expenditure**
- **Improved leptin sensitivity^**
- **Enhanced peripheral insulin sensitivity^**
- **Reduced insulin resistance, ER stress and neuroinflammation#**

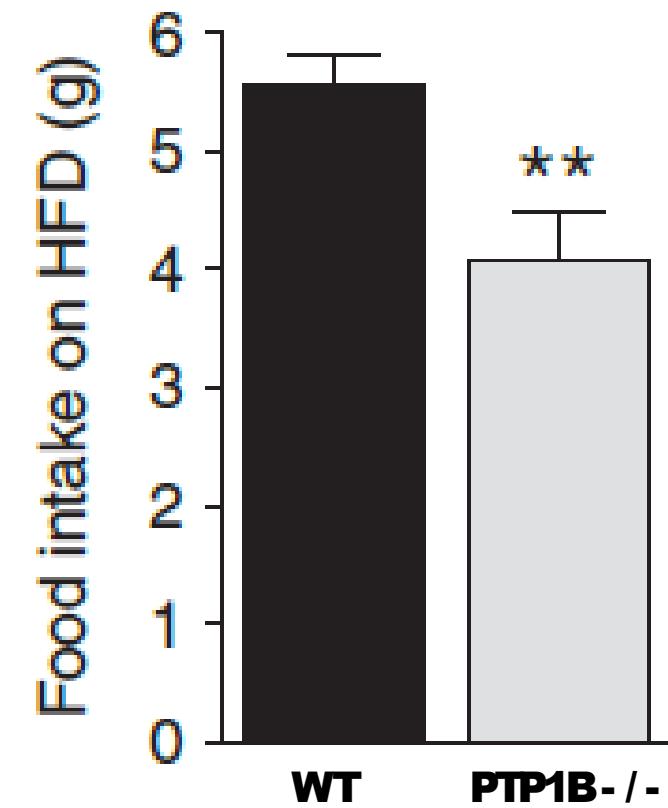
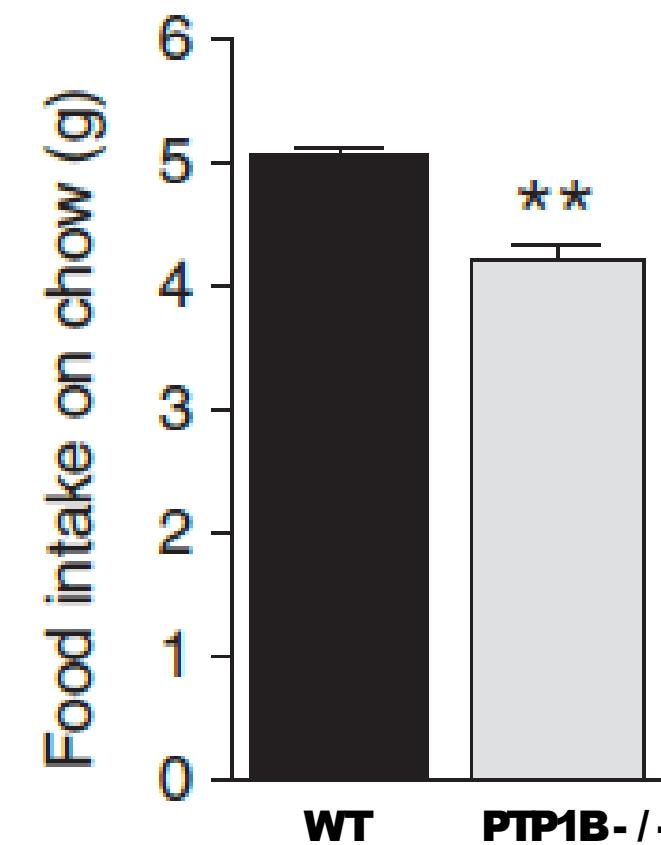
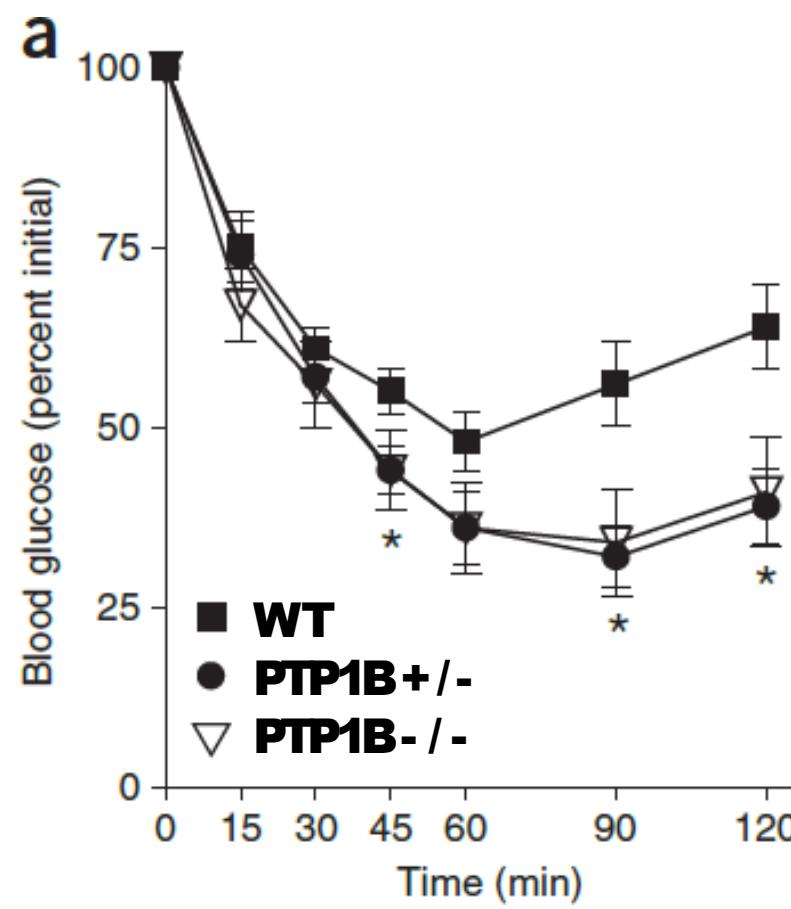
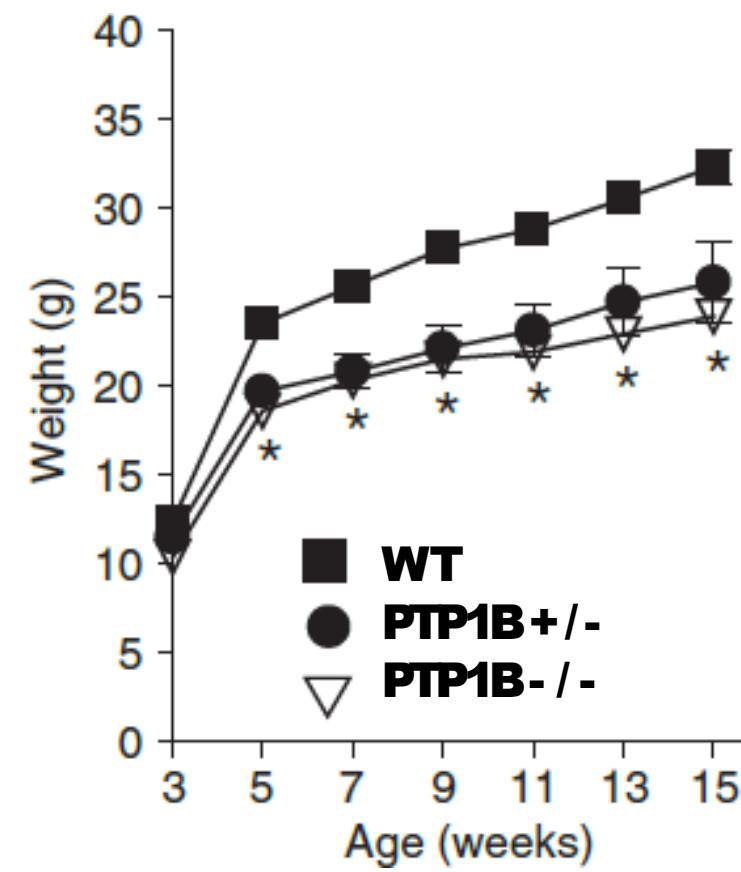
\*<https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0032700>;

^<https://doi.org/10.1016/j.metabol.2017.01.029>;

#<https://doi.org/10.1016/j.biopha.2022.113709>



# Mice lacking neuronal PTP 1 B are resistant to diet-induced obesity and are protected from developing leptin resistance

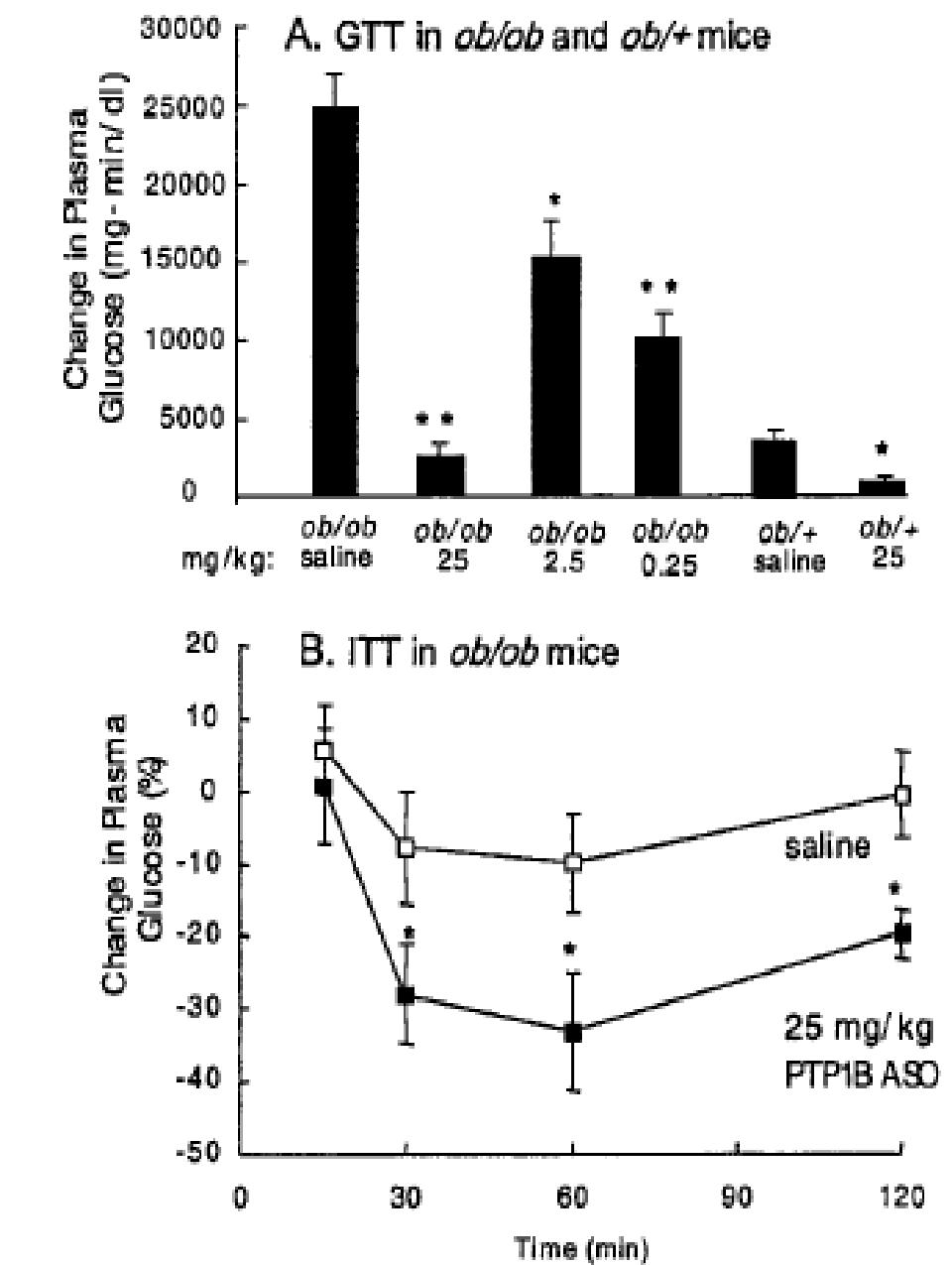
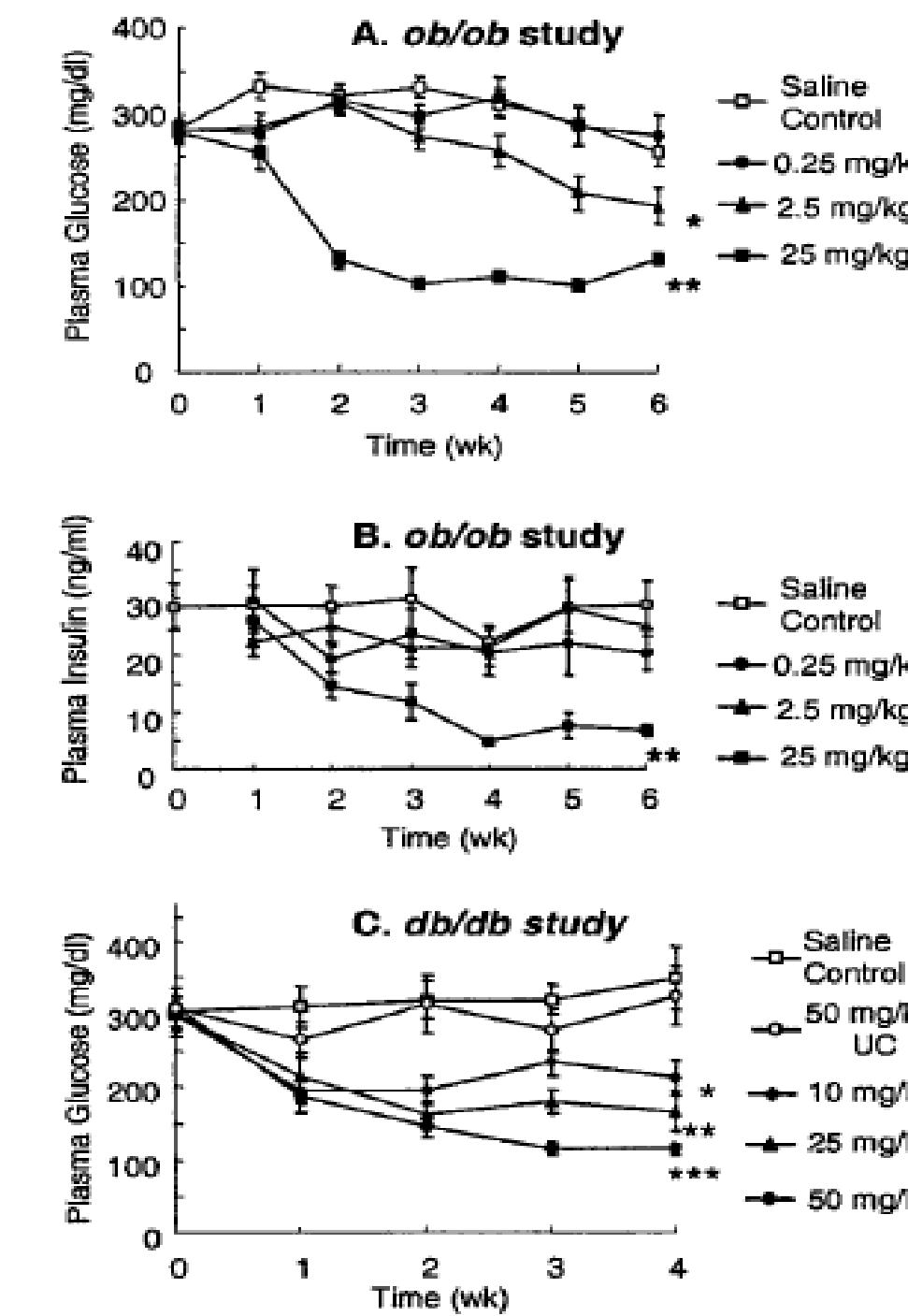
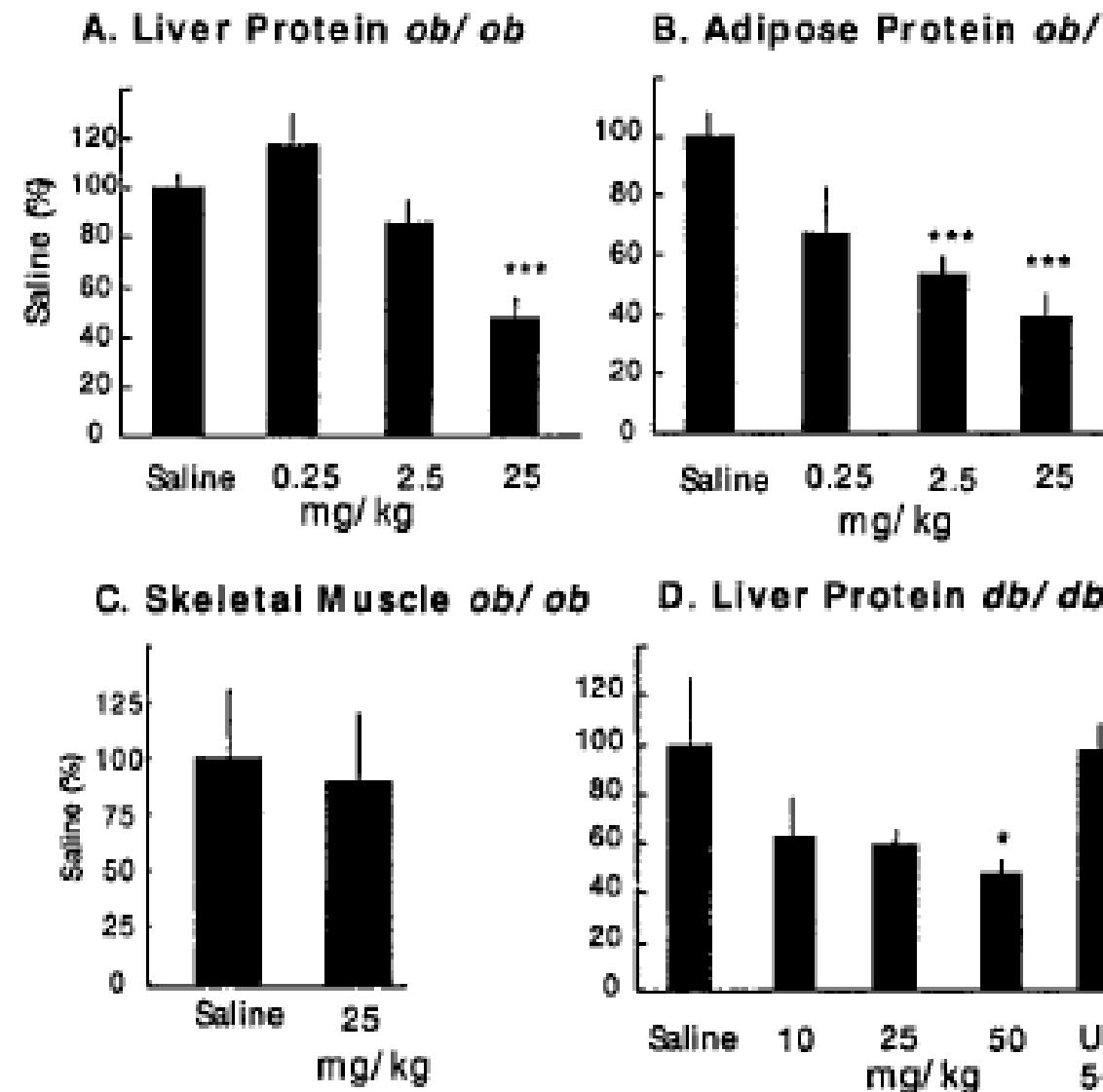


Neuronal PTP1B regulates body weight, adiposity and leptin action

Kendra K Bence<sup>1,4</sup>, Mirela Delibegovic<sup>1</sup>, Bingzhong Xue<sup>2</sup>, Cem Z Gorgun<sup>3</sup>, Gokhan S Hotamisligil<sup>3</sup>, Benjamin G Neel<sup>1</sup> & Barbara B Kahn<sup>2</sup>

**Conclusion of the study:** “*for effective obesity treatment and optimal therapy for type 2 diabetes, PTP1B inhibitors must be directed to the brain*”

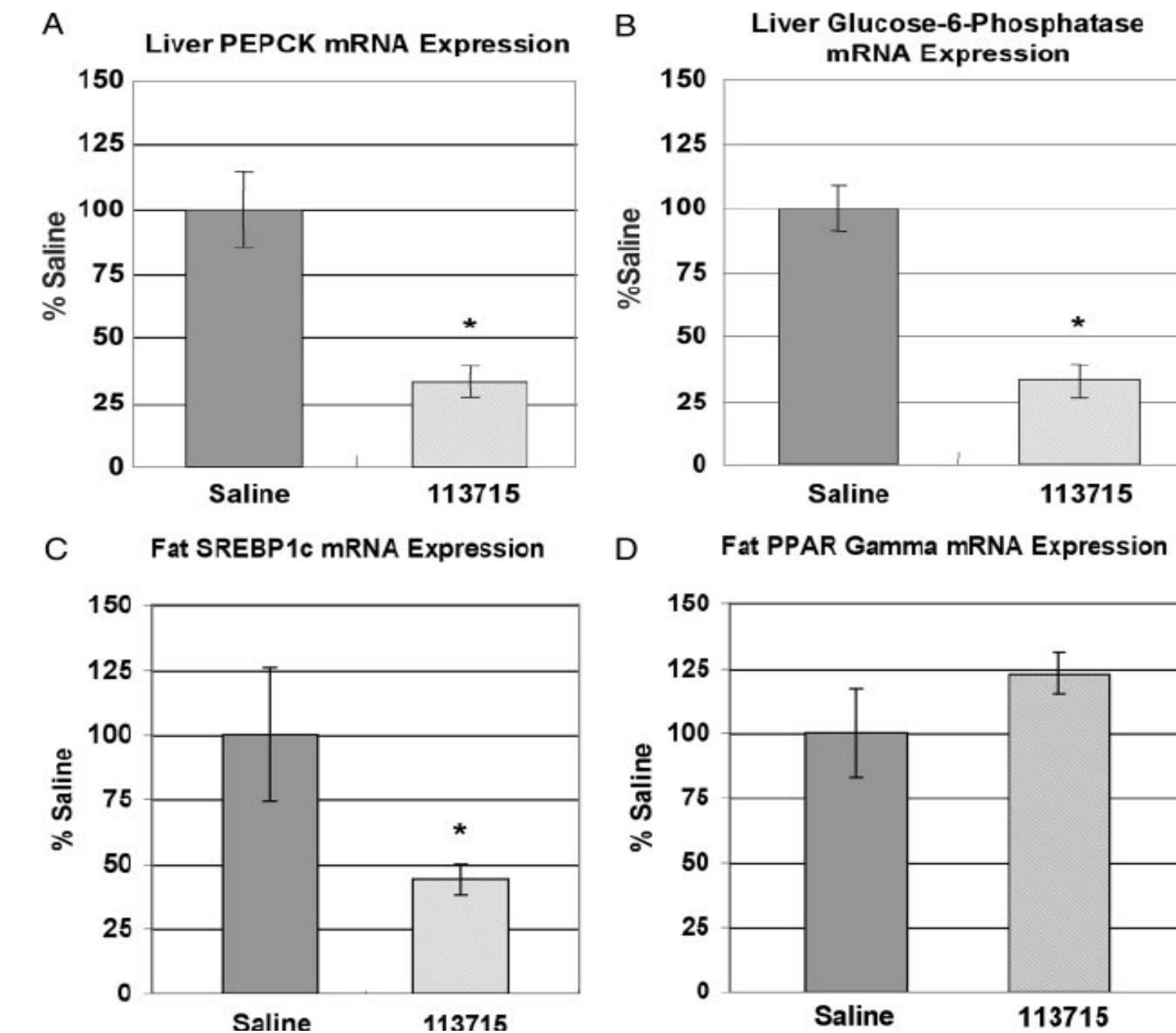
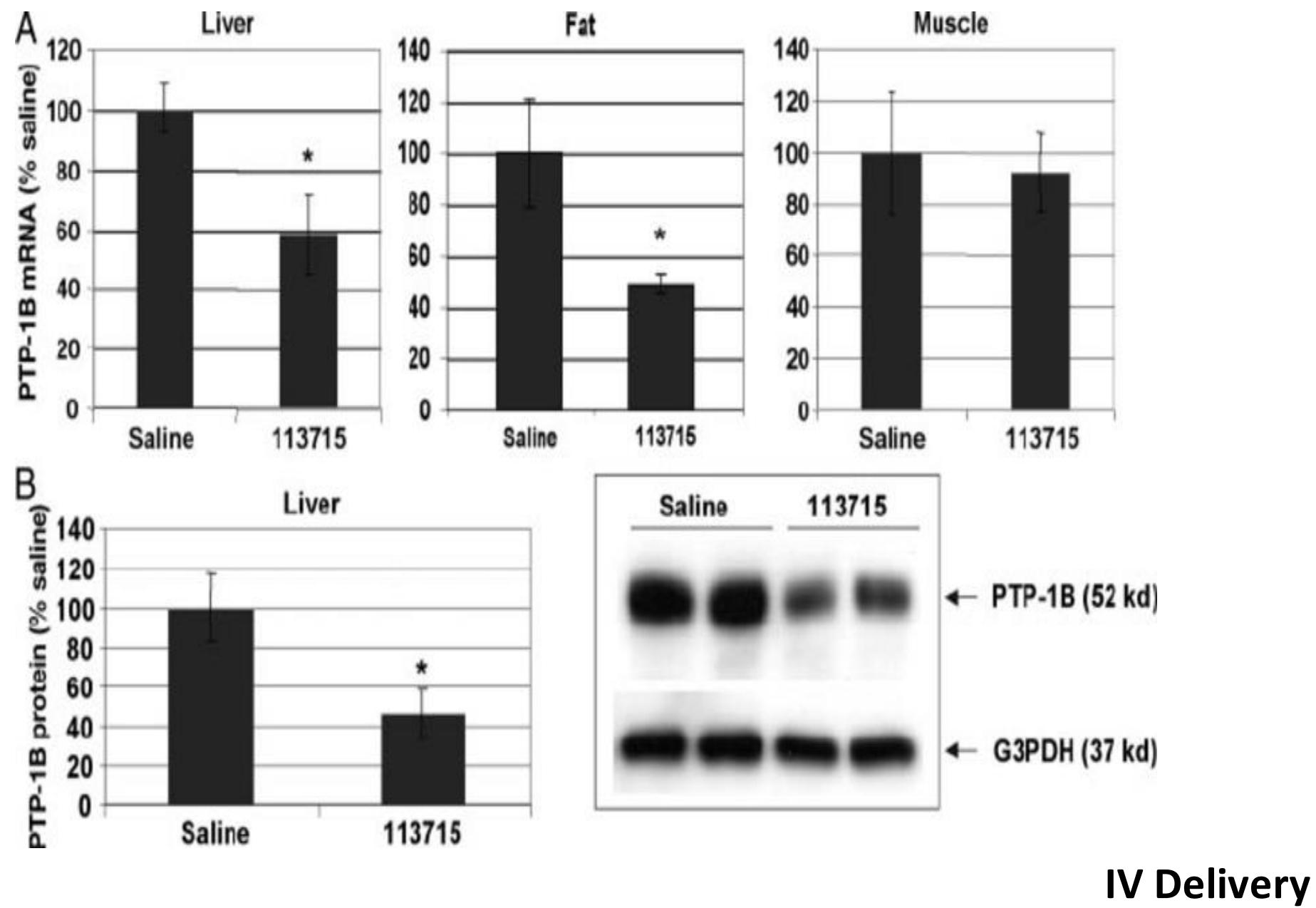
# PoC for PTP1B Targeting In Vivo: PTP1B antisense oligonucleotide lowers PTP1B protein, normalizes blood glucose, and improves insulin sensitivity in diabetic mice



Zinker B, Rondinone CM et al. PNAS, August 2002, 99(17): 11357-11362

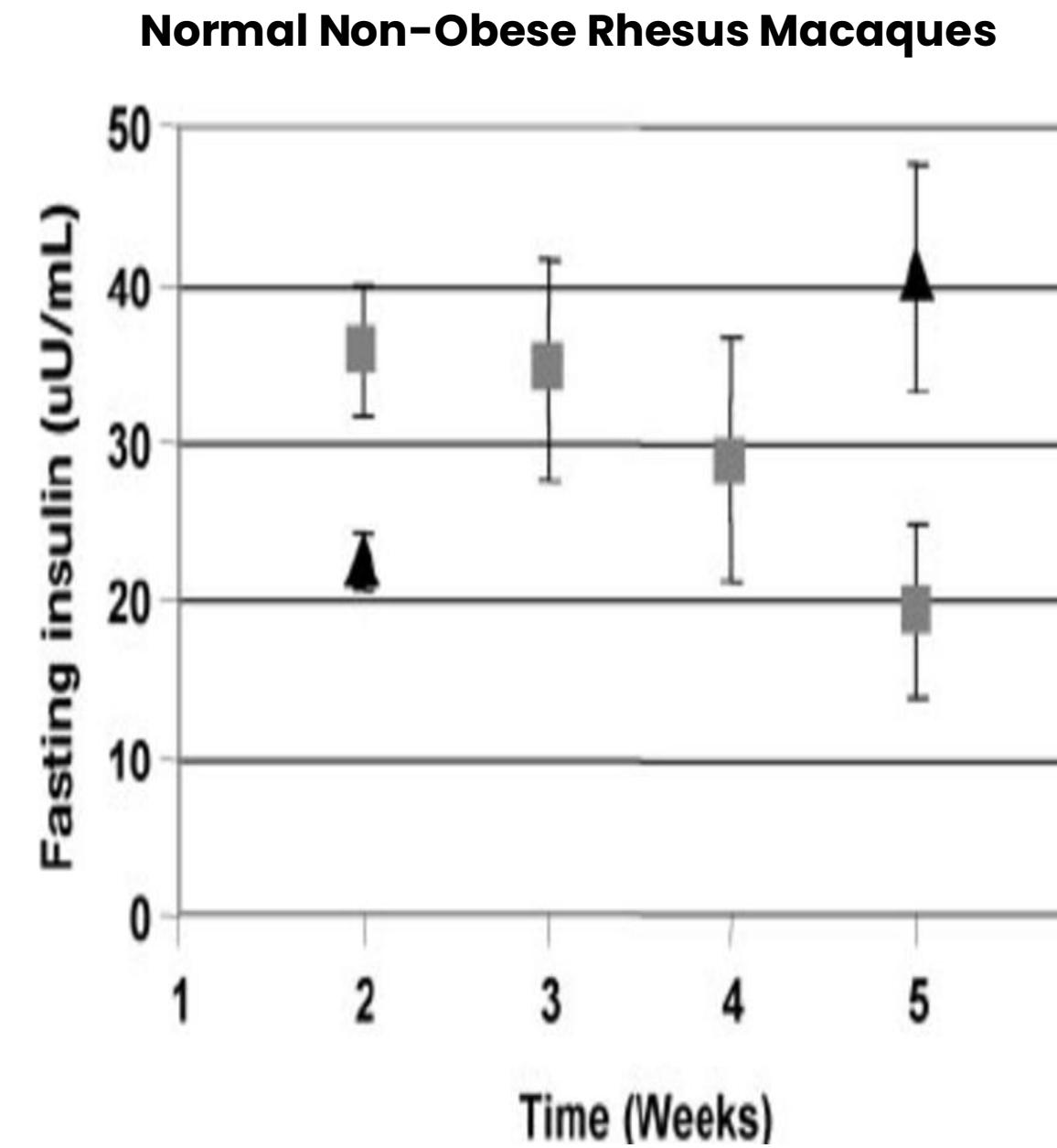
IV Delivery

# PoC for PTP1B Targeting In Vivo: Antisense oligonucleotides suppresses Protein Tyrosine Phosphatase-1B and modulates key regulators of glucose and fat metabolism in non-obese monkeys

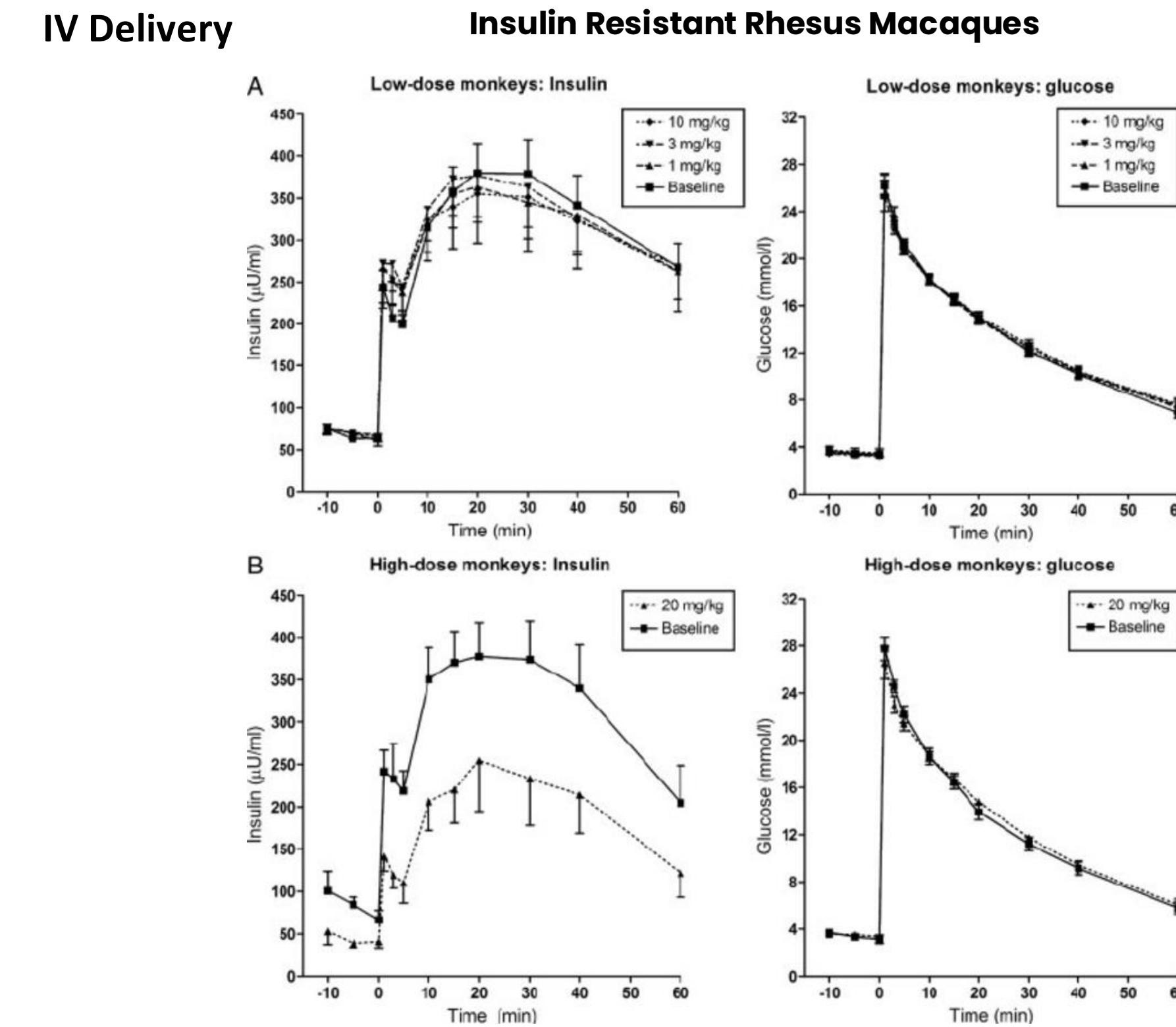


Swarwick M et al. Endocrinology, April 2009, 150(4):1670–1679

# PoC for PTP1B Targeting In Vivo: Inhibition of Protein Tyrosine Phosphatase-1B with antisense oligonucleotides improves insulin sensitivity in monkeys in a dose-dependent manner



Swarwick M et al. Endocrinology, April 2009, 150(4):1670–1679



# Comparison of targets – GLP1RAs & PTP1B

## Mechanism of action:

**GLP1RAs** - increase insulin secretion (pancreas), delay gastric emptying (direct GI effects) and reduce appetite (CNS)

**PTP1B inhibition** - enhances insulin and leptin receptor signalling in brain, liver, muscle & adipose tissue, targeting the root cause improving body weight, energy homeostasis, and glucose metabolism

## Key CNS-specific outcomes of PTP1B inhibition that are not evident with GLP1RAs:

- ↑ Thermogenesis via central leptin sensitivity PLUS browning adipose tissue (BAT) activation
  - **GLP1RAs suppress only appetite with no effect on thermogenesis**
- Reduced ER stress in the liver, along with lowered neuroinflammation and insulin resistance
  - **GLP1RAs ‘possibly’ suppress systemic inflammation (only) as a consequence of weight loss, while placing further stress on the pancreas**

## Side effect profiles

**GLP1RAs** - Nausea, vomiting, diarrhoea, constipation affect 50–75% of users, often requiring dose titration; incidence of gall bladder-related issues\*; muscle loss reported

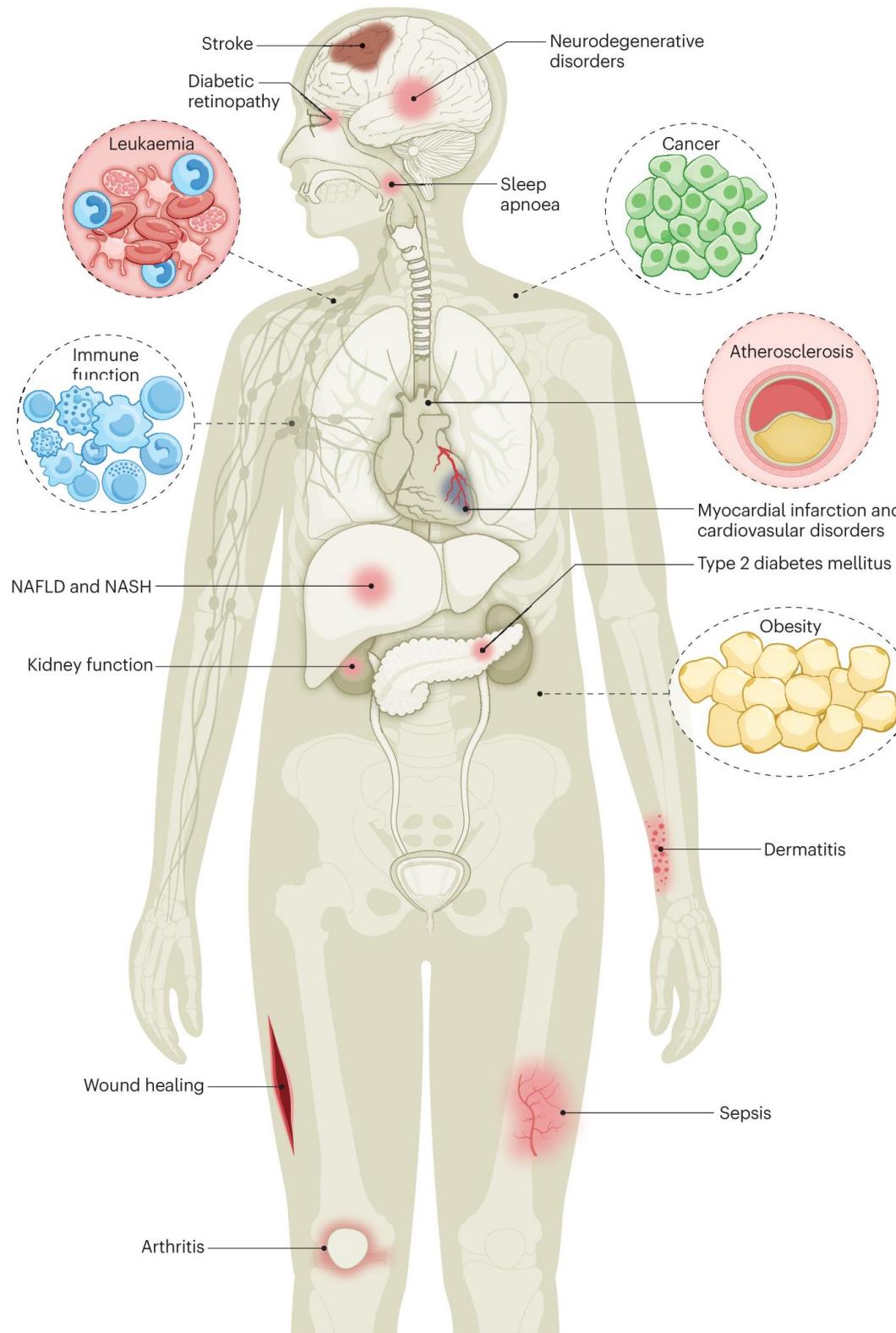
**PTP1B** – Preclinical studies in PTP1B knockout mouse models show potent and broad pro-metabolic effects with minimal side effects and no evidence of muscle loss\*, both of which can be comprehensively circumvented by direct, nose-to-brain (N2B) sol-gel administration

<https://federalhealthgroup.com/posts/glp-1-receptor-agonist-side-effects-and-clinical-management/>;

\*Data derived from phenotypes in genetic constitutive knockdowns in mice - lab of Prof Mirela Delibegović FRSE, The University of Aberdeen, UK:

Delibegovic M, Dall'Angelo S and Dekertye R. Protein tyrosine phosphatase 1B in metabolic diseases and drug development. *Nature Reviews Endocrinology* 20, 366-378 (2024)

# PTP1B ↓ : Obesity, T2D AND BEYOND!



PTP1B inhibition reduces neuroinflammation and fronto-temporal dementia in animal models displaying potential for the treatment of **Alzheimer's Disease**

Source: Pharmacological PTP1B inhibition rescues motor learning, neuroinflammation, and hyperglycaemia in a mouse model of Alzheimer's disease, Franklin et al, *Exp Neurology*, **2024**

PTP1B inhibition has been demonstrated to enhance anti-tumor immunity and combat **solid state cancers**

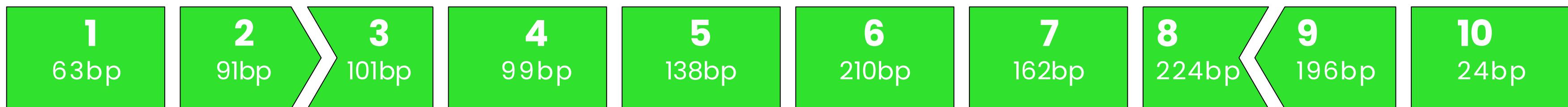
Source: A small molecule inhibitor of PTP1B and PTPN2 enhances T cell anti-tumor immunity, Liang et al, *Nat Comm*, **2023**

Ongoing clinical trials:

- PTP1B Implication in the Vascular Dysfunction Associated With **Obstructive Sleep Apnea**, Angers, France (NCT04235023)
- Correlation Between PTP1B Expression and **Organ Failure During Sepsis**, Univ Hospital Rouen, France (NCT03189355)
- MSI1436 – PTP1B inhibitor for **metastatic breast cancer**

# Gene Targeting Strategy with BioGene's 'Smart-siRNAs' against the *PTPN1* gene

The *PTPN1* gene comprises 10 exons, each potential targets for siRNA:



01

Successfully engineered selective, potent siRNA's independently targeting multiple exons of *PTPN1*

02

siRNA's against both mouse and human variants of distinct exons were engineered in parallel, paving the way for PoC preclinical and clinical studies

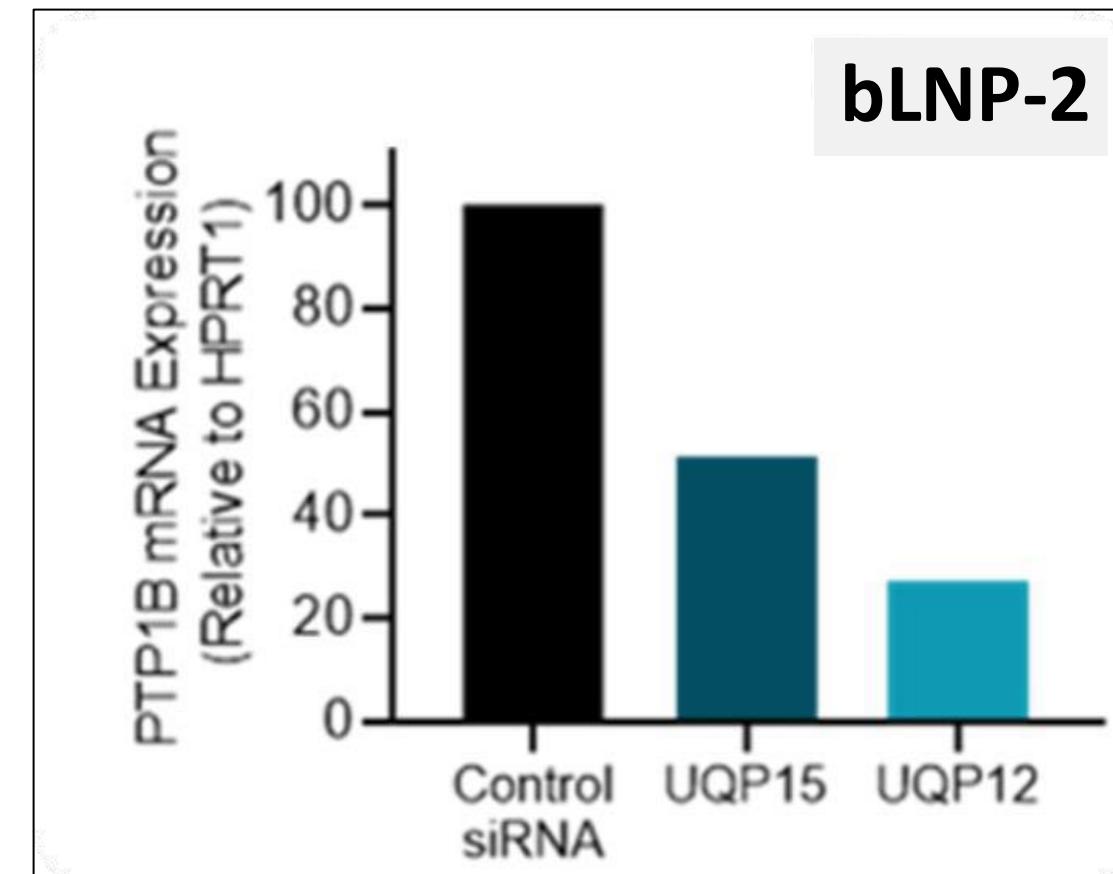
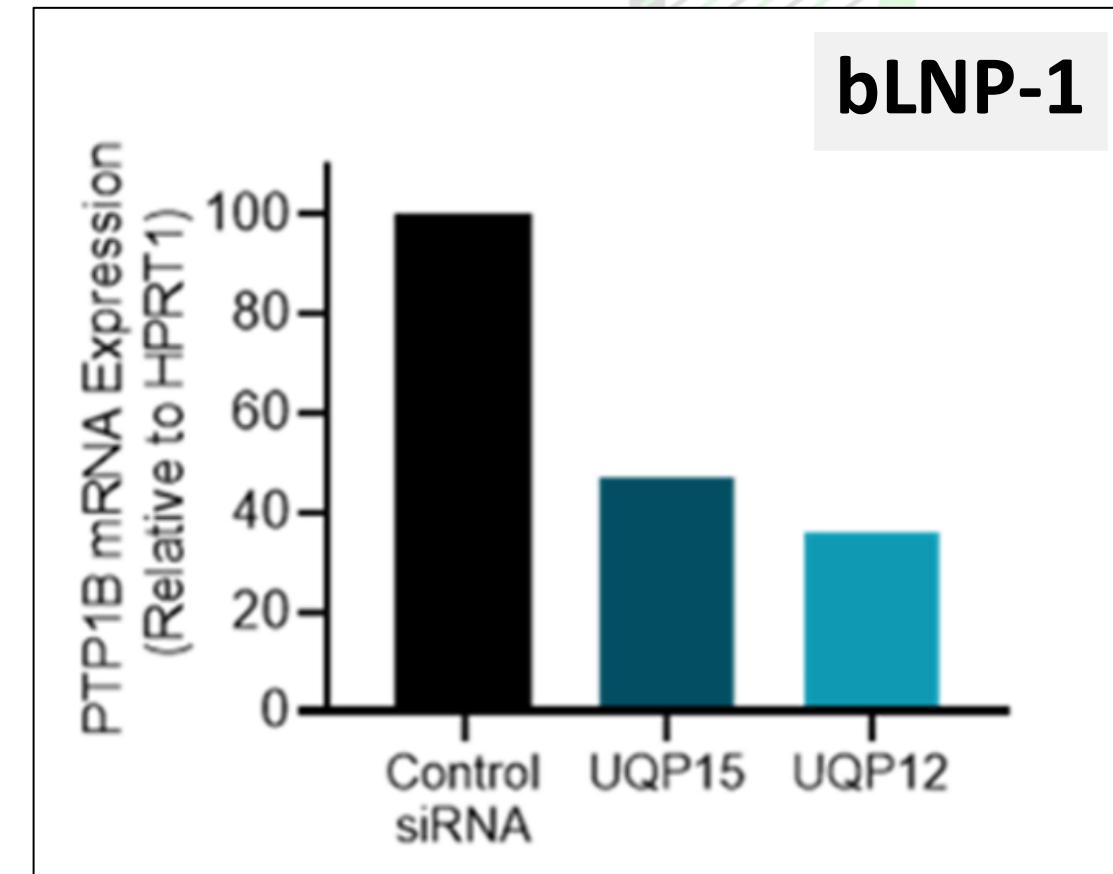
03

siRNA sequences were engineered to be metabolically & thermostable ('Smart-siRNAs'), and novel w.r.t the prior art/published sequences

Adv Cancer Res. 2021; 152: 263–303. doi:10.1016/bs.acr.2021.06.001; Acc Chem Res. 2017 January 17; 50(1):122–129. doi:10.1021/acs.accounts.6b00537

# Potent Gene Silencing Confirmed with BioGene's Bioresponsive LNPs (bLNPs)

- bLNPs possess the unique bioresponsive 'gene-releasing' linker (US Patent #11,566,044 – granted 31/Mar/23).
- UQP12& UQP15 (top and bottom graphs) represent select Smart-siRNAs showing potent gene silencing when formulated with two distinct bLNPs in liver tissue (ex vivo).
- UQP12& UQP15 represent only two uniquely designed metabolically-stabilized siRNAs from our library that display potent gene & protein silencing.



# Planned Diabetes and Obesity Preclinical Study

The study will evaluate BioGene's Smart-siRNAs using bioresponsive LNP formulations versus conventional standard of care drugs (i.e. semaglutide) in rodent models of diabetes and obesity.

The study design includes mice cohorts for robust statistical analysis, appropriate control groups, and comparison of administration routes.

- 01 Location: The University of Queensland, Brisbane
  - Extensive expertise with Sol-Gel engineering, bLNP formulation & preclinical models of obesity and diabetes
- 02 Research Team Led by BioGene's Chief Scientific Officer & Co-Founder, Dr. Harry Parekh.
- 03 Objectives: Assess weight changes, PTP-1B levels in major tissues, tissue histology, and classical blood and urine biomarkers (e.g. glucose, triglycerides) throughout the extended treatment period.
- 04 Success Criteria: Weight reduction; Restoration of glucose levels/insulin sensitivity, increased activity, and improved behavioral patterns in diabetic and obese mice.

# Key Milestones: Path to IND and Phase 1

	2025	2026				2027			
	Q2-Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
CMC	Vector & formulation	cGMP DP Package & Stability Initiation	Drug Release						
	<i>In vivo proof-of-concept (PoC) sol-gel N2B delivery &amp; biodistribution study in wild-type non-obese mice after a single administration</i>		<i>In vivo diabetes model-STZ high fat diet (HFD) monotherapy +/- SMG study</i>		<i>In vivo PTP1B<sup>+</sup> db/db genetic mouse (DGM) study</i>		<i>In vivo PTP1B<sup>+</sup> ob/ob genetic mouse (OGM) study</i>		
Preclinical Research (Schedule being finalized)						POC Obesity			
		28 Day GLP Toxicology: Mouse & NHP							
Regulatory/Clinical				Pre-IND Meeting			IND Filing		Start Phase 1

# Key Activities, Inflection Points and Regulatory Milestones

## Next 18 months

- Initiate and complete obesity/diabetes animal model studies
- Initiate GLP toxicology studies
- Manufacture clinical supplies
- File IND and begin phase I trials

Program	Development Stage	Key Activities	IND Status and Target Date	Key Milestones
Lead Candidate	Preclinical	GMP manufacturing GLP toxicology Obesity/T2D mouse study	IND filing (q2-2027)	Phase I (q3-2027)

Note: Detail included related to the timing of potential milestones are estimates, and are subject to change

# Revenue and Corporate Strategy



# Global Collaborators



THE UNIVERSITY  
OF QUEENSLAND  
AUSTRALIA



UNIVERSITY OF  
ABERDEEN

# Thank you

**CHEMICAL REVIEWS**

Review  
pubs.acs.org/CR

**Type 2 Diabetes Mellitus: Limitations of Conventional Therapies and Intervention with Nucleic Acid-Based Therapeutics**

Ganesh R. Kokil,<sup>†</sup> Rakesh N. Veedu,<sup>\*,‡,§,||</sup> Grant A. Ramm,<sup>†,#</sup> Johannes B. Prins,<sup>†,V</sup> and Harendra S. Parekh<sup>\*,†</sup>

**Research Article**  
Received: 12 October 2010 Revised: 24 November 2010 Accepted: 1 December 2010  
Published online in Wiley Online Library: (wileyonlinelibrary.com) DOI 10.1002/psc.1347

**Journal of Peptide Science**

**Low-generation asymmetric dendrimers exhibit minimal toxicity and effectively complex DNA**

Neha Shah,<sup>a,b</sup> Raymond J. Steptoe<sup>b,\*</sup> and Harendra S. Parekh<sup>a,\*</sup>

**J. Phys. Chem. B** 2010, 114, 9231–9237

**Structure and Dynamics of Multiple Cationic Vectors–siRNA Complexation by All-Atom Molecular Dynamics Simulations**

Defang Ouyang,<sup>†,‡</sup> Hong Zhang,<sup>‡</sup> Harendra S. Parekh,<sup>\*,†</sup> and Sean C. Smith<sup>\*,‡</sup>  
School of Pharmacy and Centre for Computational Molecular Science, Australian Institute of Bioengineering and Nanotechnology, The University of Queensland, Brisbane, QLD 4072, Australia

Received: December 17, 2009; Revised Manuscript Received: June 1, 2010

**Advanced Drug Delivery Reviews**  
Available online 8 January 2015  
In Press, Corrected Proof — Note to users

Are caveolae a cellular entry route for non-viral therapeutic delivery systems? <sup>†</sup>

Prarthana V. Rewatkar<sup>a</sup>, Robert G. Parton<sup>b</sup>, Harendra S. Parekh<sup>a</sup>, Marie-Odile Parat<sup>a</sup>

**Journal of Peptide Science**  
The official Journal of the European Peptide Society  
EPS

**Research Article** | **Full Access**

**Low-generation asymmetric dendrimers exhibit minimal toxicity and effectively complex DNA**

Neha Shah, Raymond J. Steptoe, Harendra S. Parekh

First published: 24 February 2011 | <https://doi.org/10.1002/psc.1347> | Citations: 46

**Pharm Res (2014) 31:3150–3160**  
DOI 10.1007/s11095-014-1408-1

**RESEARCH ARTICLE**

**Asymmetric Peptide Dendrimers are Effective for Antibody-Mediated Delivery of Diverse Payloads to *in Vitro* and *in Vivo***

**SCIENTIFIC REPORTS**

**OPEN**

**Self-assembling asymmetric peptide-dendrimer micelles – a platform for effective and versatile *in vitro* nucleic acid delivery**

Received: 29 August 2017  
Accepted: 12 February 2018  
Published online: 19 March 2018

Ganesh R. Kokil<sup>1</sup>, Rakesh N. Veedu<sup>2,3</sup>, Bao Tri Le<sup>2,3</sup>, Grant A. Ramm<sup>4,5,6</sup> & Harendra S. Parekh<sup>1</sup>

**ADVANCED THEORY AND SIMULATIONS**

**Full Paper** | **Full Access**

**Cell Membrane Penetration without Pore Formation: Chameleonic Properties of Dendrimers in Response to Hydrophobic and Hydrophilic Environments**

Sergio de Luca, Prasenjit Seal, Harendra S. Parekh, Karnaker R. Tupally, Sean C. Smith

First published: 03 June 2020 | <https://doi.org/10.1002/adts.201900152>

**ACS Biomaterials**  
SCIENCE & ENGINEERING

**Article**  
pubs.acs.org/journal/absba

**Express *in Vitro* Plasmid Transfection Achieved with 16<sup>+</sup> Asymmetric Peptide Dendrimers**

Prarthana V. Rewatkar,<sup>†</sup> David P. Sester,<sup>‡</sup> Harendra S. Parekh,<sup>\*,†</sup> and Marie-Odile Parat<sup>\*,†</sup>

<sup>†</sup>School of Pharmacy, The University of Queensland, 20 Cornwall Street, Woolloongabba, Queensland 4102, Australia  
<sup>‡</sup>School of Chemistry and Molecular Biosciences, The University of Queensland, Brisbane, Queensland 4072, Australia

**Supporting Information**