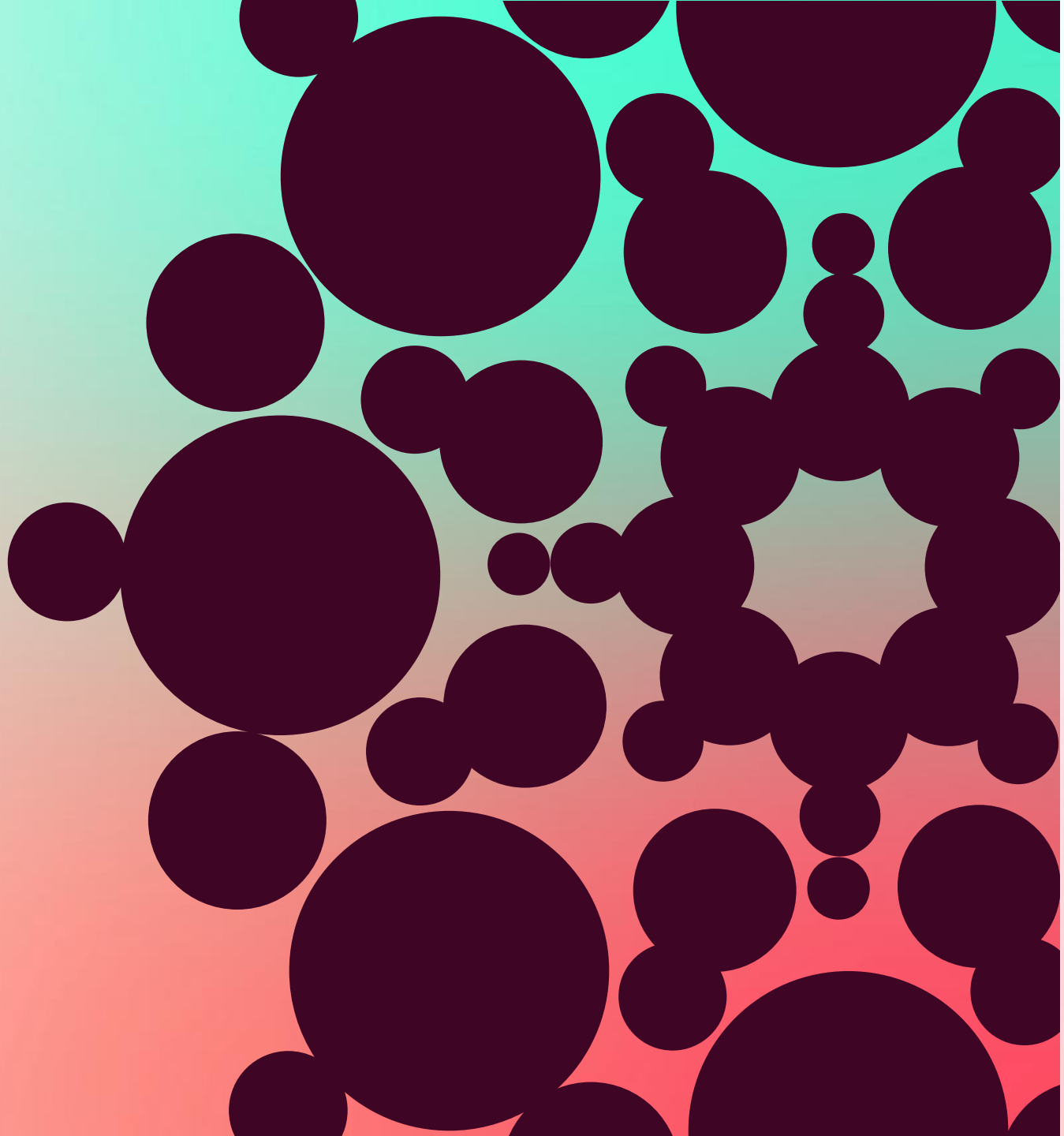
FRACTYL health

Breaking the Pattern in Obesity and Type 2 Diabetes

Corporate Presentation | October 2024



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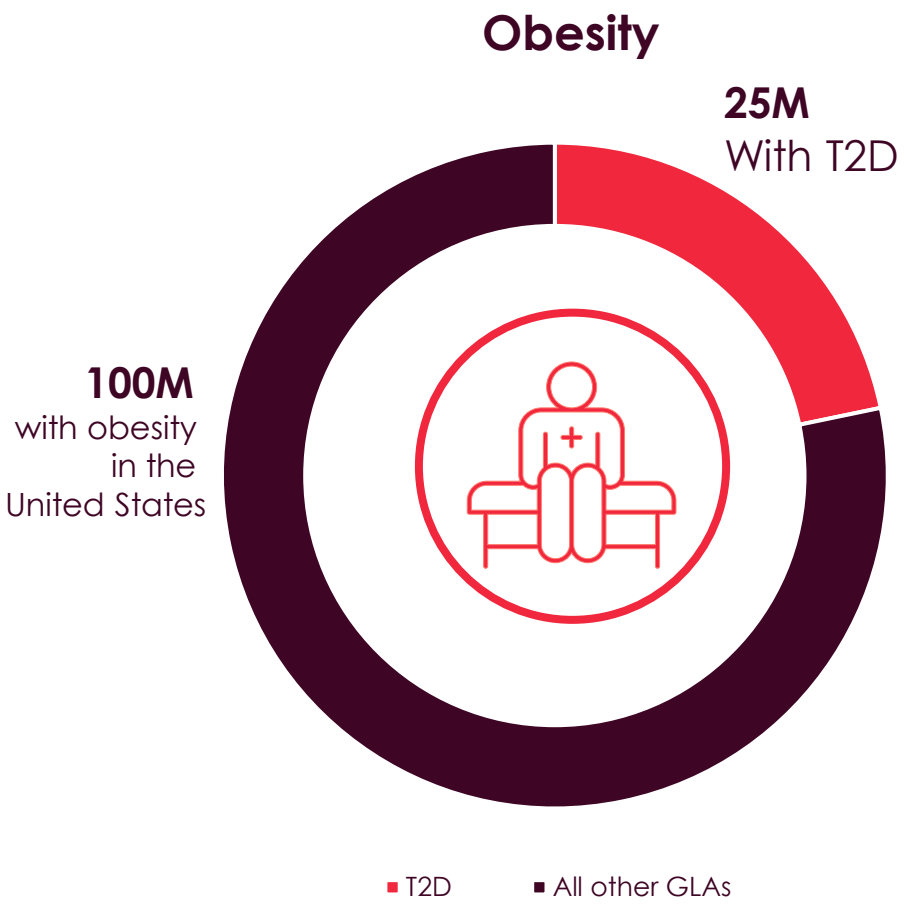
Fractyl Health aims to end obesity and T2D

- Developing pattern-breaking therapies to treat root causes of obesity and type 2 diabetes (T2D)
- **Revita** in late-stage development – an outpatient endoscopic procedure addressing a root cause of obesity and type 2 diabetes in the gut – with multiple study readouts starting in Q4 2024
- Developing **Rejuva** – a one-and-done pancreatic gene therapy platform for obesity and T2D – anticipate entering the clinic with a Smart GLP-1™ in H1 2025
- Management Team and Board of Directors with deep expertise and track record of success
- Well-capitalized with $102 million in cash and cash equivalents as of June 30, 2024

Obesity is the largest market opportunity in healthcare

Metabolic dysfunction drives substantial disease risk



40% of adult Americans have obesity today[1]

Individuals with a BMI ≥ 30 kg/m^2 carry more than a 40% increased risk for overall mortality[2]

New scientific insights point to a dysfunctional metabolic setpoint as a root cause of disease[3]

Other than bariatric surgery, **there are no treatments today that can durably correct obesity**

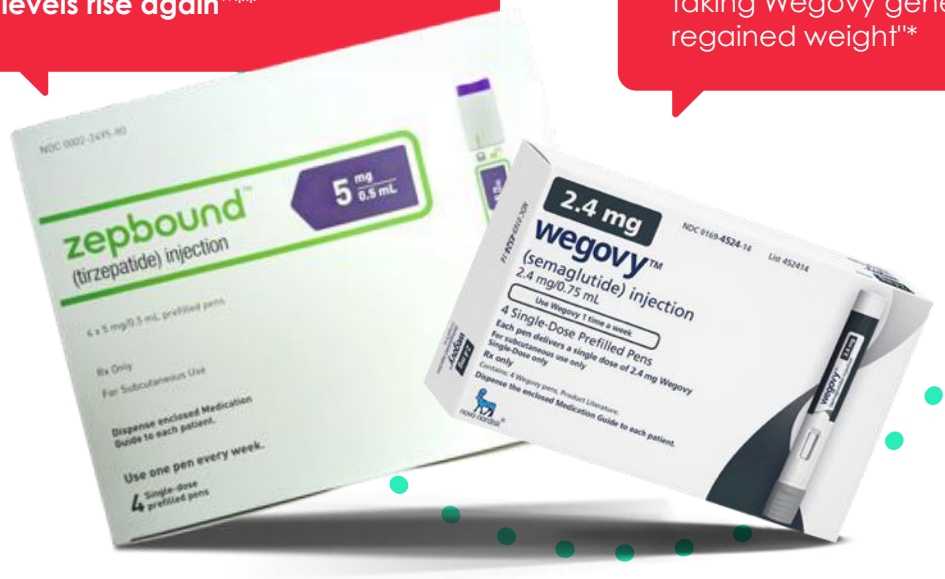
1. CDC 2. Adams et al NEJM 2006 3. Garvey WT Endo Practice Feb 2022

Chronic drug therapy fails most people with obesity

Poor persistence and weight rebound prevent sustained benefits in real world

"Many people who stop using Zepbound may regain the weight they lost while on the drug, **and they might also experience increased hunger and insulin resistance as their blood sugar levels rise again**"**

"People who stopped taking Wegovy generally regained weight"*



High discontinuation rates: > 50% of patients discontinue GLP-1 drugs in less than 1 year[1]

Rapid weight rebound: Weight and metabolic rebound occur rapidly upon discontinuation[2]

Approved drugs and drugs in late-stage development may cause weight loss, but **do not solve the biggest problem in obesity - durable weight maintenance**

*Wegovy DTC television commercial **www.drugs.com 1. Blue Health Intelligence, Issue Brief May 2024, Blue Cross Blue Shield 2. Wilding JPH, Diabetes Obes Metab.2022;24:1553–1564

Fractyl plans to break the pattern of obesity and T2D

Developing therapies designed to provide a durable metabolic reset

Revita

- ~40-minute outpatient procedure targeting a root cause of obesity and T2D in the duodenum
- Real-world and clinical study data show meaningful and sustained weight loss for at least one year after single procedure
- Enrolling pivotal study in weight maintenance; data expected starting in Q4 2024
- T2D pivotal study topline readout expected mid-2025

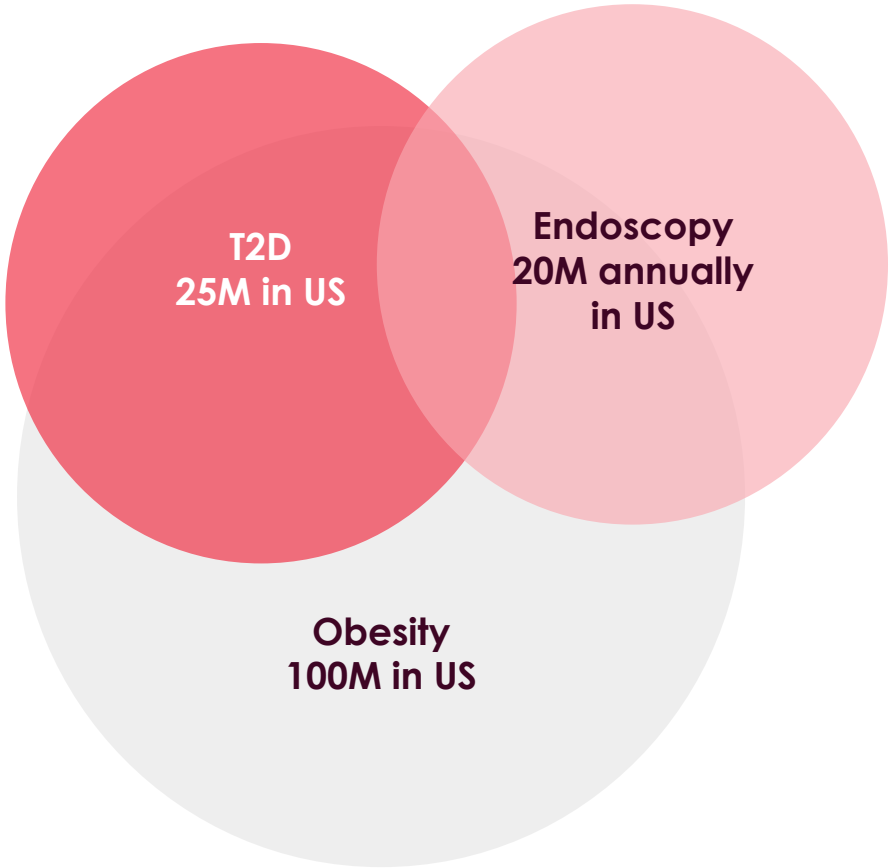
Rejuva

- Novel pre-clinical platform - potentially one and done pancreatic gene therapy
- Pre-clinical data with a one-time Smart GLP-1 show sustained weight maintenance and improved blood sugar and body composition in multiple efficacy models
- Candidate nomination for obesity planned H2 2024
- FIH study for T2D planned H1 2025

Potential for multi-billion dollar annual revenue

Leveraging skills, capacity, and channel of GI endoscopy

- Of the estimated 20 million endoscopies performed annually in US, 8 million are performed on people with obesity – these are potential Fractyl patients
- Fractyl solutions are designed to fit into high volume, highly scalable workflow in endoscopy centers
- Strong clinical and economic value proposition for GI physicians
- Seamless transition to commercial selling model; GI endoscopists focused on obesity and metabolic disease therapies are currently participating in clinical studies



Unlocking value with focused execution in 2024 and beyond

Accomplishments (YTD)

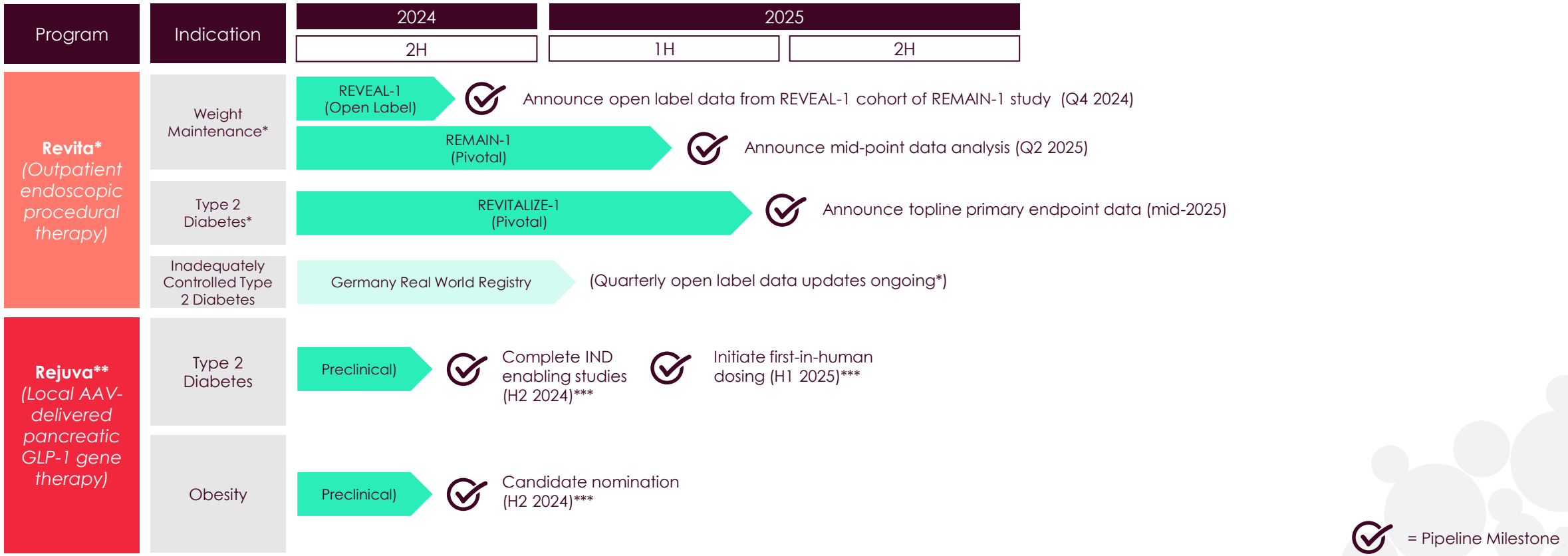
- ✓ Investigational Device Exemption (IDE) approval from FDA in REMAIN-1 study
- ✓ Accelerated REVEAL/REMAIN study in weight maintenance
- ✓ Breakthrough Device designation from FDA in weight maintenance after discontinuation of GLP-1 based drugs
- ✓ Protocol amendment for REVITALIZE-1; expands potential U.S. treatment population by nearly six-fold
- ✓ Compelling 12-month German Real-World registry data (n=11) confirms earlier clinical results showing meaningful and sustained weight loss for at least one year after single Revita procedure
- ✓ Comprehensive and superior proof-of-concept data for Rejuva Smart GLP-1 candidate in head-to-head studies vs. semaglutide in obesity and T2D

Anticipated Milestones (H2 2024+)

- ❑ Open label study updates from the REVEAL-1 cohort of the REMAIN-1 weight maintenance study beginning in Q4 2024
- ❑ Continued readouts from German Real-World Registry
- ❑ Complete IND enabling studies or equivalent for Rejuva in T2D in H2 2024
- ❑ Nominate first candidate for Rejuva in obesity in H2 2024
- ❑ Mid-point analysis from REMAIN-1 in Q2 2025
- ❑ Topline data from REVITALIZE-1 in T2D in mid-2025

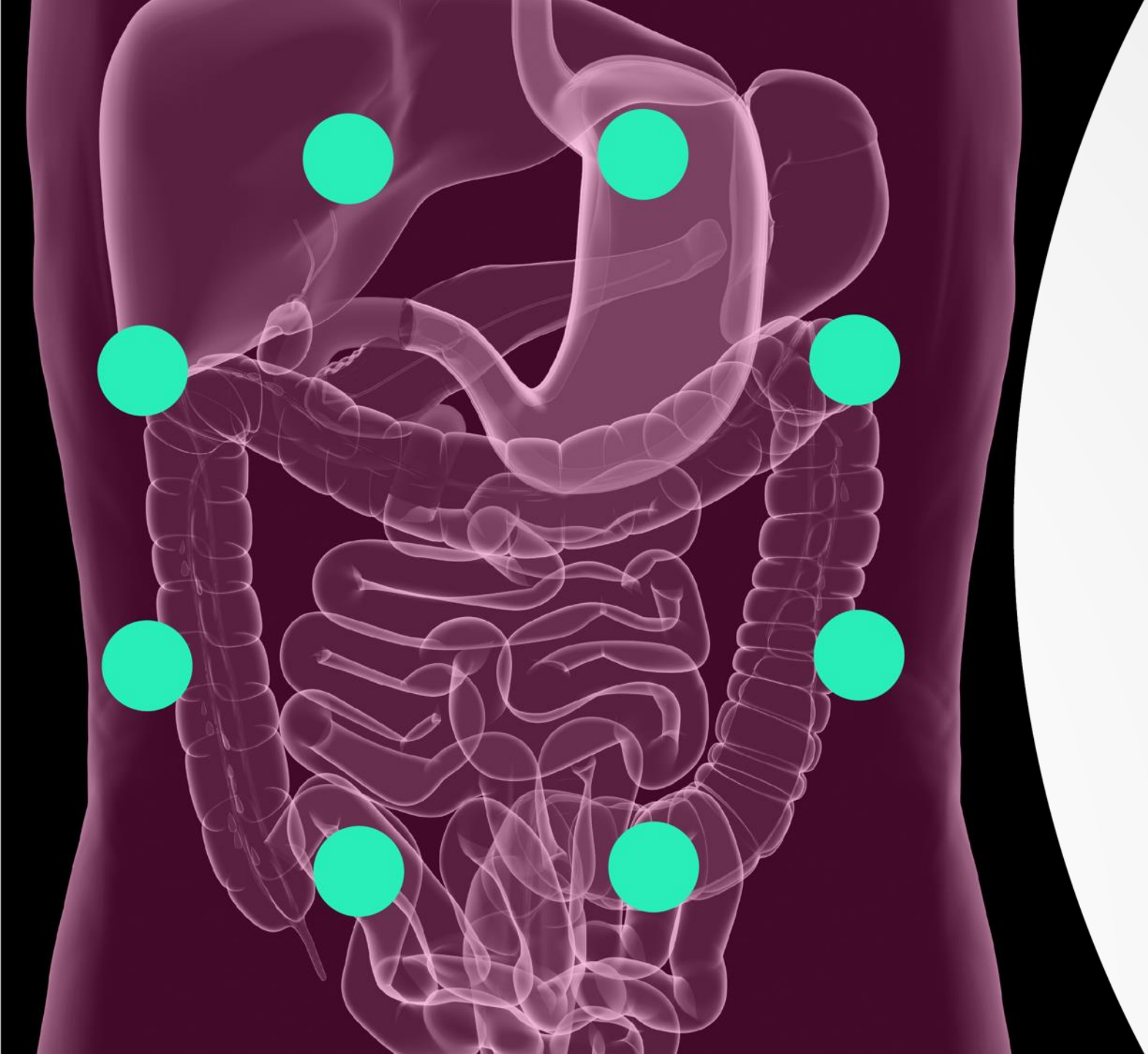
Building on significant opportunity with value-driving execution across pipeline in 2024

Key Pipeline Milestones



*Revita has been granted Breakthrough Device designation in T2D patients on insulin and for weight maintenance after GLP-1 discontinuation in obesity; and CE mark obtained from EU and UK in 2016 for Revita for the improvement of glycemic control in patients with inadequately controlled T2D despite oral and/or injectable glucose lowering medications and/or long-acting insulin; **Product candidates under our Rejuva gene therapy platform will undergo Phase 1, Phase 2 and Phase 3 clinical studies ***subject to IND approval

IND = Investigational New Drug Application with FDA or comparable regulatory body; IDE = Investigational Device Exemption with FDA or comparable regulatory body; FIH = first-in-human; PMA = Premarket Approval



FRACTYL® health

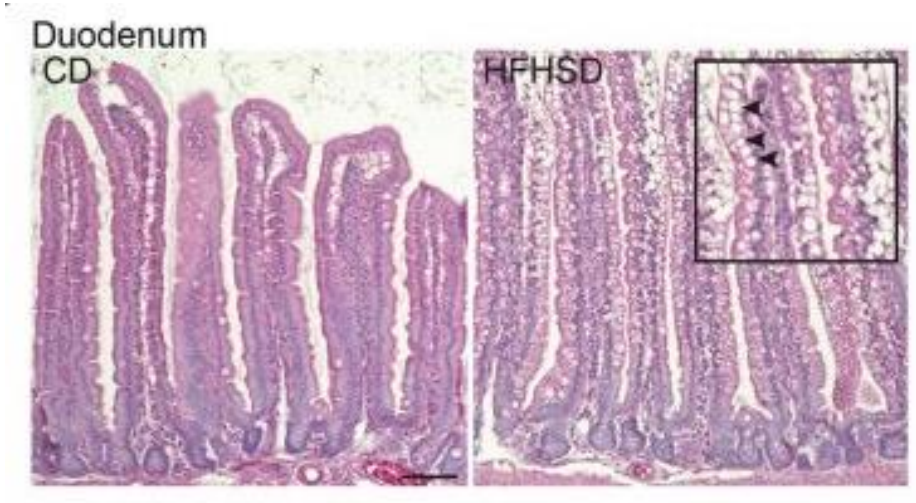
Revita

Potential long-term solution to the problem of weight regain

Revita is for investigational use only in the United States. Revita has a CE mark in the EU/UK.

Gut dysfunction is a root cause of obesity & T2D[1]

Altered gut-brain signaling is caused by high fat and sugar diets[2]



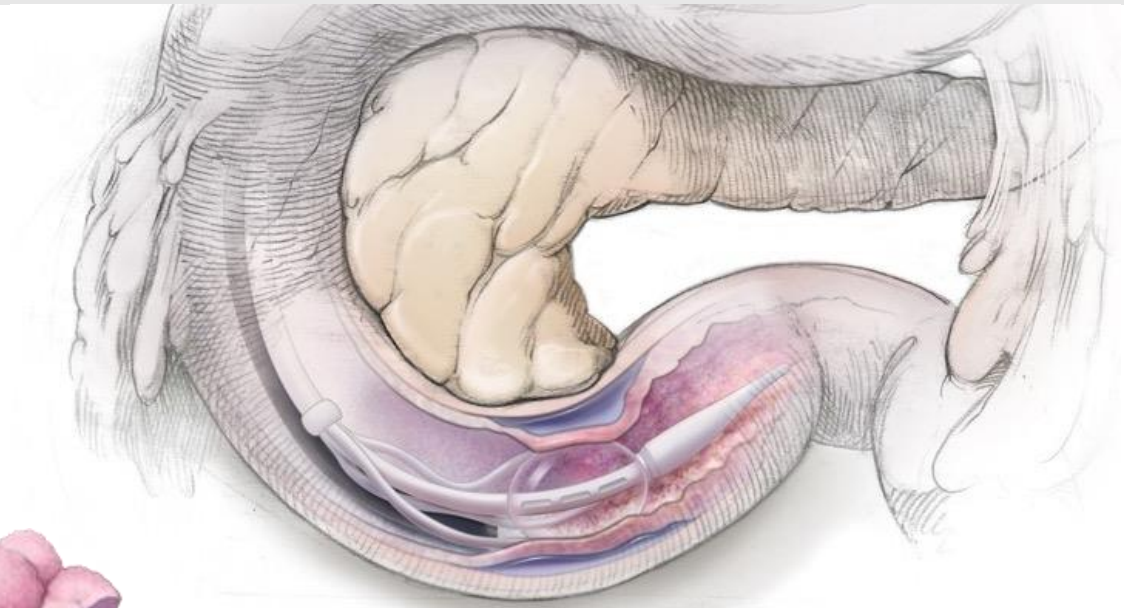
High fat and **high sugar** diets cause structural and functional changes to the gut lining

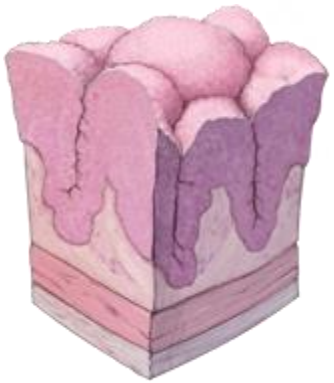
Chronic high fat and high sugar diets **cause gut dysfunction** → **Gut dysfunction** alters gut-brain signaling[1-2] → Altered gut-brain signaling **drives obesity and T2D[2]**

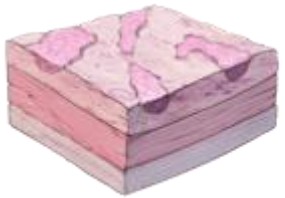
[1]Aliluev et al Nat Metab. 2021 3:1202-1216 [2]Duca et al Cell Metab. 2015 22:367-380 CD = Chow Diet HFHSD = High Fat High Sugar Diet

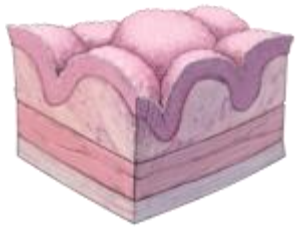
Revita targets this gut dysfunction

First-in-class procedural therapy designed to durably reset metabolism[1-4]









Dysfunctional → **Ablated** → **Regenerated**

Outpatient endoscopic procedural therapy

Clinical studies in > 300 participants

2-year durable improvements in weight and glucose[4-10]

1. Mah AT et al. Endocrinology. 2014 155:3302-3314. 2. Mao J et al. Diabetes. 2013 62:3736-3746. 3. de Moura EGH et al. Endosc Int Open. 2019 7:E685-E690. 4. Haidry RJ, et al. Gastrointest Endosc. 2019 90:673-681.e2. 5. van Baar ACG, et al. Endosc Int Open. 2020 8:E1683-E1689. 6. Rajagopalan H, et al Diabetes Care. 2016 39:2254-2261. 7. van Baar ACG, et al. Gut. 2020 69:295-303. 8. Mingrone G, et al. Gut. 2022 71:254-264. 9. van Baar ACG, et al. Gastrointest Endosc. 2021 94:111-120.e3. 10. van Baar et al. Diabetes Res. Clin. Pract. 2022 184:109194

Proprietary device designed for durable and repeatable metabolic reset

Control console

Real-time sensors

Single-use catheter

½ day training
< 1 hour procedure time
< 4 cases for proficiency

Extensively tested in hundreds of clinical trial participants

80+ issued patents covering methods, systems, devices
CE Mark in EU/UK

Reimbursed and marketed in Germany

Breakthrough Designation from FDA in weight maintenance in obesity and insulin-treated T2D

Revita is for investigational use only in the United States. Revita has a CE mark in the EU/UK. This is a rendering of a commercial prototype.

REMAIN-1 Program

Goal: Durable weight loss after GLP-1 drug discontinuation

Revita is for investigational use only in the United States. Revita has a CE mark in the EU/UK.

REMAIN-1 pivotal study in weight maintenance

Planned mid-point data analysis anticipated in Q2 2025

Patient population

- Obese patients (BMI 30) without T2D and GLP-1 drug naïve
- **Planned mid-point data analysis after ~45 participants randomized and followed for 12 weeks**
- At least 315 additional participants in pivotal phase

Co-primary endpoints

- Change from baseline in weight to week 26 and % of Revita participants who maintain at least 5% TBW loss at week 24

Key secondary endpoints

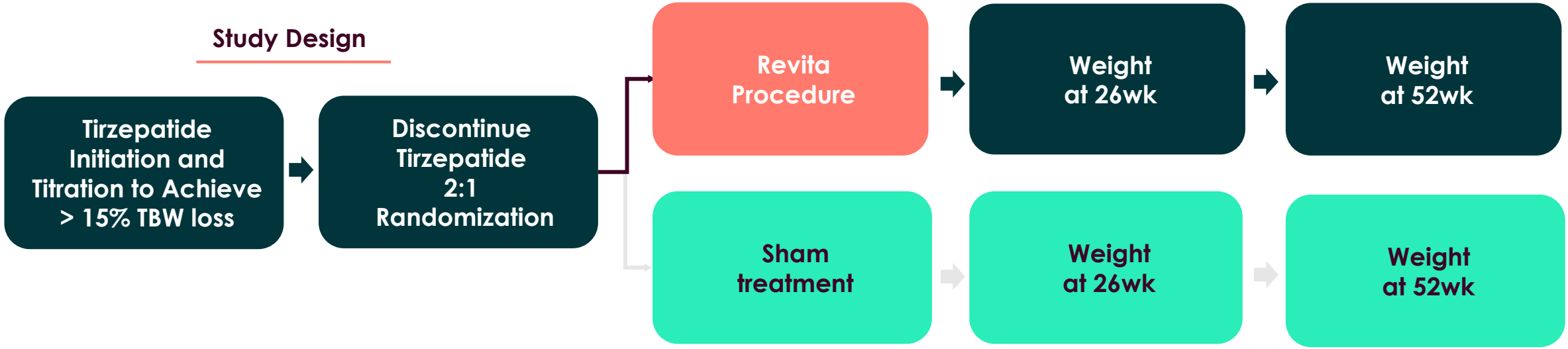
- Glucose, CV risk factors

Study design

- Randomized (2:1), double blind, sham controlled after GLP-1 discontinuation
- Diet and lifestyle counseling throughout

Anticipated timing

Planned mid-point data analysis expected in Q2 2025



TBW = total body weight

REVEAL-1 weight maintenance study[1]

Open label study for patients who need to stop GLP-1s

Patient population
- Obese patients (BMI 30) without T2D and achieving at least 15% TBW loss with tirzepatide or semaglutide and cannot continue drug
- Up to 20 participants

Co-primary endpoints
- Change from baseline in weight compared to historical controlled studies of GLP-1 withdrawal

Key secondary endpoints
- Glucose, CV risk factors

Study design
- Single-arm, open-label, cohort study of Revita after GLP-1 drug discontinuation
- Diet and lifestyle counseling throughout

Anticipated timing
Open label study updates expected starting in Q4 2024

Study Design

TBW = total body weight 1. REVEAL-1 is an open label cohort as part of the REMAIN-1 pivotal IDE. Participants may either already be taking GLP-1 based semaglutide or tirzepatide and have achieved at least 15% TBW loss or will initiate tirzepatide to achieve at least 15% TBW loss before Revita

REVITALIZE-1 Program

Goal: Durably improve glucose control, maintain weight loss, and reduce medication burden for millions of people with inadequately controlled T2D

T2D remains a major global health crisis

60+ approved drugs but market continues to grow

537M with diabetes globally in 2021[4]

> $350B annual cost of T2D in 2022[1]

> $20B in branded GLP-1 sales for T2D in 2022 (15% CAGR)[2]

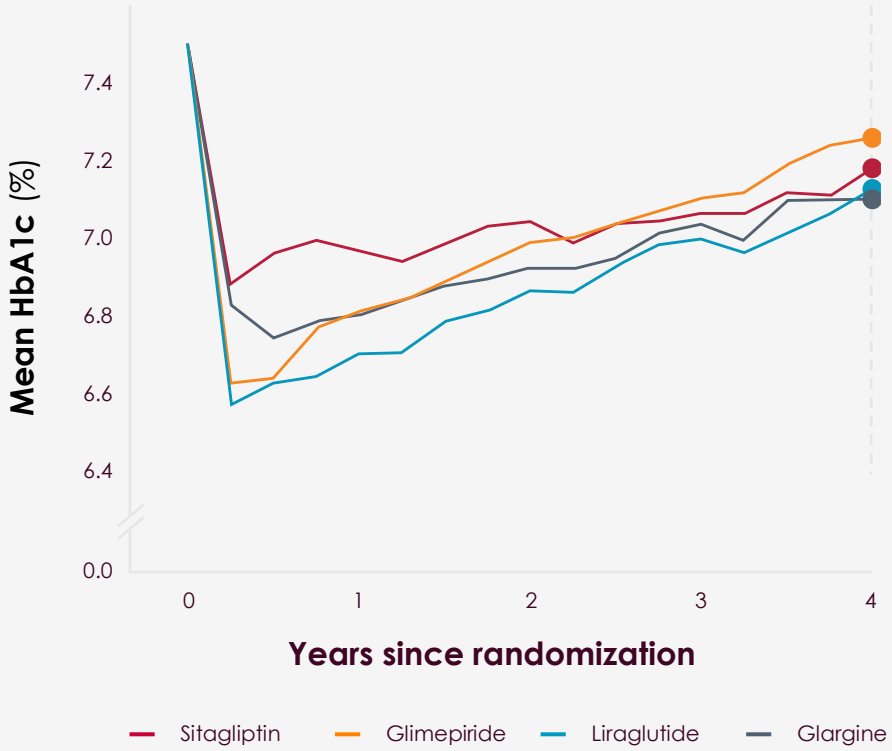
> 50M in US projected to have diagnosed T2D by 2030[3]

Map: Number of people with diabetes worldwide and per IDF Region in 2021–2045 (20–79 years)
1. CDC 2. TD Cowen estimates 3. Rowley et al Pop Health Mgmt 2017 4. IDF Diabetes Atlas 2021

Need to break the pattern of disease progression in T2D

Diminishing effectiveness of T2D therapies over time

Lack of durability of current therapies drives need for medication escalation[1]



There is no drug approved for T2D today that can **halt** or **reverse** progression of disease

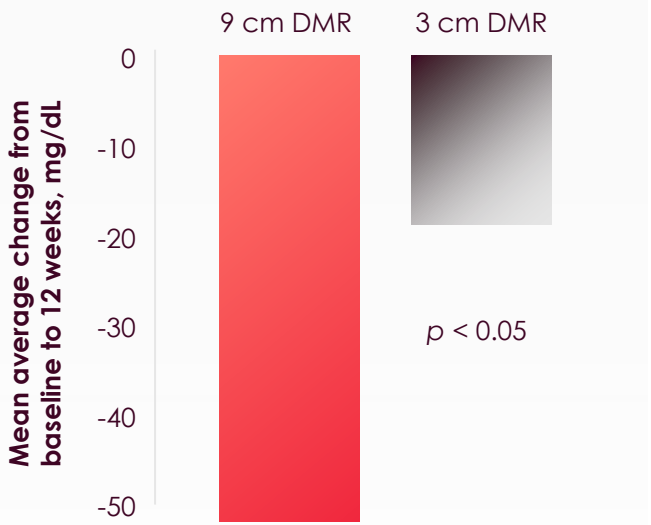
Adapted from: 1. GRADE Study 2022 HbA1c=hemoglobin A1c, IU=international units, OR=odds ratio, *p<0.05

Revita T2D clinical program overview

Consistent effects on blood glucose across clinical studies

Revita FIH[1]
Dose-dependent glucose lowering

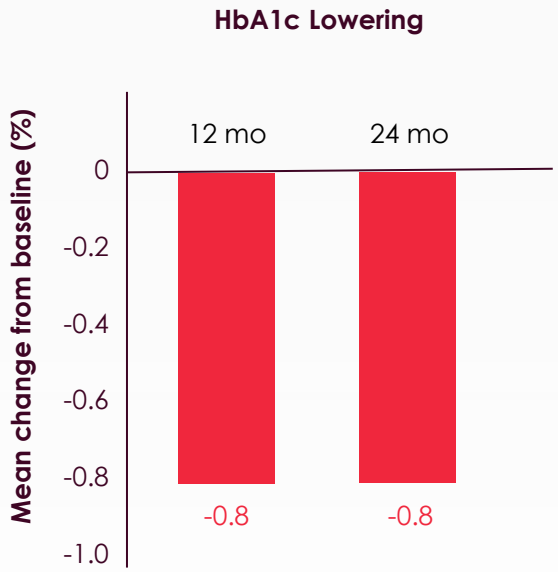
Dose-Dependent Efficacy



Axial length of treated intestine = treatment dose

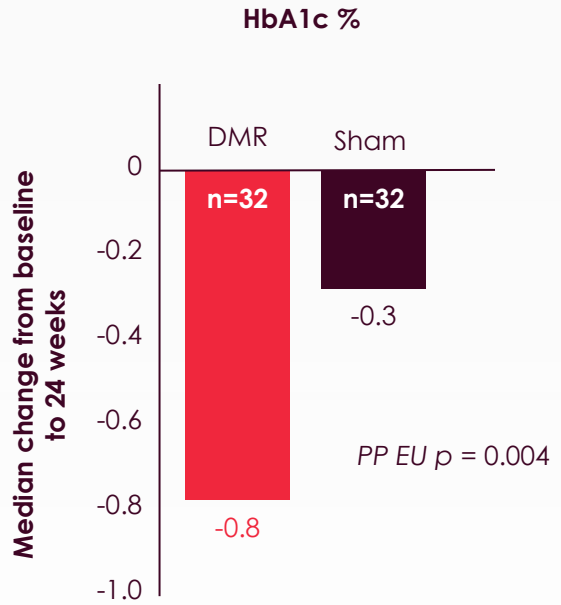
Revita-1 Open Label[2]
2-year glucose lowering and weight control

Durable Metabolic Improvements



Revita-2 Sham-Controlled[3]
Sham-controlled efficacy pilot study

Sham-Controlled Efficacy



1. Rajagopalan et al Diabetes Care 2016 2. van Baar et al. Diabetes Res Clin Pract. 2022 184:109194 3. Mingrone et al. Gut 2022 71:254-264

REVITALIZE-1 pivotal study underway

FDA Breakthrough Device designation and CMS reimbursement support

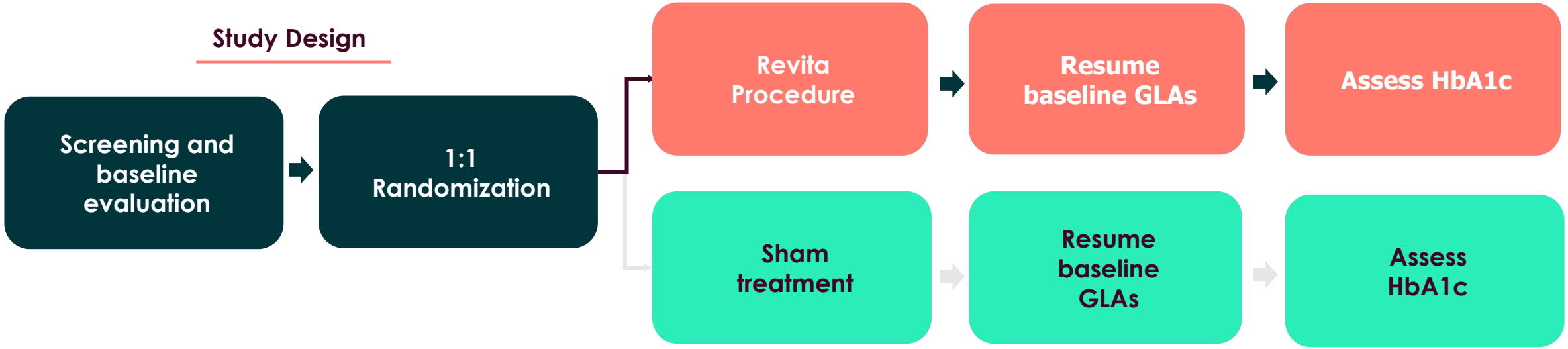
Patient population
- Inadequately controlled T2D (HbA1c > 7.5) despite use of at least 1 glucose lowering agent (GLA)

Co-primary endpoints
- Change from baseline in HbA1c at 24 weeks

Key secondary endpoints
- HbA1c targets weight loss, insulin requirement

Study design
- Randomized (1:1) double blind sham controlled

Anticipated timing
Topline data mid-2025



REVITALIZE-1 Study; ClinicalTrials.gov Identifier: NCT04419779

Post-market registry ongoing in Germany

Real-world weight maintenance and blood sugar control post-Revita procedure[1]

Patient population
Patients with obesity and advanced T2D on up to 3 GLA at baseline undergoing Revita + diet and exercise

Median baseline demographics
62 years age
BMI 32 kg/m^2

Anticipated timing
Quarterly open label data updates

	Baseline* Median	3 Month* Median	6 Month* Median	12 Month* Median
Weight (kg)	**111**	**101**	**100**	**97**
HbA1c (%)	**9.6**	**7.1**	**7.6**	**7.2**

- Revita was well-tolerated in these registry participants with no procedure-related adverse safety events reported

*N=11 at all timepoints

1. Fractyl Health, Data on File as of August 2024 NCT06256497. GLAs=glucose lowering agent, HbA1c=glycated hemoglobin

FRACTYL health

Rejuva

Potentially one-and-done pancreatic gene therapy platform

Rejuva is a preclinical asset and has yet to be assessed by regulatory agencies.

Pancreatic Gene Therapy (PGTx) to modify islet function

Potential for durable improvement in metabolic health

GLP-1 gene therapy, targeted to pancreatic islets, may offer differentiated benefit

β-cell machinery can be leveraged to produce nutrient-stimulated hormones[1,2]

Islet cells are terminally differentiated,[3] making adeno-associated virus (AAV) suitable for durable effect

Opportunity to amplify islet GLP-1 signaling to improve β-cell health

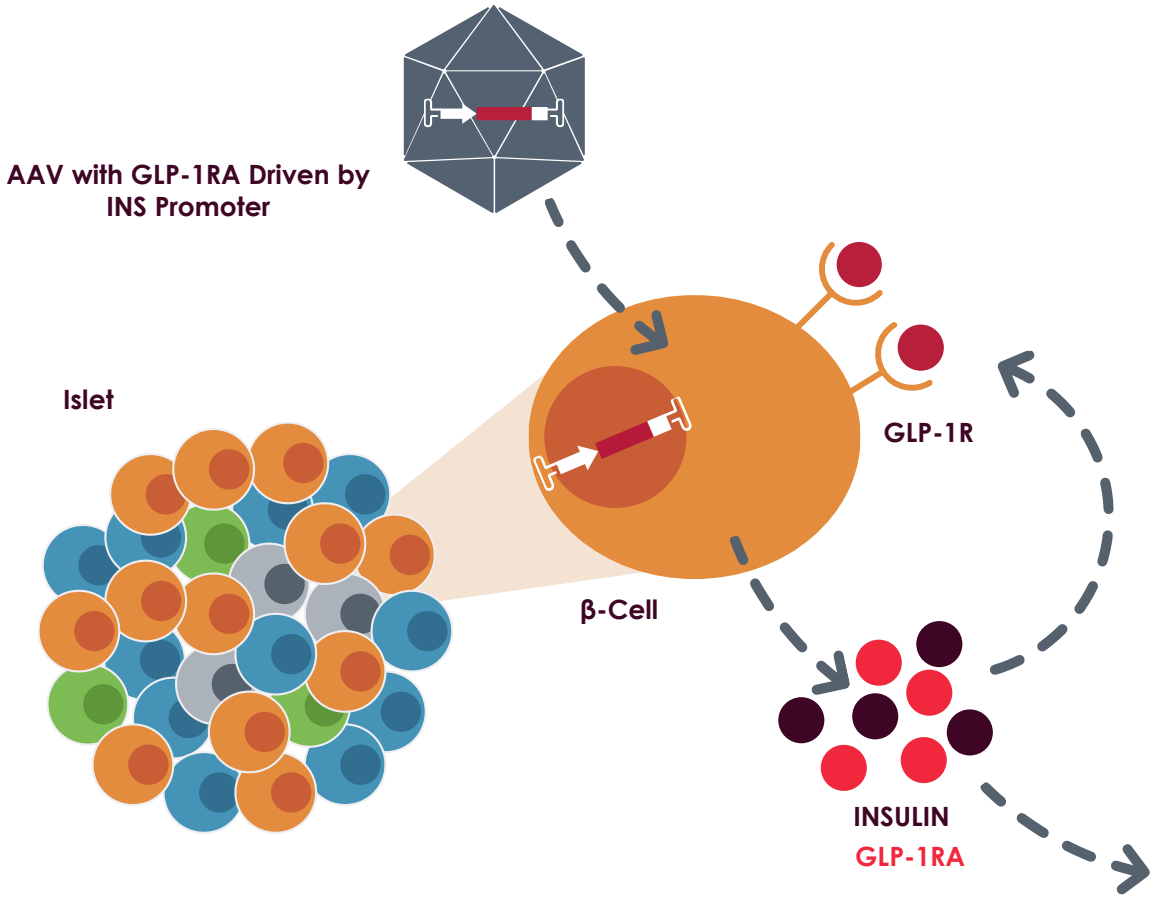


Figure adapted from Saikia et al. JCI Insight. 2021 6:e1418511. 1. Lubaczeuski et al. Keystone 2023 oral presentation. Poster no. 1025. 2. Rajagopalan et al. ADA 2023 oral presentation. Abstract no. 181-OR. 3. Perl et al. J Clin Endocrinol Metab. 2010 95: E234–E239., GLP-1=glucagon-like peptide 1, GLP-1R=GLP-1 receptor, GLP-1RA=GLP-1R agonist, INS=insulin,

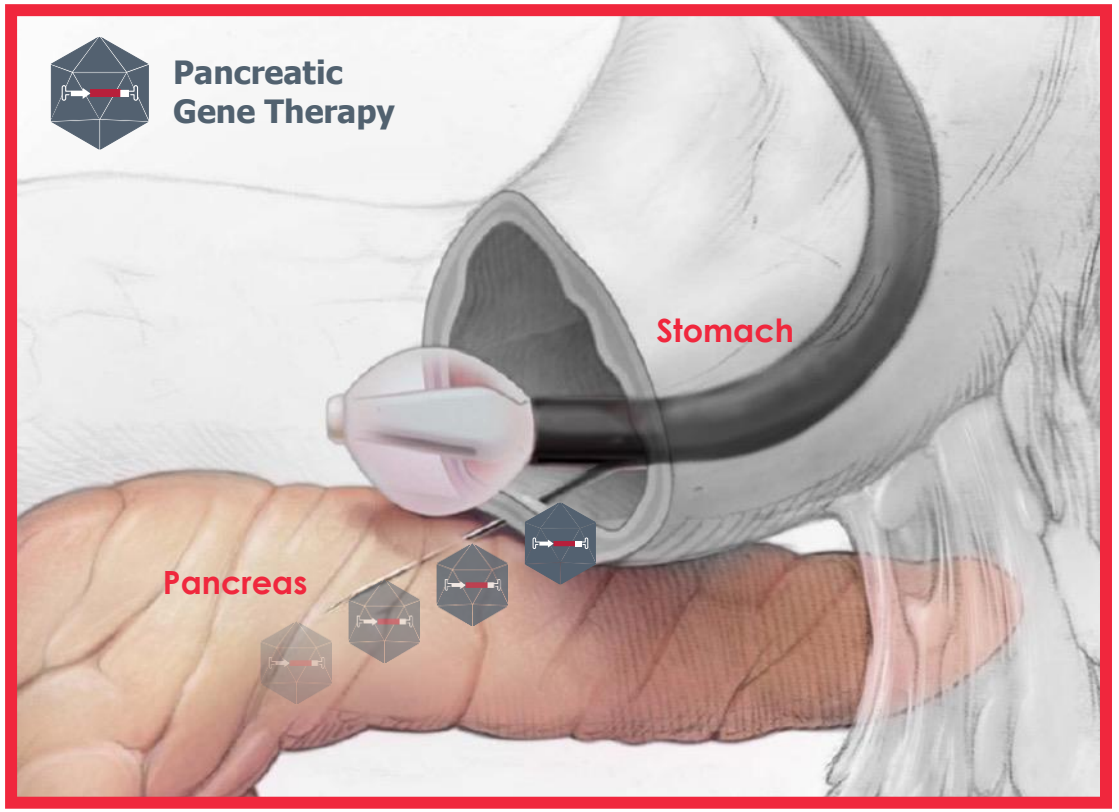
Gene therapy route of administration to pancreas

Proprietary, automated, endoscopic delivery device

Local delivery enables low viral genome dosing with limited systemic virus exposure[1]

Islets are readily accessible[2,3] via already established, routine, upper endoscopic ultrasound procedures,[4] performed in ~300K patients per year in US[5]

Procedural risk is further mitigated with device design (e.g., needle size, volume, controlled infusion rate)



Endoscopic Procedure & PGTx Delivery

1. Rajagopalan et al. ASGCT 2023 oral presentation. Abstract no. 191. 2. Docherty & Russ. Encyclopedia of Tissue Engineering and Regenerative Medicine 2019, pg. 367-374. 3. Ravi et al. Medicine (Baltimore). 2021 Apr 30;100(17):e25642. 4. Hasan & Hawes. Gastrointest Endosc Clin N Am. 2012 Apr;22(2):155-67. 5. Peery et al. Gastroenterology 2022 Feb; 162(2):621-644. PGTx=pancreatic gene therapy

Dose-dependent transduction in Yucatan Pig Model

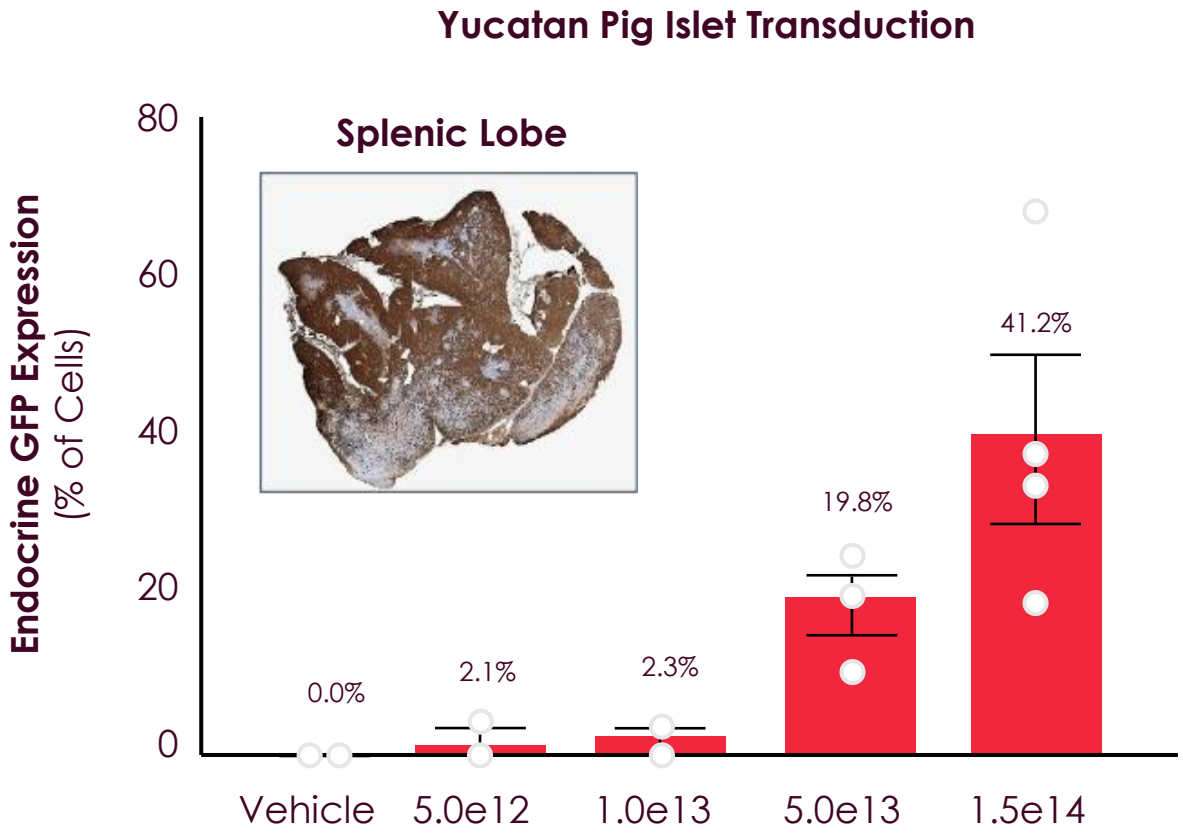
Local delivery effectively and reliably targets islets

Yucatan pig model **anatomy similar to humans**[1]

Dose-dependent AAV-GFP expression in targeted pancreatic lobe[2,3]

>60 animals treated with 100% technical success

No adverse safety signals to date (e.g., pancreatitis)

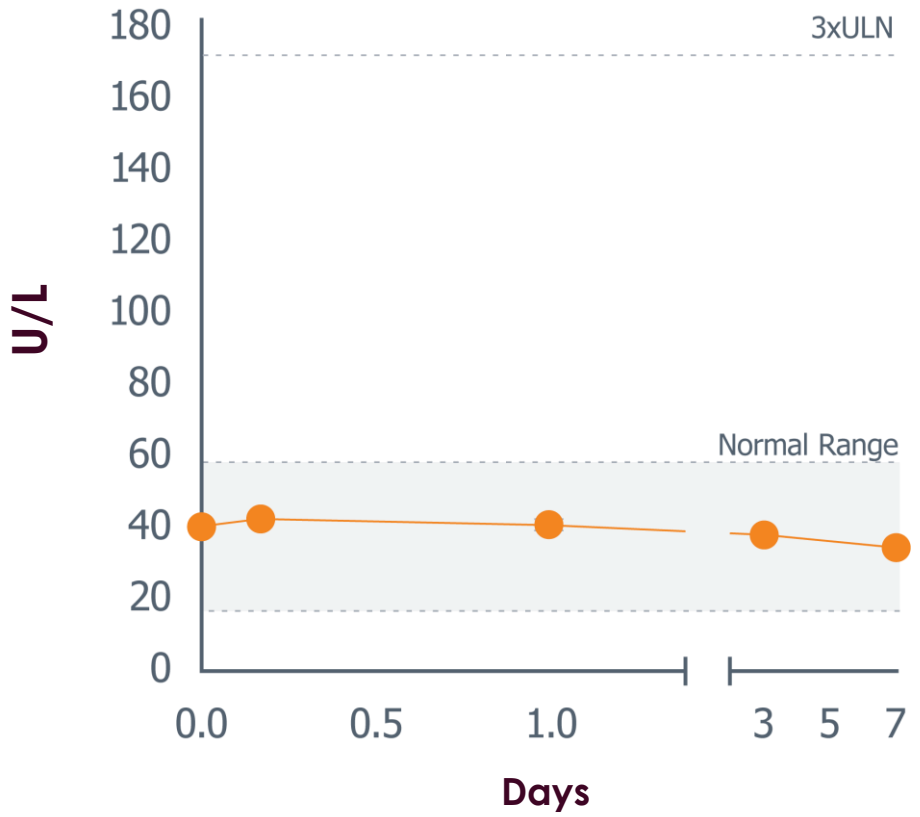


Mean ± SD shown; n=2-4 per group. 1. Walters and Prather. Mo Med. 2013 May-Jun;110(3):212-5. 2. Thompson et al. DDW 2023 poster presentation. Control no. 3862948. 3. Rajagopalan et al. ASGCT 2023 oral presentation. Abstract no. 191. AAV=adeno-associated virus, GFP=green fluorescent protein

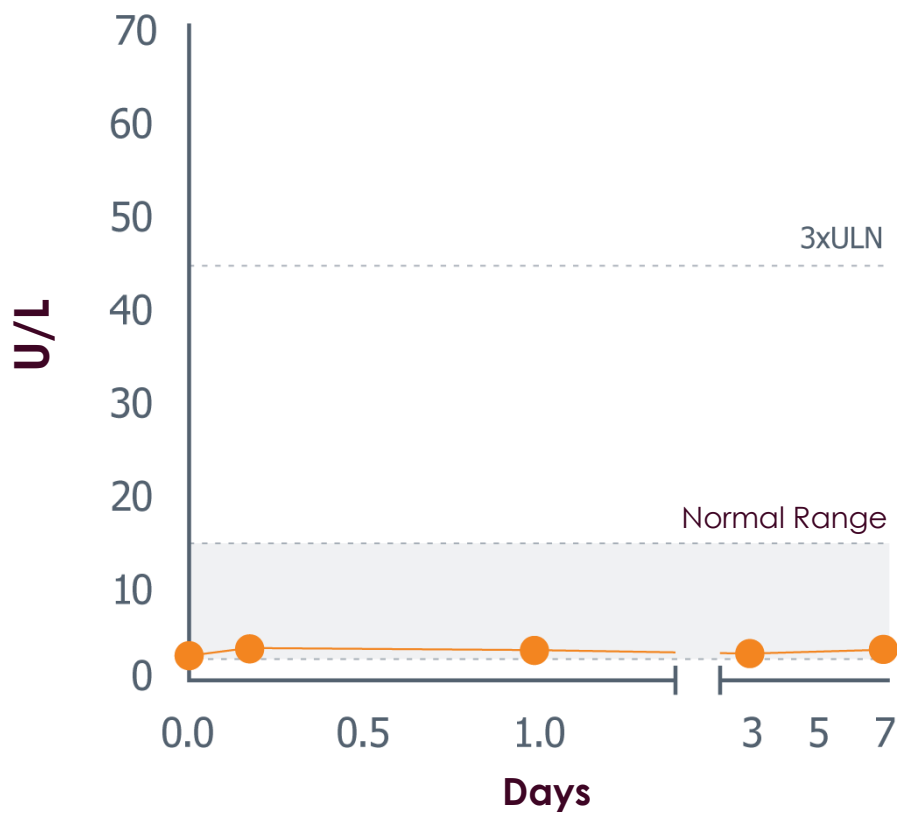
Intrapancreatic AAV9: Toxicology

ALT and lipase levels within normal range across all timepoints

A) 7-day ALT



B) 7-day Lipase



Mean ± SEM shown; n=28. 1. Thompson et al. UEGW 2023 poster presentation. Abstract no. AS-UEG-2023-02238. ALT=alanine transaminase, ULN=upper limit of normal

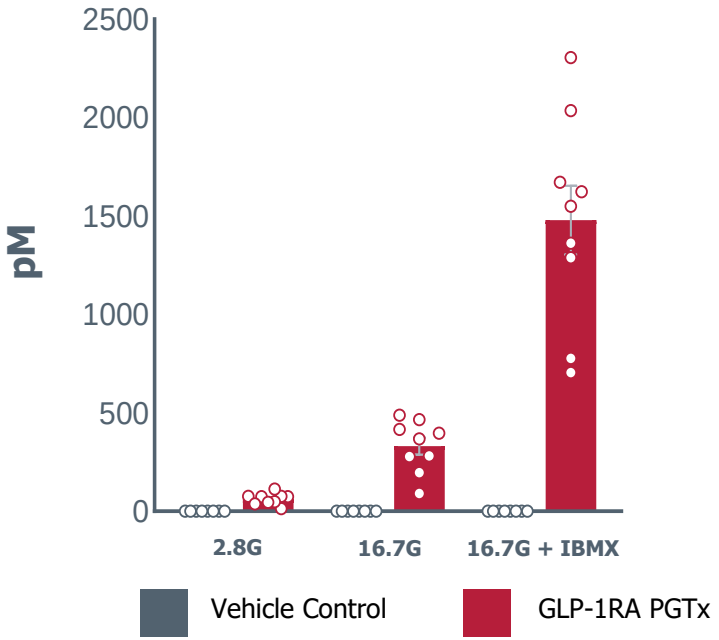
RJVA-001 for T2D

Nutrient-responsive "Smart" GLP-1 via intrapancreatic gene therapy

Smart GLP-1 Differentiation
- Expression regulated by the insulin promoter
- Enables nutrient-responsive GLP-1 expression
- Effectively transduces pancreatic islets
- One-time intrapancreatic administration

Product Design
- Vector: AAV9
- Transgene: human GLP-1
- Promoter: insulin
- Delivery: Proprietary endoscopic delivery

Glucose concentration-dependent release from pancreatic beta cells[1]



Status
IND-enabling studies

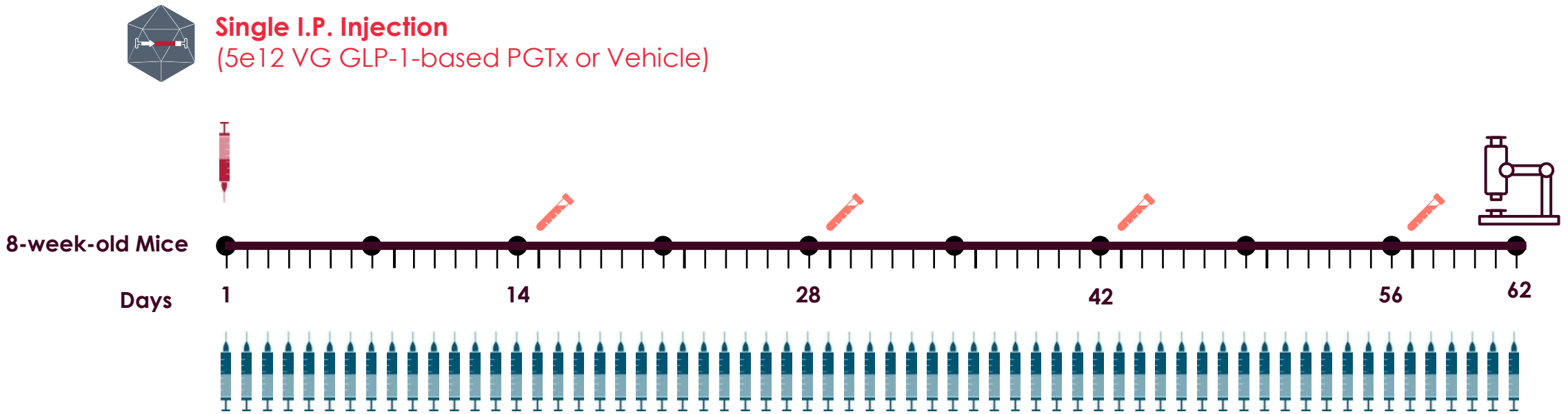
Expected Milestone
Initiate first-in-human clinical study in H1 2025

Data show GLP-1 is only released from beta cells under high glucose conditions

1. Rajagopalan et al ADA 2024

RJVA-001 prototype* vs. semaglutide

Design of POC efficacy study in db/db mouse (standard T2D model)

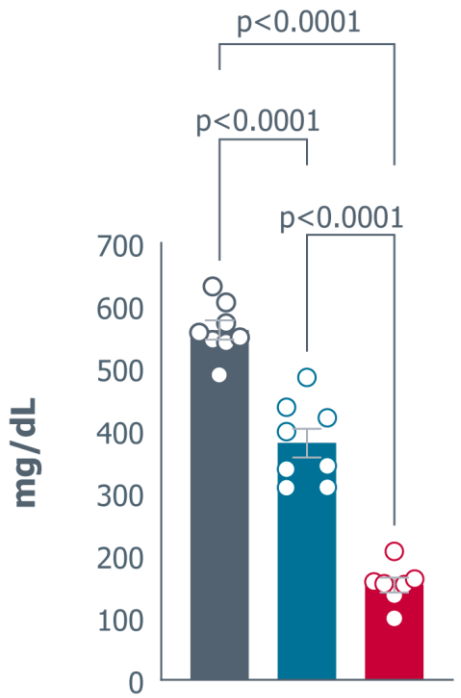


GLP-1=glucagon-like peptide 1, GLP-1RA=glucagon-like peptide 1 receptor agonist, I.P.=intraperitoneal, PGTx=pancreatic gene therapy, S.C.=subcutaneous, T2D=type 2 diabetes, VG=vector genomes

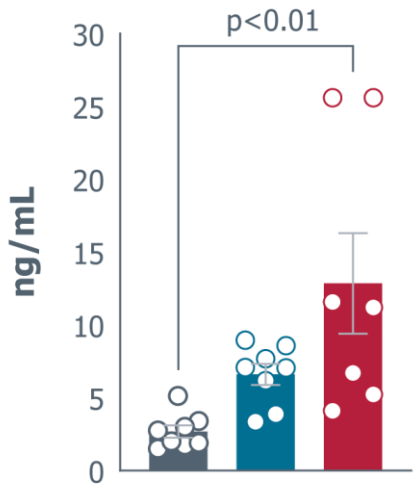
Glucose-lowering efficacy in *db/db* murine model

GLP-1RA PGTx improves glucose and weight vs. daily semaglutide

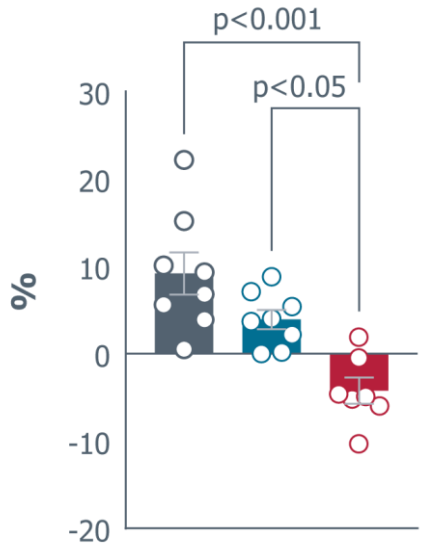
A) Fasting Blood Glucose



B) Fasting Plasma Insulin



C) Body Weight Change from Baseline



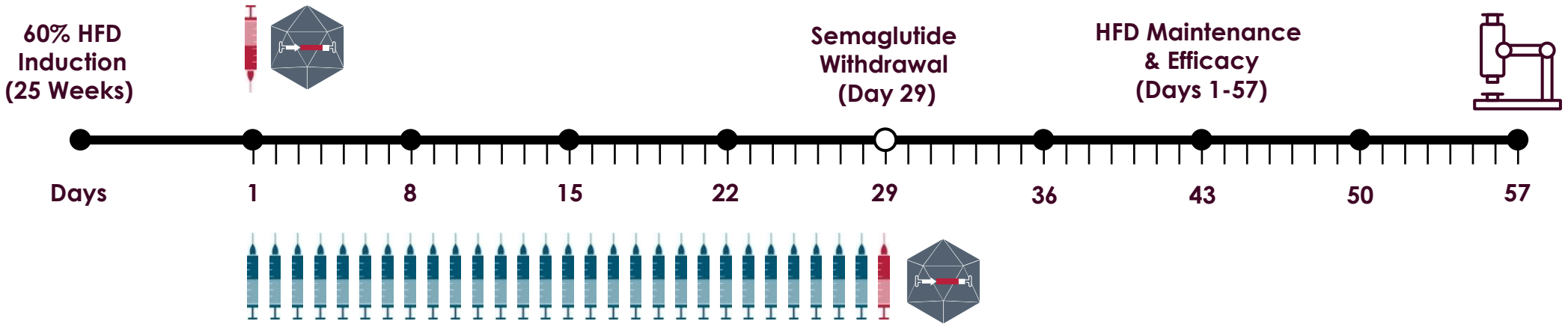
Vehicle Control | Semaglutide (10 nmol/kg/d) | GLP-1RA PGTx (5e12)

Mean ± SEM shown; n=7-8 per group, day 29 shown, Rajagopalan et al. DDW 2024 oral presentation. Abstract no. 4029196. GLP-1RA=glucagon-like peptide 1 receptor agonist, PGTx=pancreatic gene therapy

RJVA-001 prototype* vs. semaglutide

Design of POC efficacy study in DIO mouse (standard obesity model)

Single I.P. Injection
(1e13 VG GLP-1-based PGTx or Vehicle)



Daily S.C. Injection
Semaglutide (10 nmol/kg/d or Vehicle)

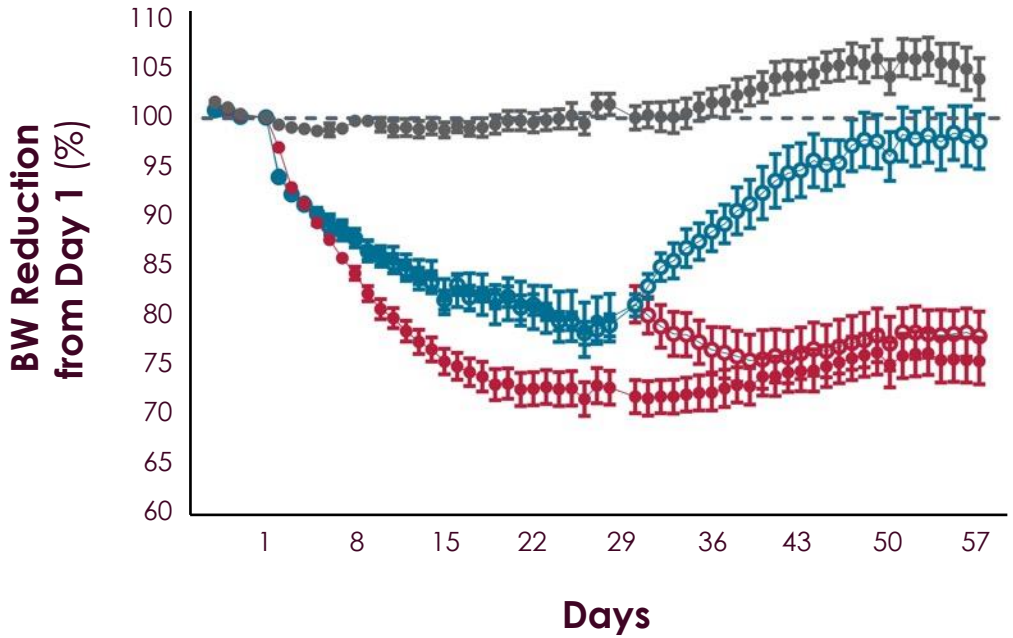
Single I.P. Injection (½ Dose)
(5e12 VG GLP-1-based PGTx or Vehicle)

Fitzpatrick AL et al. WCIRDC 2023 oral presentation; AAV=adeno-associated virus, BW=body weight, BWL=body weight loss, DIO=diet-induced obesity, GLP1=glucagon-like peptide 1, GLP1RA= GLP1 receptor agonist, HFD=high fat diet, INS=insulin promoter, I.P.=intraperitoneal, PGTx=pancreatic gene therapy, S.C.=subcutaneous

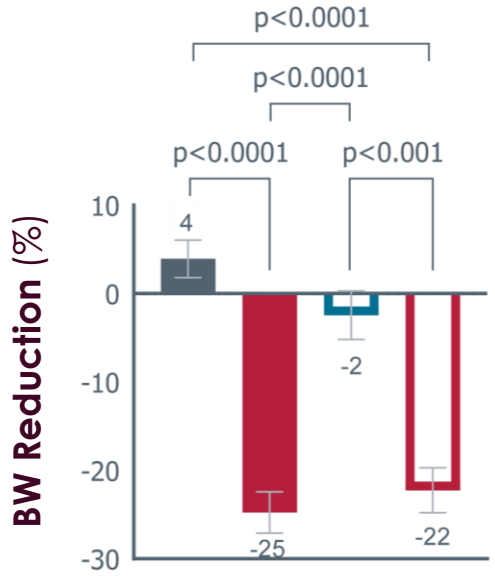
RJVA-001 prototype* vs. semaglutide

Weight loss and food intake in DIO mouse model

A) Change in BW Over Time



B) End of Study BW Change



Vehicle Control

Sema (10 nmol/kg/d)

Sema Withdrawal + Vehicle

GLP-1RA PGTx (1e13 VG)

Sema Withdrawal + GLP-1RA PGTx (5e12 VG)

Mean ± SEM shown; n=5-10 per group. Fitzpatrick et al. WCIRDC 2023 oral presentation. Abstract no. 0077. BW=body weight, DIO=diet-induced obesity, GLP-1RA=glucagon-like peptide 1 receptor agonist, PGTx=pancreatic gene therapy, Sema=semaglutide, VG=vector genomes

RJVA-001 summary

Nutrient-responsive GLP-1 via intrapancreatic gene therapy

- Utilizes Fractyl's proprietary intrapancreatic delivery system – invented to enable local delivery of pancreatic gene therapy vectors
- Designed for improved potency and tolerability compared to other approaches
- Efficacy in db/db and DIO mouse models of T2D and obesity superior to chronic semaglutide
- Regulatory alignment on IND-enabling studies for T2D FIH study
- RJVA-001 candidate nominated in H1 2024
- First-in-human clinical study initiation in T2D expected in H1 2025

Leadership team and BOD

Experience spanning biotechnology and medical technology

Harith Rajagopalan, MD, Ph.D.
Co-founder & CEO

Jay Caplan
Co-founder, President, Chief Product Officer

Tim Kieffer, Ph.D.
Chief Scientific Officer

Adrian Kimber
Chief Commercial Officer

Lisa Davidson
Chief Financial Officer

Sarah Toomey
General Counsel and Corporate Secretary

Board of Directors

Ajay Royan (Chair)
Co-founder and Managing General Partner, Mithril

William W. Bradley
Former U.S. Senator

Harith Rajagopalan, MD, PhD
Co-founder & CEO, Fractyl Health

Marc Elia
Founder of M28 Capital

Kelly Barnes
Former Partner, PwC

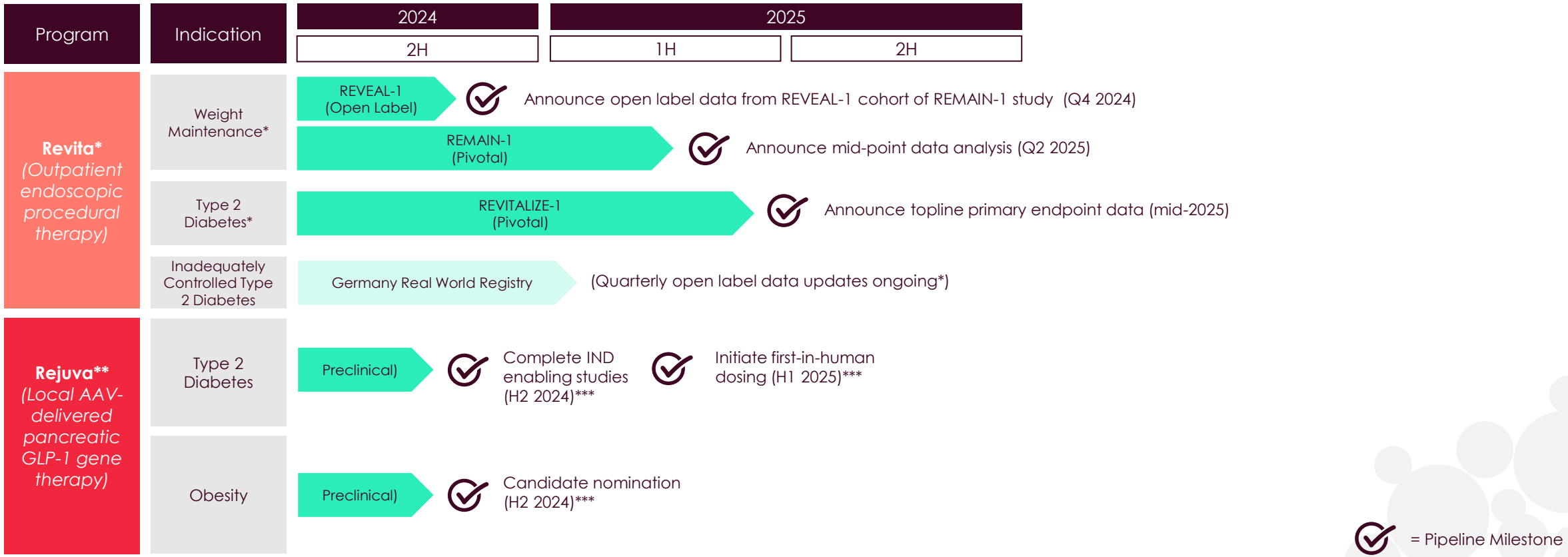
Sam Conaway
President of Boston Scientific U.S. Cardiology Sales and Chair of Close the Gap

Clive Meanwell, MB, CHB, MD
Executive Chairman and Founder of Population Health Partners

Amy Schulman
Partner, Polaris Partners

Building on significant opportunity with value-driving execution across pipeline in 2024

Key Pipeline Milestones



*Revita has been granted Breakthrough Device designation in T2D patients on insulin and for weight maintenance after GLP-1 discontinuation in obesity; and CE mark obtained from EU and UK in 2016 for Revita for the improvement of glycemic control in patients with inadequately controlled T2D despite oral and/or injectable glucose lowering medications and/or long-acting insulin; **Product candidates under our Rejuva gene therapy platform will undergo Phase 1, Phase 2 and Phase 3 clinical studies ***subject to IND approval

IND = Investigational New Drug Application with FDA or comparable regulatory body; IDE = Investigational Device Exemption with FDA or comparable regulatory body; FIH = first-in-human; PMA = Premarket Approval

Thank You!

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