



Boston, United States  
Sydney, Australia  
11 December 2019 AEST

## Corporate Presentation

**BOSTON and SYDNEY — 11 December 2019 —** GI Dynamics® Inc. (ASX:GID) (Company or GI Dynamics), a medical device company that is developing EndoBarrier® for patients with type 2 diabetes and obesity, announces that the Company has prepared the attached corporate presentation, which it may use from time to time in presentations to investors and other interested parties. A copy of the presentation will also be placed on the Company's website.

### About GI Dynamics

GI Dynamics®, Inc. (ASX:GID) is the developer of EndoBarrier®, the first endoscopically-delivered device therapy for the treatment of type 2 diabetes and obesity. EndoBarrier is not approved for sale and is limited by federal law to investigational use only. EndoBarrier is subject to an Investigational Device Exemption by the FDA in the United States and is entering concurrent pivotal trials in the United States and India. Founded in 2003, GI Dynamics is headquartered in Boston, Massachusetts. For more information please visit [www.gidynamics.com](http://www.gidynamics.com).

### Forward-Looking Statements

This announcement may contain forward-looking statements. These statements are based on GI Dynamics management's current estimates and expectations of future events as of the date of this announcement. Furthermore, the estimates are subject to several risks and uncertainties that could cause actual results to differ materially and adversely from those indicated in or implied by such forward-looking statements.

#### Investor Relations

United States:  
Janell Shields  
+1 (781) 357-3280  
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These risks and uncertainties include, but are not limited to, risks associated with our ability to continue to operate as a going concern; our ability to obtain stockholder approval of the conversion feature of the August 2019 Note and issuance of the August 2019 Warrant, our ability to raise sufficient additional funds to continue operations and to conduct the planned pivotal trial of EndoBarrier in the United States



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(STEP-1); our ability to execute STEP-1 under FDA's Investigational Device Exemption; our ability to enlist clinical trial sites and enroll patients in accordance with STEP-1; the risk that the FDA stops STEP-1 early as a result of the occurrence of certain safety events or does not approve an expansion of STEP-1; our ability to enroll patients in accordance with I-STEP; our ability to secure a CE Mark; our ability to maintain compliance with our obligations under our existing convertible note and warrant agreements executed with Crystal Amber, including our obligations to make payment on the 2017 Note that is due on 31 March 2020 and our ability to restructure the terms of the 2017 Note with Crystal Amber that is due on 31 March 2020 if we are unable to raise sufficient funds to enable us to fully repay such Note when due; obtaining and maintaining regulatory approvals required to market and sell our products; the possibility that future clinical trials will not be successful or confirm earlier results; the timing and costs of clinical trials; the timing of regulatory submissions; the timing, receipt and maintenance of regulatory approvals; the timing and amount of other expenses; the timing and extent of third-party reimbursement; intellectual-property risk; risks related to excess inventory; risks related to assumptions regarding the size of the available market; the benefits of our products; product pricing; timing of product launches; future financial results; and other factors, including those described in our filings with the U.S. Securities and Exchange Commission.

Given these uncertainties, one should not place undue reliance on these forward-looking statements. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information or future events or otherwise, unless we are required to do so by law.

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**GI Dynamics, Inc.**

endobarrier®

Insulin Zero™

# Corporate Presentation

Q4 2019



# Important Notice

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## Currency References

Financial amounts in this presentation are expressed in U.S. Dollars, except where specifically noted.

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These risks and uncertainties include, but are not limited to, risks associated with our ability to continue to operate as a going concern; our ability to obtain stockholder approval of the conversion feature of the August 2019 Note and issuance of the August 2019 Warrant, our ability to raise sufficient additional funds to continue operations and to conduct the planned pivotal trial of EndoBarrier in the United States (STEP-1); our ability to execute STEP-1 under FDA's Investigational Device Exemption; our ability to enlist clinical trial sites and enroll patients in accordance with STEP-1; the risk that the FDA stops STEP-1 early as a result of the occurrence of certain safety events or does not approve an expansion of STEP-1; our ability to enroll patients in accordance with I-STEP; our ability to secure a CE Mark; our ability to maintain compliance with our obligations under our existing convertible note and warrant agreements executed with Crystal Amber, including our obligations to make payment on the Note that is due on 31 March 2020 and our ability to restructure the terms of the Note with Crystal Amber that is due on 31 March 2020 if we are unable to raise sufficient funds to enable us to fully repay such Note when due; obtaining and maintaining regulatory approvals required to market and sell our products; the possibility that future clinical trials will not be successful or confirm earlier results; the timing and costs of clinical trials; the timing of regulatory submissions; the timing, receipt and maintenance of regulatory approvals; the timing and amount of other expenses; the timing and extent of third-party reimbursement; intellectual-property risk; risks related to excess inventory; risks related to assumptions regarding the size of the available market; the benefits of our products; product pricing; timing of product launches; future financial results; and other factors, including those described in our filings with the U.S. Securities and Exchange Commission.

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# Executive Summary

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## PROBLEM

### TREATMENT GAP IN T2DM & OBESITY

- 380m WW with diabetes, creating an economic cost of **\$2.5 Trillion by 2030**
  - Obesity #1 risk factor for type 2 diabetes, both are risk factors for cardiovascular disease
  - Lifestyle modifications do not work for many, insulin and gastric bypass: unattractive options
- 

## SOLUTION

### ENDOBARRIER®

- Minimally invasive, reversible, 20 minute procedure uniquely targeting intestinal mechanisms
  - Demonstrated efficacy in lowering HbA1c, BMI, and insulin use: ~4,000 implants
  - US Pivotal Trial: FDA IDE & IRB approval– *enrolling*
- 

## LARGE MARKET OPPORTUNITY

### HIGH ROI

- EndoBarrier fills a major treatment gap, addressing global metabolic disorder pandemic
  - High value to health systems in reducing significant costs of diabetes and related care
  - High margin, scalable, single-use implant
- 

## FINANCING

### SEEKING \$20m

- Complete Stage 1 of U.S. pivotal trial (STEP-1) → Stage 2 approval
- Complete I-STEP trial with Apollo Sugar in India → Apollo Sugar joint venture / distribution

# Type 2 Diabetes: High Cost U.S. & WW Growing Rapidly

2017

## National Diabetes Statistics Report

*Estimates of Diabetes & its Burden in the U.S.*



### 30m U.S. adults with T2DM

- ~61% with T2DM have BMI >30
- Growing at alarming rate: 5% CAGR
- 50% undiagnosed / 300% pre-diabetes

Average medical expenditures for people with diagnosed diabetes

~ **\$13,700**

per year

~ **\$7,900**

*directly attributed to diabetes*

Average medical expenditures among people diagnosed with diabetes were about **2.3 times higher** than expenditures for people without diabetes

MORE: <https://www.cdc.gov/diabetes/data/statistics-report/index.html>

## Rising Economic Costs of Diabetes

United States

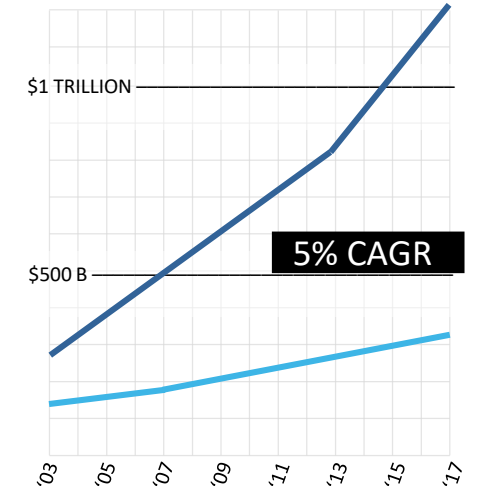
**\$327 B** 2017

**\$622 B** 2030

Worldwide

**\$1.3 T** 2017

**\$2.5 T** 2030



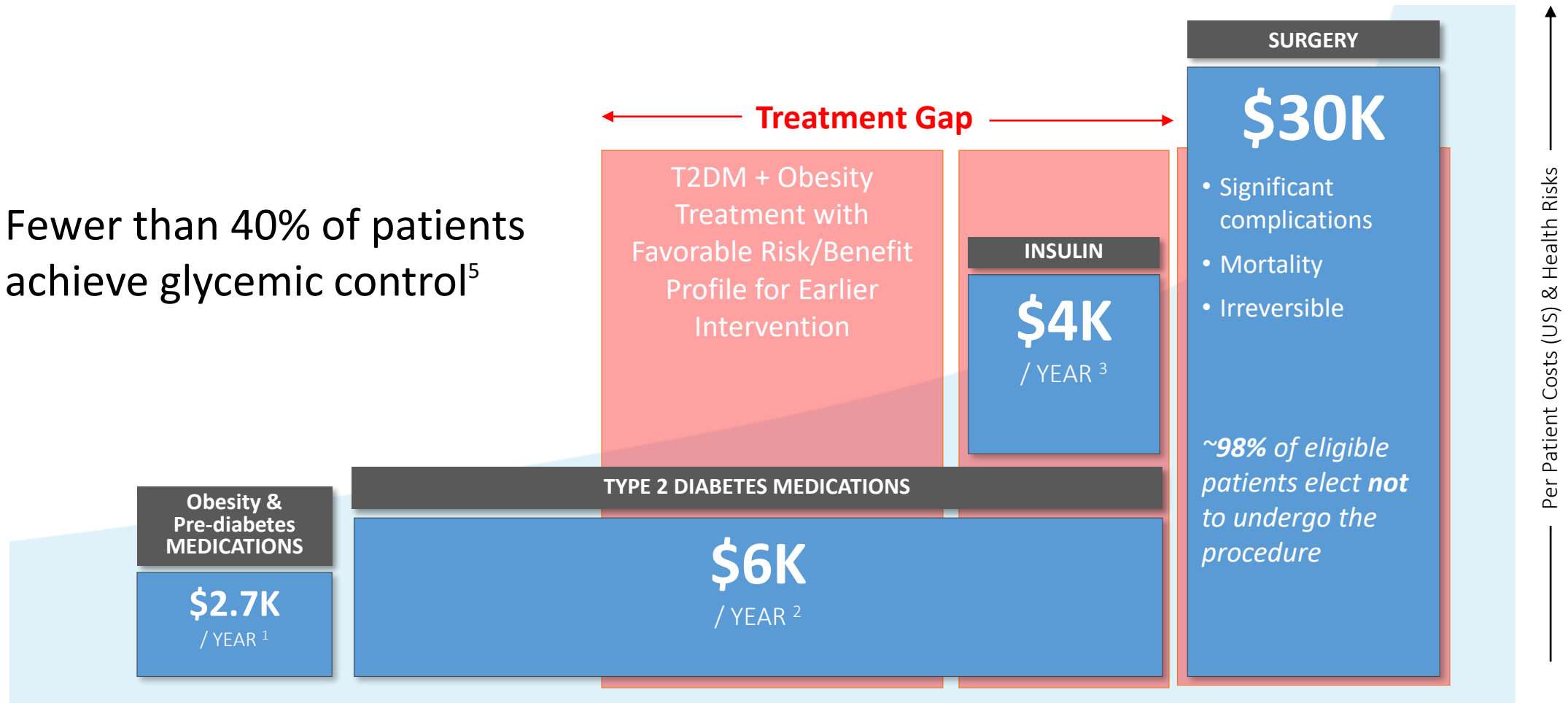
## Global Diabetes Population in 2045: ~500m Patients WW



IDF Diabetes Atlas 8th Edition 2017 Country Reports

# Type 2 Diabetes & Obesity Treatment Gap

Fewer than 40% of patients achieve glycemic control<sup>5</sup>



All costs "up to" the amount shown and in USD

1. Khan et al, Medical Care Expenditures for Individuals with Prediabetes, Population Health Management, Oct 2017.
2. Economic Costs of Diabetes in the US 2017, American Diabetes Association
3. KFF, Medicare Part D Spending on Insulin Increased 840 Percent Between 2007 and 2017
4. Doble et al, What are Real Costs of Bariatric Surgery?, Obesity Surgery, May 2017
5. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3889324/>

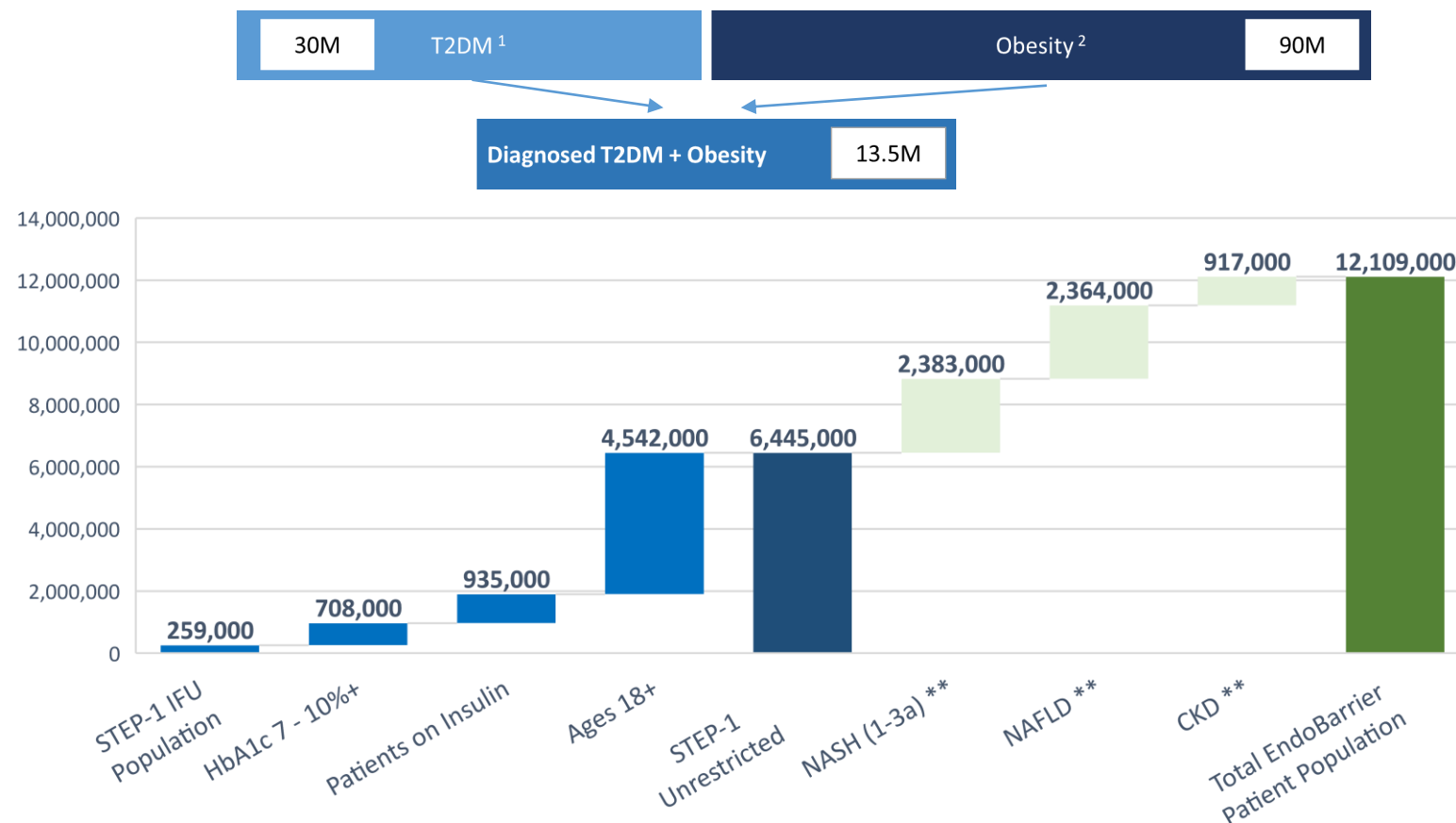
1) Avoid insulin   2) Reduce/eliminate insulin   3) Avoid gastric bypass

# Total Addressable Patient Population

## Worldwide

Worldwide Prevalence	
T2Dm Prevalence <sup>1</sup>	463,000,000
Currently controlled with Lifestyle/Medication (40%) <sup>2</sup>	(185,200,00)
<b>EndoBarrier T2DM: TAM</b>	<b>277,800,00</b>
T2DM Comorbidities	
Obesity <sup>3,4</sup>	216,850,000
NAFLD <sup>5</sup>	256,965,000
NASH <sup>5</sup>	78,710,000
CKD <sup>5</sup>	111,583,000
<b>Sub-total T2DM Comorbidities</b>	<b>664,108,000</b>
<b>WW Total TAM</b>	<b>941,908,000</b>

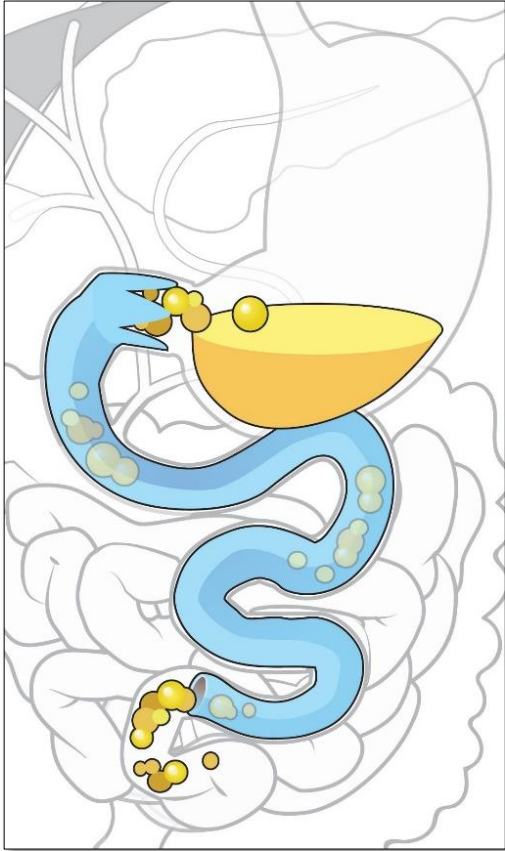
## United States



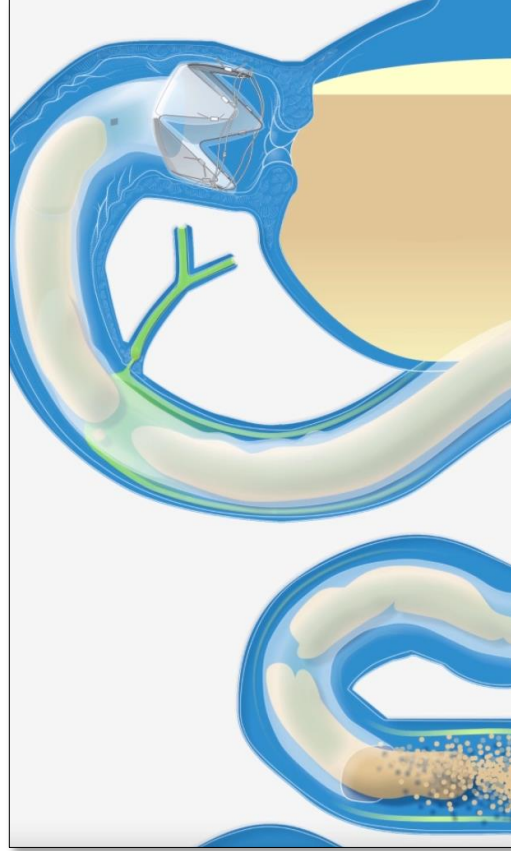
- Includes patients with T2DM & Obesity with A1c  $\geq 7\%$ , BMI  $\geq 30$  and age 18+
- \*\* Assumes same prevalence of NASH/NAFLD/CKD in both the T2DM obesity population as those without obesity, does not consider current HbA1c levels or current therapy, NAFLD excludes the population with NASH
- Sources: 1. Center for Disease Control (CDC) 2. World Health Organization (WHO) 3. CDC NHANES - 2015/2016 National Health and Nutrition Examination Survey 4. Internal Assumptions



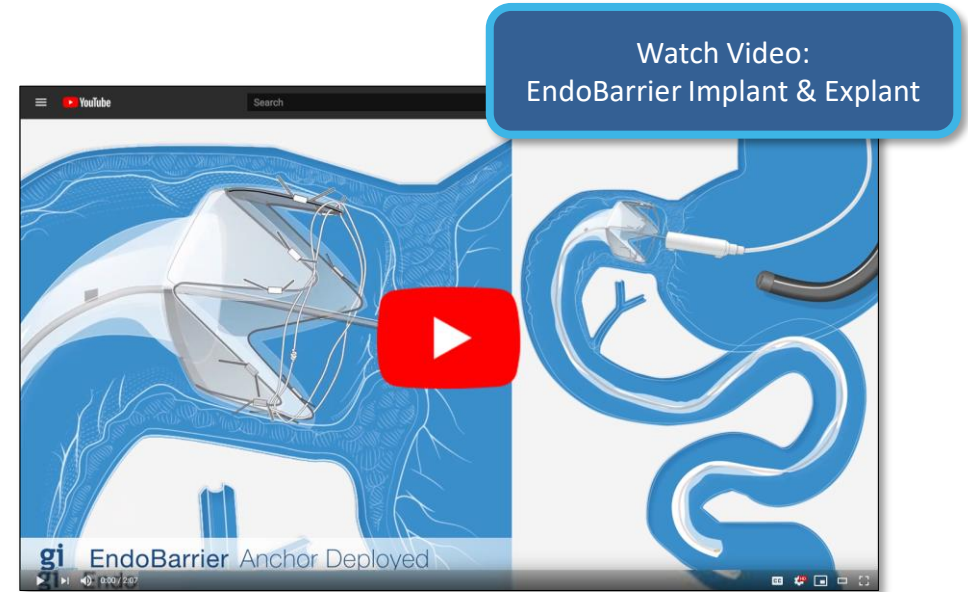
# Minimally Invasive Solution for Type 2 Diabetes



Thin, flexible EndoBarrier implant lines the proximal intestine: food bypasses duodenum + upper intestines



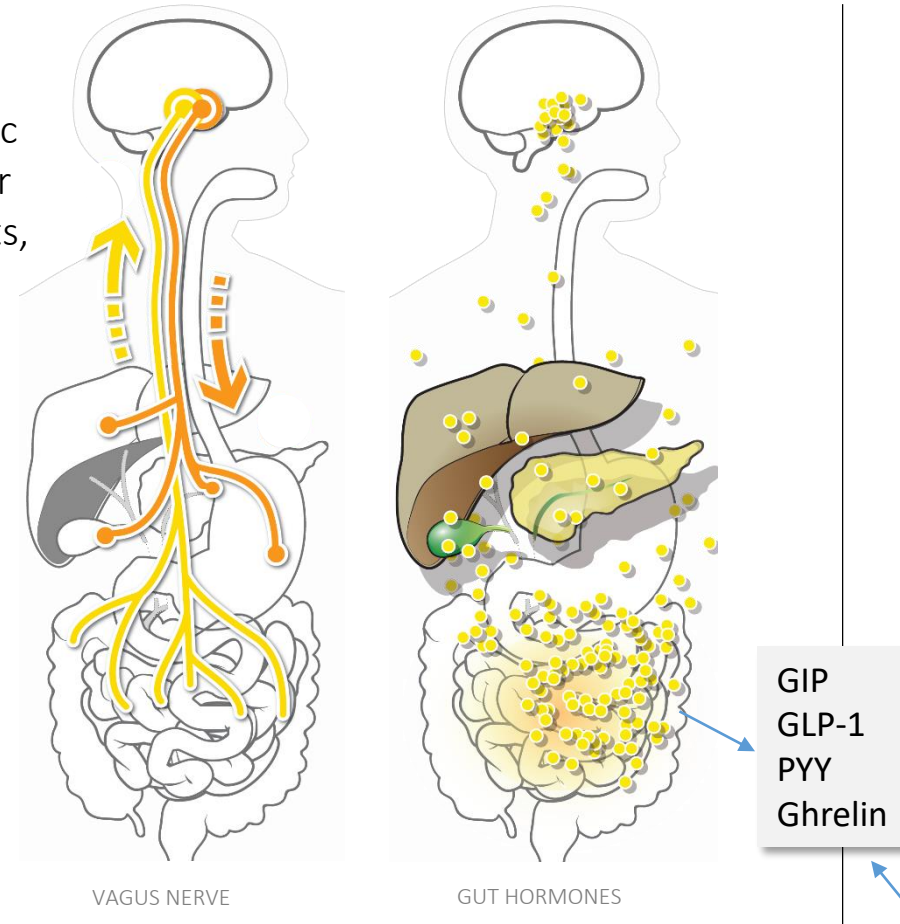
12 month implant  
Placed / removed via 20 minute Upper GI outpatient procedure



# Mechanism of Action Mimics Gastric Bypass

Similar to Roux-en-Y Gastric Bypass (RYGB), EndoBarrier harnesses metabolic effects, utilizing the body's own blood glucose control mechanisms\*:


- Gut Hormones
- Neural Circuits
- Bile Acids
- Glucose Transport




\*Mechanism of Action currently under further investigation

[Click here to read full analysis](#)

1106 Diabetes Care Volume 41, May 2018

 Check for updates

 Effect of the Duodenal-Jejunal Bypass Liner on Glycemic Control in Patients With Type 2 Diabetes With Obesity: A Meta-analysis With Secondary Analysis on Weight Loss and Hormonal Changes

Pichamol Jirapinyo,<sup>1,2</sup> Andrea V. Haas,<sup>2,3</sup> and Christopher C. Thompson<sup>1,2</sup>

Diabetes Care 2018;41:1106–1115 | <https://doi.org/10.2337/dc17-1985>

**“Conclusions: Duodenal-Jejunal Bypass Liner (DJBL) improves glycemic control and insulin resistance in T2D patients with obesity. DJBL also appears to induce significant weight loss in this population. Additionally, changes in gut hormones suggest mechanisms similar to RYGB.”**

# Demonstrated Clinical Effect on HbA1c and Weight

> 1,000 patients in recent trials / analyses:

PI	Study Title	Subjects		Type	Presented	HbA1c	Weight
		EB	Control				
Benes	The duodenal-jejunal bypass liner (EndoBarrier) for the treatment of type 2 diabetes mellitus in obese patients – efficacy and factors predicting optimal effects	45	24	RCT	DDW 2016	↓ 4.3%	EWL: 15%
Cinkajlova	Circulating lipopolysaccharide and gut permeability in obese patients with type 2 diabetes: the influence of surgical and endoscopic interventions	15	15 (gastric) 10 (ctrl)	RCT	EASD 2017	↓ 1.7%	BMI: ↓ 3.7
Guenther	Improvement in Glucose Metabolism After Bariatric Surgery: Comparison of Laparoscopic Roux-en-Y Gastric Bypass and Duodenal-Jejunal Bypass Liner	27	27 (RYGB)	RCT	DDW 2017	↓ 1.7%	BMI: ↓ 6.2
Holtmann	Improvement of Liver and Glycemic Parameters After Duodenal-Jejunal Bypass Sleeve (DJBS) Insertion	20	10	RCT	DDW 2017	n/a	↓ 11.3 kg
Jirapinyo	The effect of the duodenal-jejunal bypass liner on glycemic control in type-2 diabetic patients with obesity: a meta-analysis with secondary analysis on weight loss and hormonal changes	431	54	Meta-Analysis	DDW 2017 Diabetes Care 2018	↓ 1.3% (↓ 1.4%)	↓ 12.6kg EWL: 36.9% TWL: 18.9%
Ryder, Sen Gupta	REVISE-Diabetes Study: One Year Efficacy, Safety and Tolerability Outcomes of Endoscopic Duodenal Exclusion Using EndoBarrier® as an Adjunct to GLP-1	48	24	RCT	ADA 2017	↓ 2.1%	↓ 11.3 kg
Laubner	Comparative Efficacy & Safety of the Duodenal-jejunal Bypass Liner in Obese Patients with T2DM	111	222	Case Control	ADA 2017	↓ 1.3%	↓ 14.7kg

## ADA Diabetes Care: EndoBarrier Meta-Analysis

Endpoint	Change	# Studies	# Patients
HbA1c reduction at explant	<b>1.3%*</b> (15.5%)	14	431
Reduction v Control	<b>0.9%*</b> (10.8%)	4	123
HbA1c reduction 6 months post explant	<b>1.0%*</b> (11.9%)	2	99
Total body weight reduction	<b>12.6kg</b> (18.9%)	10	395

\* absolute %-point drop in A1Cs



# Positive OUS Patient Impact



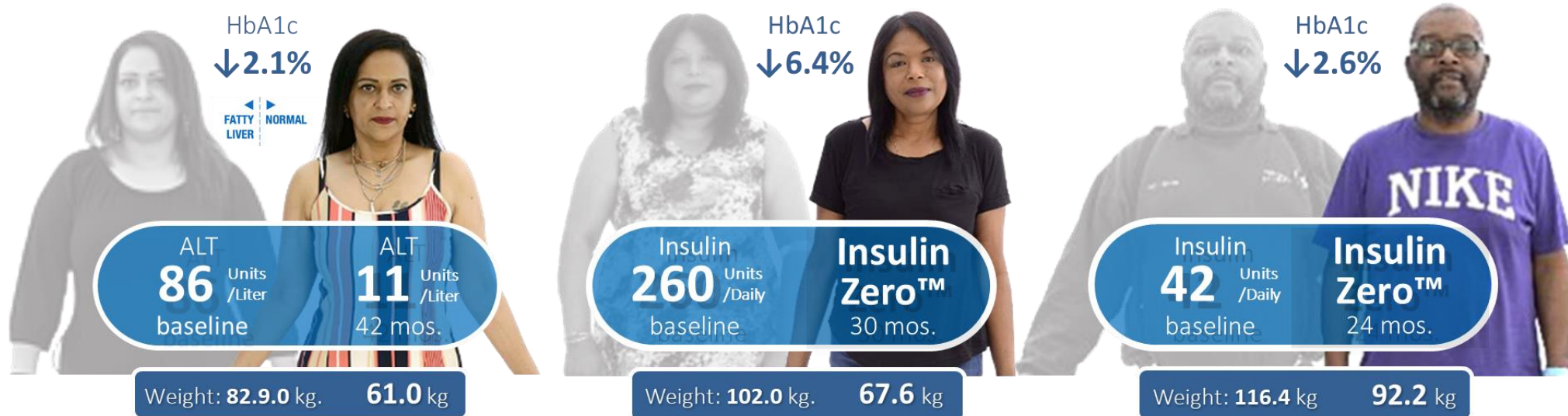
*“Patients included here are typical of our EndoBarrier treated patients, with some demonstrating additional benefits over and above weight and HbA1c.”*

– Dr. Robert Ryder, PI for EndoBarrier® Trials Sandwell and West Birmingham, UK Hospital NHS Trust

• View online: [ABCD REVISE Study](#)

▶ Watch Video:  
Patient Testimonials

**~4,000 EndoBarrier Implants in Studies & Early Commercial Experience**



# Treatment Effect: Clinical Durability

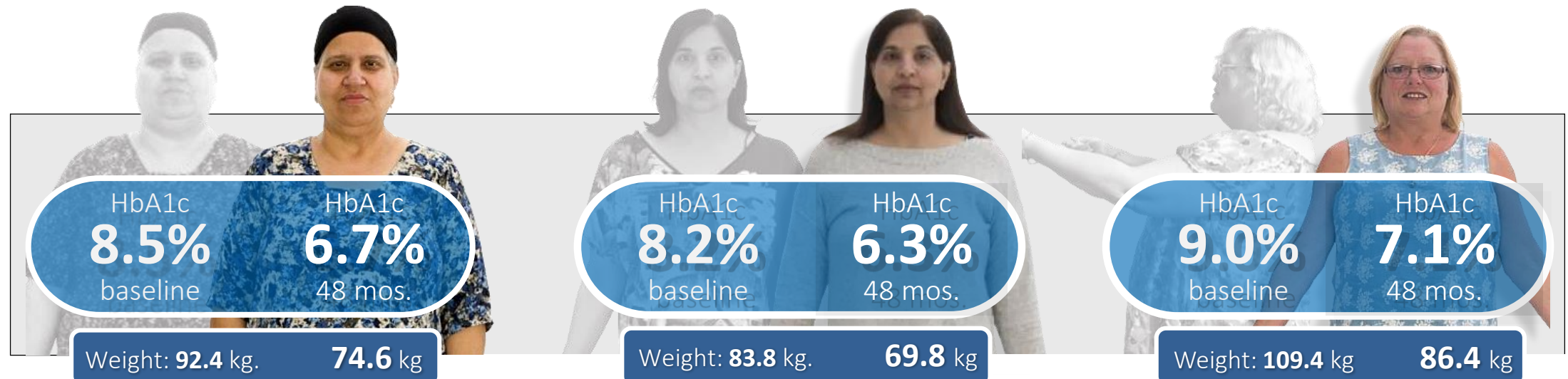
REVISE Study: Baseline to Post Removal (12 months post removal)					
Responder Level (month 12)	HbA1c Reduction (at Month 12)	Month 24: 12 months post removal			
		n	% of total	Δ HbA1c, %	Δ Weight, LB
Super	≥ 1.5 %	14	78%	-2.1%	-20
High	1.0 - 1.49 %	1	6%	-0.3%	-55
Medium	.5-.99 %	1	6%	-1.7%	-11
Low	.1- .49 %	0	0%	-	-
Non- Responder	≤ 0%	2	11%	-1.1%	-45

Subset data from REVISE RCT

~80% of patients maintained-

- 2.1% drop in HbA1c
- 20 lb. weight loss

At 2 years / 12 months post removal



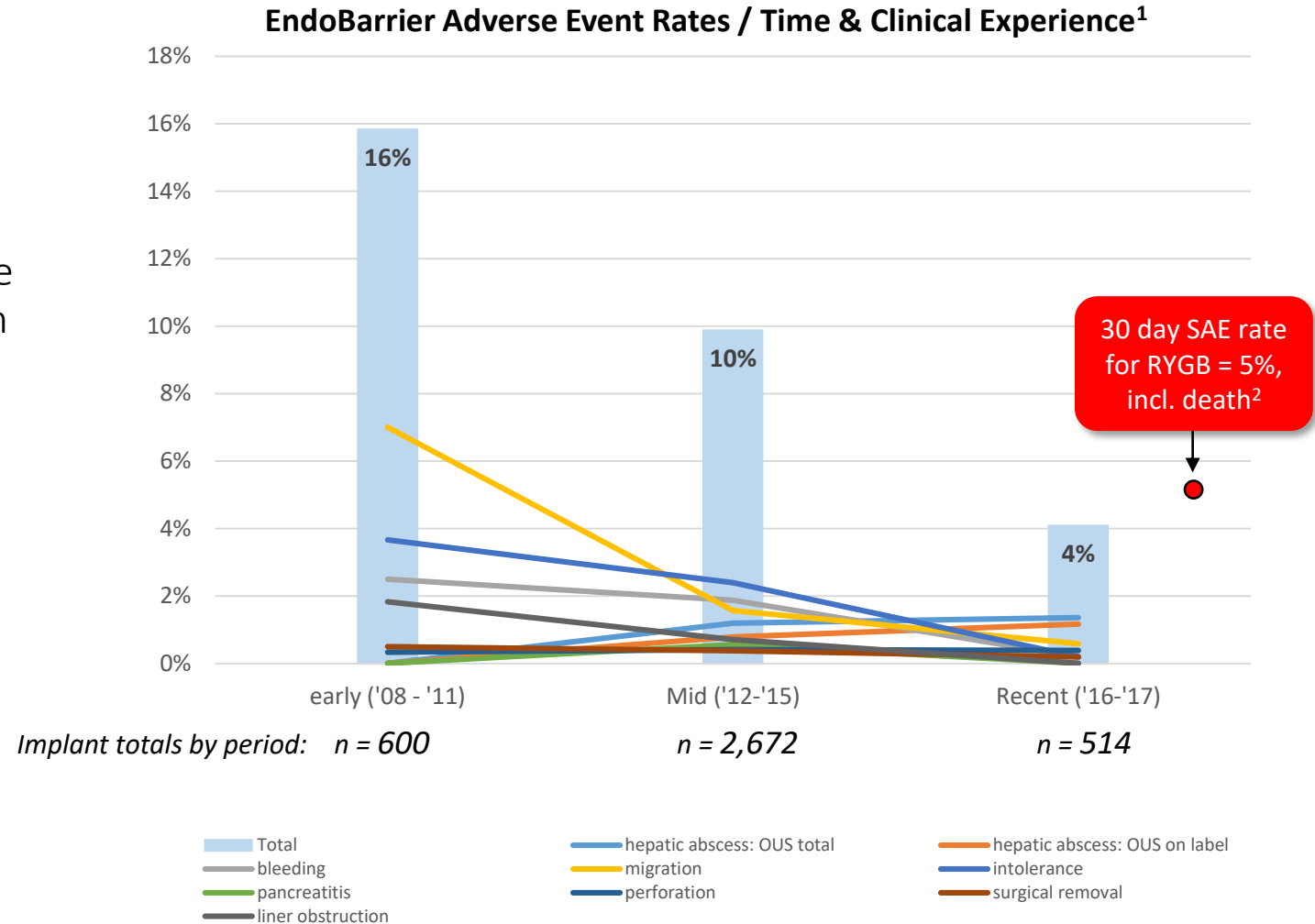
# Strong Safety Profile

- EndoBarrier adverse event rates declined significantly over time due to numerous refinements including: procedure refinement, clinician training & patient selection
- EndoBarrier risk is associated with indwell time only; no long-term sequelae or risks have been identified post removal

In August 2018, FDA approved IDE for the U.S. pivotal study



In February 2019, IRB approval received for U.S. pivotal study

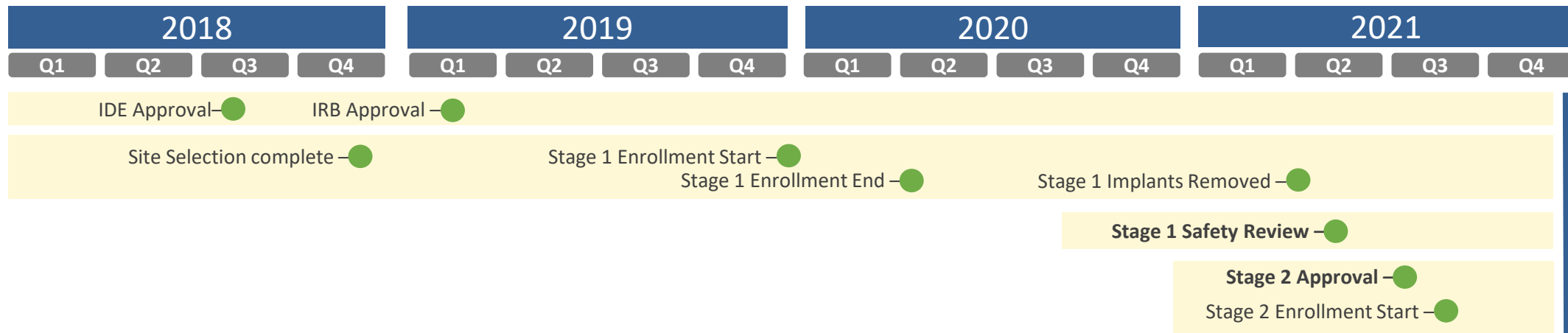


1. GI Dynamics, Inc. Internal Complaint Handling System OUS data

2. Aterbern et al, Comparative Effectiveness and Safety of Bariatric Procedures for Weight Loss: A PCORnet Cohort Study, Annals of Internal Medicine, 4 December 2018

# U.S. Pivotal Study Design & Target Timeline

U.S. Pivotal Trial:	<b>STEP-1: <u>S</u>ingle <u>T</u>herapy <u>E</u>uglycemic <u>P</u>rocedure</b>	ClinicalTrials.gov: <a href="#">link</a>
<b>Primary Endpoint</b>	Reduction of HbA1c at 12 month implant removal	
<b>Secondary Endpoints</b>	Weight, NAFLD / NASH, CV risk, CKD, Insulin avoidance (at 12 & 24 months)	
<b>Randomization</b>	3 EndoBarrier : 1 Control	
<b>Control</b>	Double-blinded sham procedure	
<b>Stages</b>	<ul style="list-style-type: none"> <li>○ Stage 1: 50 EndoBarrier / ~17 control</li> <li>○ Stage 2: 130 EndoBarrier / ~43 control (proposed)</li> </ul>	



# Apollo Sugar Clinical Trial and Partnership



**Apollo Hospitals**

**Apollo Sugar**

Largest private hospital system in India, >65m patients in 141 countries

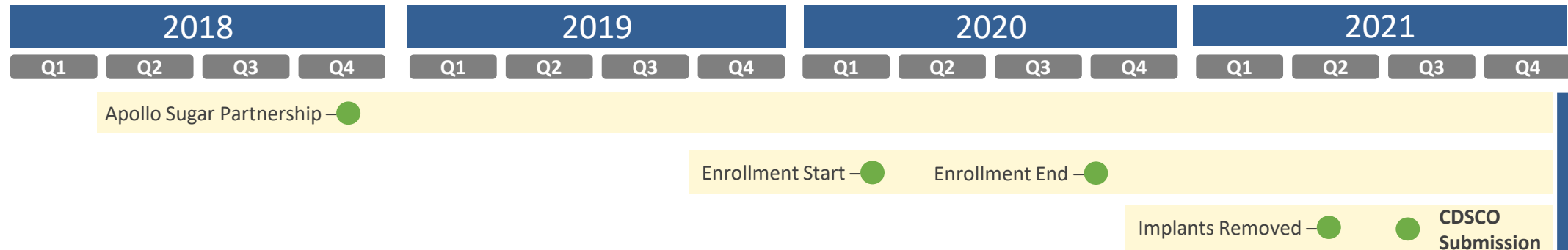
Apollo Hospitals & Sanofi partnership focused on treatment of diabetes

*“We believe EndoBarrier can provide a novel and powerful clinical tool for our clinicians, and we look forward to studying EndoBarrier in our hospitals for patients based in India and Southeast Asia.”*

– Gagan Bhalla, CEO of Apollo Sugar

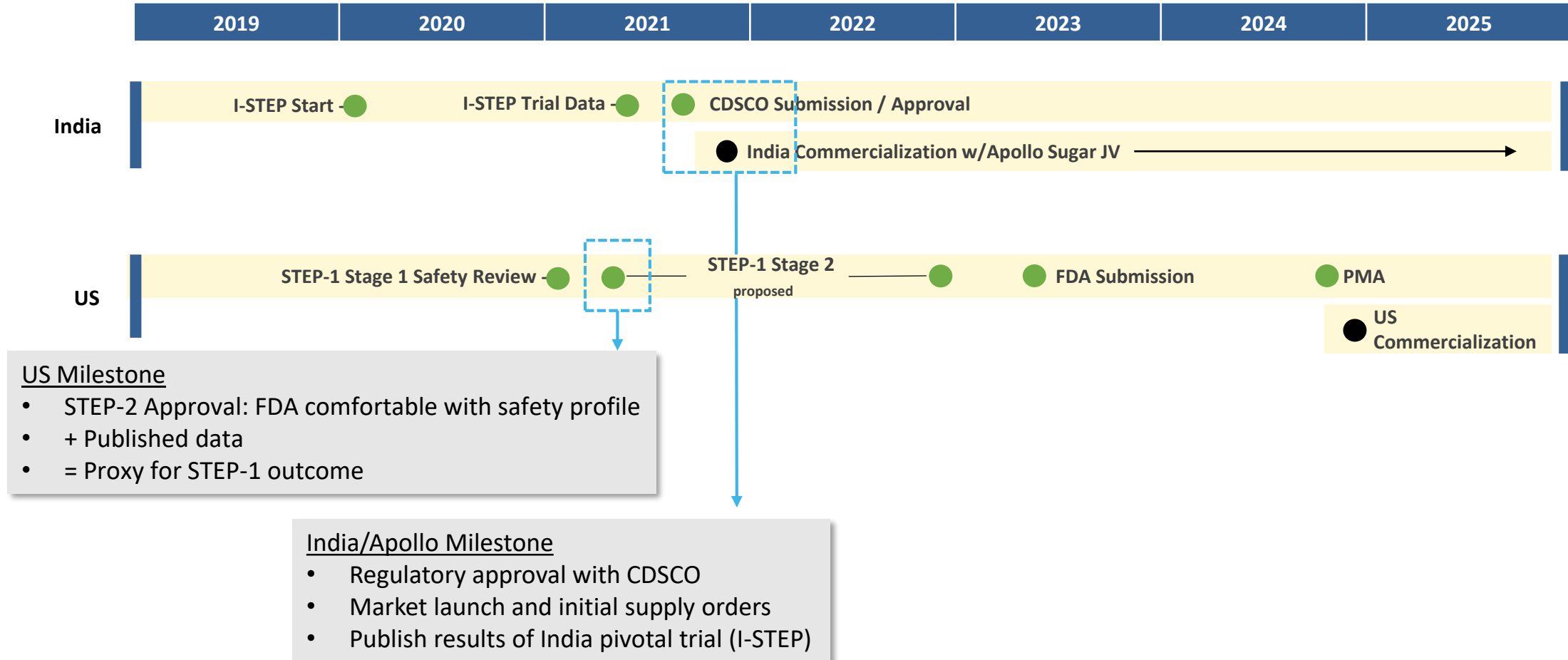
## Apollo Sugar Study in Collaboration with GI Dynamics: **I-STEP** **India - Single Therapy Euglycemic Procedure**

Primary Endpoint	Reduction in HbA1c at 12 month implant removal
Secondary Endpoints	Weight, NAFLD / NASH, CV risk, Insulin avoidance
Study Size	100 at 5 leading Apollo Sugar clinical sites
Randomization	3 EndoBarrier : 1 Control
GI Dynamics Cost	~\$1-1.5 m over life of study





# Significant milestones in < 2 years



# Corporate Value Creation

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## Financing

- Seeking \$20m
  - Continue STEP-1 , I-STEP clinical trials
  - Continue evaluating NASDAQ listing options
- 

## STEP-1 Clinical Trial US Pivotal RCT

- Stage 1: 50 EndoBarrier / ~17 Control (3:1)
  - *Currently enrolling*
  - Target enrollment completion: Q1 2020
- 

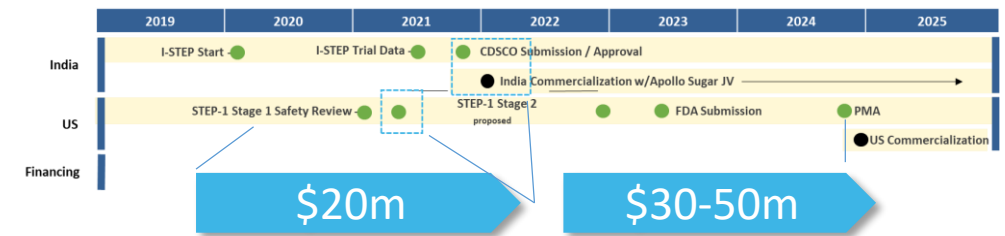
## I-STEP Clinical Trial India Pivotal RCT with Apollo Sugar

- 100: 75 EndoBarrier / 25 Control (3:1)
  - Site Ethics Committees, CDSCO *reviews underway*
  - Target enrollment: Q1 – Q3 2020
- 

## Additional

- Intellectual Property: continuing to develop IP and add to IP portfolio
- New feature development, COGS reduction

# Financing Assumptions / Use of Proceeds



USD, \$m / rounded		proforma							
	Stage 1	Stage 2	2020	2021	2022	2023	2024	Total	
Revenue			-	-	5	13	25	43	
Step 1	5	11	3	6	5	2	-	16	
I-Step	0.4	0.1	0.3	0.2	-	-	-	1	
Clinical Department	5	12	3	3	3	4	4	17	
<b>Clinical Total</b>	<b>10</b>	<b>23</b>	<b>6</b>	<b>9</b>	<b>8</b>	<b>6</b>	<b>4</b>	<b>34</b>	
Other (Mfg, Quality, G&A)	11	57	8	7	12	16	24	67	
<b>Total Expense</b>	<b>22</b>	<b>80</b>	<b>14</b>	<b>16</b>	<b>20</b>	<b>22</b>	<b>28</b>	<b>101</b>	
<b>Net Spend</b>			<b>(14)</b>	<b>(16)</b>	<b>(15)</b>	<b>(9)</b>	<b>(3)</b>	<b>(58)</b>	
<b>Cumulative Net Spend</b>			<b>(14)</b>	<b>(31)</b>	<b>(46)</b>	<b>(55)</b>	<b>(58)</b>		

## Assumptions

1. INDIA / I-STEP / Apollo Sugar:
2. US / STEP -1
3. COGS Reduction
4. CE Mark / EU Revenue
5. MODEL
6. MODEL / US Launch

India revenues / JV opportunity: potential near-term impact  
 Will work to improve timing of trial with FDA  
 Production costs from \$2,100/unit to \$550 with DFM  
 CE Mark: 2020, reimbursement/revenue not actively pursued in this model  
 Model is cash basis, not expenses/P&L basis  
 No U.S. market priming is included in model in advance of U.S. sales

# Scientific Advisory Board

## Endocrinology



David Cummings, MD  
Seattle, WA, USA



Judith Korner, MD  
New York, NY USA



Carel le Roux, MD, PhD  
Dublin, Ireland

## Gastroenterology



Manoel Galvao Neto, MD  
Sao Paulo, Brazil



Thomas Rösch, MD  
Hamburg, Germany



Gerald Holtmann, MD  
Brisbane, Australia

## Renal Disorders



Allon Friedman, MD  
Indianapolis, IN USA

## Infectious Disease



Steven Opal, MD  
Providence, RI USA

## Metabolic Surgery



Ricardo Cohen, MD  
Sao Paulo, Brazil



Jan Willem Greve, MD, PhD  
Heerlen, Netherlands



Francesco Rubino, MD  
London, UK



Philip Schauer, MD  
Cleveland, OH USA

# Experienced Leadership – Healthcare, Operations, Financing/M&A

## Leadership Team



Over 90 years experience in medical devices

- Janel Shields** – Manager Marketing & I.R.
- Steve Linhares** – VP of Clinical & Regulatory
- Scott Schorer** – President & CEO
- Charley Carter** – Chief Financial Officer
- Paul Pelletier** – Director of Quality

## Executive



**Scott Schorer**  
President & CEO

**20+ years** as executive in medical device, biologics, healthcare IT companies

Significant early-stage, new product experience

Raised >\$120m through private equity, public equity and debt financings

Systagenix Wound Management; IST; CentriMed/Global Healthcare Exchange (GHX)

US Army, Airborne Ranger

## Non Executive Directors



**Dan Moore**  
Chairman

**30+ years** in medical device companies

**Boston Scientific:** 18 years in domestic and international sales, operations and executive management in global medical device manufacturing. Served as CEO of **Cyberonics, Inc.**

NED: LivaNova (NASDAQ: LIVN), ViewRay (NASDAQ: VRAY), Epilepsy Foundation of America, BioHouston, Weldon School of Bio-engineering, BrainScope



**Juliet Thompson**

**20+ years** experience healthcare banking

**Nomura Code:** Founder, Head Corporate Finance: executed **>150 life sciences transactions, including 40 IPOs raising more than €4bn**

NED: Nexstim (NXTMH.HE), Novacyt (NYCT.L), Vectura PLC (VEC.L)



**Oern Stuge, MD**

**Physician with 30+ years** in medical device, health care and life sciences companies

**Medtronic:** 12 years in multiple senior management roles

NED: Lumenis, Mainstay Medical (MSTY.PA), Balt Extrusion, Pulmonx, Phagenesis, OrthoD Ltd, EchoSens SA



**Tim Barberich**

**40+ years** in medical device and pharmaceutical companies

**Sepracor: Founder & CEO** (NASDAQ: SEPR)

**Sold to Dainippon for \$2.6Bn**

NED: BioNevia, Verastem (NASDAQ: VSTM), TScan Therapeutics, Frequency Therapeutics

# Summary

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- Large and growing market with significant unmet need
- Unique implant with a well characterized Benefit : Risk Profile with
- Significant clinician support
- Turnaround efforts have largely been completed with much success
- New leadership has shown consistent execution while maintaining lean expenditure
- Company history and current pricing provide significant upside opportunity

## **Focused clinical operations drive significant shareholder value**

- U.S. pivotal trial- first of its kind: **STEP-1**
- JV with Apollo Sugar in India- significant opportunity: **I-STEP**

***GI Dynamics is fully committed to treating patients diagnosed with type 2 diabetes/obesity and bringing EndoBarrier to market while maximizing shareholder value***

*Thank you*