



GI Dynamics, Inc.

Quarter 3 2016 Shareholder Update

BOSTON, Massachusetts, United States, and SYDNEY, Australia – 10 November 2016 AEDT.

GI Dynamics, Inc. (**ASX: GID**) (the **Company**), a medical technology company that has developed an innovative device to improve outcomes for patients battling type 2 diabetes and obesity, today provided an update to its shareholders for the quarter ending 30 September 2016 (the **Quarter**).

About GI Dynamics

GI Dynamics, Inc. (ASX: GID) is the developer of EndoBarrier®, the first endoscopically delivered device approved for the treatment of type 2 diabetes and obesity. EndoBarrier is approved and commercially available in multiple countries outside the U.S. EndoBarrier is not approved for sale in the U.S. and is limited by federal law to investigational use only in the United States. Founded in 2003, GI Dynamics is headquartered in Boston, Massachusetts. For more information, please visit www.gidynamics.com.

Forward-Looking Statements

This announcement contains forward-looking statements concerning: our development and commercialization plans; our potential revenues and revenue growth, costs, excess inventory, profitability and financial performance; our ability to obtain reimbursement for our products; our clinical trials, and associated regulatory submissions and approvals; the number and location of commercial centers offering the EndoBarrier; and our intellectual property position. These forward-looking statements are based on the current estimates and expectations of future events by the management of GI Dynamics, Inc. as of the date of this announcement and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those indicated in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: risks associated with the consequences of terminating the ENDO Trial and the possibility that future clinical trials will not be successful or confirm earlier results; risks associated with obtaining funding from third parties; risks relating to 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, and the timing and extent of third-party reimbursement; risks associated with commercial product sales, including product performance; competition; risks related to market acceptance of products; intellectual property risks; risks related to excess inventory; risks related to assumptions regarding the size of the available market, 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, you 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, future events or otherwise, unless required by law.

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GI Dynamics, Inc., is a corporation incorporated in Delaware, USA, whose stockholders have limited liability. ARBN 151 239 388

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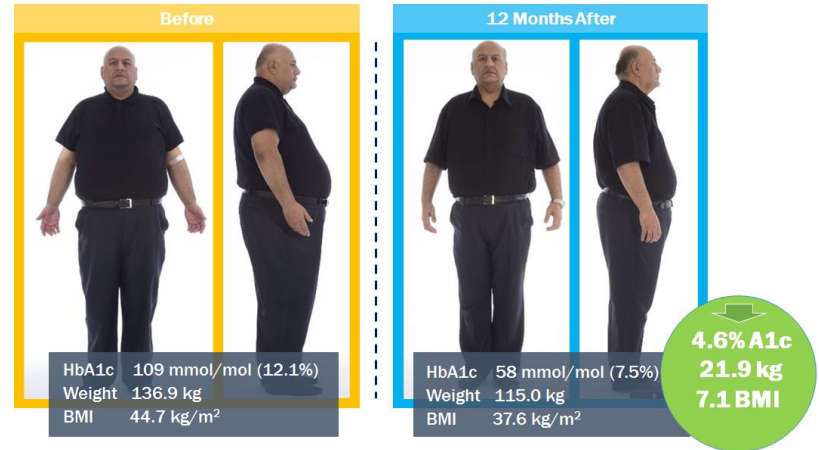
GI Dynamics, Inc.

(ASX.GID)

*Pioneering treatment
for type 2 diabetes /obesity
without invasive surgery*

Q3 2016
Shareholder Update

Focused on the Patient



"You can get another person in there"



Currency References

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

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EndoBarrier® is not available for sale in the United States (OUS patients in data are disclosed).

Corporate Priorities- from Q2 16

1

Modify Cost Structure. We will implement a leaner, more efficient cost structure by cutting expenses to extend our cash runway.

- **Completed; will always be ongoing**
- **Extended cash runway by ~12 months**

2

Rebuild Team. As CEO, I will appoint a new chief financial officer and chief compliance officer (responsible for clinical, regulatory, and quality), in addition to adding other experienced team members.

Completed; will assess the need for new hires moving forward

3

Develop Clinical Data and Core Science. We will continue to support investigator-initiated studies around the world in addition to our internal analysis of the safety and efficacy of EndoBarrier therapy.

**Ongoing, completed significant research
Full review of safety profile**

4

Focus Revenue Efforts. We will focus on strategic commercial centers outside the United States.

Working towards reimbursement, supporting clinical studies, positioning for future revenue

5

Improve Regulatory Relationships. We will collaborate with the FDA to review lessons learned as we design our next EndoBarrier therapy trial, engage with our European Notified Body and the TGA in Australia to refine our post-market surveillance.

- **Multiple legacy issues addressed**
- **TGA cancellation**
- **Focused on new FDA study design within current financing**

Q3 marked continued progress toward achieving key goals in 2016:

- Continued reduction in operating expenses and cash burn, resulting in a much healthier balance sheet as we head into 2017.
- Current cash runway extends through Q3 2017, giving the company ample time and space to focus on clinical and regulatory priorities.
- Continuing to clean up and resolve legacy issues / restructure the company
- Recently announced positive data from the EndoBarrier German registry demonstrate improved outcomes in both A1C and weight reduction and reinforce EndoBarrier safety profile
- FDA communications initiated

3Q 2016 Results

	Three Months Ended September 30,		Nine Months Ended September 30,	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Revenue	\$ 136	\$ 175	\$ 477	\$ 1,101
Cost of Revenue	<u>138</u>	<u>918</u>	<u>1,128</u>	<u>3,816</u>
Gross loss	(2)	(743)	(651)	(2,715)
Operating expenses				
Research and development	962	3,865	2,993	14,142
Sales and marketing	479	1,270	1,753	4,412
General and administrative	<u>1,321</u>	<u>2,027</u>	<u>4,687</u>	<u>6,758</u>
Total operating expenses	<u>2,762</u>	<u>7,162</u>	<u>9,433</u>	<u>25,312</u>
Other income / (expense)	18	(158)	31	(579)
Tax expense	<u>(8)</u>	<u>(26)</u>	<u>(29)</u>	<u>(66)</u>
Net loss	<u>\$ (2,754)</u>	<u>\$ (8,089)</u>	<u>\$ (10,082)</u>	<u>\$ (28,672)</u>

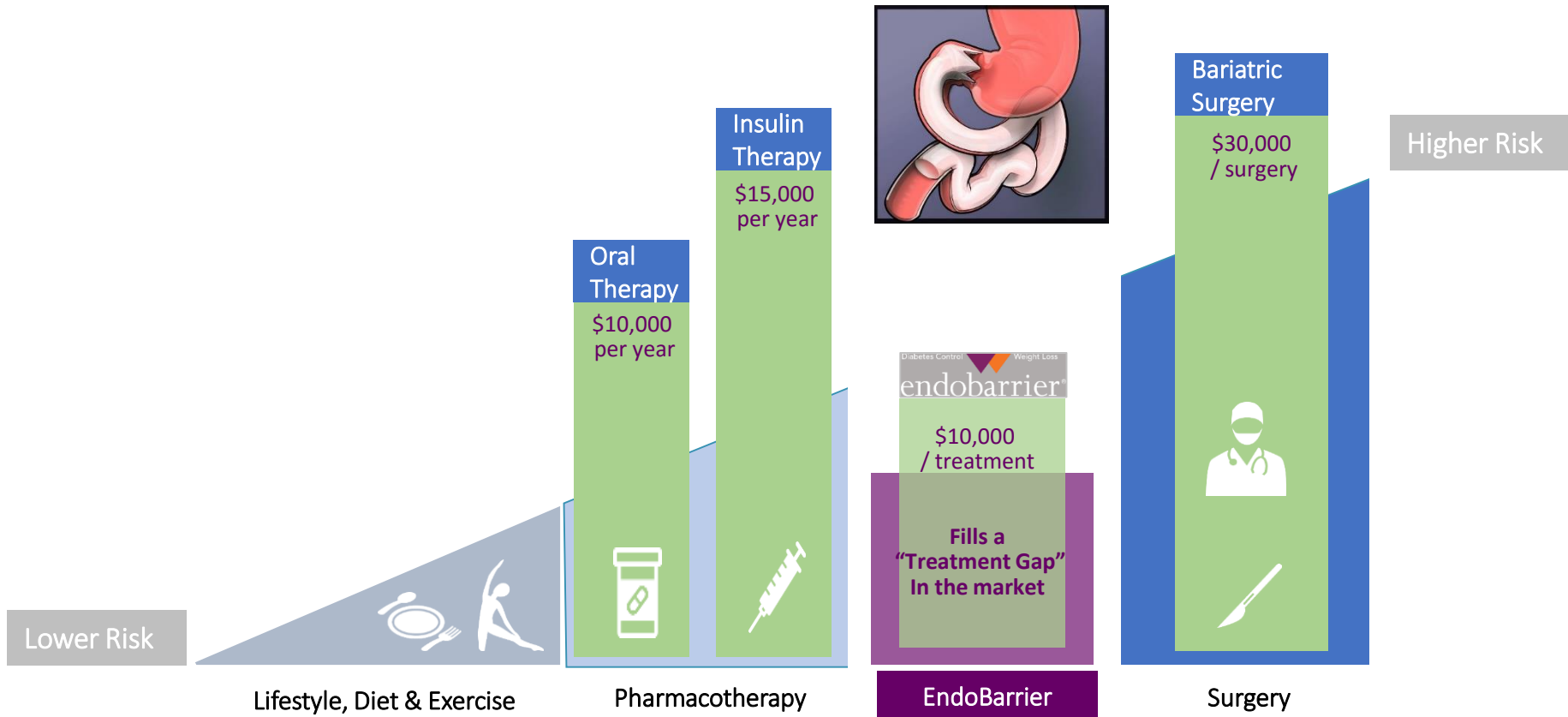
- Expected reductions in revenues in the comparative periods.
- Significant reductions in operating expenses – 60+% in both three and nine month periods.
 - Primarily due to conclusion of ENDO trial, significant reduction in headcount and lower professional services costs for the comparative periods.

Rolling Quarterly Results

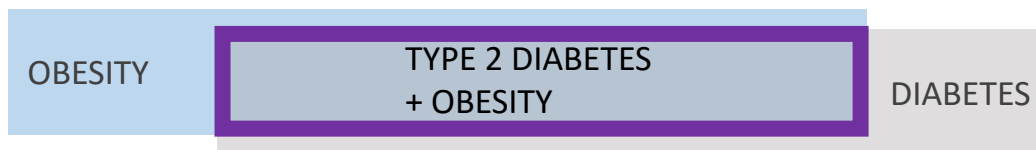
	<u>SEP '15</u>	<u>DEC '15</u>	<u>MAR '16</u>	<u>JUN '16</u>	<u>SEP '16</u>
Net Revenue	175	214	209	132	137
Operating Expenses	7,162	4,786	3,321	3,350	2,762
Net Loss	(8,088)	(6,489)	(3,439)	(3,890)	(2,754)
Consolidated Cash Balance	24,439	19,590	15,632	12,254	9,662

- Q3 Non-recurring costs: \$340k
 - employee departures (\$220k)
 - write-off of remaining base rent at 25 Hartwell (\$111k)
- Cash sufficient to carry operations through Q3 2017 based on current and expected future expense reductions.
- Reducing cash burn further from Q2 avg. of \$1 million per month.

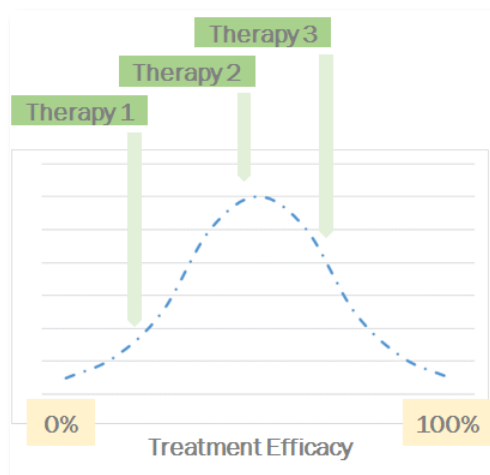
Simplified Treatment Options



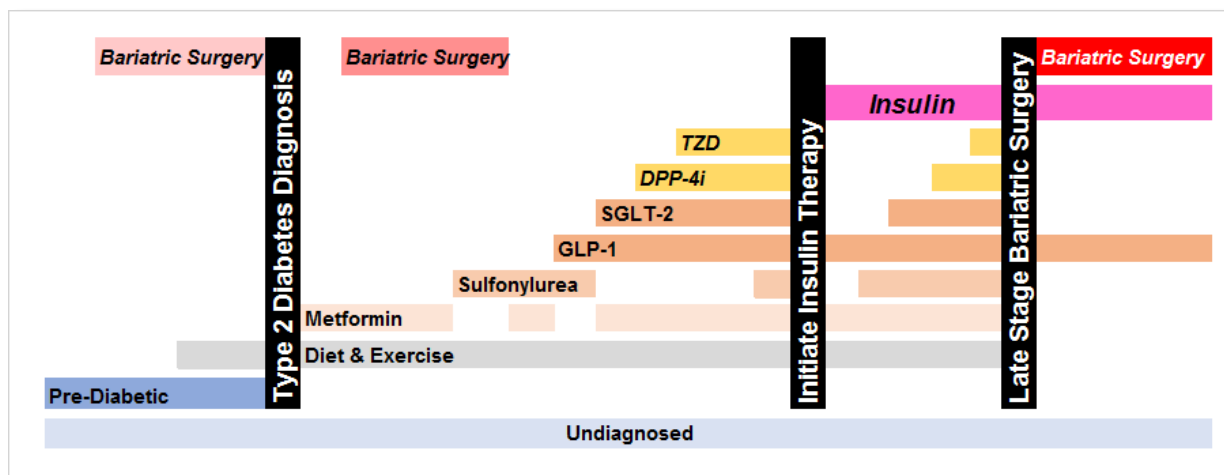
Progression of Type 2 Diabetes & Obesity



Combination Therapy Principle



Type 2 Diabetes Treatment Options



1

EndoBarrier Target
Avoid Insulin




2

INSULIN 0™

3

Prep for Bariatric
Surgery

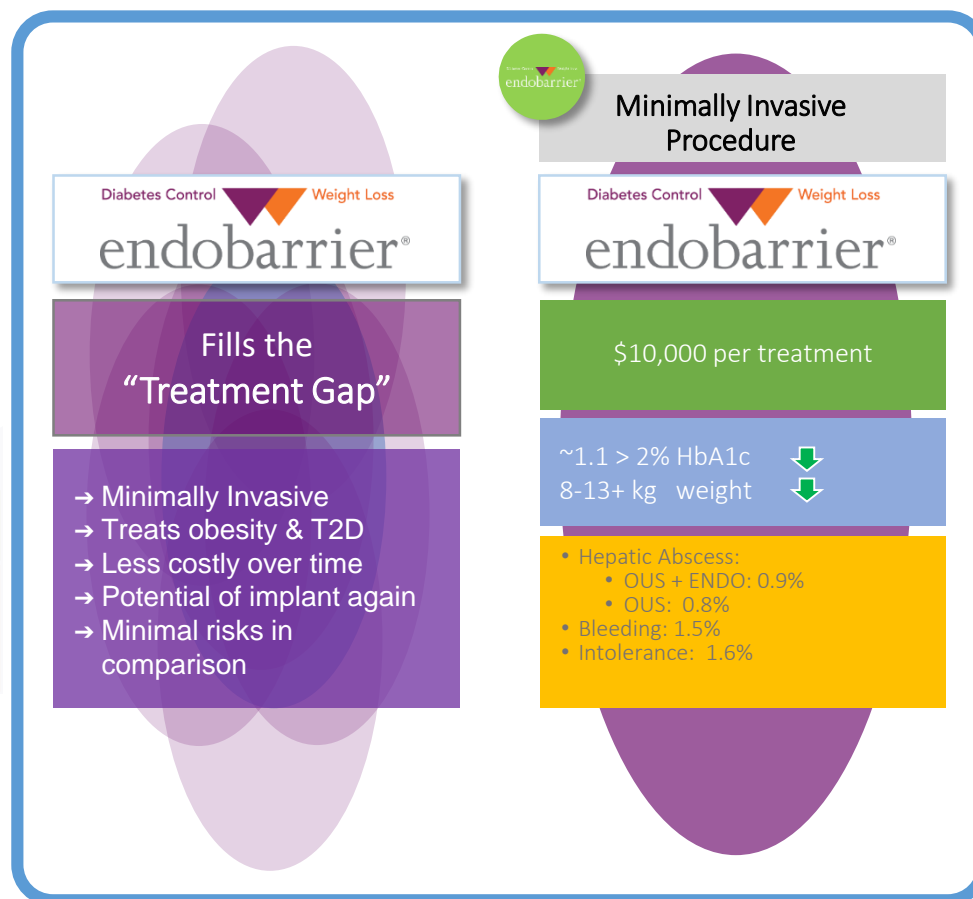
Type 2 Diabetes Treatment Options

	 Diet & Exercise	 Pharmacotherapy	 Open Surgery
Type	Running Shoes / Fitbit Weight Watchers	GLP-1 Insulin	<ul style="list-style-type: none"> • RYGB: Roux-en-Y • Sleeve Gastrectomy • LAGB: Gastric Banding
Cost	~\$1k Annual	\$8k - \$15k Annual	\$30k One-time
Efficacy	Limited ENDO Sham control: • 0.4% HbA1c ↓ • 2.4kg ↓	<div>1-1.5% HbA1c ↓ Weight Loss</div> <div>HbA1c ↓ + 1.5 Kg ↑</div>	HbA1c ↓ Weight ↓
Safety	n/a	<p>Mortality "A 19% increase in all cause mortality and a 43% increase in cardiovascular mortality cannot be excluded."</p> <ul style="list-style-type: none"> • Cardiovascular • Hypertension • Dyslipidemia • Acute/hemorrhagic necrotizing • Pancreatitis • C-cell Thyroid cancer • Acute hypoglycemia • Renal impairment • Edema/Heart failure • Genitourinary Infections 	<p>Mortality: .1 - .4%</p> <ul style="list-style-type: none"> • Perforation • Bleeding • Erosion • Intra-abdominal abscess • Port-site complication • Dehiscence / Leakage

Unaddressed
Clinical/Medical
Need
"TREATMENT GAP"

Type 2 Diabetes Treatment Options

Type	Diet & Exercise	Pharmacotherapy	
	Running Shoes / Fitbit Weight Watchers	GLP-1	Insulin
Cost	~\$1k Annual	\$8k - \$15k Annual	
Efficacy	Limited ENDO Sham control: • 0.4% HbA1c ↓ • 2.4kg ↓	1-1.5% HbA1c ↓ Weight Loss	HbA1c ↓ + 1.5 Kg ↑
Safety	n/a	Mortality: "A 19% increase in all cause mortality and a 43% increase in cardiovascular mortality cannot be excluded." • Cardiovascular • Hypertension • Dyslipidemia • Acute/hemorrhagic necrotizing • Pancreatitis • Gallbladder cancer • Acute hypoglycemia • Renal impairment • Edema/Heart failure • Genitourinary Infections	



EndoBarrier Treatment Effect

Before



HbA1c	128 mmol/mol (13.9%)
Weight	102 kg
BMI	39.3 kg/m ² (Obese BMI)
Insulin	260 units

12 Months After



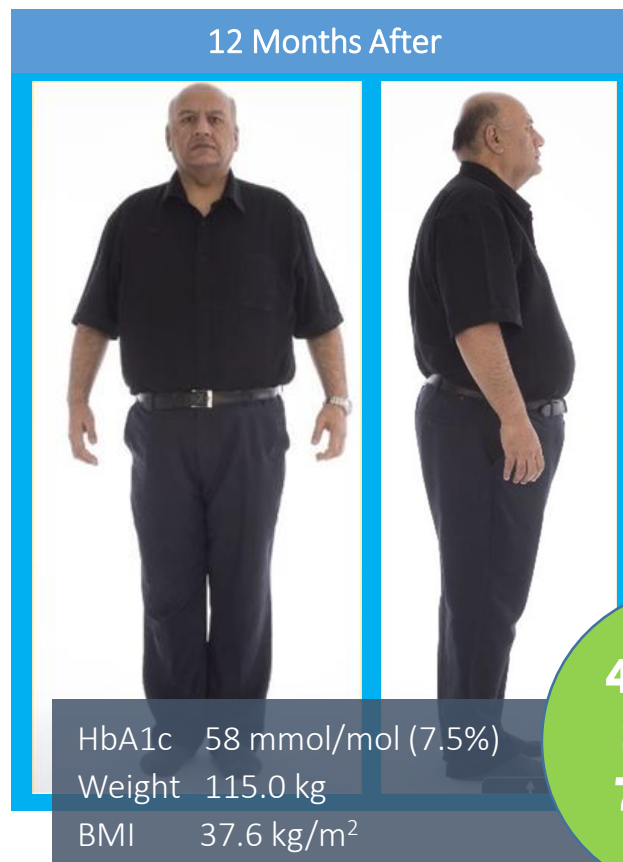
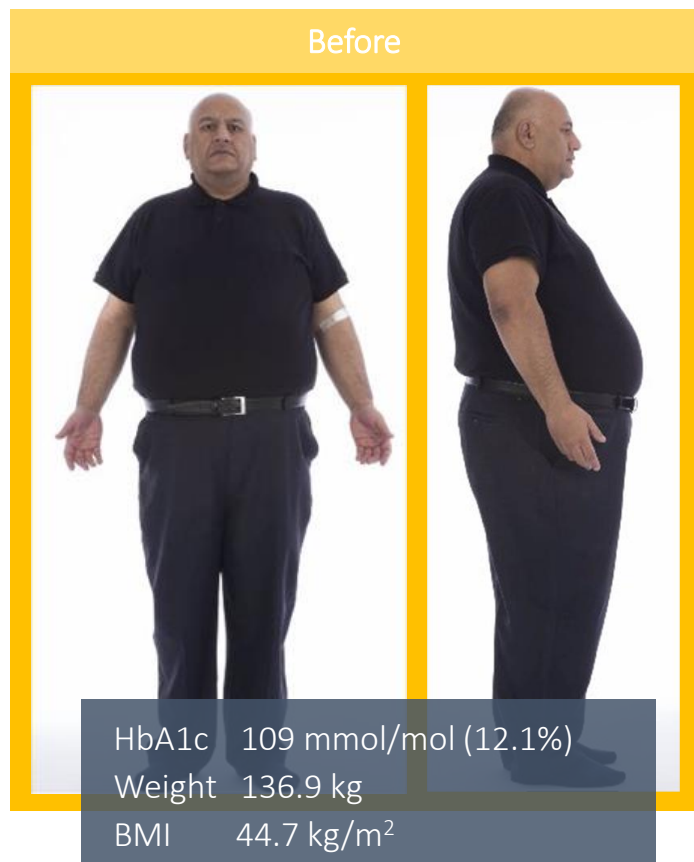
HbA1c	49 mmol/mol (6.6%)
Weight	64.2 kg
BMI	24.46 kg/m ²
Insulin	0 units

Cumulative Results

HbA1c Loss:	7.4	%
Weight Loss:	37.8	kg
Daily Insulin:	-260	units

7.3% A1c
37.8 kg
Normal BMI
No Insulin needed

EndoBarrier Treatment Effect



Cumulative Results

HbA1c Loss:	11.9	%
Weight Loss:	59.7	kg
Daily Insulin:	-260	units

↓
4.6% A1c
21.9 kg
7.1 BMI

EndoBarrier Treatment Effect

Before



HbA1c	77 mmol/mol (9.2%)
Weight	105.6 kg
BMI	35.3 kg/m ²
Insulin	100 units

12 Months After



HbA1c	40 mmol/mol (5.8%)
Weight	80.0 kg
BMI	26.7 kg/m ²
Insulin	0 units


Cumulative Results

HbA1c Loss:	15.3	%
Weight Loss:	85.3	kg
Daily Insulin:	-360	units

3.4% A1c
25.6 kg
8.6 BMI


EndoBarrier Treatment Effect

Before



HbA1c 61 mmol/mol (7.7%)
Weight 86.6 kg
BMI 35.1 kg/m²
Obstructive Sleep Apnea / CPAP

12 Months After



HbA1c 43 mmol/mol (6.1%)
Weight 65.6 kg
BMI 26.2 kg/m²
No sleep Apnea, NO CPAP

Cumulative Results

HbA1c Loss:	16.9	%
Weight Loss:	106.3	kg
Daily Insulin:	-360	units

↓
1.6% A1c
21.0 kg
8.9 BMI
No CPAP

EndoBarrier Treatment Effect

Before



HbA1c	76 mmol/mol (9.1%)
Weight	116.4 kg
BMI	38.0 kg/m ²
Insulin	42 units / Ambulatory O2

12 Months After



HbA1c	49 mmol/mol (6.6%)
Weight	88 kg
BMI	28.8 kg/m ²
Insulin	0 units / No O2

Cumulative Results

HbA1c Loss:	19.4	%
Weight Loss:	134.7	kg
Daily Insulin:	-402	units

↓
2.5% A1c
28.4 kg
9.2 BMI

EndoBarrier Treatment Effect

Before

12 Months After



HbA1c	70 mmol/mol (8.6%)
Weight	82.9 kg
BMI	33.6 kg/m ²



HbA1c	51 mmol/mol (6.8%)
Weight	62.2 kg
BMI	24.7 kg/m ²

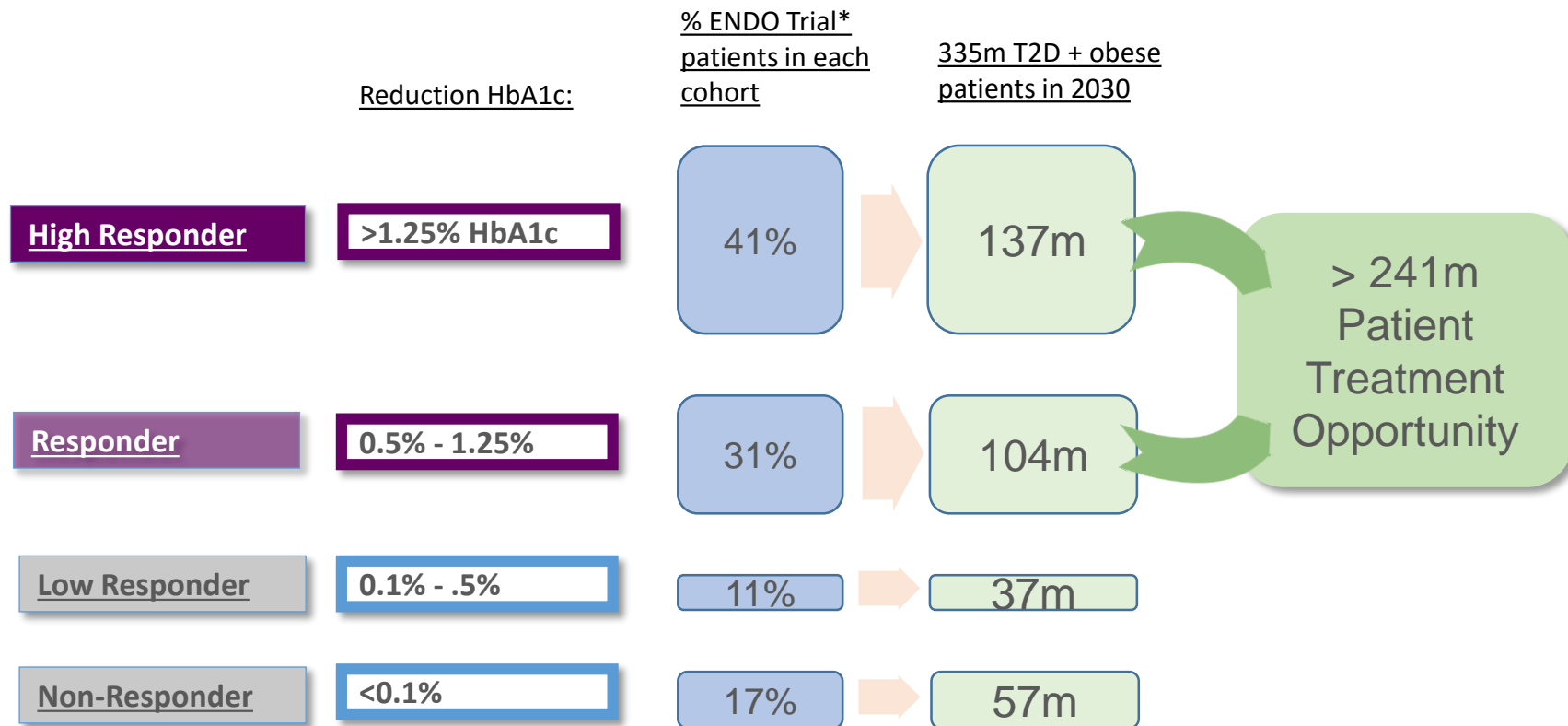
Cumulative Results

HbA1c Loss: 21.2 %

Weight Loss: 155.4 kg

Daily Insulin: -402 units

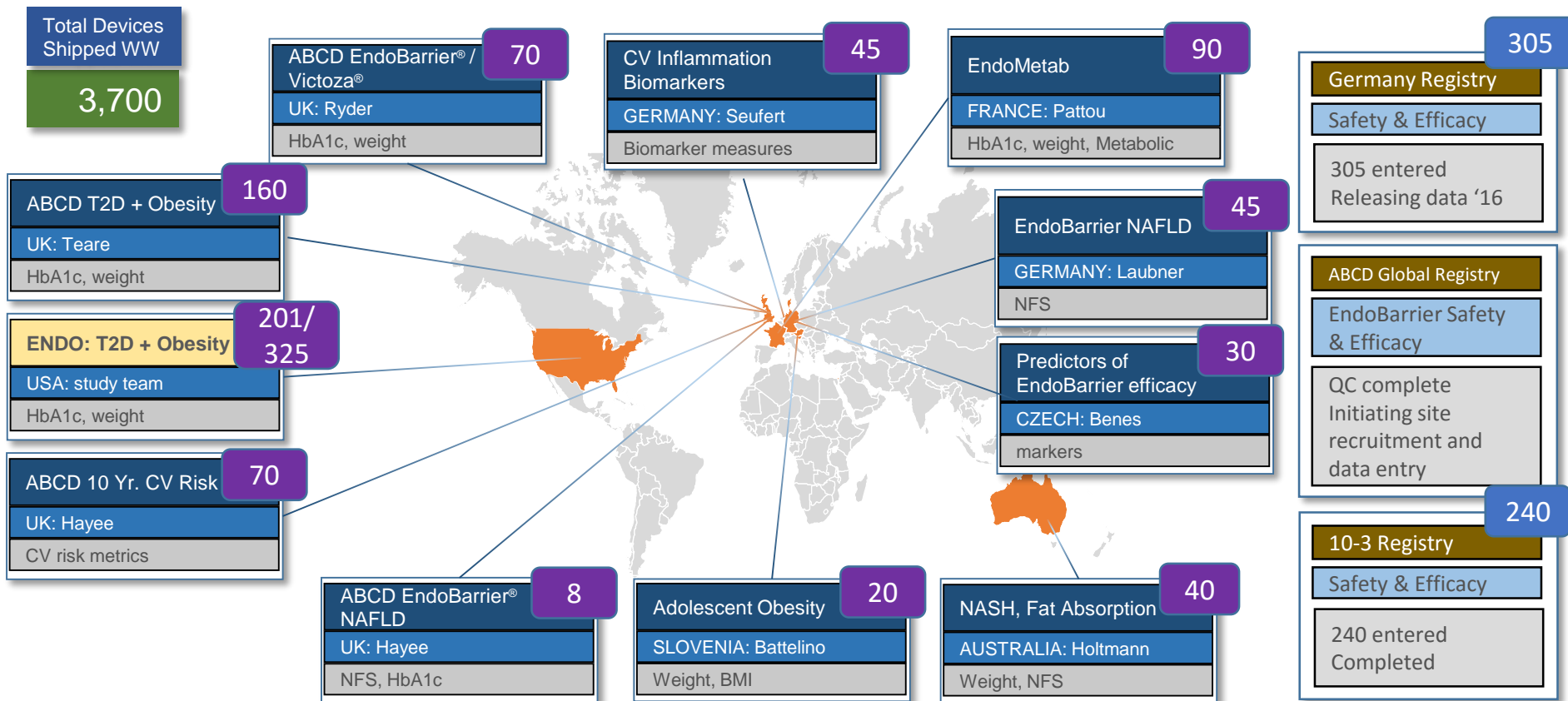
↓
1.8% A1c
20.7 kg
Normal BMI



- >40% of ENDO patients achieved very high HbA1c reduction
- < 20% of ENDO patients are non-responders

*ENDO Trial
("A Randomized, Multicenter, Pivotal Efficacy and Safety Study Comparing the EndoBarrier® Gastrointestinal Liner vs. Sham for Glycemic Improvement in Inadequately-Controlled Obese Type 2 Diabetic Subjects on Oral Anti-Diabetes Agents," conducted under FDA IDE G090144 between January 2013 and February 2016)

Comprehensive Clinical Evidence Worldwide



German EndoBarrier Registry Data Announced at EASD

- 243 patients included >300 now enrolled
- 12 month data

Type 2 Diabetes

- **HbA1c** **1.3% reduction** on absolute mean basis **8.5% → 7.2%**
- **Insulin** **dropped 42%** on mean basis
- **Antidiabetic medication** **dropped in 78%** of patients

Obesity

- **Weight Loss** **15 kg mean**
- **Excess Weight Loss** **29% of excess weight**

Safety

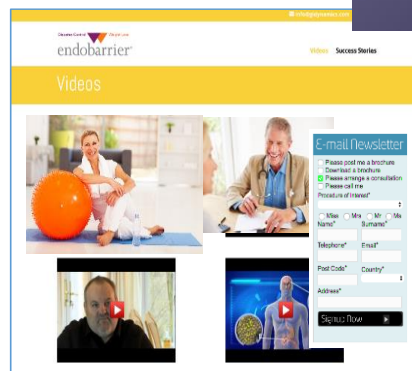
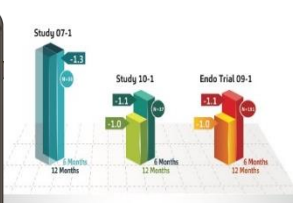
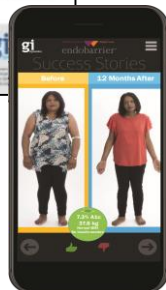
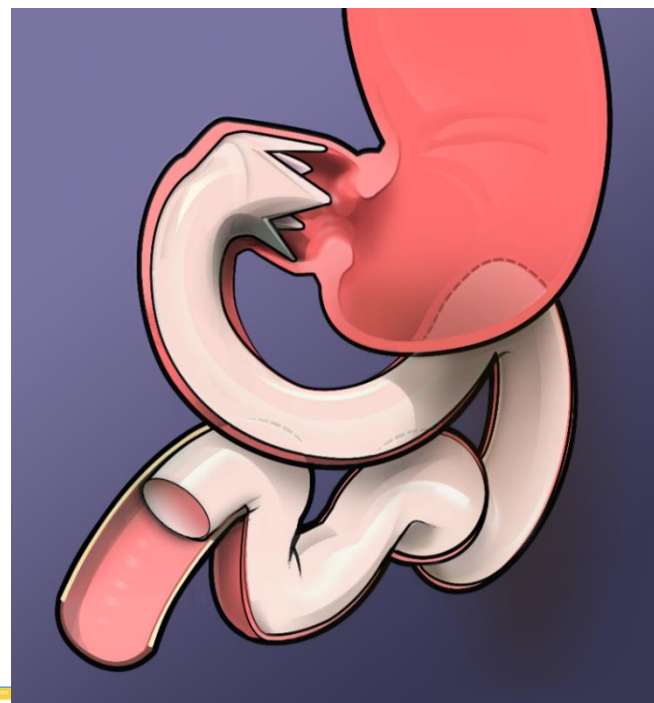
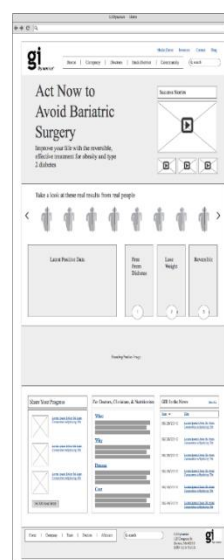
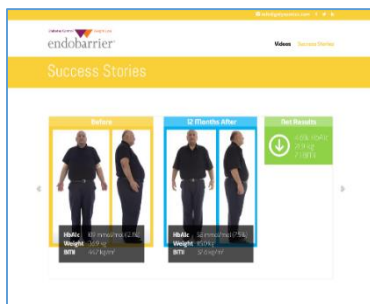
- **Hepatic Abscess rate** **1.7%** (4/243)
- **Severe Bleeding rate** **0.4%**

“Patients significantly benefitted from improvement of HbA1c, reduction of antidiabetic medication, reduction of weight and were able to improve obesity-associated comorbidities”

Dr. Nina Riedel
University Hospital Hamburg-Eppendorf

The registry is supported by a grant from GI Dynamics with no access by the company to non-published or primary results. GI Dynamics has no influence on analysis of the registry results.

Patient-Centric Approach to Marketing



US Regulatory Clearance

- Re-engage with FDA
- Secure agreement for new study
- Initiate enrollment

OUS Clinical & Reimbursement

- Continue supporting clinical operations
- Drive for reimbursement in target markets
- Continue to refine scientific understanding of EndoBarrier and improve safety profile

Revenue in Targeted Markets

- Once clinical support and reimbursement are in place

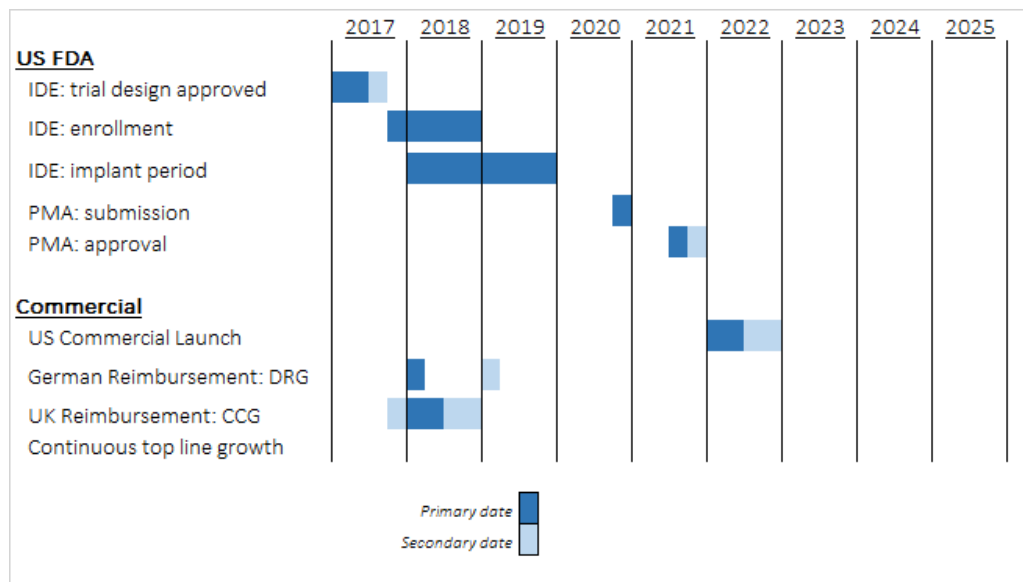
Appropriately capitalize

- Proper financings coupled with lean spend environment → healthy balance sheet
- Opportunistic business development

Continuing Momentum into 2017

Key milestones in the remainder of 2016 and 2017 include:

- Launch Scientific Advisory Board, which will aid development of both clinical and commercial strategies.
- Finalize plans and protocol for US IDE.
- Commence enrollment in US IDE trial.
- Capital raise to secure funding for executing US clinical and commercial plans.
- Continue to develop reimbursement options.



Unique implant for treating the large unmet need of **type 2 diabetes and obesity**

Significant efficacy in glucose control, weight loss and other risk factors

Less invasive therapy with advantageous cost-benefit profile

Substantial commercial & clinical experience **> 3,700** shipped

New team rebuilding confidence

Significant upside potential
