



GI Dynamics, Inc. – ASX Announcement

## **GI Dynamics presentation to UBS Global Life Sciences Conference**

**Lexington, Massachusetts, United States and Sydney, Australia – 21 September, 2011 AEST –** GI Dynamics, Inc. (ASX: GID) (GI Dynamics or the Company) is presenting at the UBS Global Life Sciences Conference on Wednesday, September 21, 2011, at 8 a.m. EDT (10 p.m. Australian EST) to be held at the Grand Hyatt New York Hotel in New York City.

A copy of the presentation being delivered by Stuart A. Randle, president and chief executive officer of GI Dynamics, is attached. This contains an overview of the company and the EndoBarrier, a novel approach for the treatment of type 2 diabetes and obesity.

A live webcast of the GI Dynamics presentation can be accessed by visiting the investors section of the company's website at [investor.gidynamics.com](http://investor.gidynamics.com). A replay of the webcast will be archived on the GI Dynamics website ([www.gidynamics.com](http://www.gidynamics.com)) for two weeks following the presentation date.

**Robert Crane**  
**Chief Financial Officer & Company Secretary**

### **About GI Dynamics**

GI Dynamics, Inc. (ASX: GID) is pioneering the development and commercialization of effective, non-surgical treatments targeting the large and growing global patient populations with type 2 diabetes and obesity. The company's flagship product, the EndoBarrier®, is a novel, non-surgical device proven to lower blood glucose levels and promote weight loss in diabetic and obese patients during the implant period. GI Dynamics currently markets the EndoBarrier in select regions in Europe and South America and is planning significant near-term commercial expansion into Australia and additional European countries. Founded in 2003, GI Dynamics is headquartered in Lexington, Massachusetts. For more information, please visit [www.gidynamics.com](http://www.gidynamics.com).

### **Forward-Looking Statements**

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to our ability to commercialize our EndoBarrier® including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialize new products including our ability to obtain reimbursement for our products; our expectations with respect to our clinical trials, including enrolment in or completion of our clinical trials and our associated regulatory submissions and approvals; our expectations with respect to the integrity or capabilities of our intellectual property position. Management believes that these forward-looking statements are reasonable as and when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. GI Dynamics does not assume any obligation to publicly

[www.gidynamics.com](http://www.gidynamics.com)

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

update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. GI Dynamics may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, described in “Risk Factors” in our Prospectus lodged with the Australian Securities & Investments Commission on 3 August 2011.

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ASX: GID

UBS Global Life Sciences Conference

September 21, 2011

New York City



***A breakthrough treatment for  
type 2 diabetes and obesity***

# Important Notice

## Disclaimer

This presentation has been prepared by GI Dynamics, Inc (**GI Dynamics**) based on information available to it as of September 2011. The information in this presentation is an overview and does not contain all information necessary to an investment decision.

This presentation does not constitute an offer, invitation, solicitation or recommendation with respect to the purchase or sale of any security in GI Dynamics nor does it constitute financial product advice nor take into account your investment objectives, taxation situation, financial situation or needs. An investor must not act on the basis of any matter contained in this presentation but must make its own assessment of GI Dynamics and conduct its own investigations and analysis. Before making an investment in GI Dynamics, an investor should consider whether such an investment is appropriate to their particular investment objectives, financial situation and particular needs and consult a financial adviser if necessary.

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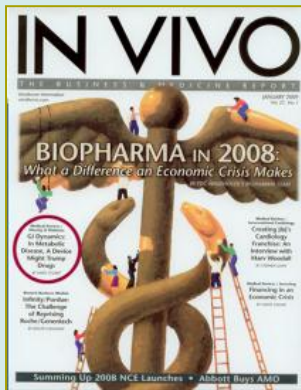
# Investment Highlights

- ✓ **Commercializing nonsurgical treatments for type two diabetes and obesity**
- ✓ **EndoBarrier® treats largest markets in healthcare**
- ✓ **Regulatory approval and commercialization in select markets**
  - CE Mark approval in Europe in 2010; launched in 2Q 2011 in select markets
  - Commercially available in select regions of South America
  - Received TGA approval in Australia in 3Q 2011
- ✓ **Commercial expansion**
  - Launching in additional markets in Europe, South America and elsewhere
  - Pilot clinical trial approved by FDA in U.S.
- ✓ **Experienced Executive Team and Board**
- ✓ **Large IP Portfolio**
- ✓ **Completed IPO & U.S. private placement of \$84 million (AU\$80 million) in Sept. 2011 – now listed on the ASX**

# Management Team with Proven Track Record

Executives	Background
<b>Stuart A. Randle</b> President & Chief Executive Officer	30-year record of turn-arounds and large- scale life sciences companies, including Baxter Healthcare Corporation, Allegiance Corporation and Advanced Technology Ventures. Mr. Randle has served as the company's president and CEO since 2004. Prior experience includes engineering, sales, marketing, senior management and leadership roles in developing companies and also divisions of major medical corporations.
<b>Robert W. Crane</b> Chief Financial Officer & Corporate Secretary	Nearly 30 years in a number of public and private life science company roles in the U.S. and Europe. Mr. Crane has experience in initial public offerings, other public and private financings, acquisitions, divestments, joint ventures and recapitalizations. Prior experience includes Sirtris Pharmaceuticals, I-STAT, Inkine and Seragen.
<b>Andy Levine</b> Founder and Chief Technology Officer	30 years of engineering and medical device research, development and manufacturing experience. Previously co-founded Seedling Enterprises, LLC, a medical device incubator and held various senior engineering, research and development positions at Boston Scientific Corporation, Microsurge, Inc., C.R. Bard; and Thermedics, Inc.
<b>Karl-Heinz Blohm, Ph.D.</b> Vice President, International Sales	More than 20 years of medical device industry experience, combining capital equipment and medical devices with AB Medica SAS, EndoGastric Solutions, Inc., Accuray Europe, and Siemens AG
<b>Sherrie Coval-Goldsmith</b> Vice President, Clinical & Regulatory Affairs	27 years of experience in clinical, quality and regulatory affairs in life sciences companies, including Neothermia Corporation, Nitinol Medical Technologies, Inc., Stryker Biotech, and the Vascular Systems Division of C.R. Bard.

# EndoBarrier®: breakthrough treatment for type 2 diabetes & obesity



MEDICAL DEVICES / OBESITY & DIABETES

## GI DYNAMICS: IN METABOLIC DISEASE A DEVICE MIGHT TRUMP DRUGS

*A device start-up looks to succeed where devices have failed; influencing multiple metabolic pathways to treat obesity and reverse type 2 diabetes.*

*“It is not often that a company in the medical device industry... has a chance to change the world.”*

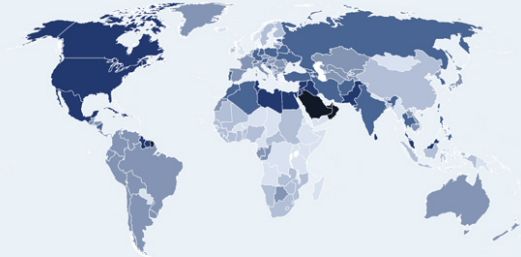
**SOURCE:** Article on GI Dynamics, In Vivo Magazine, January 2009, Vol. 27, No. 1



# Diabetes and obesity have reached epidemic proportions

- ✓ **Diabetes** - abnormally high levels of glucose in the blood
  - diabetes puts patients **at risk of heart disease, stroke, blindness, kidney disease and limb amputation**
  - **type 2 diabetes** occurs when the pancreas no longer produces enough insulin to overcome insulin resistance – **approximately 90% of all cases of diabetes**
  
- ✓ **Obesity** - abnormal and excessive fat accumulation
  - the **risk of coronary heart disease and stroke increase** with obesity, **as do the risk of certain cancers**
  
- ✓ Globally approximately **250M people have type 2 diabetes** and **500M adults are obese**
  
- ✓ **Treatment options** for each condition **are limited**

Estimated proportion of people with diabetes (20 -79 years), 2010



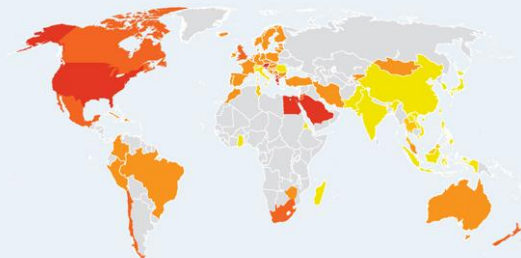
Diabetes in population %



Map shows type 1 and type 2 diabetes. Obesity and type 2 diabetes are casually linked

SOURCE: IDF Diabetes Atlas 4th ed, International Diabetes Federation, 2009

Estimated incidence of obese adults (BMI >=30%)



Obese adults in population %



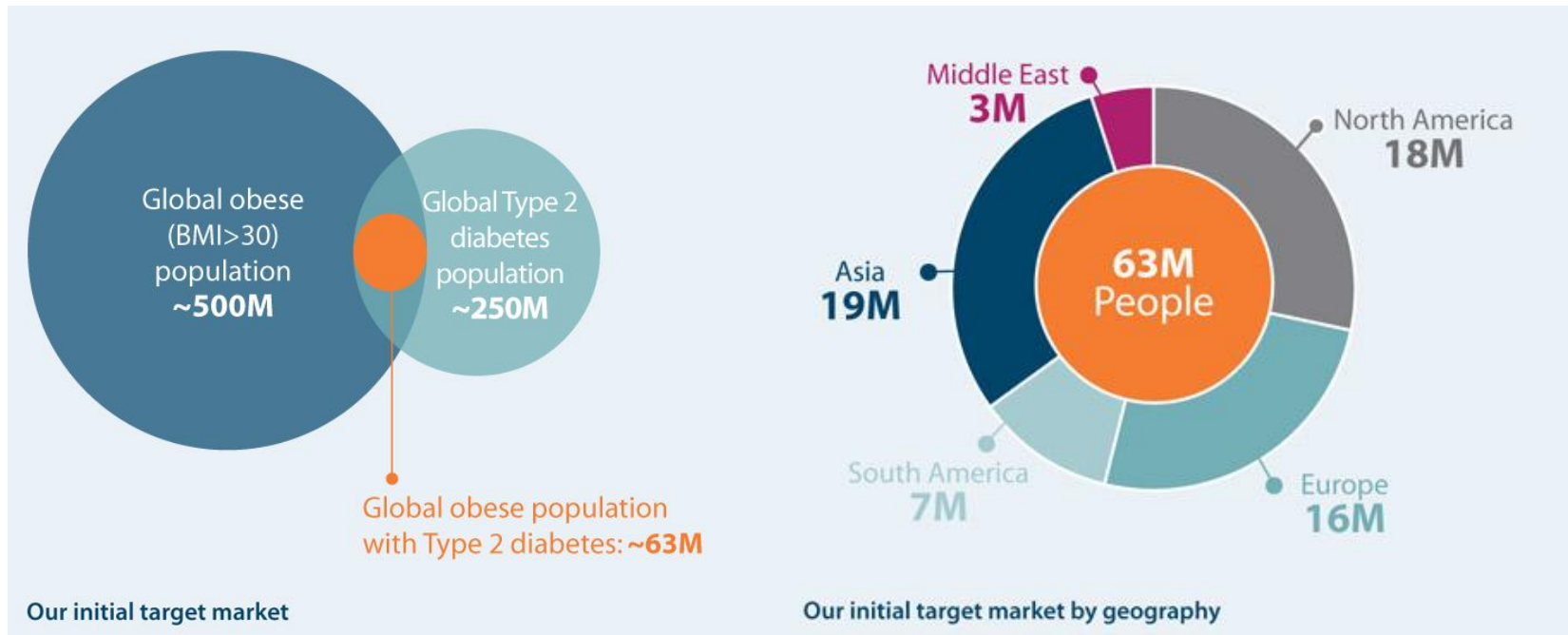
An obese adult is classified as having a Body Mass Index equal to or greater than 30

SOURCE: WHO, Global Database on Body Mass Index, June 2011



# Initial target market is 63 million people

*Our initial target market is obese patients with type 2 diabetes*



*... we plan to expand our target markets to treat the general obese population and diabetic patients who are overweight but not obese*

# Current treatment options

## ✓ Lifestyle changes

- healthy diet and increased exercise – proven to reduce obesity and therefore slow progression of diabetes
- many attempt but not a successful treatment for most in the long term

## ✓ Drug therapy

- **Diabetes** includes *Insulin*, *Metformin*, *Actos*<sup>®</sup>, *Januvia*<sup>®</sup>, *Byetta*<sup>®</sup>, *Victoza*<sup>®</sup>
  - do not measurably impact the progression of the disease
  - usually taken by patients for long periods – often for life
  - average annual treatment cost in the U.S. ~ \$11,700 over patient lifetime
- **Obesity** – limited success with a number of drugs being withdrawn in recent years
  - Orlistat marketed as *Xenical*<sup>®</sup> has low efficacy and can cause side effects



# Current surgical treatment options

## ✓ Adjustable gastric bands

- a silicone band surgically implanted around the top part of the stomach
- **risks** and **side effects** – some patients may have their gastric bands removed in a further surgery due to side effects
- obesity focus

## ✓ Gastric bypass surgery or Roux-en-Y gastric bypass

- significant changes to patient's anatomy and physiology
- most common and effective surgery for obesity and type 2 diabetes
  - ~175,000 surgeries each year in the U.S., or **1% of candidate population**
- **risks** and **side effects** include **surgical complications**, infection, nausea, vomiting, ulcers, gallstones, anaemia, osteoporosis and blood clots

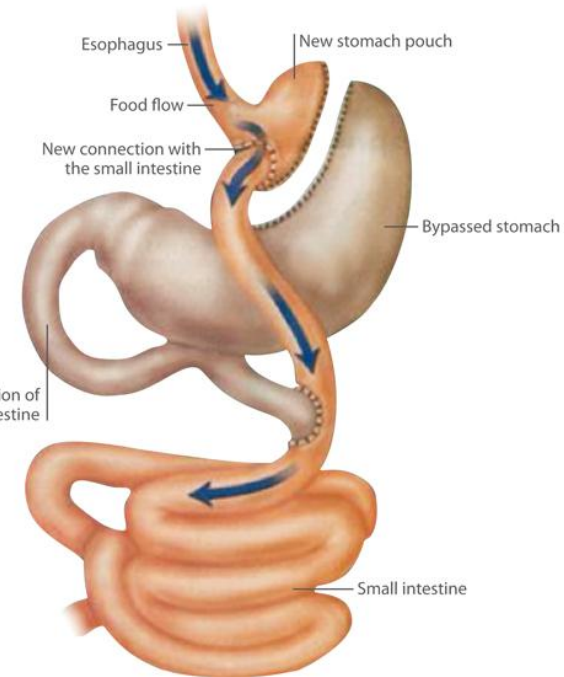
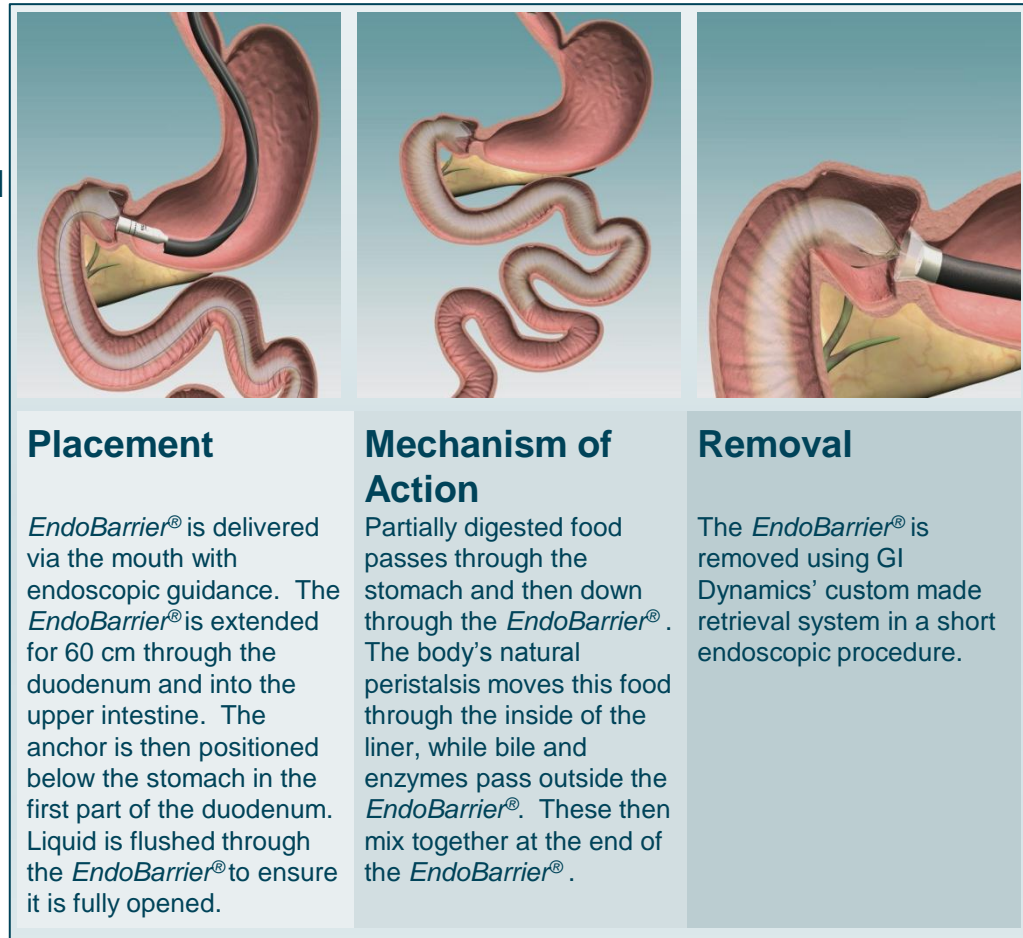


Diagram: Gastric Bypass surgery

# EndoBarrier<sup>®</sup>: nonsurgical solution shown to control glucose levels and lose weight

- ✓ **One solution**
  - glucose control improves within days of implant
  - significant weight loss over implant period
  - reductions in coronary risk factors
- ✓ **Nonsurgical**
  - placed by endoscopy – no cutting of tissue
  - far less invasive than surgical procedures
- ✓ **Safe, effective and easily removable**
- ✓ **Cost savings**
  - less expensive than available surgical treatments for obesity
  - we believe potential significant broader cost savings for the healthcare system



# The EndoBarrier® System

## ✓ The liner

- 60 cm long implant
- impermeable fluoropolymer – thin and flexible
- anchor at one end to attach to intestine
- anchor is made of nitinol wire (biocompatible)
- retrieval drawstrings

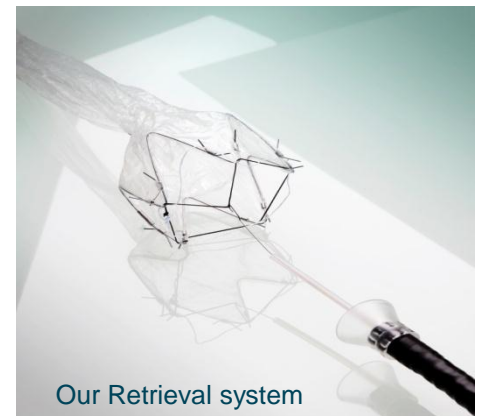
## ✓ Delivery system

- 300cm custom made catheter with *EndoBarrier®* inside a capsule
- sterile, single use
- delivery procedure ~30 minutes



## ✓ Retrieval system

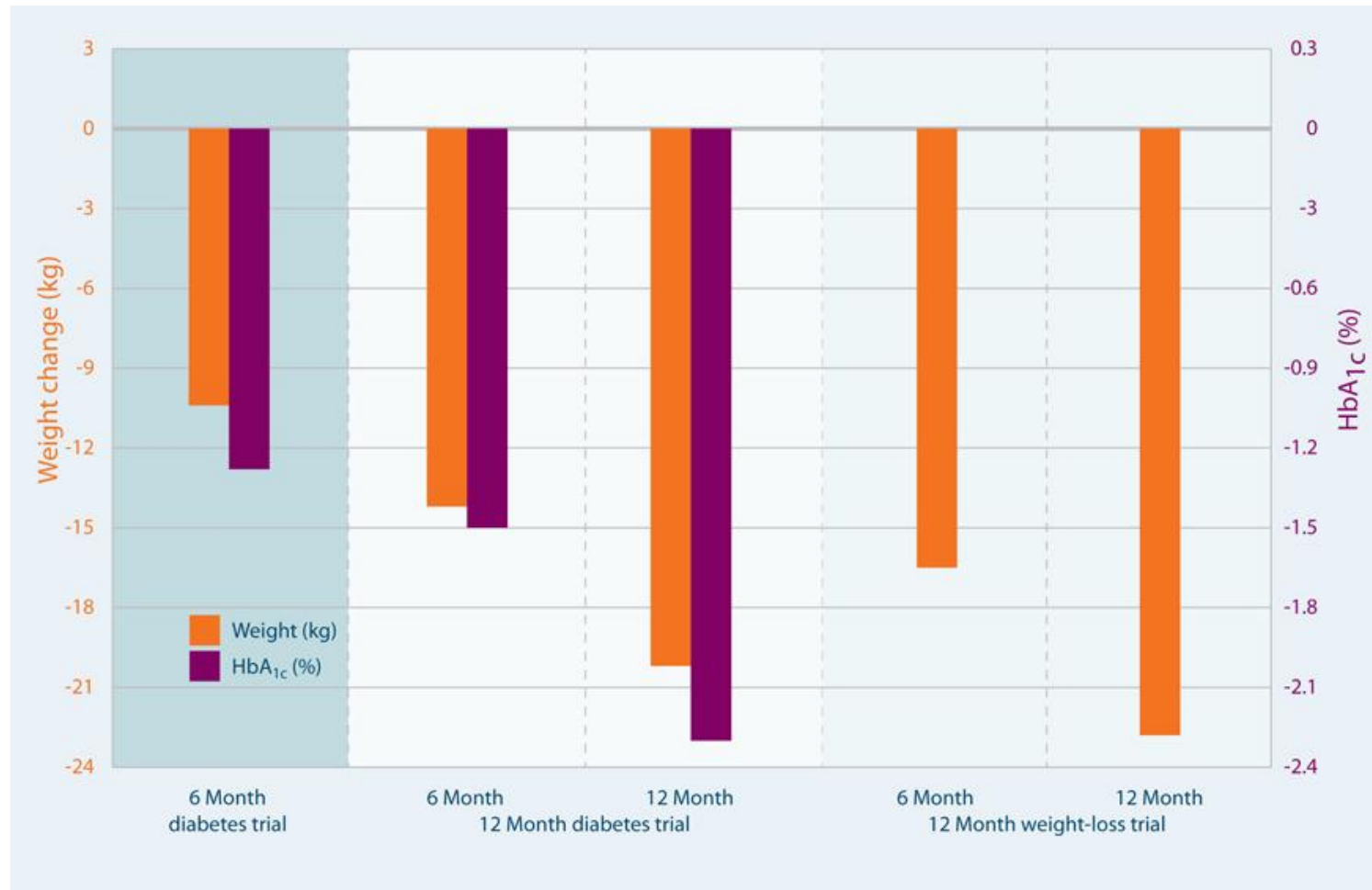
- custom endoscopic grasper and retrieval hood
- sterile, single use
- retrieval procedure ~15 minutes



*\*The EndoBarrier® is not approved for sale in the United States and is considered investigational.*

# Clinical results demonstrate significant treatment outcomes

*Our 6 month diabetes trial, 12 month diabetes trial and 12 month obesity trial demonstrate the significant treatment outcomes for our patients*



# Clinical results – 12 month diabetes & obesity trials

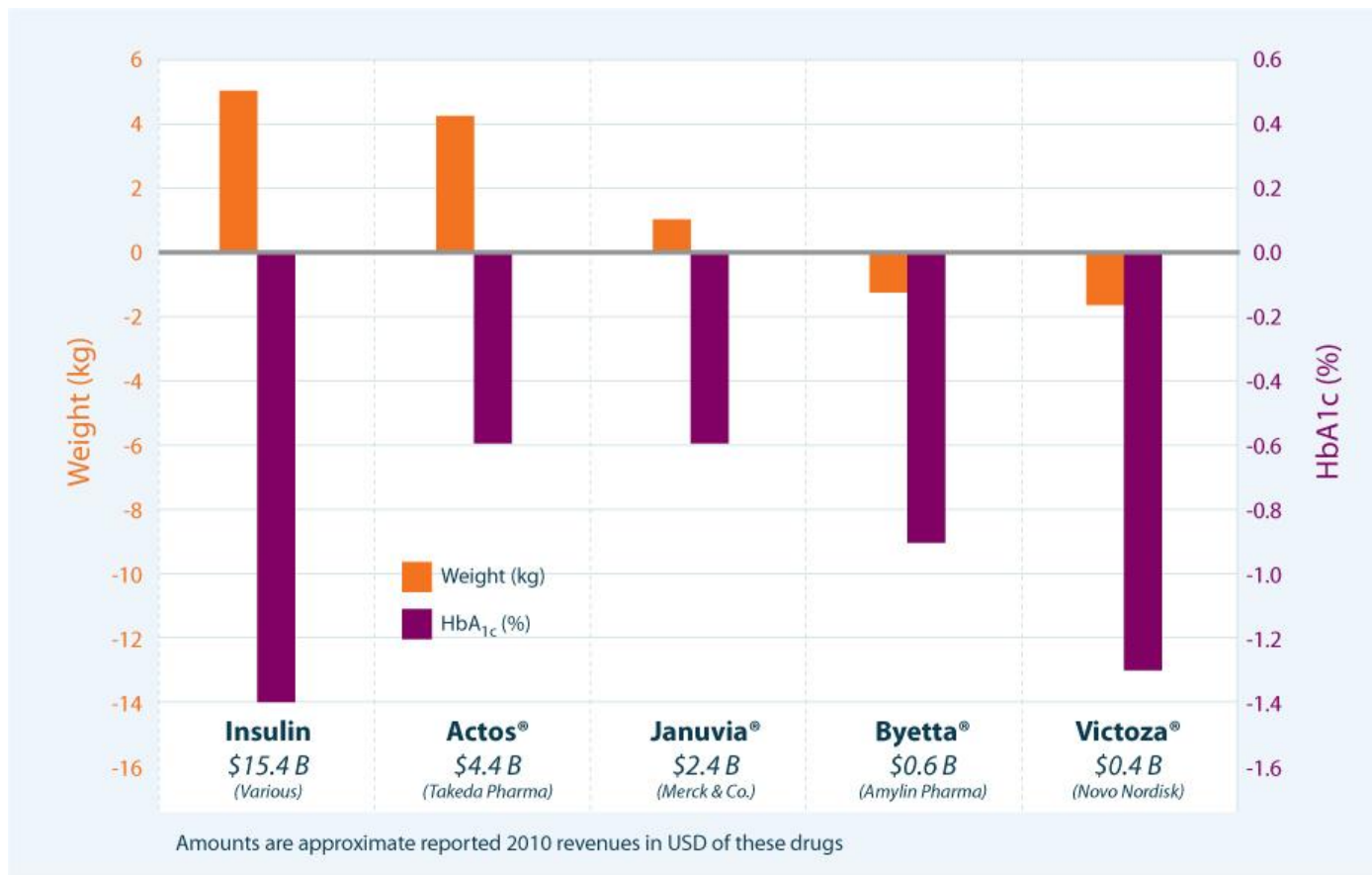
*Significant positive effects also include blood pressure and cholesterol*

	12 Month Diabetes Trial (n = 13)			12 Month Obesity Trial (n = 27)		
	Baseline	52 Weeks	P value	Baseline	52 Weeks	P value
<b>Weight (kg)</b>	<b>121.8 ± 7.6</b>	<b>101.6 ± 5.7</b>	<b>&lt; .0001</b>	<b>112.4 ± 2.4</b>	<b>89.8 ± 3.2</b>	<b>&lt; .0001</b>
<b>BMI (kg/m<sup>2</sup>)</b>	<b>45.3 ± 2.4</b>	<b>37.8 ± 1.8</b>	<b>&lt;.0001</b>	<b>45.3 ± 0.8</b>	<b>36.1 ± 1.1</b>	<b>&lt;.0001</b>
<b>Blood Pressure (mmHg)</b>						
Systolic	131.7 ± 2.7	127.2 ± 5.0	NS	134.0 ± 2.7	124.7 ± 2.3	0.003
Diastolic	78.2 ± 3.2	77.4 ± 2.8	NS	85.7 ± 1.3	71.8 ± 1.8	<.0001
<b>Total Cholesterol (mg/dl)</b>	<b>205.4 ± 10.9</b>	<b>177.3 ± 8.9</b>	<b>0.0003</b>	<b>195.1 ± 7.0</b>	<b>159.6 ± 7.4</b>	<b>&lt;.0001</b>
HDL	44.1 ± 3.7	43.1 ± 4.4	NS	44.3 ± 1.7	43.5 ± 1.5	NS
LDL	121.8 ± 9.7	104.4 ± 7.3	0.005	119.9 ± 5.7	93.9 ± 6.1	<.0001
Triglycerides	214.2 ± 27.2	151.8 ± 14.2	0.005	155.4 ± 14.2	111.5 ± 10.0	0.001
<b>Glucose (mg/dl)</b>	<b>174.9 ± 13.7</b>	<b>137.8 ± 13.1</b>	<b>0.009</b>	N/a	N/a	
<b>Insulin (uU/mL)</b>	<b>21.1 ± 4.9</b>	<b>11.0 ± 1.5</b>	<b>0.03</b>	N/a	N/a	
HOMA IR	8.6 ± 1.9	3.7 ± 0.6	0.02	N/a	N/a	
<b>HbA1c (%)</b>	<b>8.9 ± 0.5</b>	<b>6.6 ± 0.3</b>	<b>&lt;.0001</b>	N/a	N/a	

Source: Company 12 month obesity trial in Chile and 12 month diabetes trial in Brazil (Mean +- Standard error)

# EndoBarrier® offers differentiated profile

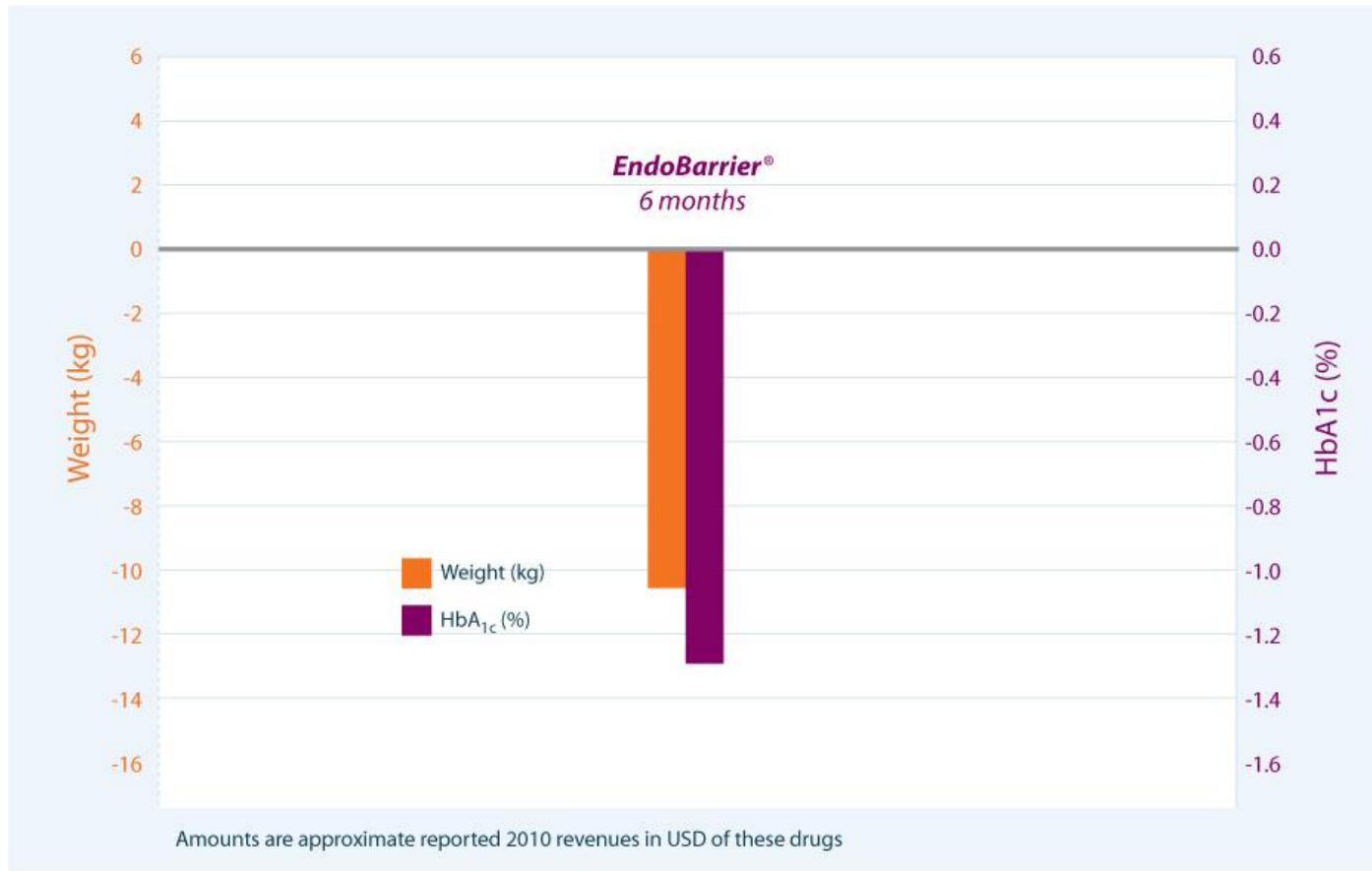
*Data from clinical trials of EndoBarrier® compare favorably to independent, published data on the five main diabetes drugs currently marketed in terms of weight loss*



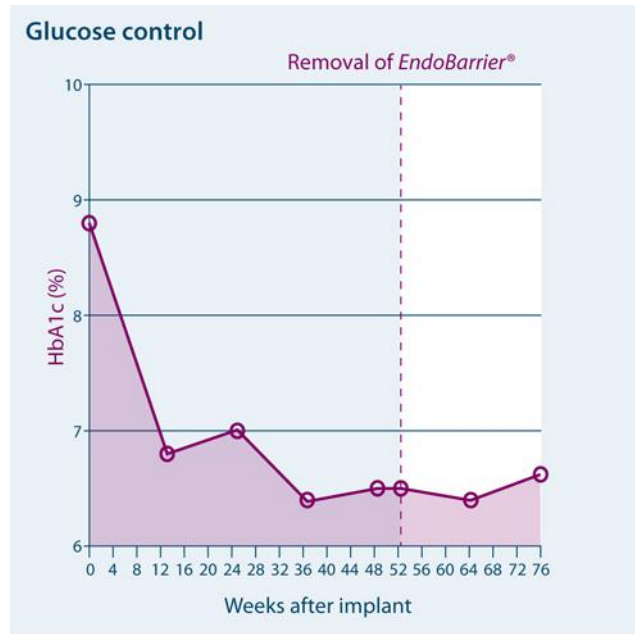


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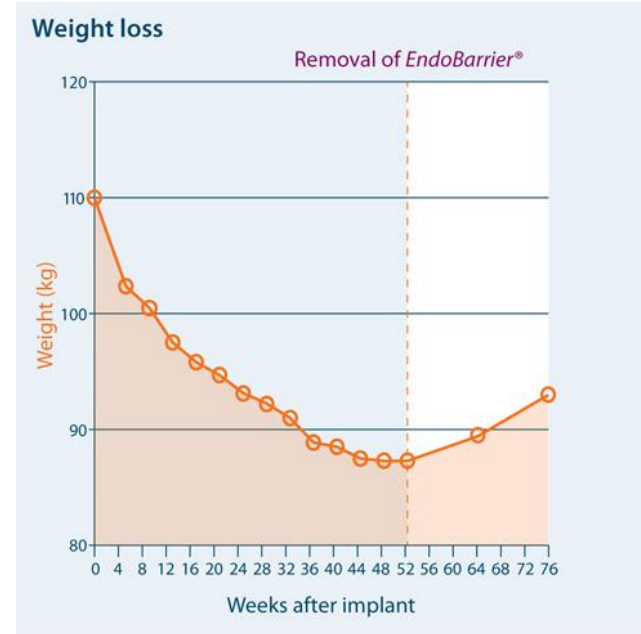
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# Ongoing benefits after removal of the *EndoBarrier*<sup>®</sup>



ABOVE: Continued effect on glucose control after removal of the *EndoBarrier* at 52 weeks, from patients who completed our 12 month diabetes trial (n=9)



ABOVE: Effect on weight after removal of the *EndoBarrier* at 52 weeks, from patients who completed our 12 month obesity trial (n=22)

## ✓ Ongoing monitoring for 6 months post removal of the *EndoBarrier*<sup>®</sup>

- 12 month diabetes trial – follow-up of 9 of total 13 patients who completed trial
  - **HbA<sub>1c</sub> increased only slightly** indicating continued glucose control
- 12 month obesity trial – follow-up of 22 of total 27 patients who completed trial
  - 5kg average weight gain – **significantly less than 22kg average weight loss during the implant period**

# Safety Profile

- ✓ The most common adverse events with the *EndoBarrier*<sup>®</sup> in our trials
  - movement of the implant – leading to pain
  - intestinal bleeding
  - incomplete deployment of the liner/early liner removal
  
- ✓ **12 month obesity and diabetes trial results – supported CE Mark application**
  - Treatment related early removal results for the *EndoBarrier*<sup>®</sup>
    - 6% up to 3 months
    - 2% in 3 - 6 months
    - 6% in 6 - 9 months
    - 6% in 9 - 12 months
  
- ✓ **Continued reduction in incidence of treatment related early removals**
  - 6 month diabetes trial in the Netherlands
  - 1 of 34 or ~3% of the *EndoBarrier*<sup>®</sup>s removed prior to the end of the 6 month implant period
  
- ✓ **No deaths related to the use of the *EndoBarrier*<sup>®</sup>**

# Scalable, State-of-the-Art Manufacturing

## ✓ Manufacture of commercial devices in Lexington, Massachusetts, U.S.

- 2,500 square feet of manufacturing and packaging space
- FDA compliant Quality Management System
  - certified to the ISO 13485:2003 standard
- assemble from outsourced components

## ✓ Production capacity

- **currently** we can produce approximately **1,000** *EndoBarrier*<sup>®</sup> systems per year
- **plan to increase** to a capacity of approximately **60,000** *EndoBarrier*<sup>®</sup> systems per year



Our *EndoBarrier*<sup>®</sup> packaged for use

# Current Commercial Footprint



## Europe

- **CE Mark** for the treatment of diabetes and obesity
  - Q2 2011 commercial launch
- **Sales** at 5 commercial centers
- **Infrastructure established** in Netherlands - warehousing, logistics, call center, and invoicing
- Vice President International Sales is based in Europe
- **Reimbursement activities underway** in United Kingdom, The Netherlands and Germany
  - local and/or national level

## South America

- **Chilean regulatory approval** - CE Mark recognized
  - Q4 2010 commercial launch
- **Sales** at 1 center with another in the near term
- Infrastructure currently supported from United States

# Transitioning from Clinical to Commercial Use

## Focused on expanding commercial presence

- Establish up to 15 Centers of Excellence in Europe & South America
- Broaden network of key opinion leaders
- Build clinical and economic data to support applications for reimbursement

## 2012 – significant growth of commercial activities

- Ramp-up through distributors and direct sales



# Key EndoBarrier® Milestones Achieved

- ✓ CE Mark for EndoBarrier for up to 12 months of treatment for type 2 diabetes and obesity
- ✓ Identify and train Centers of Excellence (COEs) in select markets
  - Eleven certified: U.K., The Netherlands, Germany, Austria and Chile
- ✓ Received FDA approval to commence U.S. pilot clinical trial
- ✓ Additional ex-U.S. regulatory approvals & launch: TGA approval in Australia
- ✓ Presented data in prestigious and influential forums
  - 2<sup>nd</sup> World Congress on Interventional Therapies for Type 2 Diabetes
  - Digestive Disease Week 2011
  - International Federation for the Study of Obesity
  - European Association for the Study of Diabetes

# Further developments and our product pipeline

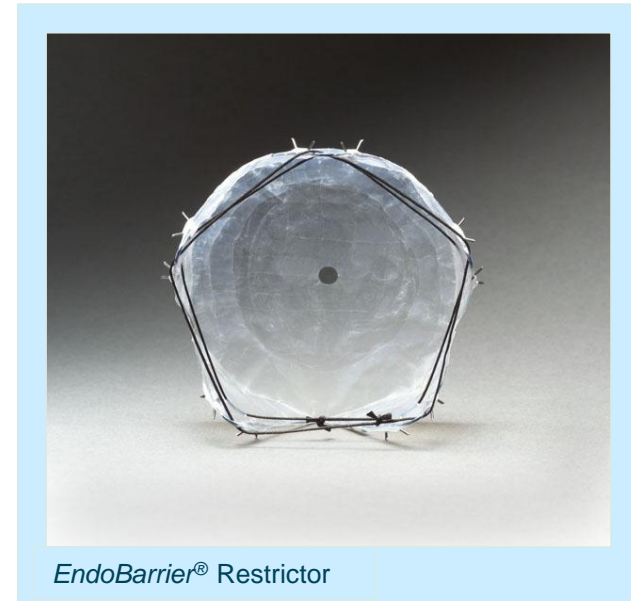
## ✓ Further developing our technology

- Current trial to **expand the use of our technology**
  - lower BMI diabetics
- Current trial for **retreatment with the *EndoBarrier*<sup>®</sup>**
- Current trial with **improved anchor**

## ✓ Other products we are developing

- ***EndoBarrier*<sup>®</sup> Restrictor**
  - targeted at cosmetic or short term weight loss market
  - small hole to slow gastric emptying – feeling of ‘fullness’
- ***EndoBarrier*<sup>®</sup> Liner with *EndoBarrier*<sup>®</sup> Restrictor**
  - treat diabetes and create greater weight loss than either device alone
  - Completed a 12 week human clinical trial of 10 patients
    - Excess weight loss of  $40\% \pm 3\%$
    - Total weight loss of  $16.7 \text{ kg} \pm 1.4 \text{ kg}$

## ✓ Expanding our intellectual property portfolio





# Summary

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